U.S. Department of Health and Human Services
Public Health Services

Grants.gov SBIR/STTR Application Guide SF424 (R&R)

A guide for preparing and submitting SBIR/STTR applications via Grants.gov

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PART I

Instructions for Preparing and Submitting an Application

1. Foreword

This application guide contains instructions and other useful information for preparing SBIR/STTR grant applications to the National Institutes of Health (NIH) and other Public Health Service (PHS) agencies for:

Small Business Innovation Research (SBIR) Grants
Small Business Technology Transfer (STTR) Grants

This application guide is used as a companion document to a new set of application forms, the SF424 Research and Related (R&R). In addition to the SF424 (R&R) form components, applications to NIH and other PHS agencies will include agency-specific form components, titled "PHS398" and "SBIR/STTR Information." These PHS398 and SBIR/STTR Information components were developed to continue the collection of agency-specific data required for a complete application. While these agency-specific components are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete SBIR/STTR application to NIH and other PHS agencies will include SF424 (R&R) components, PHS398 components, and the SBIR/STTR Information component. Instructions for all application components, SF424 (R&R), PHS398, and SBIR/STTR Information, are found in this document.

The use of these new forms also involves electronic submission of completed applications through Grants.gov. NIH and other PHS agencies will gradually transition all mechanisms to the new application forms and Grants.gov submission. Specific Funding Opportunity Announcements (FOAs) will clearly indicate which forms and submission process an applicant should use. NIH will continue to use Requests for Applications (RFAs) and Program Announcements (PAs) as categories of FOAs. See Section 2.4.2 for definitions.

Applicants must carefully review FOAs for guidance on when to use the 424 (R&R) forms, instructions, and electronic submission for a specific mechanism (i.e., R43, R44, etc.). This new process will apply to all types of submissions for the announced mechanism – new, resubmission (formerly "revised/amended"), renewal (formerly "competing continuation"), and revision (formerly "competing supplemental") grant applications. Each FOA will include a link to the most current version of these instructions. Applicants are encouraged to check the web site frequently for the most current version.

For purposes of this document, any references to "NIH" may also mean "NIH and other PHS agencies" such as the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease and Prevention (CDC), and the Food and Drug Administration (FDA).

1.1 Application Guide Format

This application guide is organized into three distinct parts:

Part I: Instructions for Preparing and Submitting the Application. Part I includes specific instructions for completing the application form components as well as information on electronically submitting applications through Grants.gov.

Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan. Part II is to be used if your proposed research will involve human subjects. These instructions assist you in determining whether human subjects are involved and include six possible scenarios and detailed instructions to assist you in completing Items 6 – 10 of the PHS 398 Research Plan component.

Part III: Policies, Assurance, Definitions, and Other Information. Part III includes information on policies, assurances, definitions, and other information relating to submission of applications for

traditional, solicited and unsolicited, investigator-initiated, research project grants, and cooperative agreements to the PHS. Applicants should refer to this document as well as the instructional materials, Grants Information (GrantsInfo), and *NIH Grants Policy Statement* sections for additional sources of information.

1.2 NIH Extramural Research and Research Training Programs

The NIH Office of Extramural Research Grants homepage (http://grants.nih.gov/grants/oer.htm) provides an array of helpful information. Applicants are encouraged to bookmark this site and visit it often.

The Division of Extramural Outreach and Information Resources (DEOIR) is the central source for general information about NIH extramural research and research training programs, funding mechanisms, the peer review system, and application procedures. Grants Information (GrantsInfo) is a communication service within the DEOIR. Information about the NIH extramural research and research training programs, funding opportunities, and the grant application process, can be obtained by emailing your request to: GrantsInfo@nih.gov or by calling (301) 435-0714.

1.3 Program Guidelines

1.3.1 Three-Phase Program

Both the SBIR and STTR programs are structured in three phases, the first two of which are supported using SBIR/STTR funds. The stated Phase I and Phase II award levels and project periods are statutory guidelines, not ceilings. Therefore, applicants are encouraged to propose a budget and project duration period that is reasonable and appropriate for completion of the research project.

Deviations from the indicated statutory award amount and project period guidelines are acceptable, but must be well justified and should be discussed with NIH Program Staff *prior to submission* of the application. (CDC and FDA do not make awards greater than the stated guidelines.)

Phase I. The objective of Phase I is to establish the technical/scientific merit and feasibility of the proposed R/R&D efforts. *Preliminary data may be included but are not required*. The application should concentrate on R/R&D efforts that will significantly contribute to proving the scientific or technical feasibility of the approach or concept that would be a prerequisite to further support in Phase II.

SBIR Phase I awards normally may not exceed $100,000 total (direct costs, facilities and administrative (F&A)/indirect costs, and fee) for a period normally not to exceed 6 months. STTR Phase I awards normally may not exceed $100,000 total for a period of 1 year.

Phase II. The objective of Phase II is to continue the research or R&D efforts initiated in Phase I. Funding shall be based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II application.

All Phase II applications must include a succinct **Commercialization Plan**. Specific details for preparing this section are described in Section 5.6 of this Application Guide.

SBIR and STTR Phase II awards normally may not exceed $750,000 total (direct costs, F&A/indirect costs, and fee) for a period normally not to exceed 2 years.

Only Phase I awardees are eligible to apply for and obtain Phase II funding. Awardees identified via a "successor-in-interest" or "novated" or similarly-revised funding agreement, or those that have reorganized with the same key staff, regardless of whether they have been assigned a different tax identification number, are eligible to apply for Phase II funding. Agencies may require the original awardee to relinquish its rights and interests in an SBIR/STTR project in favor of another applicant as a condition for that applicant's eligibility to participate in the SBIR/STTR program for that project.

Only one Phase II award may be made for a single SBIR/ STTR project.

You may submit a Phase II application either before or after expiration of the Phase I budget period, unless you elect to submit a Phase I and Phase II application concurrently under the Fast-Track procedure. *To maintain eligibility to seek Phase II support, a Phase I grantee organization should submit a Phase II application within the first six receipt dates following the expiration of the Phase I budget period*.

Phase III. An objective of the SBIR/STTR program is to increase private sector commercialization of innovations derived from Federal R/R&D. During Phase III, the small business concern (SBC) is to pursue commercialization with non-SBIR/STTR funds (either Federal or non-Federal). In some Federal agencies, Phase III may involve follow-on, non-SBIR/STTR funded R&D, or production contracts for products or processes intended for use by the U.S. Government.

The competition for SBIR/STTR Phase I and Phase II awards satisfies any competition requirement of the Armed Services Procurement Act, the Federal Property and Administrative Services Act, and the Competition in Contracting Act. Therefore, an agency that wishes to fund an SBIR/STTR Phase III project is not required to conduct another competition in order to satisfy those statutory provisions. As a result, in conducting actions relative to a Phase III SBIR/STTR award, it is sufficient to state for purposes of a Justification and Approval pursuant to FAR 6.302-5 that the project is a SBIR/STTR Phase III award that is derived from, extends, or logically concludes efforts performed under prior SBIR/STTR funding agreements and is authorized under 10 U.S.C. 2304(b)(2) or 41 U.S.C. 253(b)(2).

1.3.2 Fast-Track Applications

CDC and FDA do not accept Fast-Track applications.

The NIH Fast-Track mechanism expedites the decision and award of SBIR and STTR Phase II funding for scientifically meritorious applications that have a high potential for commercialization. Fast-Track incorporates a submission and review process in which both Phase I and Phase II grant applications are submitted and reviewed together. The Phase I portion of a Fast-Track must specify clear, measurable goals (milestones) that should be achieved prior to initiating Phase II work. In addition, as is required for all Phase II applications, the Phase II portion of a Fast-Track application must present a Commercialization Plan (maximum 15 pages) that addresses specific points (see Section 5.6).

In the past, applicant small business concerns (SBCs) submitting SBIR/STTR Fast-Track grant applications to NIH were required to complete two separate applications – one for Phase I and another for Phase II. Beginning with the December 1, 2005, submission date, all SBCs wishing to propose SBIR/STTR Fast-Track projects to NIH must prepare one grant application package consisting of both Phase I and Phase II activities. To be eligible for the Fast-Track option, the Phase I research plan must include well defined, quantifiable milestones that will be used to judge the success of the proposed research, as well as a credible development plan for the Phase II application. The Fast-Track must have a section labeled "Milestones" at the end of the PHS 398 Research Plan component for Phase I activities.

The Fast-Track application will receive a single rating for the entire proposed project (i.e., it will receive a numerical score or it will receive an "unscored" designation).

Below are general instructions for preparing NIH SBIR/STTR Fast-Track applications. More specific instructions are provided in Sections 4 and 5 of this application guide.

- Follow the instructions as provided through Section 3, using the Grant Application Package.
- Use the forms in Section 4.6, R&R Budget Component: Complete Budget Period 1 for Phase I; complete Budget Periods 2 and 3 (or more, if appropriate) for Phase II; complete the Cumulative Budget form page used to accumulate total amounts for the entire Fast-Track project period.
- Prepare the Research Plan in accordance with Section 5.4, Research Plan Component, using the PHS 398 Research Plan for items 2-5 in each Phase (Phase I and Phase II plans must be contained within 25 pages).
- Identify the application as "Fast-Track" at the beginning of the "Specific Aims" portion of the PHS 398 Research Plan.
- Under the heading "Phase I Segment," follow the instructions for the remainder of the application as provided in the Research Plan Component.

  Upon completion of all the requirements for Phase I, use the heading "Phase II Segment" and repeat the process for that portion of the proposed project

1.3.3 Supplemental Applications

Under special circumstances, requests for supplemental funds to existing NIH SBIR/STTR grants or requests for an extension of the period of support with funds may be considered. *(The awarding of supplemental funds applies to NIH ONLY, as CDC and FDA do not make awards greater than the stated guidelines.)* See Section 2.8.

1.3.4 SBIR/STTR Program Eligibility

Each applicant submitting an SBIR/STTR grant application must qualify as a small business concern (SBC) *at the time of award*. The following sections provide more details about these eligibility criteria.

1.3.4.1 Organizational Criteria

A small business concern is one that, for both Phase I and Phase II awards, meets all of the following criteria:

1. Is independently owned and operated, is not dominant in the field of operation in which it is proposing, has a place of business in the United States and operates primarily within the United States or makes a significant contribution to the U.S. economy, and is organized for profit.
2. Is (a) at least 51% owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States, or (b) for SBIR only, it must be a for-profit business concern that is at least 51% owned and controlled by another for-profit business concern that is at least 51% owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States.
3. Has, including its affiliates, an average number of employees for the preceding 12 months not exceeding 500, and meets the other regulatory requirements found in 13 C.F.R. Part 121. Business concerns are generally considered to be affiliates of one another when either directly or indirectly, (a) one concern controls or has the power to control the other; or (b) a third-party/parties controls or has the power to control both.

Control can be exercised through common ownership, common management, and contractual relationships. The term "affiliates" is defined in greater detail in 13 C.F.R. 121.103. The term "number of employees" is defined in 13 C.F.R. 121.106.

A business concern may be in the form of an individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust, or cooperative. Further information may be obtained at http://sba.gov/size, or by contacting the Small Business Administration's Government Contracting Area Office or Office of Size Standards.

One of the circumstances that would lead to a finding that an organization is controlling or has the power to control another organization involves sharing common office space and/or employees and/or other facilities (e.g., laboratory space). Access to special facilities or equipment in another organization is permitted (as in cases where the awardee organization has entered into a subcontractual agreement with another organization for a specific, limited portion of the research project). *However, research space occupied by an SBIR/STTR awardee organization must be space that is available to and under the control of the SBIR/STTR awardee for the conduct of its portion of the proposed project*.

Title 13 C.F.R. 121.3 also states that control or the power to control exists when "key employees of one concern organize a new concern ... and serve as its officers, directors, principal stockholders, and/or key employees, and one concern is furnishing or will furnish the other concern with subcontracts, financial or technical assistance, and/or other facilities, whether for a fee or otherwise." Where there is indication of sharing of common employees, a determination will be made on a case-by-case basis of whether such sharing constitutes control or the power to control.

For purposes of the SBIR/STTR program, personnel obtained through a Professional Employer Organization or other similar personnel leasing company may be considered employees of the awardee. This is consistent with SBA's size regulations, 13 C.F.R. 121.106 – Small Business Size Regulations.

All SBIR/STTR grant applications will be examined with the above eligibility considerations in mind. If it appears that an applicant organization does not meet the eligibility requirements, NIH will request a size determination by the SBA. If eligibility is unclear, NIH will not make an SBIR or STTR award until the SBA provides a determination.

1.4 Interactions with PHS Staff

The PHS agencies encourage applicants to communicate with staff throughout the entire application, review and award process. Web site addresses and staff phone numbers of relevant NIH awarding components and other PHS agencies are listed in the table below.

All inquiries regarding the assignment, review, or recommendation on funding of applications are to be made only to PHS officials.

Table 1.4-1. Awarding Component Contact Information Table

AWARDING COMPONENT	PROGRAM CONTACT	GRANTS MGMT. CONTACT
National Institute on Aging http://www.nia.nih.gov	Dr. Michael-David A.R.R. Kerns Phone: 301-496-9322 Fax: 301-402-2945 Email: mk417e@nih.gov	Ms. Linda Whipp Phone: 301-496-1472 Fax: 301-402-3672 Email: lw17m@nih.gov

AWARDING COMPONENT	PROGRAM CONTACT	GRANTS MGMT. CONTACT
National Institute on Alcohol Abuse and Alcoholism http://www.niaaa.nih.gov	Dr. Karen Peterson Phone: 301-451-3883 Fax: 301-443-6077 Email: kp177z@nih.gov	Ms. Judy Fox Phone: 301-443-4704 Fax: 301-443-3891 Email: js182a@nih.gov
National Institute of Allergy and Infectious Diseases http://www.niaid.nih.gov	Dr. Gregory Milman Phone: 301-496-8666 Fax: 301-402-0369 Email: gm16s@nih.gov	Ms. Mary Kirker Phone: 301-496-7075 Fax: 301-480-3780 Email: mk35h@nih.gov
National Institute of Arthritis and Musculoskeletal and Skin Diseases http://www.niams.nih.gov/	Dr. Cheryl Kitt Phone: 301-594-2463 Fax: 301-480-4543 Email: ck82j@nih.gov	Ms. Melinda Nelson Phone: 301-435-5278 Fax: 301-480-5450 Email: mn23z@nih.gov
National Institute of Biomedical Imaging and Bioengineering http://www.nibib.nih.gov/	Mr. Todd Merchak Phone: 301-496-8592 Fax: 301-480-1614 Email: tm311u@nih.gov	Ms. Florence Turska Phone: 301-496-9314 Fax: 301-480-4974 Email: ft7p@nih.gov
National Cancer Institute http://www.nci.nih.gov or http://www.cancer.gov	Mr. Michael Weingarten Phone: 301-496-1550 Fax: 301-480-7807 Email: weingartenm@mail.nih.gov	Mr. Ted Williams Phone: 301-496-8785 Fax: 301-496-8601 Email: tw133b@nih.gov
National Institute of Child Health and Human Development http://www.nichd.nih.gov	Dr. Louis A. Quatrano Phone: 301-402-4221 Fax: 301-402-0832 Email: lq2n@nih.gov	Mr. Chris Robey Phone: 301-435-6996 Fax: 301-402-0915 Email: robeyj@mail.nih.gov
National Institute on Drug Abuse http://www.nida.nih.gov	Dr. Cathrine Sasek Phone: 301-443-6071 Fax: 301-443-6277 Email: cs106o@nih.gov	Ms. Diana Haikalis Phone: 301-443-6710 Fax: 301-594-6849 Email: dh84m@nih.gov
National Institute on Deafness and Other Communication Disorders http://www.nidcd.nih.gov	Dr. Lynn E. Luethke Phone: 301-402-3458 Fax: 301-402-6251 Email: lh99s@nih.gov	Mr. Christopher P. Myers Phone: 301-402-0909 Fax: 301-402-1758 Email: cm143g@nih.gov
National Institute of Dental and Craniofacial Research http://www.nidcr.nih.gov	Dr. Rosemarie Hunziker Phone: 301-451-3888 Fax: 301-480-8318 Email: rh71k@nih.gov	Ms. Mary Daley Phone: 301-594-4808 Fax: 301-480-3562 Email: md74u@nih.gov
National Institute of Diabetes and Digestive and Kidney Diseases http://www.niddk.nih.gov	Dr. Sanford A. Garfield Phone: 301-594-8803 Fax: 301-402-6271 Email: sg50o@nih.gov	Ms. Helen Y. Ling Phone: 301-594-8857 Fax: 301-480-3504 Email: hl12d@nih.gov
National Institute of Environmental Health Sciences http://www.niehs.nih.gov	Dr. Jerrold Heindel Phone: 919-541-0781 Fax: 919-541-5064 Email: jh190f@nih.gov	Mr. Dwight Dolby Phone: 919-541-7824 Fax: 919-541-2860 Email: dd45g@nih.gov

AWARDING COMPONENT	PROGRAM CONTACT	GRANTS MGMT. CONTACT
National Eye Institute http://www.nei.nih.gov	Dr. Ralph Helmsen Phone: 301-451-2020 Fax: 301-402-0528 Email: rjh@nei.nih.gov	Mr. William Darby Phone: 301-451-2020 Fax: 301-496-9997 Email: wwd@nei.nih.gov
National Institute of General Medical Sciences http://www.nigms.nih.gov/	Dr. Peter Preusch Phone: 301-594-3827 Fax: 301-480-2802 Email: pp27g@nih.gov	Ms. Patrice Molnar Phone: 301-534-5136 Fax: 301-480-2554 Email: pm32e@nih.gov
National Heart, Lung, and Blood Institute http://www.nhlbi.nih.gov	Ms. Susan Pucie Phone: 301-435-0079 Fax: 301-480-0867 Email: sp34j@nih.gov	Ms. Suzanne White Phone: 301-435-0144 Fax: 301-480-3310 Email: sw52h@nih.gov
National Human Genome Research Institute http://www.genome.gov	Dr. Bettie J. Graham Phone: 301-496-7531 Fax: 301-480-2770 Email: bg30t@nih.gov	Ms. Cheryl Chick Phone: 301-435-7858 Fax: 301-402-1951 Email: cc149o@nih.gov
National Institute of Mental Health http://www.nimh.nih.gov	Dr. Michael F. Huerta Phone: 301-443-3563 Fax: 301-443-1731 Email: mh38f@nih.gov	Ms. Rebecca Claycamp Phone: 301-443-2811 Fax: 301-443-6885 Email: rc253d@nih.gov
National Institute of Neurological Disorders and Stroke http://www.ninds.nih.gov	Dr. Randall Stewart Phone: 301-496-1917 Fax: 301-402-1501 Email: StewartR@ninds.nih.gov	Mr. Mike Loewe Phone: 301-496-5707 Fax: 301-402-0219 Email: ml170m@nih.gov
National Institute of Nursing Research http://www.nih.gov/ninr	Dr. Paul A. Cotton Phone: 301-402-6423 Fax: 301-480-8260 Email: pc272a@nih.gov	Mr. Brian Albertini Phone: 301-594-6869 Fax: 301-402-4502 Email: ba18b@nih.gov
National Center for Research Resources http://www.ncrr.nih.gov	Dr. Louise E. Ramm Phone: 301-435-0879 Fax: 301-480-3658 Email: lr34m@nih.gov	Ms. Holly Atherton Phone: 301-435-0840 Fax: 301-480-3777 Email: ha5i@nih.gov
National Center for Complementary and Alternative Medicine http://www.nccam.nih.gov/	Dr. Carol Pontzer Phone: 301-496-7498 Fax: 301-480-3621 Email: cp253q@nih.gov	Mr. George Tucker, MBA Phone: 301-594-8853 Fax: 301-480-1552 Email: gt35v@nih.gov
National Center on Minority Health and Health Disparities http://www.ncmhd.nih.gov	Mr. Vincent Thomas, MSW, MPA Phone: 301-402-2516 Fax: 301-480-4049 Email: vt5e@nih.gov	Mr. Bryan Clark, MBA Phone: 301-594-8412 Fax: 301-480-4049 Email: bc208o@nih.gov

AWARDING COMPONENT	PROGRAM CONTACT	GRANTS MGMT. CONTACT
National Library of Medicine http://www.nlm.nih.gov	Dr. Hua-Chuan Sim Phone: 301-496-4253 Fax: 301-402-2952 Email: simh@mail.nih.gov	Mr. Dwight Mowery Phone: 301-496-4221 Fax: 301-402-0421 Email: dm99n@nih.gov
Centers for Disease Control and Prevention (CDC) http://www.cdc.gov	Mr. Curtis L. Bryant Phone: 770-488-2806 Fax: 770-488-2828 Email: ckb9@cdc.gov	Ms. Nealean Austin (OGDP, NCCDPHP, NCBDDD) Phone: 770-488-2716 Fax: 770-488-2777 Email: naustin@cdc.gov Ms. Mildred Garner (NCEH) Phone: 770-488-2745 Fax: 770-488-2777 Email: mgarner@cdc.gov Ms. Edna Green (NCIPC) Phone: 770-488-2743 Fax: 770-488-2777 Email: egreen@cdc.gov Mr. Larry Guess (NIOSH) Phone: 412-386-6826 Fax: 412-386-6429 Email: lguess@cdc.gov
Food and Drug Administration (FDA) http://www.fda.gov	Mr. Phillip Osborne Phone: 301-827-2476 Fax: 301-827-7106 Email: phillip.osborne@fda.gov	Ms. Tya Marks Phone: 301-827-7179 Fax: 301-827-7106 Email: tya.marks@fda.gov

Before Submission

You may wish to contact NIH/CDC/FDA staff with a variety of questions before submitting an application.

Contact GrantsInfo and/or the Division of Receipt and Referral, Center for Scientific Review (CSR), NIH:

- To identify Institutes/Centers (ICs) at NIH or other non-NIH agencies and/or a Scientific Review Group (SRG) that might be appropriate for your application. Note requests for assignment to an Institute/Center and/or a SRG may be made in a cover letter at the time of application submission.
- To learn about grant mechanisms.

Contact program staff in the relevant awarding component:

- To determine whether your proposed application topic would fit into the NIH IC's or other non-NIH agency's programmatic area.
- To learn about programmatic areas of interest to the IC or other non-NIH agencies.
- To find out about requesting an assignment to an IC.
- To discuss whether you should respond to an RFA.

Contact Scientific Review Administrators in the CSR to discuss requesting assignment to a SRG.

After Submission

If the initial assignment to an IC or SRG seems inappropriate, the Project Director/Principal Investigator (PD/PI) may request reassignment. Such requests should be made in writing to:

Division of Receipt and Referral
Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Suite 2030, MSC 7720
Bethesda, MD 20892-7720
Fax requests (301-480-1987) are also acceptable.

Although these requests will be carefully considered, the final determination will be made by the PHS agency.

Applicants must never contact reviewers regarding their applications because discussion of the scientific content of an application or an attempt to influence review outcome will constitute a conflict of interest in the review process. Reviewers are required to notify the Scientific Review Administrator if they are contacted by an applicant. Communication by the applicant to a reviewer may delay the review or result in the return of the application without review.

After Assignment

Contact your Scientific Review Administrator to discuss the review assignment, to request permission to send additional/corrective materials, and/or to discuss any review concerns (e.g., expertise needed on your study section, conflicts, reviewers that may have bias).

After Peer Review

Feedback to applicants is very important. Once the PD/PI receives the Summary Statement, s/he may contact the appropriate awarding component program official (noted on the Summary Statement):

- To discuss the review outcome of the application and obtain guidance.
- To get feedback and answers to any questions about the Summary Statement.
- To find out the meaning of a numerical designation pertaining to human subjects or vertebrate animals on the Summary Statement.
- To find out the funding status of an application.

More detailed information on each of the NIH awarding components, as well as the CDC and the FDA, and their research interests are available electronically on the home pages cited in Table 1.4-1 and in the NIH, CDC, and FDA Program Descriptions and Research Topics of the SBIR and STTR funding opportunity announcements.

Note a paper copy of the Peer Review Outcome Letter and Summary Statement is no longer mailed to the PI. PIs must now access this information in the eRA Commons.

1.5 Grants Policy Statements

The *PHS Grants Policy Statement* serves as a term and condition of award and is a compilation of the salient features of policies and various policy issues regarding the administration of PHS grant awards, excluding NIH awards.

The *NIH Grants Policy Statement* serves as a term and condition of award and is a compilation of the salient features of policies and various policy issues regarding the administration of NIH awards.

Both publications are available from the following NIH website:
http://grants.nih.gov/grants/policy/policy.htm.

1.6 References

Applicants New to NIH: Getting Started

http://grants.nih.gov/grants/useful_links.htm

Award Data

(CRISP, extramural research grants, award trends, training and career awards)
http://grants.nih.gov/grants/award/award.htm

Contact Information for an NIH Staff Person

http://directory.nih.gov
NIH locator: (301) 496-4000

Electronic Receipt

For additional information on preparing for electronic receipt, see:
http://era.nih.gov/ElectronicReceipt/preparing.htm

eRA Commons

For electronic submission of applications, organizations/institutions are required to register with the eRA Commons. Registered PDs/PIs can check assignment/contact information, review outcome, and other important information at https://commons.era.nih.gov/commons/index.jsp. For more details on Commons registration, see Section 2.2.2.

Email the Commons Help Desk at commons@od.nih.gov.

You can call the Commons Help Desk at 1-800-504-9552 (toll-free) or 301-402-7469; 301-451-5939 (TTY). Business hours are M-F 7am-8pm Eastern Time.

Grant Writing Tips

http://grants.nih.gov/grants/grant_tips.htm

Grants Information

http://grants.nih.gov/grants/giwelcome.pdf

Email: GrantsInfo@nih.gov
Telephone: (301) 435-0714

Grants.gov User Guide

The Grants.gov User Guide is a comprehensive reference to information about Grants.gov. Applicants can download the User Guide as a Microsoft Word document or as a PDF document. The user guide can be accessed at the following address: http://www.grants.gov/CustomerSupport.

NIH Office of Extramural Research Human Subjects Website

This site provides, in one place, HHS and NIH requirements and resources for the extramural community involved in human subjects research http://grants.nih.gov/grants/policy/hs/index.htm.

Office for Human Research Protections

(Human Subject Protections, Institutional Review Boards, or related assurances)
http://www.hhs.gov/ohrp

Telephone: 1-866-447-4777 or (301) 496-7005

Office of Laboratory Animal Welfare (OLAW)

(Animal Welfare and related regulations and assurances)
http://grants.nih.gov/grants/olaw/olaw.htm
Telephone: (301) 496-7163

Receipt/Referral of an Application

Division of Receipt and Referral
Center for Scientific Review
http://www.csr.nih.gov/EVENTS/AssignmentProcess.htm
Telephone: (301) 435-0715
TTY: (301) 451-0088
Fax: (301) 480-1987

Specific Application: Before Review

Telephone or email the Scientific Review Administrator named on the electronically-generated "notification of assignment" that is sent to you upon assignment of your application.

Specific Application: Post Review

Telephone or email the NIH Program Official named on the Summary Statement of your application.

1.6.1 Other Resources

Collaboration Opportunities and Research Partnerships (CORP)

Are you in need of a collaborator or researcher with specific scientific expertise to work on an SBIR/STTR project? NIH wants to foster collaborative opportunities related to the SBIR/STTR programs. Therefore, if you are looking for a research partner or looking to partner with a small research firm, please visit http://grants.nih.gov/cfdocs/corp/add.htm to submit your needs or capabilities. Submissions considered appropriate for this site will be added to the CORP list (http://grants.nih.gov/grants/funding/corp.htm).

FDA Resources and Useful Websites

The Food and Drug Administration offers various types of information to small businesses engaged in research projects that will ultimately require FDA approval. This information could be valuable in formulating research aims designed for this purpose, especially those in later stages of development (e.g., Investigational New Drug [IND] filing).

Small Business Assistance: http://www.fda.gov/cder/about/smallbiz/default.htm

Drug Approval Application Process: http://www.fda.gov/cder/regulatory/applications/

Center for Drug Evaluation and Research (CDER): http://www.fda.gov/cder/

Center for Biologics Evaluation and Research (CBER): http://www.fda.gov/cber/

Center for Devices and Radiological Health (CDRH): http://www.fda.gov/cdrh/

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH): http://www.ich.org

Guidance Documents: http://www.fda.gov/cder/guidance
Applicants should be aware that not all information in these documents apply to drugs intended for use in patients with serious and life-threatening diseases (e.g., for refractory metastatic cancers).

Drug development, drug review, and postmarketing activities:

The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective. (9/2002). *FDA Consumer* magazine article.

From Test Tube to Patient: Improving Health Through Human Drugs (9/1999). In-depth review of drug development and post-marketing activities.

New Drug Development in the United States. Online seminar provides healthcare professionals with an overview of FDA's role in the new drug development process.

SBIR/STTR LISTSERV

To get timely information about the SBIR/STTR programs, send an email to LISTSERV@LIST.NIH.GOV with the following text in the message body: *subscribe SBIR-STTR <your name>* (*e.g., subscribe SBIR-STTR Jane Doe*). (The LISTSERV will retrieve your email address from the "From:" section of your email message.)

1.7 Authorization

The PHS requests the information described in these instructions pursuant to its statutory authorities for awarding grants, contained in Sections 301(a) and 487 of the PHS Act, as amended (42 USC 241a and 42 USC 288). Therefore, such information must be submitted if an application is to receive due consideration for an award. Lack of sufficient information may hinder the ability of the PHS to review an application and to monitor the grantee's performance.

SBIR: This request for SBIR information is issued pursuant to the authority contained in P.L. 106-554. The current law authorizes the program through September 30, 2008. Government-wide SBIR policy is provided by the Small Business Administration (SBA) through its SBIR Program Policy Directive. Federal agencies with extramural research and development budgets over $100 million are required to administer SBIR programs using an annual set-aside of 2.5% for small companies to conduct innovative research or research and development (R/R&D) that has potential for commercialization and public benefit. Currently, 11 Federal agencies participate in the SBIR program: the Departments of Health and Human Services (DHHS), Agriculture (USDA), Commerce (DOC), Defense (DOD), Education (ED), Energy (DOE), Homeland Security (DHS), and Transportation (DOT); the Environmental Protection Agency (EPA), the National Aeronautics and Space Administration (NASA), and the National Science Foundation (NSF).

STTR: This request for STTR information is issued pursuant to the authority contained in P.L. 107-50. The current law authorizes the program through September 30, 2009. Government-wide STTR policy is provided by the SBA through its STTR Program Policy Directive.

Federal agencies with extramural R&D budgets over $1 billion are required to administer STTR programs using an annual set-aside of 0.30%. Currently, five Federal agencies participate in the STTR program: DOD, DHHS (NIH), DOE, NASA, and NSF.

1.8 Paperwork Burden

The PHS estimates that it will take approximately 40 hours to complete this application for a regular research project grant. This estimate excludes time for development of the scientific plan. Items such as human subjects and vertebrate animals are cleared and accounted for separately. Therefore, these items are also not part of the time estimate. An agency may not conduct or sponsor the collection of information unless it displays a currently valid OMB control number. Nor is a person required to respond to requests for the collection of information without this control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Office, 6705 Rockledge Drive MSC 7974, Bethesda, MD 20892-7974, ATT: PRA (0925-0001). Do not send applications to this address.

2. Process for Application Submission via Grants.gov

Application submission through Grants.gov involves several steps. Access the "Get Started" tab on the Grants.gov Web site (http://grants.gov). Some of the steps need only be done one time. Others are ongoing steps that will be necessary for each application submission. Before beginning the application process, you are encouraged to review Grants.gov and all the resources available there.

2.1 Overview

The following steps must be taken in order to submit a grant application through Grants.gov:

1. Register your organization at Grants.gov. (This is a one-time only registration process for all Federal agencies. If your organization has already completed this step for any Federal agency submission, skip to step #2. If your organization has not completed this step, see Section 2.2 for more details.)
2. Register your organization and PD/PI in the eRA Commons. (This is a one-time only registration process. If your organization has already completed this step, skip to step #3. If your organization has not completed this step, see Section 2.2 for more details.)
3. Find a Funding Opportunity Announcement (FOA) using the Grants.gov "Apply" feature that reflects use of the SF424 (R&R) forms and electronic submission through Grants.gov. (See Section 2.4 for more details.)

   SBIR-PA-06-120: PHS 2006-2 Parent Solicitation of the NIH, CDC, and FDA for Small Business Innovation Research Grant Applications (SBIR [R43/R44]): Electronic Submission through Grants.gov

   STTR-PA-06-121: PHS 2006-2 Parent Solicitation of the NIH for Small Business Technology Transfer Grant Applications (STTR [R41/R42]): Electronic Submission through Grants.gov.

   A complete list of SBIR/STTR FOAs is available on the NIH Small Business Funding Opportunities Web site.
4. Download the associated Application Package from Grants.gov. (PureEdge Viewer required before download. See Section 2.3 for more details.)

5. Complete the appropriate application components, including all text (PDF) and PureEdge attachments. Upload all attachments into the appropriate application component. (See Section 2.6 for more details on the requirements for text (PDF) attachments.)
6. The completed application should be reviewed through your own organizational review process.
7. Coordinate with an Authorized Organizational Representative (AOR) at the applicant organization to submit the application by the date specified in the FOA. (**Keep a copy locally at the Applicant Organization/Institution.**)
8. Receive the Grants.gov tracking number.
9. After agency validation, receive the agency tracking number (accession number).
10. PD/PI and Signing Official (SO) complete a verification process in the eRA Commons. (See Section 2.11 for detailed information.)

The following sections explain each step in more detail.

2.2 Registration Processes

2.2.1 Grants.gov Registration

Grants.gov requires a **one-time** registration *by the applicant organization.* PDs/PIs do not have to register individually in Grants.gov unless they also serve as the Authorized Organizational Representative (AOR) for their institution/organization. If an applicant organization has already completed Grants.gov registration for another Federal agency, they can skip this section and focus on the NIH eRA Commons registration steps noted below. For those applicant organizations still needing to register with Grants.gov, registration information can be found at Grants.gov/GetStarted (http://www.grants.gov/GetStarted). While Grants.gov registration is a one-time only registration process, it does involve several steps and will take some time. Applicant organizations needing to complete this process are encouraged to **start early** allowing several weeks to complete all the steps before actually submitting an application through Grants.gov.

The AOR is an individual authorized to act for the applicant organization and to assume the obligations imposed by the Federal laws, requirements, and conditions for a grant or grant application, including the applicable Federal regulations. This individual has the authority to sign grant applications and required certifications and/or assurances that are necessary to fulfill the requirements of the application process. Once this individual is registered, the organization can then apply for any government funding opportunity listed in Grants.gov, including NIH and other PHS agencies grants.

Questions regarding Grants.gov registration should be directed to the Grants.gov Contact Center at telephone: 1-800-518-4726. Contact Center hours of operation are Monday–Friday from 7:00 a.m. to 9:00 p.m. Eastern Time.

2.2.2 eRA Commons Registration

The applicant organization and the PD/PI must also complete a **one-time** registration in the eRA Commons. Access to the Commons is vital for all steps in the process after application submission. An organization and PDs/PIs must be registered in the Commons before they can take advantage of electronic submission and retrieval of grant information, such as reviewing grant applications, institute/center assignments, review outcomes, and Summary Statements. Institutional/organizational officials are responsible for registering PDs/PIs in the eRA Commons. PDs/PIs should work with their AOR (also known as the Signing Official in the eRA Commons) to determine their institutional/organizational process for registration.

IMPORTANT: The eRA Commons registration process should be started at least **two (2) weeks** prior to the submittal date of a Grants.gov submission. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field of the Senior/Key Profile Component will prevent the successful submission of an electronic application to NIH

2.2.2.1 Commons Registration for the Organization

Organizations may verify their current registration status by accessing the "List of Grantee Organizations Registered in NIH eRA Commons (http://era.nih.gov/userreports/ipf_com_org_list.cfm).

To register an organization in the eRA Commons:

1. Open the eRA Commons homepage (https://commons.era.nih.gov/commons/).
2. Click Grantee Organization Registration (found in "About the Commons" links on the right side of the screen).
3. Follow the step-by-step instructions. Remember to fax in the registration signature page to eRA.
4. Click Submit. The organization is registered when the NIH confirms the information and sends an email notification of registered Signing Official (SO) account (userid/password).

This registration is independent of Grants.gov and may be done at any time.

Organizational data elements, such as Institutional Profile Number (IPF), Entity Identification Number (e.g., 5555555555A5) and DUNS Number must be accurately identified. **Note the DUNS number must be included in the Institutional Profile for applications to be accepted. In addition, the DUNS number in the Institutional Profile must match that entered in the SF424 (R&R) Cover Component in Section 5, Applicant Information.** This information will be used to generate the electronic grant application image that the Signing Official and the PD/PI will be asked to verify within the eRA Commons. See Section 2.11 for details on the Commons application verification process.

Since eRA has not required a DUNS number during eRA Commons registration, there are many accounts that do not contain valid information in this field. Prior to submission, the AOR/SO should verify that their organization's eRA Commons profile contains the valid DUNS number that will be used for the submission process. The SO has the ability to edit this field in the organization profile in Commons.

To confirm that your organization has a DUNS number or to find out if the DUNS number you have matches the one in Commons, access the List of Grantee Organizations Registered in NIH eRA Commons (http://era.nih.gov/userreports/ipf_com_org_list.cfm). This listing of grantee organizations registered in Commons and their DUNS numbers can be accessed without logging into Commons.

2.2.2.2 Commons Registration for the Project Director/Principal Investigator (PD/PI)

The individual designated as the PD/PI on the application must also be registered in the Commons. The PD/PI must hold a PI account **and** be affiliated with the applicant organization. **This registration must be done by an organizational official (or delegate) who is already registered in the Commons.** To register PDs/PIs in the Commons, refer to the NIH eRA Commons User Guide (http://era.nih.gov/Docs/COM_UGV2630.pdf). Assure that the Person Profile in the Commons for Employments has entered the applicant organization as the preferred address (it must be current for one of the employments). Check the box to the right of "Is this your preferred employment address?" The address on the SF424 (R&R) form and the employments section must match.

Once the PD/PI has received email confirming his/her registration within the Commons, the PD/PI must verify that all Personal Information located within the Personal Profile tab in the eRA Commons System is accurate. Please have the PD/PI review and update, as needed, data elements such as first name, middle initial, last name, prefix and/or suffix to PD/PI name (including all embedded punctuation), email, phone,

fax, street address, city, state, country, zip code and degrees earned. These data must contain the most recent information in order for the application to be processed accurately.

Both PD/PI and SO need separate accounts in Commons since both need to verify the application. If you are the SO for your organization as well as a PI of the grant, you will need two separate accounts with different user names – one with SO authority and one with PI authority. When an organization is registered, an SO account is created. Log on to the account with the SO authority role and create another account with PI authority.

It is important to note that if a PD/PI is also an NIH peer-reviewer with an Individual DUNS and CCR registration, that particular DUNS number and CCR registration are for the individual reviewer only. These are different than any DUNS number and CCR registration used by an applicant organization. Individual DUNS and CCR registration should be used only for the purposes of personal reimbursement and should not be used on any grant applications submitted to the Federal Government.

For additional information on how to prepare for electronic submission, see: http://era.nih.gov/ElectronicReceipt/preparing.htm.

The STTR applicant organization must officially affiliate the PD/PI with the small business concern in the Commons if the PD/PI is not an employee of the small business concern.

Following are the steps to affiliate a PD/PI to the applicant organization/institution:

1. PD/PI gives commons user ID and email address to the administrator of the applicant organization/institution. (The email address must be the one that is contained in the Personal Profile for the PI.)
2. Administrator logs into the Commons. (The Administrator can be the Signing Official, Administrative Official, or the Accounts Administrator.)
3. Administrator selects “Administration” tab and then “Accounts” tab.
4. Administrator selects “Create Affiliation” tab.
5. Administrator enters the Commons User ID and email address into the appropriate fields and clicks “Submit.”

The account cannot have any other roles attached to it other than the PD/PI.

2.3 Software Requirements

2.3.1 PureEdge

In order to access, complete and submit applications, applicants need to download and install the PureEdge Viewer. For minimum system requirements and download instructions, please see the Grants.gov User Guide.

2.3.2 Creating PDFs for Text Attachments

NIH and other PHS agencies *require* all text attachments to the PureEdge forms to be submitted as Portable Document Format (PDF) files.

Attachments generated from PureEdge forms, such as the R&R SubAward Budget Attachment Form, should *not* be converted to PDF.

Applicants should prepare text attachments using any word processing program (following the format requirements in Section 2.6) and then convert those files to PDF before attaching the files to the appropriate component in the application package. (The PDF format is used to preserve document formatting.)

Some type of PDF-creation software is necessary to create the PDF. (The free Adobe Reader *will not create* a PDF.) To assist applicants searching for PDF-creation software, Grants.gov has published the following list of available tools and software: http://www.grants.gov/assets/PDFConversion.pdf. Additionally, applicants may find Planet PDF's "Find PDF Software" feature (http://www.planetpdf.com/find_software.asp) useful to browse or search a comprehensive database of free, shareware, or commercial PDF products. Applicants should choose the PDF-creation software that best suits their needs.

It is recommended that, as much as possible, applicants avoid scanning text documents to produce the required PDFs. Instead, NIH recommends producing the documents electronically using text or word-processing software and then converting documents to PDF. Scanning paper documents, without the proper Optical Character Recognition (OCR) process, will hamper automated processing of your application for NIH analysis and reporting.

DISCLAIMER: References to software packages or Internet services neither constitute nor should be inferred to be an endorsement or recommendation of any product, service, or enterprise by the NIH or other PHS agencies, any other agency of the United States Government, or any employee of the United States Government. No warranties are stated or implied.

2.3.3 Special Instructions for Macintosh Users

If the applicant does not have a Windows operating system, the applicant can still use PureEdge by using a Windows emulation program. PureEdge has created detailed instructions for Macintosh users:

http://www.grants.gov/GrantsGov_UST_Grantee/!SSL!/WebHelp/MacSupportforPureEdge.pdf

If the applicant has problems setting-up the software, he or she may not have security permissions to install new programs on the organization's computer system. If that is the case, the applicant should contact their organization's system administrator.

2.4. Funding Opportunities

Grants for health-related research and research training projects or activities make up the largest category of funding provided by the NIH Institutes/Centers (ICs) and other non-NIH agencies. Most applications for support are investigator-initiated and originate with individual investigators who develop proposed plans for research or research training within an area that is relevant to the NIH. Research project grants are awarded to organizations/institutions on behalf of PDs/PIs to facilitate the pursuit of a scientific objective when the idea for the research is initiated by the investigator. If the funding agency anticipates substantial program involvement during the conduct of the research, a cooperative agreement will be awarded, rather than a grant. The NIH awards grants and cooperative agreements for terms ranging from one to five years. Organizational/institutional sponsorship assures that the awardee organization will provide the facilities and the financial stability necessary to conduct the research, and be accountable for the funds. For a list and brief description of grant mechanisms, see Part III: Policies, Assurances, Definitions, and Other Information.

2.4.1 NIH Guide for Grants and Contracts

The *NIH Guide for Grants and Contracts* (http://grants.nih.gov/grants/guide), a weekly electronic publication, contains announcements about funding opportunities, such as Requests for Applications (RFAs) and Program Announcements (PAs) from NIH and other PHS agencies. The *NIH Guide* also contains vital information about policies and procedures. To subscribe to the *NIH Guide*, visit http://grants.nih.gov/grants/guide/listserv.htm.

2.4.2 Grant and Cooperative Agreement Solicitations

To hasten the development of a program or to stimulate submission of applications in an area of high priority or special concern, an awarding component will encourage applications through the issuance of a PA to describe new, continuing, or expanded program interests, or issuance of an RFA inviting applications in a well-defined scientific area to accomplish a scientific purpose.

Definitions of PAs and RFAs are as follows:

Program Announcement (PA): A formal statement about a new or ongoing extramural activity or mechanism. It may serve as a reminder of continuing interest in a research area, describe modification in an activity or mechanism, and/or invite applications for grant support. Most applications in response to PAs may be submitted to a standing submission date and are reviewed with all other applications received at that time.

Request for Applications (RFA): A formal statement that **solicits** grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program objectives. An RFA indicates the estimated amount of funds set aside for the competition, the estimated number of awards to be made, and the application **submission date**(s). Applications submitted in response to an RFA are usually reviewed by a Scientific Review Group (SRG) specially convened by the awarding component that issued the RFA.

Specific PAs and RFAs are published in the *NIH Guide for Grants and Contracts* (http://grants.nih.gov/grants/guide), the *Federal Register* (http://www.gpoaccess.gov/nara/index.html), and on Grants.gov/Find Grant Funding Opportunities (http://www.grants.gov/Find). Read the RFA or PA carefully for special instructions. The instructions in the RFA or PA may differ from the general instructions, and they supersede the general instructions. Each RFA or PA published in the *NIH Guide for Grants and Contracts*, the *Federal Register*, Grants.gov Find, or other public document contains contact information under *Inquiries* in addition to information specific to the RFA or PA.

While individual announcements will continue to carry an announcement number reference to "PA" or "RFA," all announcements are "Funding Opportunity Announcements (FOAs)." This general term will be used to reference any type of funding announcement. NIH will continue to use the PA and RFA references in the actual announcement number to distinguish between the various types of announcements.

In reading any Funding Opportunity Announcement (FOA) in the *NIH Guide for Grants and Contracts*:

- A "release/posted date" refers to the date the FOA is posted on Grants.gov/Apply. An applicant can download the application package on that date and begin filling it out. However, the applicant has to wait until the FOA's "opening date" to submit the application.
- An application can be submitted anytime between the "opening date" and the "application submission date(s)" noted for AIDS and non-AIDS applications. (Standard dates may apply; check http://grants.nih.gov/grants/funding/submissionschedule.htm for details.)
- When you download an application package from Grants.gov, the "expiration date" is prepopulated. Do not go strictly by this date since it may not apply to your particular situation; for

instance, it may reflect the submission date for AIDS applications and you may be submitting a non-AIDS application that is due earlier. In this case, the prepopulated date has no bearing on your application and you should not be concerned by it.

2.4.3 Finding a Funding Opportunity Announcement (FOA) for Grants.gov Submission

Implementation of the SF424 (R&R) application and electronic submission through Grants.gov will be announced through specific FOAs posted in the *NIH Guide for Grants and Contracts* and on Grants.gov under "Find Grant Opportunities" (a.k.a. "Find") and "Apply for Grants" (a.k.a "Apply"). While all FOAs are posted in Grants.gov Find, not all reference electronic submission via Grants.gov at this time. FOAs posted in Grants.gov Apply reflect those the agency is prepared to receive through electronic Grants.gov submission. Applicants are encouraged to read each FOA carefully for specific guidance on the use of Grants.gov submission.

There are several ways a prospective applicant can find a FOA on Grants.gov.

Using the *NIH Guide for Grants and Contracts*

FOAs in the *NIH Guide for Grants and Contracts* that reference electronic submission via Grants.gov now include a link from the FOA directly to the Grants.gov site where you can download the specific application package. The "Apply for Grants Electronically" button is found in the *NIH Guide* FOA directly under the announcement number. This link is only provided in those announcements involving electronic submission through Grants.gov.

Using "Find Grant Opportunities" (Find) Feature

Grants.gov Find provides general search capabilities. To perform a **basic search** for a grant, complete the "Keyword Search"; the "Search by Funding Opportunity Number"; **OR** the "Search by CFDA Number" field; and then click the "Start Search" button below. Search for application packages on Grants.gov by funding opportunity number rather than CFDA. Grants.gov can only associate one CFDA number with an application package, so currently only the first CFDA number appears in the Grants.gov Apply system. Note that NIH has made it easier for applicants by adding a button ("Apply for Grant Electronically") to the *NIH Guide for Grants and Contracts* announcements that allows applicants to access the Grants.gov application package directly from the *NIH Guide*.

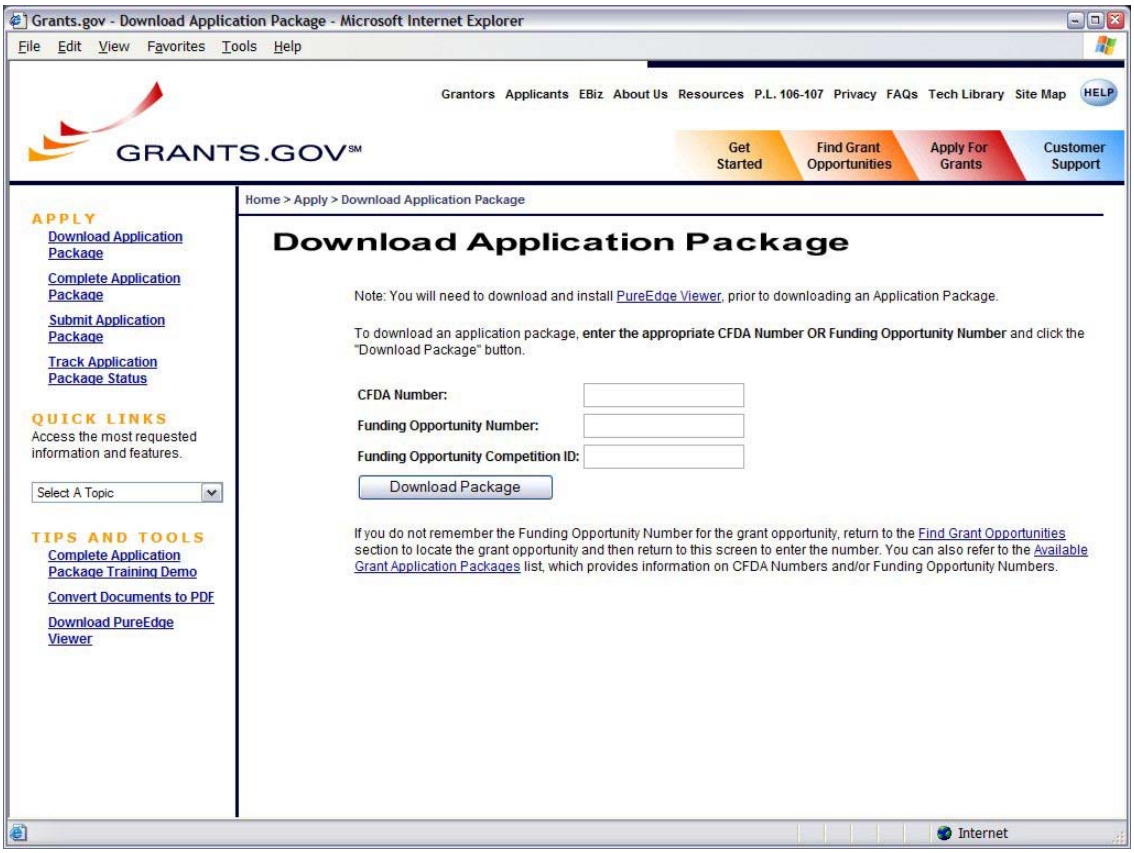
Access Search Tips for helpful search strategies, or click the Help button in the upper right corner of Grants.gov to get help with the Search screen.

You must download the SF424 (R&R) Application Package and Application Guide for a specific FOA (e.g., PA-06-120, PA-06-121) through Grants.gov/Apply. Only the forms package directly attached to a specific FOA may be used.

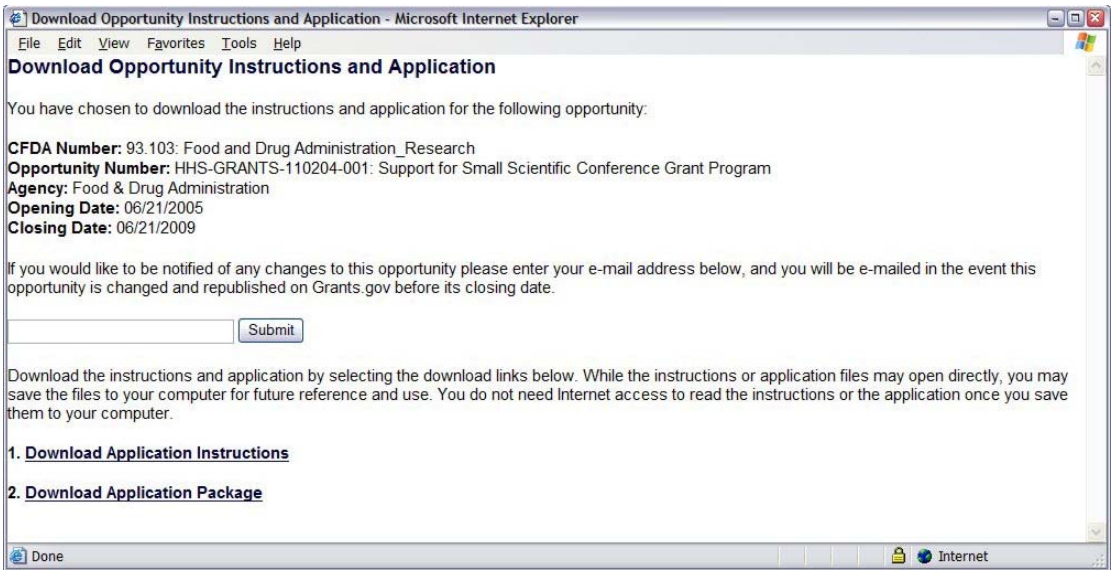
Remember, before you can apply electronically, the applicant small business organization must be registered at BOTH Grants.gov and the eRA Commons.

Using "Apply for Grants" (Apply) Feature

If you know the specific funding opportunity number, a more direct route is to use the "Apply" feature. From the Grants.gov home page, select "Apply for Grants" and follow the steps provided. "Apply Step 1" allows you to download an application package by inserting a specific Funding Opportunity Number (FOA). On the "Download Application Package page," there is a link to FOAs available for submission through Grants.gov, "Available Grant Application Packages" if you do not know the specific Funding Opportunity Number. A list of all FOAs, "Find Grant Opportunities," is also available on this page.



A Funding Opportunity Number is referenced in every announcement. It may be called a Program Announcement (PA) Number or a Request for Application (RFA) Number. Enter this number in the Funding Opportunity Number field and click "Download Package." This takes you to a "Selected Grant Applications for Download" screen. If you searched only on a specific opportunity number, only one announcement is provided in the chart. Click the corresponding "download" link to access the actual application form pages and instruction material. The following screen appears:



To access the instructions, click "Download Application Instructions." For NIH opportunities and other PHS agencies using this Application Guide, this action will download a document containing a link to the NIH Web site where the most current set of application instructions is available (http://grants.nih.gov/grants/funding/424/index.htm). Applicants are encouraged to check this site regularly for the most current version.

To access the form pages, click "Download Application Package." Section 2.5 provides specific information regarding the components of an Application Package. Section 3 provides additional instructions for properly using a package.

On the Download Opportunity Instructions and Applications screen you will be given an opportunity to provide an e-mail address if you would like to be notified of any changes to this particular opportunity. Applicants to NIH and other PHS agencies are strongly encouraged to complete this information. The agency can then use it to provide additional information to prospective applicants.

Note: If multiple CFDA numbers are cited in the FOA, the Download Opportunity Instructions and Applications screen may prefill a CFDA number and description that may not correspond to the Institute/Center of interest to you, or the CFDA information may not appear at all. In either case, do not be concerned since the Center for Scientific Review, NIH does not use the CFDA number for assignment of the application. Be assured the correct CFDA number will be assigned to the record once the appropriate IC assignment has been made.

2.5 Components of an Application to NIH or Other PHS Agencies

The SF424 (R&R) form set is comprised of a number of components, each listed in the table below as a separate "document." In addition to these components, NIH and other PHS agencies applicants will also complete supplemental components listed as "PHS398" components in the table below.

SBIR/STTR applicants will also complete the "SBIR/STTR Information" component.

Table 2.5-1. Components of an NIH or Other PHS Agencies Application

Document	Required	Optional	Instructions
SF424 (R&R) Cover	✔		Section 4.2
SF424 (R&R) Project/Performance Site Locations	✔		Section 4.3
SF424 (R&R) Other Project Information	✔		Section 4.4
SF424 (R&R) Senior / Key Person Profile(s)	✔		Section 4.5
SF424 (R&R) Budget	✔		Section 4.6
SF424 (R&R) Subaward Budget Attachment Form		✔	Section 4.7
PHS398 Cover Letter		✔	Section 5.2
PHS398 Cover Page Supplement	✔		Section 5.3
PHS398 Research Plan	✔		Section 5.4
PHS398 Checklist	✔		Section 5.5
SBIR/STTR Information	✔		Section 5.6

2.6 Format Specifications for Text (PDF) Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are concatenated into a single document that is used by peer reviewers and agency staff.

When using Adobe Acrobat (and possibly other tools), the signature has to be "off" when you create the originals. Please go to the security options menu selection in Adobe to ensure the signature is off. If you do not have the originals, copy the content of the signed documents and create a new document. Save this document without signing it.

Applicants should not submit protected PDF documents. Protected documents prevent NIH from opening and processing the document. Security settings vary by PDF tool, but please ensure security settings are not marked. The applicant needs to look at the Document Security tab under Document Properties (directly from the tab) and set the security parameters to ensure open access so NIH can process the content. For instance, do not password protect the document and do not mark Content Extraction or Copying, Document Assembly, etc. as "Not Allowed."

If you are having trouble fixing the PDF settings, simply cut and paste from the PDF document into a Microsoft Word document and then reconvert (in some cases it may be better to use another PDF converter).

NIH and other PHS agencies require all text attachments to the PureEdge forms to be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted below. Failure to follow these requirements may lead to rejection of the application during agency validation or delay in the review process. (See Section 2.3.2 for more information on creating PDFs.)

Font

Use an Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.)

Type density, including characters and spaces, must be no more than 15 characters per inch.

Type may be no more than six lines per inch.

Page Margins

Use *standard paper size (8 ½" x 11)*.

Use at least one-half inch margins (top, bottom, left, and right) for all pages.

Page Formatting

Since a number of reviewers will be reviewing applications as an electronic document and not a paper version, applicants are strongly encouraged to use only a standard, single-column format for the text. Avoid using a two-column format since it can cause difficulties when reviewing the document electronically.

Do not include any information in a header or footer of the attachments. A header will be system-generated that references the name of the PD/PI. Page numbers for the footer will be system-generated in the complete application, with all pages sequentially numbered.

Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes

You may use a smaller type size but it must be in a black font color, readily legible, and follow the font typeface requirement. Color can be used in figures; however, all text must be in a black font color, clear and legible.

Grantsmanship

Use English and avoid jargon.

If terms are not universally known, spell out the term the first time it is used and note the appropriate abbreviation in parentheses. The abbreviation may be used thereafter.

Page Limits

Although many of the sections of this application are separate text (PDF) or PureEdge attachments, page limitations referenced in these instructions and/or funding opportunity announcement must still be followed. Agency validations will include checks for page limits. Some accommodation will be made for sections that when combined must fit within a specified limitation. Note that while these computer validations will help minimize incomplete and/or non-compliant applications, they do not replace the validations conducted by NIH staff. Applications found not to comply with the requirements may lead to rejection of the application during agency validation or delay in the review process.

All applications and proposals for NIH and other PHS agency funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet website addresses (URLs) may not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Moreover, reviewers are cautioned that they should not directly access an Interne sit as it could compromise their anonymity. Observe the page number limitations given in Table 2.6-1.

Table 2.6-1. Page Limitations and Content Requirements

Section	Page Limit	Content
Introduction - New applications - Resubmission applications - Resubmission Phase I SBIR/STTR applications - Revision applications	 Not required/Not to be submitted 3 1 1	See Instructions
Research Plan - Sections 2-5 - Sections 6 - 14	 Phase I SBIR/STTR: 15 pages Phase II SBIR/STTR: 25 pages Fast-Track SBIR/STTR: 25 pages none	Text including all figures, charts, tables, and diagrams. For Sections 2-5 of a Fast-Track application, Phase I and Phase II plans must be contained within the 25 page limitation.
Biographical Sketches	4	No more than four pages for each person listed as Senior/Key Persons.
Appendix	none Phase I SBIR/STTR: Not permitted unless specifically requested by NIH.	No more than 10 publications (including *accepted* manuscripts); photographs (include a copy in the Research Plan); questionnaires; and other materials that do not photocopy well.
FOAs (PAs and RFAs)	Page limitations specified in the PA and RFA announcement in the *NIH Guide* take precedence.	See specific instructions in FOAs (PAs and RFAs) published in the *NIH Guide* and Grants.gov.

2.7 "Resubmission" (*Revised*) Applications

NIH allows the submission of up to two revised applications (now known as "Resubmission" applications) and no longer restricts those submissions to a two-year timeframe. See NIH Policy on Submission of a Revised (amended) Application in Part III.

NIH has established new policies for application resubmissions of certain categories. See Resubmission of Unpaid RFA Applications and Resubmission of Applications with a Changed Grant Activity Mechanism in Part III.

Before a resubmission application can be submitted, the Project Director/Principal Investigator (PD/PI) must have received the Summary Statement from the previous review.

Acceptance of a resubmission application automatically withdraws the prior version, since two versions of the same application cannot be pending simultaneously.

Introduction to Resubmission Application. The resubmission must include an "Introduction" of not more than three pages (one page limitation for SBIR and STTR Phase I resubmission) that *summarizes* the substantial additions, deletions, and changes. The Introduction must also include responses to the criticisms and issues raised in the Summary Statement. **Use Item 2.1, Introduction to Application, of the PHS 398 Research Plan component to provide this information.**

Research Plan of Resubmission Application. A resubmission application must include substantial changes. Identify the changes in each section of the Research Plan clearly by bracketing, indenting, or changing typography, unless the changes are so extensive as to include most of the text. This exception should be explained in the Introduction. **Do not underline or shade changes.** The Preliminary Studies/Progress Report section should incorporate any work done since the prior version was submitted.

Application processing may be delayed or the application may be returned if it does not comply with all of these requirements.

Investigators who have submitted three versions of an application and have not been successful often ask NIH staff how different the next application submitted needs to be, as it will be considered a new application. It is recognized that investigators are trained in a particular field of science and are not likely to make drastic changes in their research interests. However, a new application following three reviews is expected to be substantially different in content and scope with more significant differences than are normally encountered in a resubmission application. Simply rewording the title and Specific Aims or incorporating minor changes in response to comments in the previous Summary Statement does not constitute a substantial change in scope or content. Changes to the Research Plan should produce a significant change in direction and approach for the research project. Thus, a new application would include substantial changes in all sections of the Research Plan, particularly the Specific Aims and the Research Design and Methods sections.

In the referral process, NIH staff look at all aspects of the application, not just the title and Project Summary/Abstract. Requesting review by a different review committee does not affect the implementation of this policy. When necessary, previous applications are analyzed for similarities to the present one. Thus, identical applications or those with only minor changes will not be accepted for review.

2.8 "Revision" (*Competing Supplemental*) Application

A competing supplemental application (now known as a "Revision" application) may be submitted to request support for a significant expansion of a project's scope or research protocol. Applications for revisions are **not appropriate** when the sole purpose is to restore awards to the full SRG-recommended

level if they were administratively reduced by the funding agency. A revision application **should not be submitted** until after the original application has been awarded and **may not extend beyond the term of the current award period.**

Provide a one-page "Introduction" that describes the nature of the supplement and how it will influence the specific aims, research design, and methods of the current grant. Use Item 2.1. Introduction to Application, of the PHS 398 Research Plan component to provide this information. Any budgetary changes for the remainder of the project period of the current grant should be discussed in Section K., Budget Justification, of the Research and Related Budget component. The body of the application should contain sufficient information from the original grant application to allow evaluation of the proposed supplement in relation to the goals of the original application.

If the revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the SRG, then the applicant must respond to the criticisms in the prior Summary Statement, and substantial revisions must be clearly evident and summarized in the "Introduction."

Administrative "Revisions" (*a.k.a. Supplements*)

An administrative supplement provides additional funding to meet increased costs that are within the scope of your approved application, but were unforeseen when the new or competing renewal (formerly "competing continuation") application was submitted. If you are contemplating supplemental funding, you must consult in advance with your designated Grants Management Officer and Program Official. It is important for you to submit a request before your grant expires. To be considered for an administrative supplement, you must submit a request in writing to the IC (not to CSR), signed by the PD/PI and the authorized Business Official, describing the need for additional funding and the categorical costs. In your letter, also be sure to point out what you will NOT be able to accomplish if such a request is denied. At this time, administrative revisions/supplements will not be submitted through Grants.gov.

2.9 Similar, Essentially Identical, or Identical Applications

Submissions of identical applications to one or more components of the PHS are not allowed.

The NIH will not accept similar grant applications with essentially the same research focus from the same applicant organization. This includes derivative or multiple applications that propose to develop a single product, process or service that, with non-substantive modifications, can be applied to a variety of purposes. Likewise, identical or essentially identical grant applications submitted by different applicant organizations will not be accepted. Applicant organizations should ascertain and assure that the materials they are submitting on behalf of the principal investigator are the original work of the principal investigator and have not been used elsewhere in the preparation and submission of a similar grant application. Applications to the NIH are grouped by scientific discipline for review by individual Scientific Review Groups and not by disease or disease state. The reviewers can thus easily identify multiple grant applications for essentially the same project. In these cases, application processing may be delayed or the application(s) may be returned to the applicant without review.

Essentially identical applications will not be reviewed except for: 1) individuals submitting an application for an Independent Scientist Award (K02) proposing essentially identical research in an application for an individual research project; and 2) individuals submitting an individual research project identical to a subproject that is part of a program project or center grant application.

2.10 Submitting Your Application Via Grants.gov

The Applicant Organizational Representative (AOR) registered in Grants.gov is the only official with the authority to actually submit applications through Grants.gov. Therefore, PDs/PIs will need to work closely with their AORs to determine that all the necessary steps have been accomplished prior to submitting an application. This includes any internal review process required by the applicant organization.

Before starting the final submission step, **applicants are encouraged to save a copy of the final application locally**. Once all required documents are properly completed and the application has been saved, the "Submit" button will become active. Click the "Submit" button to submit the application to Grants.gov. A confirmation page will appear asking for verification that this is the funding opportunity and Agency to which you want to submit an application. Applicants should review the provided application summary to confirm that the application will be submitted to the intended program. Click the "Yes" button if this information is correct and you are ready to submit the application. If not already connected to the Internet, applicants will be directed to do so. Log in to Grants.gov using the username and password that was established in the Register with Grants.gov process.

Once logged in, the application package will be automatically uploaded to Grants.gov. A confirmation screen will appear once the upload is complete and a Grants.gov Tracking Number will be provided on this screen. Applicants should record this number so that they may refer to it should they need to contact Grants.gov Customer Support.

For additional information, access Grants.gov/Submit Application Package (http://grants.gov/SubmitApplication).

Note, on-time submission of an application is currently a 2-step process: 1) accepted by Grants.Gov on or before 5 p.m. local time (of the applicant institution/organization) on the submission date; and 2) verified within two business days of the image being available in Commons. Note, the image is available only once all errors are corrected. For this initial transition period, NIH provided a one week window for correction of any validation errors after initial submission.

2.11 After You Submit Your Application Via Grants.gov

The Authorized Organizational Representative (AOR) can use Grants.gov to check the status of an application at any time. Note that Grants.gov requires a user login and password. To check the status of an application, go to https://apply.grants.gov/ApplicantLoginGetID.

Once an application has been submitted via Grants.gov, several emails are generated by Grants.gov and sent to the AOR (also known as the Signing Official [SO]) named in the grant application indicating a Grants.gov tracking number that is assigned to the submission:

1) Submission Receipt: An email is sent indicating your application has been received by Grants.gov and is currently being validated.

2) Submission Validation Receipt: An email is sent indicating your application has been received and validated by Grants.gov and is being prepared for Grantor agency retrieval.

3) Grantor Agency Retrieval Receipt: An email is sent indicating your application has been retrieved by the Grantor agency.

4) Agency Tracking Number Assignment for Application: An email is sent indicating your application has been assigned an Agency Tracking Number.

If the AOR/SO has not received a confirmation message from Grants.gov within 2 business days of submission, please contact:

Grants.gov Contact Center
Telephone: 1-800-518-4726
Email: support@grants.gov

At that point, the application will be scheduled for download into the eRA system for agency validation. It is imperative that the email address provided in blocks 15 for the PD/PI and 19 for the AOR/SO on the SF424 (R&R) Cover component be current and accurate. Once agency validation is completed, an agency notification (not Grants.gov) will be emailed to the PD/PI and AOR/SO named in the application.

This email notification will inform the PD/PI and AOR/SO that the application has been received and processed by the agency and will indicate whether any errors or warnings resulted during the validation process. The PD/PI and AOR/SO will be invited to log on the eRA Commons, to either view/verify the application (agree to terms), or review the list of warnings/errors that were encountered during the validation process.

If there were no validation errors, this email notification will also inform the PD/PI and AOR/SO of an agency accession number, which represents the "agency tracking number." This number replaces the Grants.gov tracking number that was assigned when the application was first submitted. The Grants.gov system will indicate that the agency tracking number has been assigned, and will reflect both numbers. In subsequent interaction with the eRA Commons, however, it is the agency accession number that will be used to refer to the application, not the Grants.gov tracking number.

April 2006 Notice: Applicants should be aware that the PD/PI and AOR/SO verification steps referenced below will be replaced with a new business process beginning with submissions made on or after May 10, 2006.

Once an application package has been successfully submitted through Grants.gov, all errors are corrected and an application has been assembled by the eRA Commons, PDs/PIs and AORs/SOs will have two business days to view the application. If everything is acceptable, no further action is necessary. The application will automatically move forward to the Division of Receipt and Referral in the Center for Scientific Review for processing after two business days.

If, however, it is determined that some part of the application was lost or did not transfer correctly during the submission process, the AOR/SO will have the option to "Reject" the application and submit a Changed/Corrected application.

The "Reject" feature should also be used if you determine that warnings are applicable to your application and need to be addressed now. Remember, warnings do not stop further application processing. If an application submission results in warnings (but no errors), it will automatically move forward after two business days if no action is taken. Some warnings may need to be addressed later in the process.

PIs should work with their AOR/SO to determine when the "Reject" feature is appropriate.

The PD/PI and AOR/SO must verify the application in the eRA Commons within two (2) business days of the application being downloaded and validated by the eRA system. The eRA system will make every effort to send an email to the PD/PI and AOR/SO summarizing download and validation results. However, since email can be unreliable, applicants are strongly encouraged to periodically check on their application status in the Commons, so that the application verification can be effected in the timeliest manner possible. Both individuals need to perform the review and verification process. The order in which the review and verification is completed does not matter as long as both the PD/PI and AOR/SO

complete the process. Timely verification will enable the application to continue through the remaining steps in the agency review process. Failure to perform this review and verification process in the time allotted may prevent the application from receiving further consideration by the agency.

The PD/PI can verify in Commons by performing the following steps:

1. After the application has been downloaded and validated by the eRA system, access the eRA Commons (https://commons.era.nih.gov/commons/). Although the PD/PI will usually receive an email indicating that the download and validation has been completed, the PD/PI is strongly encouraged to also periodically monitor the eRA Commons to track the status of the application.
2. Click the **Status** tab on the Commons menu bar.
3. Click **eApplications**.
4. Search under the PI eApplication Status header for *All* or *Requires Verification*.
5. When you find the appropriate application, click **Verify PI** on the right-hand side under Action.
6. The verification page appears, and the electronic grant application image (as a PDF) appears in a separate window for you to examine, download, and print at your discretion. There is no need to sign off immediately; you can review your application before you sign off.
7. When complete, close the PDF window and select that you agree to the terms on the verification page.
8. Click **Save**.

The AOR/SO can verify in Commons by performing the following steps:

1. After the application has been downloaded and validated by the eRA system, access the eRA Commons (https://commons.era.nih.gov/commons/). Although the AOR/SO will usually receive an email indicating that the download and validation has been completed, the AOR/SO is strongly encouraged to also periodically monitor the eRA Commons to track the status of the application..
2. Click the **Status** tab on the Commons menu bar.
3. Click **eApplications**.
4. Search under the AOR/SO eApplication Status header for *All* or *Requires Verification*.
5. When you find the appropriate application, click **Verify SO** on the right-hand side under Action.
6. The verification page appears, and the electronic grant application image (as a PDF) appears in a separate window for you to examine, download, and print at your discretion. There is no need to sign off immediately; you can review your application before you sign off.
7. When complete, close the PDF window and select that you agree to terms on the verification page.
8. Click **Save**.

2.12 Correcting Errors

Prior to a specified submission date, applicants may make corrections and resubmit a corrected application through Grants.gov. After a specified submission date, if applicants make corrections and resubmit, the application will be considered late. In this case, applicants *must* include a cover letter explaining the reasons for the delay. Also see Section 2.14 for additional information on submission dates.

If validation errors or warnings result from the validation process, the PD/PI and AOR/SO will be issued an email instructing them to log on to the eRA Commons to review the list of warnings/errors that were encountered during the validation process. The eRA system will make every effort to send an email to the PD/PI and AOR/SO indicating whether errors or warnings were detected. However, since email can be unreliable, applicants are strongly encouraged to periodically check on their application status in the eRA Commons, so that any errors or warnings can be resolved in the timeliest manner possible.

Please be aware of the distinction between *errors* and *warnings*. The word *error* is used to characterize any condition which causes the application to be deemed unacceptable for further consideration. Generally, errors will indicate significant inaccuracies, inconsistencies, omissions, or incorrect formatting that have been identified in the body of the application. Conversely, the word *warning* characterizes any condition that is acceptable, but worthy of bringing to the applicant's attention. It is at the applicant's discretion whether a warning condition requires any action.

The PD/PI and AOR/SO will only be allowed to verify an application if there have been no errors identified during the validation process. Error conditions must be corrected, and then the application may be submitted as a changed/corrected application (as outlined below) in order for the application to be accepted. Please note that if validation has identified *warnings only*, then the PD/PI and SO will be allowed to verify the application. Warnings do not require any action or submission of a changed/corrected application at this time. However, please be aware that some warnings may need to be addressed later in the process or review stages. Failure to comply with stated NIH policies can also result in a submitted and verified application being returned to the applicant without review. For this reason, applicants are strongly encouraged to review all warnings, to ensure that they require no further attention and that they are satisfied with the validation results. If desired, warnings can be corrected in the same manner as errors.

A changed/corrected application may also be submitted if the PDF image, as viewed in the eRA Commons is incomplete or inaccurate from that submitted.

Errors and warnings may be reviewed in the Commons by performing the following steps:

1. After the application has been downloaded from Grants.gov and validated by the system, access the eRA Commons (https://commons.era.nih.gov/commons/).
2. Click the **Status** tab on the Commons menu bar.
3. A hitlist of application numbers is displayed. If the application was validated with warnings only, or without encountering any problems whatsoever, then it is identified in the hitlist by its NIH accession number (e.g., "AN:2911064"). This is the same number that Grants.gov displays, and refers to as the "agency tracking number."

   If any *errors* were identified during validation, then the application still appears in the hitlist, but in this case it is identified by its Grants.gov tracking number (e.g., "TN:21236"). This is the number that Grants.gov assigned to your application at the time of submission.
4. When you find the appropriate application in the hitlist, click its application link.
5. The error/warning page appears, and you are then able to review all conditions that were identified during validation. If only *warnings* were identified, you may elect to take action and resubmit; however you may accept the warnings and proceed to verify the application, as described earlier.

To correct errors and resubmit the application:

1. Make whatever corrections are necessary, wherever appropriate. Most often this means that you have to edit the PureEdge application forms to correct whatever problem or inconsistency that was noted.

2. Check the "Changed/Corrected Application" box in block 1 of the SF424 (R&R) Cover component.
   - If submitting after the submission date, include an explanation in the Cover Letter Component.
   - When you check the Changed/Corrected Application box, Item 4. Federal Identifier becomes a required field.
   - When submitting a Changed/Corrected Application for a "New" Type of Application (Item 8 = New), in the Federal Identifier field (Item 4) enter the Grants.gov tracking number for the previous application that you are correcting. If you are unable to recall the Grants.gov tracking number, enter "N/A."
   - When submitting a Changed/Corrected Application for a "Resubmission," "Renewal," or "Revision" Type of Application (Item 8 = Resubmission, Renewal, or Revision), in the Federal Identifier field (Item 4) enter the previously assigned grant number (e.g., CA123456).
   - Do not use the Changed/Corrected Application box to denote a submission of a revised or amended application. That will be indicated in item 8, Type of Application.
3. Have the AOR/SO submit the revised PureEdge forms to Grants.gov again.

The same email notifications will be issued once the agency has downloaded and validated the re-submitted application and the PD/PI and AOR/SO will once again be required to log on to the Commons either to view/verify the application, or to review the errors that were encountered during validation.

The application will only be assigned for scientific review once errors are resolved, and both the PD/PI and AOR/SO have viewed and verified the application.

In addition to the validations performed by the eRA system, further administrative review will be conducted by agency staff. The PD/PI and/or the applicant organization may be contacted for further corrections/clarifications.

2.13 Submission of Supplementary or Corrective Information

Unless specifically required by these instructions (e.g., vertebrate animals verification), do not send supplementary or corrective material after the submission date unless the Scientific Review Administrator (SRA) of the Scientific Review Group solicits or agrees to accept this information. Such additional information will be sent directly to the SRA and will not be submitted through Grants.gov.

2.14 Application Submission Dates

For electronic submission through Grants.gov, each FOA posted in Grants.gov Apply includes an Opportunity Open Date and an Opportunity Close Date. Many announcements, including those using the "Standard Submission Dates" noted in Table 2.15-1 below, include multiple submission/receipt dates and are active for several years. These announcements are posted in Grants.gov showing an Open/Close period that spans the entire active period of the announcement. Applicants should read the Funding Opportunity Announcement carefully for specific submission/receipt dates. If specific dates are not referenced in the announcement, applicants should refer to the Standard Submission Dates for Competing Applications noted in Table 2.15-1.

Applications submitted for the Standard Submission Dates listed in Table 2.15-1 are considered on time if they are submitted to Grants.gov on or before the appropriate date listed. When multiple submission dates are included in a specific FOA, applications submitted for Special Receipt Dates listed in a FOA are considered on time if they are submitted to Grants.gov on or before the appropriate date listed. When only

a single submission date is referenced in the FOA, the Closing Date noted in Grants.gov Apply will be that submission date. In this case, applications are considered on time if they are submitted to Grants.gov on or before the Grants.gov posted Closing Date.

Weekend/holiday Submission Dates. If a submission date falls on a weekend, it will be extended to the following Monday; any time the date falls on a holiday, the submission date will be extended to the following business day. The application will be on time if it is submitted on or before the following business day.

Late Applications. Permission is not granted in advance for submission of a late application. Late applications are accepted only in extenuating circumstances. If an application is submitted late, use the optional PHS 398 Cover Letter component to explain the reasons for the delay and include this component with the completed application. Late applications are evaluated on an individual basis considering the reasons provided. Contacting the Division of Receipt and Referral, Center for Scientific Review (CSR), NIH in advance will not influence the acceptance of a late application. For additional information on late applications, see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-030.html.

2.15 Submission, Review and Award Cycles

The PHS submission, review, and award schedule is provided in Table 2.15-1. For specialized grant applications, consult with the appropriate PHS agency prior to the preparation of an application.

Table 2.15-1. Submission Dates, Review, and Award Cycles

SUBMISSION CYCLES:	CYCLE I	CYCLE II	CYCLE III
Non-AIDS Applications			
Small Business Innovation Research (SBIR), Small Business Technology Transfer (STTR) Grants – R41, R42, R43 and R44 *new, renewal, resubmission, revision*	April 1	August 1	December 1
AIDS and AIDS-Related Applications			
AIDS and AIDS-Related Grants All (including SBIR/STTR) *new, renewal, resubmission, revision*	May 1	September 1	January 2
NOTE: RFAs and some PARs have special receipt dates indicated in the specific NIH Guide Announcement.			
Review and Award Cycles:	**Cycle I**	**Cycle II**	**Cycle III**
Scientific Merit Review	June - July	October - November	February - March
Advisory Council Review	September - October	January - February	May - June
Earliest Project Start Date	December	April	July
Note: Awarding components may not always be able to honor the requested start date of an application; therefore, applicants should make no commitments or obligations until confirmation of the start date by the awarding component.			

Application Assignment Information

Competing grant applications that have been successfully submitted through Grants.gov (including correcting all errors and the grant application assembled by the eRA Commons system) will be processed through the Division of Receipt and Referral, CSR, NIH unless otherwise stated. The application will be assigned to an appropriate Scientific Review Group and awarding component(s). Assignment is based on the scientific content of the application using established referral guidelines. Business rule validations are conducted by the system as well as NIH staff.

Assignment to Review Group. The Center for Scientific Review (CSR) will assign appropriately completed applications to the Scientific Review Groups (commonly referred to as "SRGs" or "study sections") that will perform the scientific/technical merit review. The CSR lists the recurring review panels (https://cms.csr.nih.gov/PeerReviewMeetings/CSRIRGDescription/), and you may suggest a specific group in the PHS 398 Cover Letter component.

Assignment to Relevant Potential Awarding Component(s) (Institutes/Centers (ICs)). In addition, CSR will assign each application to the agency awarding component that is the potential funding component. When the scientific areas and the research proposed in a grant application are sufficiently relevant to the program responsibilities of two or more awarding components, CSR may assign your application to all such components. The component that has the most relevant program responsibility is designated as the primary assignee. The other components that have an interest in your application are designated as secondary assignees. If your application is eligible for funding and the primary assignee does not intend to make an award, the secondary assignees will be given the opportunity to do so. Although these suggestions will be taken into consideration, the final determination will be made by the agencies participating in this solicitation.

After the submission date, usually within six (6) weeks, the PHS will send the PD/PI and the applicant organization the application's assignment number; the name, address, and telephone number of the Scientific Review Administrator of the Scientific Review Group to which the application has been assigned; and the assigned Institute contact and phone number. Assignment information as well as review outcome and other important information is available in the Commons.

If assignment information is not available in the eRA Commons within four weeks of the submission date, contact the Division of Receipt and Referral, Center for Scientific Review (CSR), National Institutes of Health, Bethesda, MD 20892-7720, (301) 435-0715; TTY (301) 451-0088. If there is a change in assignment, you will receive a notification.

Applicant investigators must not communicate directly with any review group member about an application either before or after the review. Failure to strictly observe this policy will create serious breaches of confidentiality and conflicts of interest in the peer review process. From the time of assignment to the time the review of your application is complete, applicant investigators must direct all questions to the Scientific Review Administrator. This individual is in charge of the review group and is identified in your assignment notice.

2.16 Resources for Finding Help

2.16.1 Finding Help for Grants.gov Registration or Submissions

If help is needed with the Grants.gov registration process or with the technical aspects of submitting an application through the Grants.gov system, check first the resources available at Grants.gov (http://grants.gov/).

Grants.gov customer support is also provided by the following office:

Grants.gov Program Management Office
200 Independence Avenue, SW
HHH Building, Room 739F
Washington, DC 20201

Grants.gov Helpdesk: support@grants.gov

Grants.gov Contact Center Phone Number: 1-800-518-4726

The Contact Center's hours of operation are Monday-Friday from 7:00 a.m. to 9:00 p.m. Eastern Time.

2.16.2 Finding Help for the eRA Commons Registration or eRA Commons Validation Processes

If help is needed with the eRA Commons registration process for the applicant organization and PDs/PIs or with the application validation process in the Commons after submission through Grants.gov, check first the resources available at Electronic Submission of Grant Applications (http://era.nih.gov/ElectronicReceipt/).

eRA Commons customer support is also provided by the eRA Commons Helpdesk:

eRA website: http://era.nih.gov

eRA Commons website: https://commons.era.nih.gov/commons/index.jsp

eRA Commons Helpdesk Email: commons@od.nih.gov

eRA Commons Phone: 301-402-7469
866-504-9552 (Toll Free)
301-451-5939 (TTY)

The eRA Commons Helpdesk hours of operation are Monday-Friday from 7:00 a.m. to 8:00 p.m. Eastern Time.

2.16.3 Finding Help for Application Preparation

If after reviewing this application instruction guide, help is still needed in preparing the application, contact GrantsInfo:

GrantsInfo Phone: 301-435-0714
301-451-0088 (TTY)

GrantsInfo Email: GrantsInfo@nih.gov

2.16.4 Finding Help for SBIR/STTR Specific Inquiries

Questions of a general nature about the NIH SBIR/STTR program should be directed to:

Ms. Jo Anne Goodnight
NIH SBIR/STTR Program Coordinator
6705 Rockledge Drive
Rockledge I, Room 3534
Bethesda, MD 20892-7963

Phone: 301-435-2688
Email: sbir@od.nih.gov
Fax: 301-480-0146

Ms. Kathleen Shino

Phone: 301-435-2689
Email: sbir@od.nih.gov
Fax: 301-480-0146

Ms. Kay Etzler	Phone: 301-435-2713 Email: sbir@od.nih.gov Fax: 301-480-0146
SBIR/STTR Help Desk	Email: sbirsttr@peacetech.com

3. Using the Grant Application Package

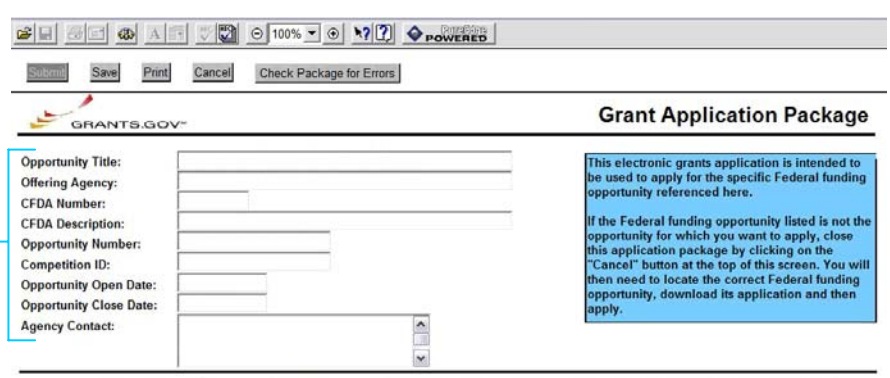
This section describes the steps an applicant takes once the appropriate FOA (see Section 2.4) has been located and the corresponding grant application package has been successfully downloaded. Note when you "Save" the package locally for the first time, you will receive an error message indicating "One or more of the items in this form contains an invalid value. Do you want to proceed anyway?" Applicants should always answer "Yes". This error message shows because no data has been entered yet. In fact, applicants will get this or a similar message every time the package is saved until all data entry is completed. Applicants can ignore this error message until the final save before the application is submitted. When an application is ready to be submitted, if this error message is still shown, applicants are encouraged to use the "Check Package for Errors" button to determine what needs to be corrected. When errors are found, a message box will appear indicating the total number of errors found and the details about the first one. Unfortunately there is no way to get a comprehensive list at this time. For instance, if five errors are found, the first one will need to corrected, and then repeat the "check package for errors" process until all are corrected.

Note the "Check Package for Errors" button only checks errors in the actual PureEdge forms. It does not check the forms for data errors against NIH business processes. Those validations will be performed by the eRA Commons system after the application has been submitted.

3.1 Verify Grant Information

When you select a funding opportunity in Grants.gov Apply, verify that the information shown in the Grant Application Package screen corresponds to the funding opportunity for which you wish to apply. Grants.gov auto-populates the following information:

- Opportunity Title
- Offering Agency
- CFDA Number
- CFDA Description
- Opportunity Number
- Competition ID
- Opportunity Open Date
- Opportunity Close Date
- Agency Contact

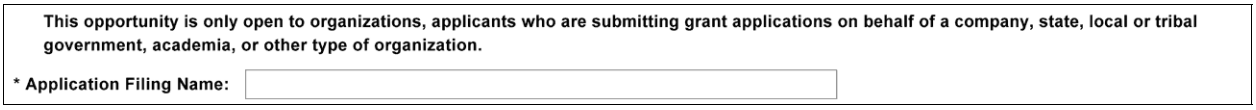


CFDA Number Field: Many FOAs include multiple CFDA (Catalog for Domestic Assistance) numbers. When this is the case, the CFDA Number and CFDA Description fields will appear blank in the Grants.gov Grant Application Package screen shown above. The appropriate CFDA number will be automatically assigned once the application is assigned to the appropriate agency awarding component.

Opportunity Open Date & Close Date Fields: Many FOAs posted by NIH and other PHS agencies include multiple submission/receipt dates and are active for several years. These announcements are posted in Grants.gov showing an Open/Close period that spans the entire active period of the announcement. Applicants should read the funding opportunity announcement carefully for specific submission/receipt dates. If specific dates are not referenced in the announcement, applicants should refer to the Standard Postmark/Submission Dates for Competing Applications found in Table 2.15-1. Submission Dates, Review, and Award Cycles. Applications submitted after a posted submission date will be held over into the next review cycle. See also Section 2.14 above for the late application policy.

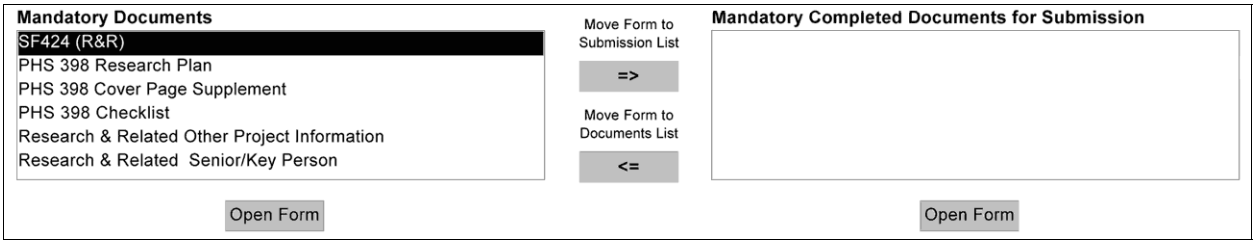
3.2 Enter the Name for the Application

Enter a name for the application in the Application Filing Name field (this is a required field). This name is for use solely by the applicant for tracking the application through the Grants.gov submission process. It is not used by the receiving agency.



3.3 Open and Complete Mandatory Documents

Open and complete all of the documents listed in the Mandatory Documents box. **Complete the component titled SF424 (R&R) first.** Data entered in this component populates other mandatory and optional forms where applicable.

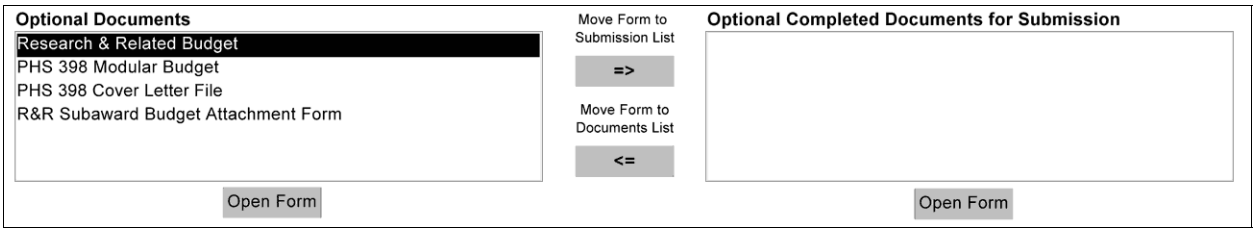


To open an item:

1. Click the document name in the Mandatory Documents box.
2. Click **Open Form**.
3. When a form or document has been completed, click the document name to select it, and then click the => button. This moves the form/document to the Completed Documents box. To remove a document from the Completed Documents box, click the document name to select it, and then click the <= button. This returns the document to the Mandatory Documents or Optional Documents box.

3.4 Open and Complete Optional Documents

These documents can be used to provide additional information for the application or may be required for specific types of grant activities. Information on each of these documents is found later in these instructions.



Once all documents have been completed and saved locally, click **Submit** to submit the application to Grants.gov. Only an AOR will be able to perform the submit action, and will be prompted to enter username and password to verify his/her identity. The Submit button does not become active until all required documents have been properly completed and the application has been saved. If an edit has been made somewhere in the application package, the file must be resaved before attempting to submit. If the Submit button is grayed out, resave the file. Reminder, the system will not consider a component form document to be complete until it has been moved to the Completed Documents box. Once you click the Submit button, a confirmation page appears asking you to verify the desired funding opportunity and Agency to which the application is being submitted.

4. Completing the SF424 Research and Related (R&R) Forms

4.1 Overview

This section contains all of the instructions you will need to complete the SF424 (R&R) forms.

Any agency-specific instructions are denoted by the DHHS logo displayed to the left of the paragraph, as illustrated here.

Conformance to all instructions is required and strictly enforced. Agencies may withdraw any applications from the review process that are not consistent with these instructions.

As you navigate through the forms, required fields are highlighted in yellow and noted with an asterisk (*). Optional fields and completed fields are displayed in white. Data entered into a specific field is not accepted until you have navigated to the next field. If you enter invalid or incomplete information in a field, you will receive an error message.

For those form components that are more than one page, click the “Next” button at the top of the form to navigate to a subsequent page. Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

4.2 Cover Component

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

2. DATE SUBMITTED

Applicant Identifier

3. DATE RECEIVED BY STATE

State Application Identifier

4. Federal Identifier

1. * TYPE OF SUBMISSION

☐ Pre-application ☐ Application
☐ Changed/Corrected Application

5. APPLICANT INFORMATION *** Organizational DUNS:**

* Legal Name:

Department: Division:

* Street1: Street2:

* City: County: * State: * ZIP Code:

* Country: USA

Person to be contacted on matters involving this application

Prefix: * First Name: Middle Name: * Last Name: Suffix:

* Phone Number: Fax Number: Email:

6. * EMPLOYER IDENTIFICATION *(EIN) or (TIN):*

7. * TYPE OF APPLICANT:

Please select one of the following

Other (Specify):

8. * TYPE OF APPLICATION: ☐ New

☐ Resubmission ☐ Renewal ☐ Continuation ☐ Revision

Small Business Organization Type

☐ Women Owned ☐ Socially and Economically Disadvantaged

If Revision, mark appropriate box(es).

☐ A. Increase Award ☐ B. Decrease Award ☐ C. Increase Duration

☐ D. Decrease Duration ☐ E. Other *(specify)*

9. * NAME OF FEDERAL AGENCY:

National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:

TITLE:

* Is this application being submitted to other agencies? Yes ☐ No ☐

What other Agencies?

11. * DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. * AREAS AFFECTED BY PROJECT *(cities, counties, states, etc.)*

13. PROPOSED PROJECT:

* Start Date * Ending Date

14. CONGRESSIONAL DISTRICTS OF:

a. * Applicant b. * Project

15. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: * First Name: Middle Name: * Last Name: Suffix:

Position/Title: * Organization Name:

Department: Division:

* Street1: Street2:

* City: County: * State: * ZIP Code:

* Country: USA

* Phone Number: Fax Number: * Email:

OMB Number: 4040-0001

Expiration Date: 04/30/2008

1. Type of Submission

Check one of the Type of Submission boxes. If this submission is to change or correct a previously submitted application, click the Changed/Corrected Application box and enter the Grants.gov tracking number in the Federal Identifier field. **Unless requested by the agency, you may not use this to submit changes after the closing date.**

Pre-Application: Unless specifically noted in a program announcement, the Pre-application option is not used by NIH and other PHS agencies.

Changed/Corrected Application: This box must be used if you need to submit the same application again because of corrections for system validation errors or if a portion of the application was lost or distorted during the submission process. This option is for correcting system validation errors only and may not be used to include last minute changes to any of the PDF attachments. When submitting a Changed/Corrected Application:

- If submitting after the submission date, include an explanation in the Cover Letter Component.
- When you check the Changed/Correct Application box, Item 4. Federal Identifier becomes a required field.
- When submitting a Changed/Corrected Application for a "New" Type of Application (Item 8 = New), in the Federal Identifier field (Item 4)) enter the Grants.gov tracking number for the previous application that you are correcting. If you are unable to recall the Grants.gov tracking number, enter "N/A".
- When submitting a Changed/Corrected Application for a "Resubmission," "Renewal," or "Revision" Type of Application (Item 8 = Resubmission, Renewal, or Revision), in the Federal Identifier field (Item 4) enter the previously assigned grant number (e.g., CA123456).
- Do **not** use the Changed/Corrected Application box to denote a submission of a revised or amended application. That will be indicated in item 8. Type of Application.

SBIR/STTR Phase II applications may be submitted either before or after expiration of the Phase I budget period. However, Phase II grant applications should be submitted no later than the first six submission dates following expiration of the Phase I budget period.

Applicant small business concerns are reminded that Phase II funding is based on the results of Phase I, demonstration of feasibility, scientific, and technical merit, and commercial potential of the Phase II application. *Applicants are cautioned that applications demonstrating insufficient results in Phase I may not receive a score in the peer review process*.

2. Date Submitted and Applicant Identifier

In the Date Submitted field, enter the date the application is submitted to the Federal agency (or state, if applicable). In the Applicant Identifier field, enter the applicant's control number (if applicable).

Note the Applicant Identifier field is a control number created by the applicant organization, not the Federal agency.

3. Date Received by State and State Application Identifier

Enter the date received by state (if applicable). In the State Application Identifier field, enter the state application identifier, if applicable.

For submissions to NIH and other PHS agencies, leave these fields blank.

4. Federal Identifier

New project applications should leave this field blank. If this is a resubmission or renewal application, enter the assigned Federal Identifier number (for example, award number).

For submissions to NIH and other PHS agencies, an example of an award number is CA 123456.

Existing definitions for NIH and other PHS agencies applications are somewhat different:

- New is the same; i.e., an application that is submitted for the first time. See also the policy Resubmission of Unpaid RFA Applications and Resubmission of Applications with a Changed Grant Activity Mechanism.
- Resubmission is equivalent to NIH and other PHS agencies Revision; i.e., a revised or amended application. See also the Revised NIH Policy on Submission of a Revised (Amended) Application.
- Renewal is equivalent to NIH and other PHS agencies Competing Continuation.
- Continuation is equivalent to NIH and other PHS agencies Progress Report. For the purposes of NIH and other PHS agencies, the box for Continuation will **not** be used.
- Revision is somewhat equivalent to NIH and other PHS agencies Competing Supplement. Applicants should contact the awarding agency for advice on submitting any revision/supplement application.

Applicants to NIH and other PHS agencies should complete this field when submitting a resubmission, renewal or revision application. When submitting a "New" application, this field should remain blank unless you are submitting a Changed/Corrected Application. In this case, where Item 1 = Changed/Corrected Application and Item 8 = New, the Federal Identifier field becomes a required field. Therefore you must enter the Grants.gov tracking number assigned to the application that you are correcting. If you are unable to recall the tracking number, enter "N/A."

5. Applicant Information

This information is for the Applicant Organization, not a specific individual.

The small business concern is ALWAYS the applicant organization for an SBIR or STTR award (e.g., ABC Incorporated).

Field Name	Instructions
Organizational DUNS	Enter your organization's DUNS or DUNS+4 number. For submission to NIH and other PHS agencies, this DUNS **must** match the number entered in the eRA Commons Institutional Profile for the applicant organization. The applicant AOR is encouraged to confirm that a DUNS has been entered in the eRA Commons Institutional Profile prior to submitting an application.
Legal Name	Enter the legal name of the applicant who will undertake the assistance activity.
Department	Enter the name of the primary organizational department, service, laboratory, or equivalent level within the organization that will undertake the assistance activity.

Field Name	Instructions
Division	Enter the name of the primary organizational division, office, or major subdivision that will undertake the assistance activity.
Street1	Enter the first line of the street address of your organization.
Street2	Enter the second line of the street address of your organization, if applicable.
City	Enter the city/place where your organization is located.
County	Enter the name of the county where your organization is located.
State	Select your state from the list provided. Use the provided two digit abbreviation for all state code entries. This field is required if your organization is located in the United States.
ZIP Code	Enter the Postal Code, or ZIP Code, of your organization. This field is required if your organization is located in the United States. This field is required if a State is selected and optional for Province.
Country	Select the country where your organization is located. For SBIR/STTR applications, the small business concern must be located in the United States.

Person to be contacted on matters involving this application:

This information is for the Administrative or Business Official, not the PD/PI. This person is the individual to be notified if additional information is needed and/or if an award is made.

Field Name	Instructions
Prefix	Select from the list the Prefix of the person to contact on matters related to this application. See also the PHS398 Cover Page Supplement for additional required contact information.
First Name	Enter the first (given) name of the person to contact on matters relating to this application.
Middle Name	Enter the middle name of the person to contact on matters relating to this application.
Last Name	Enter the last (family) name of the person to contact on matters relating to this application.

Field Name	Instructions
Suffix	Select from the list the suffix, if any, of the person to contact on matters relating to this application.
Phone Number	Enter the daytime phone number for the person to contact on matters relating to this application.
Fax Number	Enter the fax number for the person to contact on matters relating to this application.
Email	Enter the email address for the person to contact on matters relating to this application.

6. Employer Identification

Enter the TIN or EIN as assigned by the Internal Revenue Service. If your organization is outside the US, type 44-4444444.

If you have a 12-digit EIN established, include only the root nine digits. Do not include the prefix or suffix. If you are a foreign institution and have previously received NIH or other PHS agencies funding, enter the root nine digits of the assigned EIN. Otherwise, enter 44-4444444.

7. Type of Applicant

This information is for the Applicant Organization, not a specific individual.

Field Name	Instructions
Type of Applicant	Select from the list the appropriate applicant type code. For SBIR/STTR applicant organizations, select *O. Small Business.* The applicant organization must certify that it will qualify as a small business concern at the time of award.
Other (Specify)	Complete only if *P: Other* was selected as the Type of Applicant.
Woman Owned	Check the box if you are a woman-owned small business: a small business that is at least 51% owned by a woman or women, who also control and operate it.
Socially and Economically Disadvantaged	Check the box if you are a socially and economically disadvantaged small business, as determined by the US Small Business Administration pursuant to Section 8(a) of the Small Business Act U.S.C. 637(a).

8. Type of Application

Field Name	Instructions
Type of Application	Select the type from the following list. Check only one:

Field Name	Instructions
	• New: An application that is being submitted to an agency for the first time. • Resubmission: An application that has been previously submitted, but was not funded, and is being resubmitted for new consideration. • Renewal: An application requesting additional funding for a period subsequent to that provided by a current award. A renewal application competes with all other applications and must be developed as fully as though the applicant is applying for the first time. • Continuation: A non-competing application for an additional funding/budget period within a previously approved project period. • Revision: An application that proposes a change in 1) the Federal Government's financial obligations or contingent liability from an existing obligation, or 2) any other change in the terms and conditions of the existing award. Existing definitions for NIH and other PHS agencies Type of Application are somewhat different: • New is the same. Check this option when submitting an application for the first time. See also the policy Resubmission of Unpaid RFA Applications and Resubmission of Applications with a Changed Grant Activity Mechanism. • Resubmission is equivalent to NIH and other PHS agencies Revision. Check this option when submitting a revised or amended application. See also the Revised NIH Policy on Submission of a Revised (Amended) Application. • Renewal is equivalent to NIH and other PHS agencies Competing Continuation. • Continuation is equivalent to NIH and other PHS agencies Progress Report. For the purposes of NIH and other PHS agencies, the box for Continuation will **not** be used and should **not** be checked. • Revision is somewhat equivalent to NIH and other PHS agencies Supplement, but would also include other changes as noted in the definition above. In general, changes to the "terms and conditions of the existing award" (as noted in example 2 above) would not require the submission of another application through Grants.gov. Applicants should contact the awarding agency for advice on submitting any revision/supplement application.

Field Name	Instructions
If Revision, Enter Appropriate Letter(s) in Box(es)	If application is a revision, check the appropriate box(es): A. Increase Award B. Decrease Award C. Increase Duration D. Decrease Duration E. Other
Other (Specify)	If *E. Other* was selected as the Revision, enter text to explain.
Is this application being submitted to other agencies?	Check the box, if applicable.
What Other Agencies?	Enter Agency name(s).

9. Name of Federal Agency

This field is pre-filled.

10. Catalog of Federal Domestic Assistance (CFDA) Number and Title (CFDA)

These fields are pre-filled.

This field may be blank if you are applying to an opportunity that references multiple CFDA numbers. When this field is blank, leave it blank; the field will not allow any data entry. The appropriate CFDA number will be automatically assigned by the agency once the application is assigned to the appropriate awarding component.

11. Descriptive Title of Applicant's Project

Enter a brief descriptive title of the project.

A "new" application must have a different title from any other PHS project with the same PD/PI. A "resubmission" or "renewal" application should normally have the same title as the previous grant or application. If the specific aims of the project have significantly changed, choose a new title.

A "revision" application must have the same title as the currently funded grant.

NIH and other PHS agencies limit title character length to 81 characters, including the spaces between words and punctuation. Titles in excess of 81 characters will be truncated.

An SBIR/STTR Phase II application should have the same title as the previously awarded Phase I grant.

12. Areas Affected by Project (Cities, Counties, States, Etc.)

List only the largest political entities affected by the project (for example, state, counties, cities).

Enter "N/A" for not applicable.

13. Start Date and Ending Date

Enter the proposed start date of the project in the Start Date field. Enter the proposed end date in the Ending Date field. Use the following format: MM/DD/YYYY.

Phase I: Routinely, SBIR Phase I awards do not exceed six (6) months and STTR Phase I awards do not exceed one year.

Phase II: Routinely, SBIR and STTR Phase II awards do not exceed two years.

Under special circumstances, applicants to NIH may propose longer periods of time for completion of the research project (e.g., feasibility demonstration). Such requests that deviate from the guidelines must be thoroughly justified. Project duration deviations apply to NIH ONLY, as CDC and FDA do not make awards for periods longer than the stated guidelines.

14. Congressional District Applicant and Congressional District Project

Enter your Congressional District in the Congressional District Applicant field. Enter the Congressional District of the primary site where the project will be performed in the Congressional District Project field.

If the applicant organization is a foreign institution, enter all zeros. To locate your district visit http://congress.org/congressorg/dbq/officials/?lvl=L.

15. Project Director/Principal Investigator (PD/PI) Contact Information

Name the one person responsible to the applicant small business concern for the scientific and technical direction of the project. PHS staff conduct official business only with the named PDs/PIs and organizational/institutional officials. A revision/supplemental application must have the same PD/PI as the currently funded grant.

Field Name	Instructions
Prefix	Select from the list the prefix (Mr., Mrs., Rev.) of the PD/PI. See also the PHS398 Cover Page Supplement for additional PD/PI required data.
First Name	Enter the first (given) name of the PD/PI.
Middle Name	Enter the middle name of the PD/PI.
Last Name	Enter the last (family) name of the PD/PI.
Suffix	Select from the list the suffix, if any, of the PD/PI. Do not use this field to record degrees. Degrees for the PD/PI are requested separately in the PHS398 Cover Page Supplement.
Position/Title	Enter the title of the PD/PI.
Organization Name	Enter the name of the organization for the PD/PI.
Department	Enter the name of the primary organizational department, service, laboratory, or equivalent level within the organization of the PD/PI.
Division	Enter the name of the primary organizational division, office, or major subdivision of the PD/PI.
Street1	Enter the first line of the street address for the PD/PI. This field is required.

Field Name	Instructions
Street2	Enter the second line of the street address for the PD/PI, if applicable.
City	Enter the city where the PD/PI is located. This field is required.
County	Enter the county where the PD/PI is located.
State	Select from the list the state where the PD/PI is located. Use the provided two digit abbreviation for all state code entries.
ZIP Code	Enter the ZIP Code for the PD/PI address. This field is required if the PD/PI is located in the United States.
Country	Select from the list the country for the PD/PI address.
Phone Number	Enter the daytime telephone number for the PD/PI. This field is required.
Fax Number	Enter the fax number for the PD/PI.
Email	Enter the email address for the PD/PI. This field is required.

Project Director/Principal Investigator Criteria

SBIR

Under the SBIR program, for both Phase I and Phase II, the *primary employment of the PD/PI* must be with the *small business concern at the time of award and during the conduct of the proposed project*. Primary employment means that more than one half of the PD/PI's time is spent in the employ of the small business concern. *Primary employment with a small business concern precludes full-time employment at another organization.* Occasionally, deviations from this requirement may occur. Such deviations must be approved in writing by the grants management officer after consultation with the NIH SBIR/STTR Program Coordinator.

As defined in 42 C.F.R. 52, the PD/PI is the "single individual designated by the grantee in the grant application … who is responsible for the scientific and technical direction of the project." When the proposed *PD/PI* clearly does not have sufficient qualifications to assume this role, the application is not likely to receive a favorable evaluation.

If the application has the likelihood for funding, the awarding component will require documentation to verify the eligibility of the *PD/PI*, if at the time of submission of the application, the *PD/PI* is a less-than-full-time employee of the small business concern, is concurrently employed by another organization, or gives the appearance of being concurrently employed by another organization, whether for a paid or unpaid position.

If the *PD/PI* is employed or appears to be employed by an organization other than the applicant organization in a capacity such as Research Fellow, Consultant, Adjunct Professor, Clinical Professor, Clinical Research Professor, or Associate, a letter must be provided by each employing organization confirming that, if an SBIR grant is awarded to the applicant small business concern, the *PD/PI* is or will become a less-than-half-time employee of such organization and will remain so for the duration of the SBIR project. If the *PD/PI* is employed by a university, such a letter must be provided by the Dean's office or equivalent; for other organizations, the letter must be signed by a corporate official.

This requirement applies also to those individuals engaged currently as the *PD/PI* on an active SBIR project. All current employment and all other appointments of the PD/PI must be identified in his or her "Biographical Sketch" required as part of the application. Be certain that correct beginning and ending dates are indicated for each employment record listed.

STTR

The *PD/PI* must commit a minimum of 10% effort to the project and the *PD/PI* must have a formal appointment with or commitment to the applicant small business concern, which is characterized by an official relationship between the small business concern and that individual. Such a relationship does not necessarily involve a salary or other form of remuneration. In all cases, however, the *PD/PI's* official relationship with the grantee must entail sufficient opportunity for the *PD/PI* to carry out his or her responsibilities for the overall scientific and technical direction of the project. *Documentation (e.g., consultant, consortium and contractual arrangements) describing the official relationship of the PD/PI with the applicant small business concern should NOT be submitted with the grant application, but a copy must be furnished upon the request of the NIH awarding component*.

Following is guidance for such documentation, which is required prior to award: The letter should be prepared on the letterhead of the independent *PD/PI* and addressed to the Small Business Concern (SBC). *One page is recommended.* At a minimum, each letter should (1) verify the *PD/PI*'s commitment to the project; (2) refer to the specific project by name; and (3) specify what assets or services the PI will contribute (e.g. expertise, number of hours/ percent of effort) as well as the *PD/PI*'s remuneration. The letter should also indicate that the *PD/PI* and the SBC have reached an agreement on proprietary interests for the project to continue to move forward (e.g., intellectual property).

Signatures of the Authorized Organizational Representative (a.k.a. Signing Official) for the applicant organization on the SF424 (R&R) Cover component (Item 18) and the signature of the duly authorized representative of the research institution certifies, among other things, that the PD/PI has a formal relationship with/commitment to the small business concern when the PD/PI is an employee of the Research Institute (RI).

The following are examples of situations describing the official relationship of the PD/PI with the applicant small business organization:

- *PD/PI* with a full-time, university appointment may also have appointments with other organizations (with or without salary) and still appropriately consider his or her commitment to the university to be "full-time," consistent with the personnel policies and procedures of the university applied on a routine basis. The *PD/PI*'s commitment to the university and other organizations (including the applicant small business concern) cannot exceed 100% of his or her total professional effort.
- *PD/PI* with a full-time, 12-month appointment with a small business concern would be considered to have a commitment to the applicant organization of 100% of his or her total professional effort.
- *PD/PI* who has a part-time appointment with a small business concern and has concurrent commitments or appointments with organizations in addition to the small business concern would deem each commitment as a portion of 100% of his or her total professional effort.

As responsible stewards of funds, the NIH is concerned that the *PD/PI* has the time available to carry out the proposed STTR research activities. Therefore, it should be clear in the application that the time

proposed for the *PD/PI* on a particular project is reasonable and it should be clear that the PD/PI has sufficient time *(minimum 10% effort)* from among his or her total professional commitments to devote to this project.

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE **Page 2**

16. ESTIMATED PROJECT FUNDING

a. * Total Estimated Project Funding
b. * Total Federal & Non-Federal Funds
c. * Estimated Program Income

17. * IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES ☐ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE:

b. NO ☐ PROGRAM IS NOT COVERED BY E.O. 12372; OR

☐ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

18. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

☐ *** I agree**

** The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

19. Authorized Representative

Prefix: * First Name: Middle Name: * Last Name: Suffix:

* Position/Title: * Organization:

Department: Division:

* Street1: Street2:

* City: County: * State: * ZIP Code:

* Country: USA

* Phone Number: Fax Number: * Email:

*** Signature of Authorized Representative**
Completed on submission to Grants.gov

*** Date Signed**
Completed on submission to Grants.gov

20. Pre-application Add Attachment Delete Attachment View Attachment

OMB Number: 4040-0001
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16. Estimated Project Funding

Field Name	Instructions
Total Estimated Project Funding	Enter the total Federal funds, including Direct Costs, F&A Costs (Indirect Costs), and Fee, requested for the entire project period. Phase I total is normally $100,000; Phase II is normally $750,000. Deviations from these guidelines for NIH applications must be well justified and discussed with appropriate NIH staff prior to submission of the application. NOTE: CDC and FDA do not make awards above these guidelines.

Field Name	Instructions
Total Federal & Non-Federal Funds	Enter the total estimated funds for the entire project period, including both Federal and non-Federal funds. If using the Funds Requested Budget Component, item 16b will be the same as item 16a. For NIH and other PHS agencies applicants, this field will be the same as item 16a unless the specific announcement indicates that cost sharing is a requirement.
Estimated Program Income	Identify any Program Income estimated for this project period, if applicable.

17. Is Application Subject to Review by State Executive Order 12372 Process?

If yes, check the "Yes" box. If the announcement indicates that the program is covered under Executive Order 12372, you should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372. If no, check the appropriate box. This field is required.

For NIH and other PHS agency submissions using the SF424 (R&R), applicants should check "No, Program is not covered by E.O. 12372."

18. Complete Certification

Check the "I agree" box to provide the required certifications and assurances. This field is required.

The list of NIH and other PHS agencies Assurances, Certifications, and other Policies is found in Part III, Policies, Assurances, Definitions, and Other Information.

19. Authorized Representative

This is equivalent to the individual with the organizational authority to sign for an application; otherwise known as the Authorized Organizational Representative or the Signing Official.

Field Name	Instructions
Prefix	Select from the list the prefix (Mr., Mrs., Rev.) of the Authorized Representative.
First Name	Enter the first (given) name of the Authorized Representative.
Middle Name	Enter the middle name of the Authorized Representative.
Last Name	Enter the last (family) name of the Authorized Representative.
Suffix	Select from the list the suffix, if any, of the Authorized Representative.
Position/Title	Enter the title of the Authorized Representative.
Organization	Enter the name of the organization for the Authorized Representative.
Department	Enter the name of the primary organizational department, service, laboratory, or equivalent level within the organization of the Authorized Representative.

Field Name	Instructions
Division	Enter the name of the primary organizational division, office, or major subdivision of the Authorized Representative.
Street1	Enter the first line of the street address for the Authorized Representative. This field is required.
Street2	Enter the second line of the street address for the Authorized Representative, if applicable.
City	Enter the city where the Authorized Representative is located. This field is required.
County	Enter the county where the Authorized Representative is located.
State	Select from the list the state where the Authorized Representative is located. Use the provided two digit abbreviation for all state code entries.
ZIP Code	Enter the ZIP Code for the Authorized Representative address. This field is required if the PD/PI is located in the United States.
Country	Select from the list the country for the Authorized Representative address.
Phone Number	Enter the daytime telephone number for the Authorized Representative. This field is required.
Fax Number	Enter the fax number for the Authorized Representative.
Email	Enter the email address for the Authorized Representative. This field is required.
Signature of Authorized Representative	It is the organization's responsibility to assure that only properly authorized individuals sign in this capacity and/or submit the application to Grants.gov. If you are submitting this application through Grants.gov, leave this field blank. If you are submitting a hard copy, the Authorized Representative must sign in this block.
Date Signed	If you are submitting this application through Grants.gov, the system generates this date. If you are submitting a hard copy, enter the date the Authorized Representative signed the application.

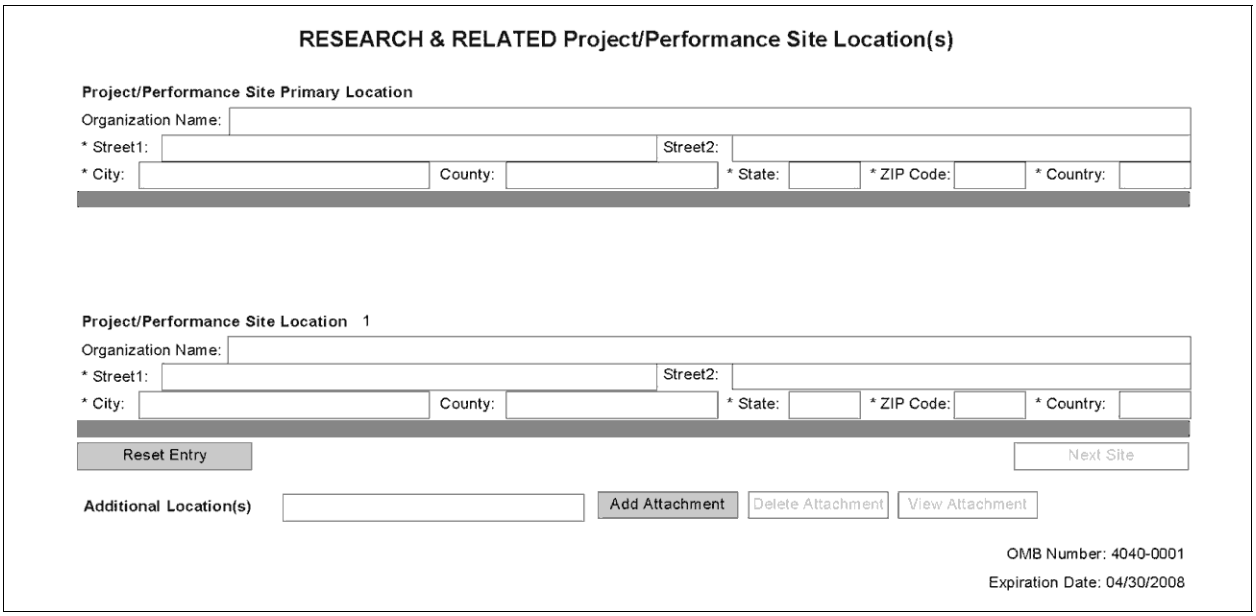
20. Pre-Application

If you are submitting a pre-application, provide a summary description of the project in accordance with the announcement and/or agency specific instructions, and save the file in a location you remember. Click "Add Attachment," browse to where you saved the file, select the file, and then click "Open."

Unless specifically noted in a program announcement, NIH and other PHS agencies do not use *Pre-applications.*

Once all data have been entered, click the "Close Form" button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

4.3 Project/Performance Site Locations Component



Indicate the primary site where the work will be performed. If a portion of the project will be performed at any other location(s), identify it in the section provided. If more than eight project/performance site locations are proposed, provide the information in a separate file, and then attach.

Project/Performance Site Primary Location

Generally, the Primary Location should be that of the applicant organization or identified as off-site in accordance with the conditions of the applicant organization's negotiated Facilities and Administrative (F&A) agreement. If there is more than one performance site, list all additional sites in the fields provided for Location 1 - # below.

For SBIR/STTR applications, one of the performance sites indicated must be that of the applicant small business concern.

For both Phase I and Phase II, the research or R&D project activity must be performed in the United States. However, based on a rare and unique circumstance, for example, if a supply or material or the study design (e.g., patient population) is not available in the United States, NIH may allow that particular portion of the research or R&D work to be performed or obtained in a foreign country. Investigators must thoroughly justify the use of these sites in the application.

These rare and unique situations will be considered on a case-by-case basis, and they should be discussed with NIH staff prior to submission of the application. Approval by the funding officer for such specific condition(s) must be in writing prior to issuance of an award. Whenever possible, non-SBIR/STTR funds should be used for other work outside of the United States that is necessary to the overall completion of the project.

The research and analytical work performed by the grantee organization is to be conducted in research space occupied by, available to, and under the control of the SBIR/STTR grantee for the conduct of its portion of the proposed project. However, when required by the project activity, access to special facilities or equipment in another organization is permitted, as in cases where the SBIR/STTR awardee has entered into a subcontractual agreement with another institution for a specific, limited portion of the research project.

Whenever a proposed SBIR/STTR project is to be conducted in facilities other than those of the applicant organization, the awarding component will request that the small business concern provide a letter from the organization stating that leasing/rental arrangements have been negotiated for appropriate research space. This letter must be signed by an authorized official of the organization whose facilities are to be used for the SBIR/STTR project and must certify that the small business concern (grantee organization) will have access to and control over the research space. In addition, the letter must include a description of the facilities and, if appropriate, equipment that will be leased/rented to the grantee organization. (If the letter is included with the application, it is excluded from the page limitations.) Attach this letter to the PHS 398 Research Plan component, Item 13, Letters of Support.

Field Name	Instructions
Organization Name	Enter the name of the organization.
Street1	Enter first line of the street address of the performance site location. This field is required.
Street2	Enter second line of the street address of the performance site location, if applicable.
City	Enter the city of the performance site location. This field is required.
County	Enter the county of the performance site location.
State	Select from the list the state or province of the performance site location. This field is required if the performance site location is in the United States.
ZIP Code	Enter the ZIP (Postal) Code of the performance site location. This field is required if the performance site location is in the United States.
Country	Select from the list the country of the performance site location.

Project/Performance Site Location 1

Field Name	Instructions
Organization Name	Enter the primary site where the work will be performed.

Field Name	Instructions
Street1	Enter first line of the street address of the performance site location. This field is required.
Street2	Enter second line of the street address of the performance site location, if applicable.
City	Enter the city of the performance site location. This field is required.
County	Enter the county of the performance site location.
State	Select from the list the state or province of the performance site location. This field is required if the performance site location is in the United States.
ZIP Code	Enter the ZIP (Postal) Code of the performance site location. This field is required if the performance site location is in the United States.
Country	Select from the list the country of the performance site location.

For additional performance site locations, click Next Site to display the fields for Project/Performance Site Locations 3 through 8.

If you need to add more than eight locations, enter the information in a separate file. On the form, click Add Attachment, select the file, and then click Open. A sample Additional Performance Sites format page for greater than 8 locations is found under "Additional Format Pages" at: http://grants.nih.gov/grants/funding/424/index.htm.

Once all data have been entered, click the "Close Form" button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

4.4 Other Project Information Component

RESEARCH & RELATED Other Project Information

1. * Are Human Subjects Involved? ☐ Yes ☐ No

1.a If YES to Human Subjects

Is the IRB review Pending? ☐ Yes ☐ No

IRB Approval Date:

Exemption Number: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

Human Subject Assurance Number:

2. * Are Vertebrate Animals Used? ☐ Yes ☐ No

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ☐ Yes ☐ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. * Is proprietary/privileged information included in the application? ☐ Yes ☐ No

4.a. * Does this project have an actual or potential impact on the environment? ☐ Yes ☐ No

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ☐ Yes ☐ No

4.d. If yes, please explain:

5.a. * Does this project involve activities outside the U.S. or partnership with International Collaborators? ☐ Yes ☐ No

5.b. If yes, identify countries:

5.c. Optional Explanation:

6. * Project Summary/Abstract Add Attachment | Delete Attachment | View Attachment

7. * Project Narrative Add Attachment | Delete Attachment | View Attachment

8. Bibliography & References Cited Add Attachment | Delete Attachment | View Attachment

9. Facilities & Other Resources Add Attachment | Delete Attachment | View Attachment

10. Equipment Add Attachment | Delete Attachment | View Attachment

11. Other Attachments Add Attachments | Delete Attachments | View Attachments ☐

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1. Are Human Subjects Involved?

If activities involving human subjects are planned at any time during the proposed project at any performance site, check the Yes box. Check this box even if the proposed project is exempt from Regulations for the Protection of Human Subjects. If no activities involving human subjects are planned, check the No box, and then skip to Step 2.

Refer to Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan.

1.a. Is the IRB review Pending?

If the Institutional Review Board (IRB) review is pending, check the Yes box. Otherwise, check the No box. In the IRB Approval Date field, enter the latest IRB approval date, if available. Leave blank if Pending.

Applicants should check "Yes" to the question "Is the IRB review Pending?" even if the IRB review/approval process has not yet begun at the time of submission. Also note that an IRB Approval Date is not required at the time of submission. This may be requested later in the pre-

award cycle as a Just-In-Time requirement.

For Exemption Number, if human subject activities are exempt from Federal regulations, provide the exemption numbers corresponding to one or more of the exemption categories. The six categories of research that qualify for exemption from coverage by the regulations are defined in the Common Rule for the Protection of Human Subjects. These regulations can be found at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm.

For Human Subject Assurance Number, enter the approved Federal Wide Assurance (FWA) Number that the applicant has on file with the Office for Human Research Protections, if available. Enter only the 8-digit number, do not enter the "FWA" before the number.

Insert "None" if the applicant organization does not have an approved assurance on file with OHRP. In this case, the applicant organization, by the signature in item 19 on the SF424 (R&R) Cover component, is declaring that it will comply with 45CFR Part 46 and proceed to obtain a human subjects assurances (see http://www.hss.gov/ohrp). **Do not insert the human subjects assurance number of any collaborating institution in the space provided.**

2. Are Vertebrate Animals Used?

If activities involving vertebrate animals are planned at any time during the proposed project at any performance site, check the Yes box. Otherwise, check the No box, and skip to Step 3.

Note that the generation of custom antibodies constitutes an activity involving vertebrate animals.

2.a. If YES to Vertebrate Animals

For the "Is the IACUC review Pending" field, if an Institutional Animal Care and Use Committee (IACUC) review is pending, check the Yes box. Otherwise check the No box. For IACUC Approval Date, enter the IACUC approval date, if available. Leave blank if Pending.

For Animal Welfare Assurance Number, enter the Federally approved assurance number, if available. (To determine if your organization holds an Animal Welfare Assurance, see http://grants.nih.gov/grants/olaw/olaw.htm#assur.)

Applicants should check "Yes" to the question "Is the IACUC review Pending?" even if the IACUC review/approval process has not yet begun at the time of submission. Also note that an IACUC Approval Date is not required at the time of submission. However, the approval date and other data may be requested later in the pre-award cycle as a Just-In-Time requirement. If the applicant organization does not have an approved Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW), NIH, enter "None" in the Animal Welfare Assurance Number field. **Do not enter the Animal Welfare Assurance number of any collaborating institution.** By inserting "None" at the time of submission, the applicant organization is essentially declaring that it will comply with the PHS Policy on Humane Care and Use of Laboratory Animals by submitting an Animal Welfare Assurance and verification of IACUC approval when requested to do so by OLAW.

3. Is proprietary/privileged information included in the application?

Patentable ideas, trade secrets, privileged or confidential commercial or financial information, disclosure of which may harm the applicant, should be included in applications only when such information is necessary to convey an understanding of the proposed project. If the application includes such information, check the "Yes" box and clearly mark each line or paragraph on the pages containing the proprietary/privileged information with a legend similar to: "The following contains proprietary/privileged information that (name of applicant) requests not be released to persons outside the Government, except for purposes of review and evaluation."

4. Environmental Questions

Unless a specific FOA indicates that the National Environmental Policy Act (NEPA) applies, applicants should check "No."

4.a. Does this project have an actual or potential impact on the environment?

If your project will have an actual or potential impact on the environment, check the Yes box, and then explain in the box provided in 4.b. Otherwise, check the No box.

4.b. If yes, please explain

If you checked the Yes box indicating an actual or potential impact on the environment, enter the explanation of the actual or potential impact on the environment here.

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) been performed?

If an exemption has been authorized or an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) been performed, check the Yes box, and then explain in the box provided in 4.d. Otherwise, check the No box.

4.d. If yes, please explain

If you checked the Yes box indicating an exemption has been authorized or an EA or EIS has been performed, enter the explanation here. If desired, you can provide the information in a separate file, and attach by clicking Add Attachments located to the right of Step 11 - Other Attachments.

5. Activities Outside US or with International Collaborators Questions

5.a. Does this project involve activities outside of the United States or partnerships with International Collaborators?

If your project involves activities outside the United States or partnerships with international collaborators, check the Yes box, and then explain in the box provided in 5.b. Otherwise, check the No box.

Applicants to NIH and other PHS agencies must check "Yes" if the applicant organization is a foreign institution or if the project includes a foreign component. For a definition of a substantial foreign component, see "Definitions" section of Part III: Policies, Assurances, Definitions, and Other Information.

5.b. If yes, identify countries

If you checked the Yes box indicating your project involves activities outside the US, enter the countries with which international cooperative activities are involved.

5.c. Optional Explanation

Use this block to provide any supplemental information, if necessary. If desired, you can provide the information in a separate file, and attach by clicking "Add Attachments" located to the right of Item 11, Other Attachments.

If you have checked "Yes" to 5.a, applicants to the NIH and other PHS agencies must describe special resources or characteristics of the research project (e.g., human subjects, animals, disease, equipment, and techniques), whether similar research is being done in the United States and whether there is a need for additional research in this area. Provide this information in a separate file, attaching it as Item 11, Other Attachments. In the body of the text, begin the section with a heading indicating "Foreign Justification." When saving this file, please name it "Foreign Justification" as well.

6. Project Summary/Abstract

The Project Summary must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should contain a statement of objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate lay reader. This Summary must not include any proprietary/confidential information.

To attach a project summary/abstract file, click Add Attachment, browse to where you saved the file, select the file, and then click Open.

The first and major component of the Project Summary/Abstract (i. e., "Description") is a **Project Summary**. It is meant to serve as a succinct and accurate description of the proposed work when separated from the application. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the **mission of the agency**). Describe concisely the research design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person. Finally, please make every effort to be succinct. This section must be no longer than 30 lines of text, and follow the required font and margin specifications. An abstract which exceeds this allowable length may be flagged as an error by the agency upon submission. This would require a corrective action before the application will be accepted.

The attachment must be in PDF format. (See Section 2.6 for additional information on preparing attachments.)

7. Project Narrative

For NIH and other PHS agencies applications, this attachment will reflect the second component of the Project Summary. The second component of the Project Summary/Abstract (i.e., "Description") is **Relevance**. Using no more than two or three sentences, describe the relevance of this research to **public** health. In this section, be succinct and use plain language that can be understood by a general, lay audience.

A separate Research Plan component is required for NIH and other PHS agencies applications. Refer to Section 5.4, Research Plan Component, for separate file uploads and instructions.

8. Bibliography & References Cited

Provide a bibliography of any references cited in the Project Narrative. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Be especially careful to follow scholarly practices in providing citations for source materials relied upon when preparing any section of the application.

To attach a bibliography, click "Add Attachment," browse to where you saved the file, select the file, and then click "Open."

Note this section (formerly "Literature Cited") should include any references cited in the PHS 398 Research Plan component (see Section 5.4 for details on completing that component). The reference should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.

9. Facilities & Other Resources

This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project.

The research to be performed by the applicant small business concern and its collaborators must be in United States facilities (i.e., foreign sites must be approved by the funding officer) that are available to and under the control of each party for the conduct of each party's portion of the proposed project.

If there are multiple performance sites, then resources available at each site should be described. In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment, or subject populations or employ useful collaborative arrangements. If research involving Select Agent(s) will occur at any performance site(s), the biocontainment resources available at each site should be described.

To attach a facilities and other resources file, click Add Attachment, browse to where you saved the file, select the file, and then click Open.

10. Equipment

List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities. To attach an equipment file, click Add Attachment, browse to where you saved the file, select the file, and then click Open.

11. Other Attachments

Attach a file to provide any other project information not provided above or in accordance with the announcement and/or agency-specific instruction by clicking Add Attachment, browsing to where you saved the file, selecting the file, and then clicking Open.

Once all data have been entered, click the "Close Form" button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

4.5 Senior/Key Person Profile(s) Component

RESEARCH & RELATED Senior/Key Person Profile

PROFILE - Project Director/Principal Investigator

Prefix | * First Name | Middle Name | * Last Name | Suffix

Position/Title: | Department:

Organization Name: | Division:

* Street1: | Street2:

* City: | County: | * State: | * Zip Code: | * Country:

* Phone Number | Fax Number | * E-Mail

Credential, e.g., agency login:

*** Project Role:** PD/PI | **Other Project Role Category:**

***Attach Biographical Sketch** | Add Attachment | Delete Attachment | View Attachment

Attach Current & Pending Support | Add Attachment | Delete Attachment | View Attachment

PROFILE - Senior/Key Person 1

Prefix | * First Name | Middle Name | * Last Name | Suffix

Position/Title: | Department:

Organization Name: | Division:

* Street1: | Street2:

* City: | County: | * State: | * Zip Code: | * Country: USA

* Phone Number | Fax Number | * E-Mail

Credential, e.g., agency login:

*** Project Role:** | **Other Project Role Category:**

***Attach Biographical Sketch** | Add Attachment | Delete Attachment | View Attachment

Attach Current & Pending Support | Add Attachment | Delete Attachment | View Attachment

Reset Entry | Next Person

ADDITIONAL SENIOR/KEY PERSON PROFILE(S) | Add Attachment | Delete Attachment | View Attachment

Additional Biographical Sketch(es) (Senior/Key Person) | Add Attachment | Delete Attachment | View Attachment

Additional Current and Pending Support(s) | Add Attachment | Delete Attachment | View Attachment

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Expiration Date: 04/30/2008

Starting with the PD/PI, provide a profile for each senior/key person proposed. Unless otherwise specified in an agency announcement, senior/key personnel are defined as all individuals who contribute in a

substantive, measurable way to the scientific development or execution of the project, whether or not salaries are requested. Consultants should be included if they meet this definition. Key Personnel must devote measurable effort to the project whether or not salaries are requested – "zero percent" effort or "as needed" are not acceptable involvements for someone designated as Key Personnel.

Special Note for STTR applicants: The STTR applicant organization must officially affiliate the PD/PI with the small business concern in the Commons if the PD/PI is not an employee of the small business concern. See Section 2.2.2.2 for steps to affiliate a PD/PI to the applicant organization/institution.

Profile – Project Director/Principal Investigator (PD/PI)

Field Name	Instructions
Prefix	This field is automatically populated from the SF 424 (R&R). It is the prefix (e.g., Mr., Mrs., Rev.) of the PD/PI.
First Name	This field is automatically populated from the SF 424 (R&R). It is the first (given) name of the PD/PI. This field is required.
Middle Name	This field is automatically populated from the SF 424 (R&R). It is the middle name of the PD/PI.
Last Name	This field is automatically populated from the SF 424 (R&R). It is the last (family) name of the PD/PI. This field is required.
Suffix	This field is automatically populated from the SF 424 (R&R). It is the suffix (e.g., Jr., Sr., PhD) for the name of the PD/PI.
Position/Title	This field is automatically populated from the SF 424 (R&R). It is the title of the PD/PI.
Department	This field is automatically populated from the SF 424 (R&R). It is the name of primary organizational department, service, laboratory, or equivalent level within the organization of the PD/PI.
Organization Name	This field is automatically populated from the SF 424 (R&R). It is the name of the organization of the PD/PI.
Division	This field is automatically populated from the SF 424 (R&R). It is the name of primary organizational division, office, or major subdivision of the PD/PI.
Street1	This field is automatically populated from the SF 424 (R&R). It is the first line of the street address of the PD/PI.
Street2	This field is automatically populated from the SF 424 (R&R). It is the second line of the street address of the PD/PI, if applicable.
City	This field is automatically populated from the SF 424 (R&R). It is the city of the PD/PI.

Field Name	Instructions
County	This field is automatically populated from the SF 424 (R&R). It is the county of the PD/PI.
State	This field is automatically populated from the SF 424 (R&R). It is the state or province of the PD/PI.
ZIP Code	This field is automatically populated from the SF 424 (R&R). It is the ZIP (Postal) Code of the PD/PI.
Country	This field is automatically populated from the SF 424 (R&R). It is the country of the PD/PI.
Phone Number	This field is automatically populated from the SF 424 (R&R). It is the daytime phone number for the PD/PI.
Fax Number	This field is automatically populated from the SF 424 (R&R). It is the fax number for the PD/PI.
Email	This field is automatically populated from the SF 424 (R&R). It is the email address for the PD/PI.
Credential, e.g., agency login	If you are submitting to an agency (e.g., NIH and other PHS agencies) where you have an established personal profile, enter the agency ID. If not, leave blank. For NIH and other PHS agencies, registration in the eRA Commons for all PDs/PIs is required. **The assigned Commons UserName (the unique name used to log into the system) for anyone assigned the PD/PI role must be entered here. This is a required field for applications submitted to NIH and other PHS agencies. Applications will not pass agency validation requirements without this field.**
Project Role	Select a project role from the list. Select "Other" if an appropriate project role is not listed.
Other Project Role Category	Complete if you selected "Other Professional" or "Other" as a project role. For example, Engineer, Chemist.
Attach Biographical Sketch	Provide a biographical sketch for the PD/PI. Recommended information includes: Education and Training, Research and Professional Experience, Collaborators and Affiliations (for conflicts of interest), Publications and Synergistic Activities. Save the information in a single file and attach by clicking Add Attachment. Biographical sketches should follow the format described below.
Attach Current & Pending	Unless otherwise required in a specific FOA, do not use this attachment

Field Name	Instructions
Support	attachment upload for NIH and other PHS agency submissions. This information is no longer required at the time of application submission. This information may be requested later in the pre-award cycle. When this occurs, you will be instructed to refer to Other Support in Part III, Policies, Assurances, Definitions and Other Information.

Profile – Senior/Key Person [*n*]

The remaining Senior/Key Person Profiles should be listed in alphabetical order. Also use this section to list any Other Significant Contributors (OSCs). OSCs should be listed after all Key Persons. OSCs are individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort (in person months) to the project. These individuals are typically presented at "effort of zero person months" or "as needed" (individuals with measurable effort cannot be listed as Other Significant Contributors). Consultants should be included if they meet this definition. This would also be an appropriate designation for mentors on Career awards.

A biosketch, including Research Support information, will be required for these individuals as this highlights their accomplishments as scientists. Reviewers use these pages to address the "investigator" review criterion. However, if an award is to be made, Other Support information will not be required or accepted since considerations of overlap do not apply to these individuals.

Should the level of involvement change for an individual listed as an OSC, they should be redesignated as "key personnel." This change should be made before any compensation is charged to the project.

Field Name	Instructions
Prefix	Select from the list the prefix (for example, Mr., Mrs., Rev.) of the Senior/Key Person.
First Name	Enter the first (given) name of the Senior/Key Person. This field is required.
Middle Name	Enter the middle name of the Senior/Key Person, if applicable.
Last Name	Enter the last (family) name of the Senior/Key Person. This field is required.
Suffix	Select from the list the suffix (for example, Jr., Sr., PhD) of the Senior/Key Person.
Position/Title	Enter the title of the Senior/Key Person.
Department	Enter the name of primary organizational department, service, laboratory, or equivalent level within the organization of the Senior/Key Person.

Field Name	Instructions
Organization Name	Enter the name of primary organizational division, office, or major subdivision of the Senior/Key Person.
Division	Enter the name of organization of the Senior/Key Person.
Street1	Enter first line of the street address for the Senior/Key Person. This field is required.
Street2	Enter second line of the street address for the Senior/Key Person, if applicable.
City	Enter the city where the Senior/Key Person is located. This field is required.
County	Enter the county where the Senior/Key Person is located.
State	Enter the State where the Senior/Key Person is located. Use the provided two digit abbreviation for all state code entries. This field is required if the Senior/Key Person is located in the United States.
ZIP Code	Enter the ZIP (Postal) code of the Senior/Key Person address. This field is required if the Senior/Key Person is located in the United States.
Country	Select from the list the country for the Senior/Key Person address.
Phone Number	Enter the daytime telephone number for the Senior/Key Person. This field is required.
Fax Number	Enter the fax number for the Senior/Key Person.
Email	Enter the email address for the Senior/Key Person. This field is required for the Senior/Key Person.
Credential, e.g., agency login	If you are submitting to an agency (e.g., NIH and other PHS agencies) where you have an established personal profile, enter the agency ID. If not, leave blank. For NIH and other PHS agencies, registration in the eRA Commons for all PDs/PIs is required. **The assigned Commons UserName (the unique name used to log into the system) for anyone assigned the PD/PI role must be entered here. This is a required field for applications submitted to NIH and other PHS agencies. Applications will not pass agency validation requirements without this field.**

Field Name	Instructions
Project Role	Select a project role from the list. Select "Other" if an appropriate project role is not listed. At this time, NIH and other PHS agencies continues to only recognize a single PD/PI. The role of "Co-PD/PI" is not currently used by NIH and other PHS agencies. If including individuals classified as "Other Significant Contributors (OSCs)," use the "Other" category and indicate "Other Significant Contributor" as the role in the "Other Project Role Category." OSCs should be listed last after all other Senior/Key Persons have been listed.
Other Project Role Category	Complete if you selected "Other Professional" or "Other" as a project role. For example, Engineer, Chemist.
Attach Biographical Sketch	Provide a biographical sketch for the Senior/Key Person. Recommended information includes: Education and Training, Research and Professional Experience, Collaborators and Affiliations (for conflicts of interest), Publications and Synergistic Activities. Save the information in a single file and attach by clicking Add Attachment. Biographical sketches should follow the format described below.
Attach Current & Pending Support	Unless otherwise required in a specific FOA, do not use this attachment upload for NIH and other PHS agency submissions. This information is no longer required at the time of application submission. This information may be requested later in the pre-award cycle. When this occurs, refer to Other Support in Part III, Policies, Assurances, Definitions, and Other Information.

Note: After completing Profile – Senior/Key Person 1, click the Next Person button to display the fields for Profile – Senior/Key Person 2.

Additional Senior/Key Person Profile(s)

If more than eight Senior/Key Person profiles are proposed, enter the information in a separate file. On the form, click Add Attachment, select the file, and then click Open. A sample Additional Senior/Key Person Profiles format page for greater than 8 profiles is found under "Additional Format Pages" at: http://grants.nih.gov/grants/funding/424/index.htm.

Additional Biographical Sketch(es) (Senior/Key Person)

Provide a biographical sketch for each Senior/Key Person. Recommended information includes: Education and Training, Research and Professional Experience, Collaborators and Affiliations (for conflicts of interest), Publications and Synergistic Activities. Save the information in a single file and attach by clicking Add Attachment.

Biographical sketches should follow the format described below.

Additional Current and Pending Support(s)

Provide a list of all current and pending support for the PD/PI and each Senior/Key Person (even if they receive no salary support from the project(s) for ongoing projects and pending proposals. Show the total award amount for the entire award period (including indirect costs) as well as the number of person-months per year to be devoted to the project by the senior/key person, regardless of source of support. Concurrent submission of a proposal to other organizations will not prejudice its review.

Unless otherwise required in a specific FOA, do not use this attachment upload for NIH and other PHS agency submissions. This information is no longer required at the time of application submission. This information may be requested later in the pre-award cycle. When this occurs, refer to Other Support in Part III, Policies, Assurances, Definitions, and Other Information.

Additional NIH and Other PHS Agencies Instructions for a Biographical Sketch

Use the sample *format* on the Biographical Sketch Format Page to prepare this section for **all** (modular *and* other) grant applications. Include biographical sketches of all **Senior/Key Personnel and Other Significant Contributors**. The Biographical Sketch may not exceed four pages per person. This 4-page limit includes the table at the top of the first page. See the sample of a completed Biographical Sketch.

If the individual is registered in the eRA Commons, include the assigned Commons User Name. This data item is currently optional. (For information on the eRA Commons, see https://commons.era.nih.gov/commons/index.jsp.)

Complete the educational block at the top of the format page, and complete Sections A, B, and C.

A. **Positions and Honors.** List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.

B. **Selected peer-reviewed publications or manuscripts in press (in chronological order)**. Do not include manuscripts submitted or in preparation.

C. **Research Support.** List both selected ongoing and completed (during the last three years) research projects (Federal or non-Federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. *Do not include number of person months or direct costs.*

Don't confuse “Research Support” with “Other Support.” Though they sound similar, these parts of the application are very different. As part of the biosketch section of the application, “Research Support” highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. In contrast, “Other Support” information is required for all applications that are selected to receive grant awards. NIH staff will request complete and up-to-date “other support” information from you after peer review. This information will be used to check that the proposed research has not already been Federally-funded.

Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the

form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

4.6 R&R Budget Component

The R&R Budget component includes three separate data entry screens: (1) Sections A and B; (2) Sections C through E; and (3) Sections F through K. To navigate between the various screens, use the "Previous" and "Next" buttons at the top of the form. Complete the R&R Budget component following the instructions provided. You must complete a separate detailed budget for each year of support requested. The form will generate a cumulative budget for the total project period. You must complete all the required information (i.e., those fields that are highlighted and noted with an "*") before the "Next Period" button is activated. If no funds are requested for a required field, enter "0." Only whole numbers should be used on the budget page, no decimals. Round calculations DOWN to the nearest dollar.

If funds are being requested for more than one budget period, click the "Next Period" button at the top of the third budget screen (Sections F through K) to navigate to screens for the next budget period.

Revision (Supplemental) Application. For a "Revision" (Supplemental) application, show only those items for which additional funds are requested. If the initial budget period of the supplementation application is less than 12 months, prorate the personnel costs and other appropriate items of the detailed budget.

4.6.1 Section A and B

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

* ORGANIZATIONAL DUNS:

* Budget Type: ☐ Project ☐ Subaward/Consortium

Enter name of Organization:

Reset Entries * Start Date: * End Date: Budget Period: 1

(If the Reset Entries button is pressed, please navigate to previous year to enable the submission of the form.)

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.						PD/PI							
2.													
3.													
4.													
5.													
6.													
7.													
8.													

9. Total Funds requested for all Senior Key Persons in the attached file

Total Senior/Key Person

Additional Senior Key Persons: Add Attachment

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
	Total Number Other Personnel					Total Other Personnel	

Total Salary, Wages and Fringe Benefits (A+B)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 04/30/2008

Organizational DUNS

Enter the DUNS or DUNS+4 number of your organization. For project applicants, this field is pre-populated from the R&R SF424 Cover Page. For subaward applicants, this field is required.

Budget Type

Check the appropriate block. Check Project if the budget requested is for the primary applicant organization. Check Subaward/Consortium if the budget requested is for subawardee/consortium organization(s). Note: Separate budgets are required only for subawardee/consortium organizations that perform a substantive portion of the project. If creating a Subaward Budget, use the R&R Subaward Budget Attachment and attach as a separate file on the R&R Budget Attachment(s) form.

If you are preparing an application that includes a subaward/consortium, see Section 4.7 Special Instructions for Preparing Applications with a Subaward/Consortium.

Enter name of Organization

Pre-populated from the R&R SF424. Enter the name of your organization.

Start Date

Enter the requested/proposed start date of each budget period. Use the following format: MM/DD/YYYY.

End Date

Enter the requested/proposed end date of each budget period. Use the following format: MM/DD/YYYY.

Budget Period

Identify the specific budget period (for example, 1, 2, 3, 4, 5). If submitting through Grants.gov, the system will automatically generate a cumulative budget for the total project period.

A. Senior/Key Person

Field Name	Instructions
Prefix	Select from the list the prefix (for example, Mr., Mrs., Rev.) of the Senior/Key Person.
First Name	Enter the first (given) name of each Senior/Key Person. This field is required.
Middle Name	Enter the middle name of each Senior/Key Person, if applicable.
Last Name	Enter the last (family) name of each Senior/Key Person. This field is required.
Suffix	Select from the list the suffix (for example, Jr., Sr., PhD) of each Senior/Key Person.
Project Role	Enter the project role of the Senior/Key person. There must be a Personnel entry listed for the PI or PD on the Detailed Budget Page for budget year 1. This field could also include such roles as Co-PD/PI, Postdoctoral Associates, and Other Professionals.
Base Salary ($)	Enter the annual compensation paid by the employer for each Senior/Key person. This includes all activities such as research, teaching, patient care, or other. You may choose to leave this column blank. An applicant organization may choose to leave this blank; however, PHS staff will request this information prior to award. STTR: If the PD/PI is an employee of the Research Institution (RI), the PD/PI salary should be entered on the RI subaward budget page.
Cal. Months	Enter the number of months devoted to the project for each Senior/Key person (for example, calendar, academic, summer). If effort does not change throughout the year, use the calendar months column. If effort varies between academic and summer months, leave the calendar months column blank and use only the academic and summer months columns.

Field Name	Instructions
Acad. Months	Enter the number of months devoted to the project for each Senior/Key person (for example, calendar, academic, summer). If your institution does not use a 9-month academic year, indicate your institution's definition of academic year in the budget justification.
Sum. Months	Enter the number of months devoted to the project for each Senior/Key person (for example, calendar, academic, summer). If your institution does not use a 3-month summer period, indicate your institution's definition of summer in the budget justification.
Requested Salary ($)	Regardless of the number of months being devoted to the project, indicate only the amount of salary being requested for this budget period for each Senior/Key person. STTR: The PD/PI may be paid by either the research institution (RI) or the small business, but not both. If the PD/PI is an employee of the small business, enter the PD/PI's salary on the small business budget. If the PD/PI is an employee of the RI, enter the PD/PI's salary on the RI's subaward budget.
Fringe Benefits ($)	Enter applicable fringe benefits, if any, for each Senior/Key person. SBIR and STTR: Leave this section blank as commercial (for-profit) organizations usually treat 'fringe benefits' as indirect costs. In certain cases, fringe benefits may be requested as a direct cost to the extent that they are treated consistently by the organization as a direct cost to all sponsors.
Funds Requested ($)	Enter the requested salary and fringe benefits for each Senior/Key person.
Total Funds requested for all Senior Key Persons in the attached file	Enter the total funds requested for all Senior/Key persons listed in the attached file.
Total Senior/Key Person	The total funds requested for all Senior/Key persons.
Additional Senior Key Persons	If funds are requested for more than eight Senior/Key persons, include all pertinent budget information and attach as a file here. Enter the total funds requested for all additional senior/key persons in line 9 of Section A. Use the same format as the budget component and include all required information.

B. Other Personnel

Field Name	Instructions
Number of Personnel	For each project role category identify the number of applicant organization personnel proposed. Note, for Secretarial/Clerical Personnel, in most circumstances the salaries of administrative or clerical staff at educational institutions and nonprofit organizations are included as part of indirect costs. Examples, however, of where direct charging of administrative or clerical staff salaries may be appropriate may be found at: http://www.whitehouse.gov/omb/circulars/a021/a21_2004.html. The circumstances for requiring direct charging of these services must be clearly described in the budget justification. For all Postdoctoral Associates and Graduate Students not already named in Section A. Senior/Key Person, individually list names, roles (e.g., PostDoc or Graduate Student), associated months, and salary & fringe benefits requested in the Budget Justification.
Project Role	If Project Role is other than Post Doctoral Associates, Graduate Students, Undergraduate Students, or Secretarial/Clerical, enter the appropriate project role (for example, Engineer, IT Professional, etc.) in the blanks. Do not include consultants in this section. Consultants are included below in Section F. Other Direct Costs.
Cal. Months	Enter the number of months devoted to the project in the applicable box for each project role category (for example, calendar, academic, summer).
Acad. Months	Enter the number of months devoted to the project in the applicable box for each project role category (for example, calendar, academic, summer). If your institution does not use a 9-month academic year, indicate your institution's definition of academic year in the budget justification.
Sum. Months	Enter the number of months devoted to the project in the applicable box for each project role category (for example, calendar, academic, summer). If your institution does not use a 3-month summer period, indicate your institution's definition of summer in the budget justification.
Requested Salary ($)	Regardless of the number of months being devoted to the project, indicate only the amount of salary/wages being requested for each project role.
Fringe Benefits ($)	Enter applicable fringe benefits, if any, for this project role category. SBIR and STTR: Leave this section blank as commercial (for-profit) organizations usually treat 'fringe benefits' as indirect costs. In certain cases, fringe benefits may be requested as a direct cost to the extent that they are treated consistently by the organization as a direct cost to all sponsors.

Field Name	Instructions
Funds Requested	Enter requested salary/wages & fringe benefits for each project role.
Total Number of Other Personnel	The total number of other applicant organization personnel.
Total Other Personnel	The total funds requested for all other Personnel.
Total Salary, Wages and Fringe Benefits (A+B)	Total Funds requested for all Senior Key Persons and all Other Personnel.

To navigate to the next page (Sections C through E), click the “Next” button at the top of the form.

4.6.2 Sections C through E

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

* ORGANIZATIONAL DUNS:

* Budget Type: ☐ Project ☐ Subaward/Consortium

Enter name of Organization:

Reset Entries * Start Date: * End Date: Budget Period: 1

(If the Reset Entries button is pressed, please navigate to previous year to enable the submission of the

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment item	* Funds Requested ($)
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11. Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: Add Attachment Delete Attachment View Attachment

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other	
Number of Participants/Trainees — Total Participant/Trainee Support Costs	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 04/30/2008

The information for Organizational DUNS, Budget Type, Name of Organization, and Start and End Dates is automatically filled in based on the information entered on the first budget screen. To edit this information, return to the initial budget screen (Sections A and B) by clicking the “Previous” button.

C. Equipment Description

Field Name	Instructions
Equipment item	Equipment is defined as an item of property that has an acquisition cost of $5,000 or more (unless the organization has established lower levels) and an expected service life of more than one year. List each item of equipment separately and justify each in the budget justification section. Ordinarily, allowable items will be limited to research equipment and apparatus not already available for the conduct of the work. General-purpose equipment, such as a personal computer, is not eligible for support unless primarily or exclusively used in the actual conduct of scientific research.
Funds Requested	Enter the estimated cost of each item of equipment including shipping and any maintenance costs and agreements. Dollar amount for item should exceed $5000.
Total funds requested for all equipment listed in the attached file	Enter the total funds requested for all equipment listed in the attached file.
Total Equipment	Total Funds requested for all equipment.
Additional Equipment	If the space provided cannot accommodate all the equipment proposed, attach a file by clicking Add Attachment. List each additional item and the funds requested. For all additional items in the attached file, list the total funds requested on line 11 of this section.

D. Travel

Field Name	Instructions
Domestic Travel Costs (Incl. Canada, Mexico, and US Possessions)	Enter the total funds requested for domestic travel. Domestic travel includes Canada, Mexico, and US possessions. In the budget justification section, include the purpose, destination, dates of travel (if known), and number of individuals for each trip. If the dates of travel are not known, specify estimated length of trip (for example, 3 days).
Foreign Travel Costs	Enter the total funds requested for foreign travel. Foreign travel includes any travel outside of North America and/or US possessions. In the budget justification section, include the purpose, destination, dates of travel (if known) and number of individuals for each trip. If the dates of travel are not known, specify estimated length of trip (for example, 3 days).
Total Travel Cost	The total funds requested for all travel.

E. Participant/Trainee Support Costs

Unless specifically stated otherwise in an announcement, NIH and other PHS agencies applicants should leave blank Section E. Note: Tuition remission for graduate students should continue to be

included in Section F. Other Direct Costs when applicable.

Field Name	Instructions
Tuition/Fees/Health Insurance	Enter the total amount of funds requested for Participant/Trainee tuition, fees, and/or health insurance.
Stipends	Enter the total funds requested for Participant/Trainee stipends.
Travel	Enter the total funds requested for Participant/Trainee travel.
Subsistence	Enter the total funds requested for Participant/Trainee subsistence.
Other	Describe any other participant trainee funds requested. Enter the total funds requested for any other Participant/Trainee costs described.
Number of Participants/Trainees	Enter the total number of proposed Participants/Trainees.
Total Participant/Trainee Support Costs	The total funds requested for all trainee costs.

4.6.3 Sections F through K

RESEARCH & RELATED BUDGET - SECTION F-K, BUDGET PERIOD 1

Next Period

* ORGANIZATIONAL DUNS:

* Budget Type: ☐ Project ☐ Subaward/Consortium

Enter name of Organization:

Reset Entries | * Start Date: | * End Date: | Budget Period: 1

(If the Reset Entries button is pressed, please navigate to previous year to enable the submission of the

F. Other Direct Costs	Funds Requested ($)
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8.	
9.	
10.	
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)
Total Direct Costs (A thru F)	

H. Indirect Costs

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1.				
2.				
3.				
4.				
			Total Indirect Costs	0.00

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	0.00

J. Fee	Funds Requested ($)

K. * Budget Justification | Add Attachment | Delete Attachment | View Attachment

(Only attach one file.)

OMB Number: 4040-0001

RESEARCH & RELATED Budget (F-K) (Funds Requested)

Expiration Date: 04/30/2008

The information for Organizational DUNS, Budget Type, Name of Organization, and Start and End Dates is automatically filled in based on the information entered on the first budget screen. To edit this information, return to the initial budget screen (Sections A and B) by clicking the "Previous" button.

F. Other Direct Costs

Field Name	Instructions
1. Materials and Supplies	Enter the total funds requested for materials and supplies. In the budget justification, indicate general categories such as glassware, chemicals, animal costs, including an amount for each category. Categories less than $1,000 do not have to be itemized.
2. Publication Costs	Enter the total publication funds requested. The proposal budget may request funds for the costs of documenting, preparing, publishing, or otherwise making available to others the findings and products of the work conducted under the award. In the budget justification include supporting information.
3. Consultant Services	Enter the total costs for all consultant services. In the budget justification, identify each consultant, the services he or she will perform, total number of days, travel costs, and the total estimated costs.
4. ADP/Computer Services	Enter total funds requested for ADP/computer services. The cost of computer services, including computer-based retrieval of scientific, technical and education information may be requested. In the budget justification, include the established computer service rates at the proposing organization if applicable.
5. Subawards/Consortium/ Contractual Costs	Enter the total funds requested for 1) all subaward/consortium organization(s) proposed for the project and 2) any other contractual costs proposed for the project.
6. Equipment or Facility Rental/User Fees	Enter the total funds requested for equipment or facility rental/use fees. In the budget justification, identify each rental user fee and justify.
7. Alterations and Renovations	Enter the total funds requested for alterations and renovations. In the budget justification, itemize by category and justify the costs of alterations and renovations including repairs, painting, removal or installation of partitions, shielding, or air conditioning. Where applicable, provide the square footage and costs.
8-10 Other	Add text to describe any "other" direct costs not requested above. Use the budget justification to further itemize and justify. Use lines 8-10 for such costs as patient care and tuition remission. If requesting patient care costs, request inpatient and outpatient costs separately using lines 8 and 9. If line space is an issue, combine all remaining "other direct costs" together on the last line and include details in the budget justification (description and funds requested).

Field Name	Instructions
Total Other Direct Costs	The total funds requested for all other direct costs.

G. Total Direct Costs (A through F)

The total funds requested for all direct costs.

H. Indirect Costs

Indirect costs are defined as costs that are incurred by a grantee for common or joint objectives and that, therefore, cannot be identified specifically with a particular project or program. If the applicant small business concern has a currently effective negotiated indirect cost rate with a Federal agency, that rate should be used when calculating proposed indirect costs. (However, these rates must be adjusted for independent [self-sponsored] research and development expenses, which are not allowable by the Department of Health and Human Services [HHS].)

If applicable, indicate your organization's most recent indirect cost rate established with the Division of financial Advisory Services (DFAS), NIH, or with another Federal agency. If your applicant organization is in the process of negotiating or renegotiating a rate, use that rate in the application.

If the applicant organization does not have a current negotiated rate, it should develop a provisional rate for application purposes. If the applicant organization has a current negotiated rate with another Federal agency, the negotiated rate must be adjusted to treat any independent research and development (IR&D) costs in accordance with HHS policy.

If this field does not allow a figure greater than 100% to be entered, use two lines to show the entire calculation.

In accordance with the Small Business Innovation Development Act of 1982 and the Small Business Technology Transfer Act of 1992, irrespective of the time period in which the costs are incurred, no SBIR/STTR funds can be used to "support" any commercialization (Phase III activities). "Support" in this case includes both direct and indirect costs.

The Small Business Administration's SBIR and STTR Program Policy Directives defined terms:

SBIR agencies must establish an SBIR Program by reserving, in each fiscal year, not less than 2.5 percent of its extramural budget for awards to SBCs for R/R&D. "R&D activities" include any activities directed toward reducing the technical risk of the technology.

- Commercialization. The process of developing marketable products or services and producing and delivering products or services for sale (whether by the originating party or by others) to government or commercial markets.
- Phase III is the period during which Phase II innovation moves from the laboratory into the marketplace. No SBIR funds support this phase. The small business must find funding in the private sector or other non-SBIR Federal agency funding.

Based on this position, when NIH is negotiating indirect costs with SBIR/STTR grantees/contractors, we are disallowing all indirect costs applicable to commercialization activities related to SBIR/STTR awards.

Note: Below is a list of cost categories NIH considers to be commercialization. In addition, these items include labor costs for the Marketing Director and Director of Business Development, as well as sales and marketing staff who are grantee/contractor employees or contractors hired for those purposes.

Commercialization cost categories: market and sales; market research; business development/product development/market plans; legal fees, travel and other costs relating to license agreements and partnerships.

You are encouraged to visit the following Division of Financial Advisory Services (DFAS) Web sites or call the DFAS staff at 301-496-2444 for guidance:
Main DFAS website, **http://ocm.od.nih.gov/dfas/dfas.htm**
FAQS, **http://ocm.od.nih.gov/dfas/faqindirectcosts.htm**

Listing of unallowable and unallocable costs and the related Federal Acquisition Regulation (FAR) citation for each, **http://ocm.od.nih.gov/dfas/ unallowables.htm**

Field Name	Instructions
Indirect Cost Type	Indicate the type of cost (for example, Salary & Wages, Modified Total Direct Costs, or Other [explain]). Also indicate if Off-site. If more than one rate/base is involved, use separate lines for each. If you do not have a current indirect rate(s) approved by a Federal agency, indicate, "None--will negotiate" and include information for a proposed rate. Use the budget justification if additional space is needed.
Indirect Cost Rate (%)	Indicate the most recent indirect cost rate(s) (also known as Facilities & Administrative Costs [F&A]) established with the cognizant Federal office, or in the case of for-profit organizations, the rate(s) established with the appropriate agency. If you have a cognizant/ oversight agency and are selected for an award, you must submit your indirect rate proposal to that office for approval. If you do not have a cognizant/oversight agency, contact the awarding agency. SBIR and STTR Phase I Applicants: If your organization does not have a currently effective negotiated F&A cost rate with a Federal agency, then propose estimated F&A costs at a rate not to exceed 40% of the total direct costs. If awarded at a rate of 40% or less of total direct costs the rate used to charge actual F&A costs to projects cannot exceed the awarded rate. SBIR and STTR Phase II Applicants: If the requested F&A rate is 25 percent or less (of total direct costs), F&A costs will be awarded at the requested rate. If the requested F&A rate is greater than 25 percent of total direct costs, additional information will be required prior to award to justify the requested rate. If awarded at a rate of 25% or less of total direct costs, the rate used to charge actual F&A costs to projects cannot exceed the awarded rate. Indirect cost rates cannot exceed 99 on any line. If the negotiated rate exceeds 99%, request the additional rate amount on the next line. This field should be entered using a rate such as "55.5".

Field Name	Instructions
Indirect Cost Base ($)	Enter the amount of the base for each indirect cost type.
Funds Requested	Enter the funds requested for each indirect cost type.
Total Indirect Costs	The total funds requested for indirect costs.
Cognizant Federal Agency	Enter the name of the cognizant Federal Agency, name and telephone number of the individual responsible for negotiating your rate. If no cognizant agency is known, enter “None.”

I. Total Direct and Indirect Institutional Costs (G + H)

The total funds requested for direct and indirect costs.

Ensure that the direct costs and the indirect costs (G+H) on Section F-K EQUAL the Total Direct and Indirect Costs (G+H) on the Cumulative Budget page.

Routinely, SBIR and STTR Phase I awards do not exceed $100,000 total costs (direct costs, indirect costs, and fee). Routinely, total costs for the entire proposed Phase II period do not exceed $750,000 for SBIR and STTR projects. However, under special circumstances, applicants may propose greater amounts of funds necessary and appropriate for completion of the project.

The ability to deviate from the statutory guidelines applies to NIH ONLY – Phase I applications to CDC and FDA are limited to total costs of $100,000. Phase II applications to CDC and FDA are limited to total costs of $750,000.

J. Fee

A reasonable fee, not to exceed 7% of total costs (direct and indirect) for each Phase (I and II) of the project, is available to small business concerns receiving awards under the SBIR/STTR program. The fee is intended to be a reasonable profit factor available to for-profit organizations, consistent with normal profit margins provided to profit-making firms for research and development work.

The fee is not a direct or indirect "cost" item and may be used by the small business concern for any purpose, including additional effort under the SBIR/STTR award. The fee applies solely to the small business concern receiving the award and not to any other participant in the project. However, the grantee may pay a profit/fee to a contractor providing routine goods or services in accordance with normal commercial practice.

Note: The electronic system automatically rounds up. If you get an error “The fee must be less than 7%,” try using 6.99% as the rate.

K. Budget Justification

Use the budget justification to provide the additional information requested in each budget category identified above and any other information you wish to submit to support your budget request. Note this is a single justification for all budget years so include all justification information for all years in the same file. Click Add Attachment to attach the file.

Use this section to also list the names, role (e.g., PostDoc or Graduate Student), associated months, salary and fringe benefits for all Postdoctoral Associates and Graduate Students included in Budget Section B. Other Personnel.

If the application includes a subaward/consortium budget, a separate budget justification is submitted for that budget. See Section 4.7 Special Instructions for Preparing Applications with a Subaward/Consortium

Completing Budget Periods 2-5

If funds are being requested for more than one budget period, you must complete a separate detailed budget for each year of support requested. To navigate to screens for the next budget period, click the "Next Period" button at the top of the 3rd budget screen (Sections F through K). You must complete all the required information (i.e., those fields that are highlighted and noted with an "*") before the "Next Period" button is activated. If no funds are requested for a required field, enter "0." Note the Budget Justification is also a required item and must be attached before the "Next Period" button is activated.

4.6.4 Cumulative Budget

All values on this form are calculated automatically. They present the summations of the amounts that you have entered previously, under Sections A through K, for each of the individual budget periods. Therefore, no data entry is allowed or required, in order to complete this "Cumulative Budget" section.

If any of the amounts displayed on this form appears to be incorrect, you may correct it by adjusting one or more of the values that contribute to that total. To make any such adjustments, you will need to revisit the appropriate budget period form(s), to enter corrected values.

RESEARCH & RELATED BUDGET - Cumulative Budget

		Totals ($)
Section A, Senior/Key Person		
Section B, Other Personnel		
Total Number Other Personnel		
Total Salary, Wages and Fringe Benefits (A+B)		
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1		
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		
Section H, Indirect Costs		
Section I, Total Direct and Indirect Costs (G + H)		
Section J, Fee		

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Expiration Date: 04/30/2008

Once all data have been entered, click the "Close Form" button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

4.7 Special Instructions for Preparing Applications with a Subaward/Consortium

SBIR

In Phase I, normally, a minimum of two-thirds or 67% of the research or analytical effort must be carried out by the small business concern. The total amount of all consultant and contractual arrangements to third parties for portions of the scientific and technical effort generally may not exceed 33% of the total amount requested (direct, F&A/indirect, and fee).

If the application is selected for an award, the Authorized Organizational Representative (AOR) will need to certify that the applicant and all proposed consortium participants understand and agree to the following statement: The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the NIH consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.

In Phase II, normally, a minimum of one-half or 50% of the research or analytical effort must be carried out by the small business concern. The total amount of consultant and contractual arrangements to third parties for portions of the scientific and technical effort generally may not exceed 50% of the total Phase II amount requested (direct, F&A/indirect, and fee).

The basis for determining the percentage of work to be performed by each of the cooperative parties in Phase I or Phase II will be the total of the requested costs attributable to each party, unless otherwise described and justified in Item 12, Consortium/Contractual Arrangements, of the PHS 398 Research Plan component.

STTR

In Phase I and Phase II, at least 40% of the work must be performed by the small business concern and at least 30% of the work must be performed by the single partnering research institution. The basis for determining the percentage of work to be performed by each of the cooperative parties will be the total of the requested costs (direct, F&A/indirect, and fee) attributable to each party, unless otherwise described and justified in Item 12, Consortium/Contractual Arrangements, of the PHS 398 Research Plan component.

The single "partnering" research institution must provide a letter to the applicant small business concern certifying that at least 30% of the work of the STTR project will be performed by the research institution. The small business concern will include this letter as an attachment upload in Item 12, Consortium/Contractual Arrangements, of the PHS 398 Research Plan component.

In addition, a small business concern must negotiate a written agreement between the small business and the research institution allocating intellectual property rights to carry out follow-on research, development or commercialization. See Model Agreement for the Allocation of Rights. This agreement is required to receive support under the STTR program but is NOT submitted with the application. A copy of the Agreement must be furnished upon request of the NIH awarding component.

A small business concern may subcontract a portion of its STTR award to a Federally Funded Research and Development Center (FFRDC), either in its capacity as the Research Institution or as a participant in the STTR project in another capacity. **However, STTR funds may not be used to pay for laboratory resources of non-FFRDCs, and no SBIR funds may be used to pay for subcontracting any portion of the SBIR award back to the issuing agency or to any other Federal government unit unless a waiver is granted by the Small Business Administration.**

R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

Instructions: On this form, you will attach the R&R Subaward Budget files for your grant application. Complete the subawardee budget(s) in accordance with the R&R budget instructions. Please remember that any files you attach must be a Pure Edge document.

Click here to extract the R&R Subaward Budget Attachment

Important: Please attach your subawardee budget file(s) with the file name of the subawardee organization. Each file name must be unique.

1) Please attach Attachment 1		Add Attachment	Delete Attachment	View Attachment
2) Please attach Attachment 2		Add Attachment	Delete Attachment	View Attachment
3) Please attach Attachment 3		Add Attachment	Delete Attachment	View Attachment
4) Please attach Attachment 4		Add Attachment	Delete Attachment	View Attachment
5) Please attach Attachment 5		Add Attachment	Delete Attachment	View Attachment
6) Please attach Attachment 6		Add Attachment	Delete Attachment	View Attachment
7) Please attach Attachment 7		Add Attachment	Delete Attachment	View Attachment
8) Please attach Attachment 8		Add Attachment	Delete Attachment	View Attachment
9) Please attach Attachment 9		Add Attachment	Delete Attachment	View Attachment
10) Please attach Attachment 10		Add Attachment	Delete Attachment	View Attachment

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A complete subaward/consortium budget component (including the budget justification section) should be completed by each consortium grantee organization. Separate budgets are required only for subawardee/consortium organizations that perform a substantive portion of the project.

To start the process, the applicant organization should:

- Select the Subaward Budget Attachment Form from the Optional Documents in the Grant Application Package.
- Open the form, and click the “Click here to extract the R&R Subaward Budget Attachment” button in the middle of the form.
- Save the file using the first 10 letters of the consortium organization’s name as the file name and leave “.xfd” as the file extension. (The extracted file is a PureEdge document.)

- Email the form to the consortium grantee. Note: consortium grantees must have installed the PureEdge Viewer before they can complete the form. The consortium grantee should complete all the budget information as instructed in the R&R Budget component instructions in Section 4.6. Note: Organizational DUNS and Name of Organization fields must reflect that of the subaward/consortium grantee.
- The consortium grantee must complete the budget component and email it back to the applicant organization.
- A fee cannot be entered for a subaward/consortium budget. Fee is allowable only for the small business applicant organization budget page.
- Return to the Subaward Budget Attachment Form and attach the consortium grantee's budget to one of the blocks provided on the form. *Do not convert this attachment to PDF*.

STTR: If more than one Subaward is included in the STTR application, identify the single, partnering research institution on the RI Subaward budget justification page.

Only text attachments must be converted to PDFs. Attachments generated from PureEdge forms, such as the R&R SubAward Budget Attachment Form, should *not* be converted to PDFs.

Once all data have been entered, click the "Close Form" button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

5. Completing PHS398 Components

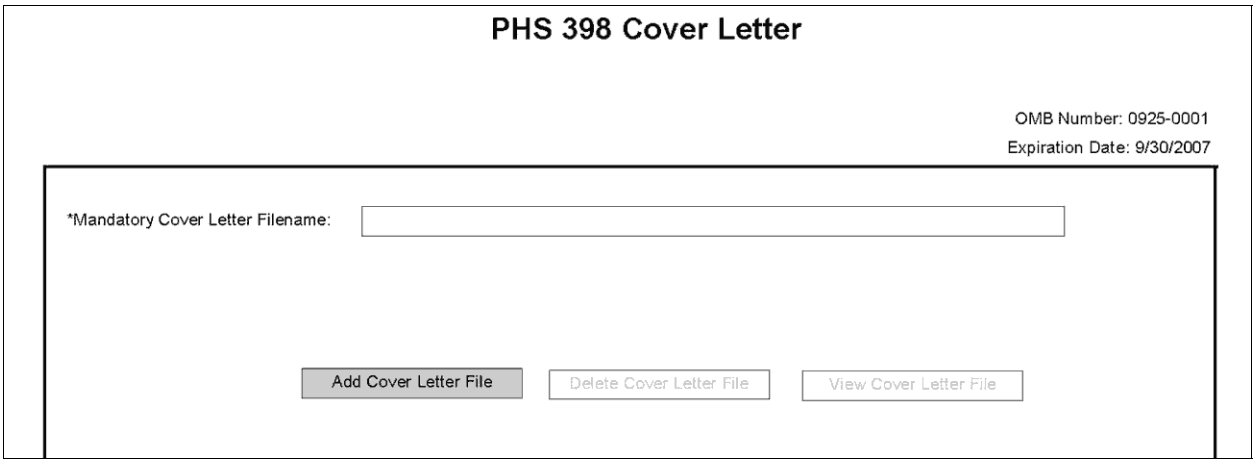
5.1 Overview

In conjunction with the SF424 (R&R) components, NIH and other PHS agencies grants applicants should also complete and submit additional components titled "PHS398." Note the PHS398 components include additional data required by the agency for a complete application. While these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to NIH and other PHS agencies will include SF424 (R&R) and PHS398 components. The PHS398 components include:

- PHS398 Cover Letter Component (optional, however applicants are strongly encouraged to include this component)
- PHS398 Cover Page Supplement (this supplements the data requirements in the R&R Cover component)
- PHS398 Research Plan Component
- PHS398 Checklist Component

Complete each component using the instructions provided below.

5.2 Cover Letter Component



Cover Letter File Name

Applicants are encouraged to include a cover letter with the application. The cover letter is only for internal agency use and will not be shared with peer reviewers. The letter should contain any of the following information that applies to the application:

1. Application title.
2. PA or RFA title, if you are responding to an NIH initiative.
3. Request of an assignment (referral) to a particular awarding component(s) or Scientific Review Group (SRG). The PHS makes the final determination.
4. List of people (e.g., competitors) who should not review your application and why.
5. Disciplines involved, if multidisciplinary.

For late applications (see Late Application policy in Section 2.14) include an explanation of the delay as part of the cover letter attachment.

When submitting a Changed/Corrected Application, a cover letter is required explaining the reason for the Changed/Corrected Application. If you already submitted a cover letter with a previous submission and are now submitting a Changed/Corrected Application, you must include all previous cover letter text in the revised cover letter attachment. The system does not retain any previously submitted cover letters until after an application is verified; therefore, you must repeat all information previously submitted in the cover letter as well as any additional information.

Save this information in a single file in a location you remember and convert the file to PDF. Click Add Cover Letter File, browse to where you saved the file, select the file, and then click Open. The name of the file attached will automatically appear in the “Mandatory Cover Letter Filename” field.

Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

5.3 Cover Page Supplement Component

PHS 398 Cover Page Supplement

OMB Number: 0925-0001
Expiration Date: 9/30/2007

1. Project Director / Principal Investigator (PD/PI)

Prefix: * First Name:
Middle Name:
* Last Name:
Suffix:

* New Investigator? ☐ No ☐ Yes

Degrees:

2. Human Subjects

Clinical Trial? ☐ No ☐ Yes

* Agency-Defined Phase III Clinical Trial? ☐ No ☐ Yes

3. Applicant Organization Contact

Person to be contacted on matters involving this application

Prefix: * First Name:
Middle Name:
* Last Name:
Suffix:

* Phone Number: Fax Number:
Email:

* Title:

* Street1:
Street2:
* City:
County:
* State:
* Zip Code: * Country: USA

1. Project Director/Principal Investigator (PD/PI)

Field Name	Instructions
Prefix	Pre-populated from the SF 424 (R&R). The prefix (for example, Mr., Mrs., Rev.) for the name of the PD/PI.
First Name	Pre-populated from the SF 424 (R&R). The first (given) name of the PD/PI. This field is required.
Middle Name	Pre-populated from the SF 424 (R&R). The middle name of the PD/PI.
Last Name	Pre-populated from the SF 424 (R&R). The last (family) name of the PD/PI. This field is required.
Suffix	Pre-populated from the SF 424 (R&R). The suffix (for example, Jr., Sr., PhD) for the name of the PD/PI.
New Investigator	Check the Yes box only if the PD/PI has not previously served as such on any PHS-supported research project other than a small grant (R03), an Academic Research Enhancement Award (R15), an exploratory/developmental grant (R21), or mentored career development awards for persons at the beginning of their research career (K01, K08, K22, K23, and K25). If the PD/PI is not a new investigator, check the No box. Current or past recipients of Independent Scientist and other non-mentored career awards (K02, K05, K24, K26, K99/R00) are not considered new investigators. When Multiple Principal Investigators are proposed, **all** PIs must meet the definition of New Investigator for this box to be checked.
Degrees	Indicate up to three academic and professional degrees or other credentials, such as licenses (for example, R.N.). These degrees should be a subset of the degrees that are listed on the PD/PI's Commons account. If the PD/PI's Commons account does not include the degrees listed here, please update the Commons account information accordingly.

2. Human Subjects

Field Name	Instructions
Clinical Trial	Check the Yes or No box to indicate whether the project is a clinical trial. The NIH defines a clinical trial as a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).
Agency-Defined Phase III Clinical Trial	Check the Yes or No box to indicate whether the project is an NIH-defined Phase III clinical trial. An NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of

Field Name	Instructions
	either evaluating an experimental intervention in comparison with a standard or control intervention or of comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

3. Applicant Organization Contact

Person to be contacted on matters involving this application

Field Name	Instructions
Prefix	Pre-populated from the SF 424 (R&R). The prefix (for example, Mr., Mrs., Rev.) of the contact person for matters related to this application.
First Name	Pre-populated from the SF 424 (R&R). The first (given) name of the contact person. This field is required.
Middle Name	Pre-populated from the SF 424 (R&R). The middle name of the contact person.
Last Name	Pre-populated from the SF 424 (R&R). The last (family) name of the contact person. This field is required.
Suffix	Pre-populated from the SF 424 (R&R). The suffix (for example, Jr., Sr., PhD) of the contact person.
Phone Number	Pre-populated from the SF 424 (R&R). The daytime phone number for the contact person.
Fax Number	Pre-populated from the SF 424 (R&R). The fax number for the contact person.
Email	Pre-populated from the SF 424 (R&R). The email address for the contact person.
Title	Enter the title of the contact person. This field is required.
Street1	Enter first line of the street address where the contact person is located. This field is required.
Street2	Enter second line of the street address for the person to contact on matters related to this application, if applicable.
City	Enter the city where the contact person is located. This field is required.

Field Name	Instructions
County	Enter the county where the contact person is located.
State	Enter the state where the contact person is located.
Zip Code	Enter the ZIP (Postal) code where the contact person is located.
Country	Select from the list the country where the contact person is located. This field is required.

PHS 398 Cover Page Supplement

OMB Number: 0925-0001
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4. Human Embryonic Stem Cells

* Does the proposed project involve human embryonic stem cells? ☐ No ☐ Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://stemcells.nih.gov/registry/index.asp . Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Cell Line(s): ☐ Specific stem cell line cannot be referenced at this time. One from the registry will be used.

4. Human Embryonic Stem Cells

Field Name	Instructions
Does the proposed project involve human embryonic stem cells?	If the proposed project does not involve human embryonic stem cells, check the No box. If the proposed project involves human embryonic stem cells, check the Yes box, and then complete the section below.
Cell Line(s)	List in this section the registration number of the specific cell line(s) from the NIH Human Embryonic Stem Cell Registry.
Specific stem cell line cannot be referenced at this time. One from the registry will be used.	If a specific line cannot be referenced at the time of application submission, check this box.

Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

5.4 Research Plan Component

OMB Number: 0925-0001
Expiration Date: 9/30/2007

PHS 398 Research Plan

1. Application Type:

From SF 424 (R&R) Cover Page and PHS398 Checklist. The responses provided on these pages, regarding the type of application being submitted, are repeated for your reference, as you attach the appropriate sections of the research plan.

*Type of Application:

☐ New ☐ Resubmission ☐ Renewal ☐ Continuation ☐ Revision

2. Research Plan Attachments:

Please attach applicable sections of the research plan, below.

1. Introduction to Application (for RESUBMISSION or REVISION only)		Add Attachment	Delete Attachment	View Attachment
2. Specific Aims		Add Attachment	Delete Attachment	View Attachment
3. Background and Significance		Add Attachment	Delete Attachment	View Attachment
4. Preliminary Studies / Progress Report		Add Attachment	Delete Attachment	View Attachment
5. Research Design and Methods		Add Attachment	Delete Attachment	View Attachment

Human Subjects Sections

Attachments 6-10 apply only when you have answered "yes" to the question "are human subjects involved" on the R&R Other Project Information Form. In this case, attachments 6-10 may be required, and you are encouraged to consult the Application guide instructions and/or the specific Funding Opportunity Announcement to determine which sections must be submitted with this application.

6. Protection of Human Subjects		Add Attachment	Delete Attachment	View Attachment
7. Inclusion of Women and Minorities		Add Attachment	Delete Attachment	View Attachment
8. Targeted/Planned Enrollment Table		Add Attachment	Delete Attachment	View Attachment
9. Inclusion of Children		Add Attachment	Delete Attachment	View Attachment
10. Data and Safety Monitoring Plan		Add Attachment	Delete Attachment	View Attachment

Other Research Plan Sections

11. Vertebrate Animals		Add Attachment	Delete Attachment	View Attachment
12. Consortium/Contractual Arrangements		Add Attachment	Delete Attachment	View Attachment
13. Letters of Support		Add Attachment	Delete Attachment	View Attachment
14. Resource Sharing Plan(s)		Add Attachment	Delete Attachment	View Attachment

15. Appendix Add Attachments Remove Attachments View Attachments

The Research Plan should include sufficient information needed for evaluation of the project, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies.

Your SBIR/STTR application should represent a sound approach to the investigation of an important biomedical research, behavioral research, technological, engineering or scientific question, and be worthy of support under the stated criteria of this program solicitation. It should be self-contained and written with the care and thoroughness accorded to papers for publication. Review the application carefully to ensure that information essential for evaluation is included. The scientific and technical merit of the proposed research is the primary concern for all research supported by NIH, CDC, and FDA.

You are *strongly encouraged to contact agency program staff for pre-application guidance and/or for more specific information* on the research topics described in this solicitation.

A firm must not propose market research, patent applications, or litigation. The research may be carried out through construction and evaluation of a laboratory prototype, where necessary.

1. Application Type

This field is pre-populated from the SF 424 (R&R) Cover Component. Corrections to this field must be made in that component.

2. Research Plan Attachments (see also Section 2.3.2 Creating PDFs for Text Attachments)

Although many of the sections of this application are separate PDF attachments, page limitations referenced in the instructions and/or funding opportunity announcement must still be followed. Agency validations will include checks for page limits (and use of appropriate font). Some accommodation will be made for sections that, when combined, must fit within a specified limitation.

Since a number of reviewers will be reviewing applications as an electronic document and not a paper version, applicants are strongly encouraged to use only a standard, single-column format for the text. Avoid using a two-column format since it can cause difficulties when reviewing the document electronically.

Full-sized glossy photographs of material such as electron micrographs or gels may be included in the Appendix; however, an image of each (may be reduced in size) must also be included within the page limitations of the Research Plan.

Separate Attachments

Separate attachments have been designed for the Research Plan sections to maximize automatic validations conducted by the eRA system. When the application is received by the agency, all of the Research Plan sections will be concatenated in the appropriate order so that reviewers and agency staff will see a single cohesive Research Plan.

While each section of the Research Plan needs to eventually be uploaded separately, applicants are encouraged to construct the Research Plan as a single document, separating sections into distinct PDF attachments just before uploading the files. In this way the applicant can better monitor formatting requirements such as page limits. When validating for page limits, the eRA Commons will not count the white space created by breaking the text into separate files for uploading.

Page Limitations

Do not exceed the following page limitations for Items 2 – 5. All tables, graphs, figures, diagrams, and charts must be included within the specified page limits. Be succinct and remember that there is no requirement to use all pages allotted to items 2-5 of the Research Plan. We suggest that you create the Research Plan in MS Word or some other word processing software; keep it to the specified page limits for Sections 2-5. Then “excise” the appropriate sections for each Item 2-5 and create a pdf from each excised part. There will be white space, which is fine and expected.

For SBIR and STTR Phase I, Items 2-5 of the Research Plan are limited to 15 pages. All tables, graphs, figures, diagrams and charts must be included within the page limit.

For SBIR and STTR Phase II, Items 2-5 of the Research Plan are limited to 25 pages total.

For SBIR and STTR Fast-Track, Items 2-5 of the Research Plan may not exceed a total of 25 pages.

Follow page limitations as specified in Funding Opportunity Announcements.

All applications and proposals for NIH funding must be self-contained within specified page limitations. Agency validations will include checks for page limits. Some accommodation will be made for sections that when combined must fit within a specified limitation. Note that while these computer validations will help minimize incomplete and/or non-compliant applications, they do not replace the validations

conducted by NIH staff. Applications found not to comply with the requirements may be delayed in the review process. Unless otherwise specified in an NIH solicitation, Internet website addresses (URLs) may not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Moreover, reviewers are cautioned that they should not directly access an internet site as it could compromise their anonymity.

Notice of Proprietary Information

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, when the application contains information that constitutes trade secrets, information that is commercial or financial, or information that is confidential or privileged, make sure you have checked the "Yes" box of question #3 in the "Other Project Information" component. Identify the pages in the application that contain this information by marking those paragraphs or lines with an asterisk (*) in the left-hand margin. Include a legend at the beginning of Section 2, similar to "The following sections marked with an asterisk contain proprietary/priviledged information that (name of Applicant) requests not be released to persons outside the Government, except for purposes of review and evaluation."

When information in the application constitutes trade secrets or information that is commercial or financial, or information that is confidential or privileged, it is furnished to the Government in confidence with the understanding that the information shall be used or disclosed only for evaluation of this application. If a grant is awarded because of or in connection with the submission of this application, the Government shall have the right to use or disclose the information to the extent authorized by law. This restriction does not limit the Government's right to use the information if it is obtained without restriction from another source.

Begin each text section of the Research Plan with a section header (e.g., Introduction, Specific Aims, Background & Significance, etc).

Field Name	Instructions
1. Introduction to Application (Resubmission or Revision only)	Use only if you are submitting an R&R Resubmission or Revision (Cover Page Item 8). Deviations from these general guidelines will be noted in particular funding announcement. All Resubmission (previously known as a revision or amendment) or Revision (previously known as competing supplements) applications must include an Introduction that summarizes the substantial additions, deletions, or changes. The Introduction must also include responses to the criticisms and issues raised in the Summary Statement. A resubmission application must include substantial changes. Identify the changes in the Research Design and Methods section clearly by bracketing, indenting, or changing typography, unless the changes are so extensive as to include most of the text. This exception should be explained in the Introduction. Do not underline or shade changes. **Phase I and Supplemental Applications:** Do not exceed one page for a revised Phase I or supplemental application. **Phase II and Fast-Track Applications:** Do not exceed three pages for a revised Phase II or Fast Track application. The Introduction is excluded from the page limitations of the Phase I, Phase II or Fast-Track application. Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.
2. Specific Aims	**Phase I Applications:** State the specific objectives of the Phase I research and development effort, including the technical questions you will try to answer to determine the Phase I feasibility of the proposed approach. State concisely and realistically what the proposed research is intended to accomplish in terms of its potential for technological innovation and commercial application. *Define the proposed product, process or service to ultimately be developed*. Include milestones for each of the aims as these will be used in the evaluation process. *One page is recommended*. **Phase II Applications:** State the specific objectives of the Phase II research and development effort. State concisely and realistically what the proposed research is intended to accomplish in terms of its potential for technological innovation and commercial application. *Define the proposed product, process or service to ultimately be developed.* Include milestones for each of the aims as these will be used in the evaluation process. *One page is recommended*. **Fast-Track Applications:** Create a heading titled “Phase I Specific Aims”, and follow the instructions above for “Phase I Applications.” Next, create a heading titled “Phase II Specific Aims” and follow the instructions above for “Phase II Applications.” Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and

Field Name	Instructions
	then click Open.
3. Background and Significance	Provide a clear statement of the specific technical problem or opportunity. Describe significant R/R&D that is directly related to the proposal including any conducted by the proposing small business concern. Describe how it relates to the proposed effort, and any planned coordination with outside sources. Briefly sketch the background to the present grant application, critically evaluate existing knowledge, and specifically identify the commercial opportunities and societal benefits that the project is intended to address. Two to three pages are recommended. **Phase I and Fast-Track Applications:** State concisely the importance of your proposed Phase I research by relating its specific aims to the longer-term objectives of Phase II. This discussion is important in providing a foundation for the Phase II R/R&D effort. State the anticipated outcomes of the proposed approach if the project (Phase I and II) is successful. **Phase II Applications:** State the anticipated outcomes of the proposed Phase II approach if the project (Phase I and II) is successful. Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.
4. Preliminary Studies/Progress Report	**Phase I applications:** Preliminary data are not required for Phase I applications; however, such results may assist reviewers in assessing the likelihood of success of the proposed project and should be included in this section. If you are not including preliminary data, proceed to Item 5. For resubmissions or revisions, the Preliminary Studies/Progress Report section should incorporate any work done since the prior version was submitted. **Phase II applications:** A Phase I Final Report is required for all Phase II applications. There is no form page for the Phase I Final Report. The report should be a presentation of the accomplishments of the Phase I effort. Abbreviations and language that may not be generally known to the broader scientific community should be avoided unless clearly defined. The format for the Phase I Final Report is as follows: 1. State the beginning and ending dates for the period covered by the SBIR/STTR *Phase I* grant. 2. List all key personnel who have worked on the project during that period, their titles, dates of service, and number of hours devoted to the project. 3. Summarize the specific aims of the Phase I grant. 4. Provide a succinct account of published and unpublished results,

Field Name	Instructions
	indicating progress toward their achievement. Summarize the importance of the findings. Discuss any changes in the specific aims of Phase I since the project was initiated. Include the Inclusion Enrollment Report with the final enrollment data for clinical research. 5. List titles and complete references to publications and manuscripts accepted for publication, if any, that resulted from the Phase I effort. Up to 10 such publications may be included in the appendix attachment. Do not include manuscripts **submitted** for publication. • **Publications in press:** Include only a publication list with a link to the publicly available on-line journal article or the NIH PubMed Central (PMC) submission identification number. Do not include the entire article. • **Manuscripts accepted for publication but not yet published:** The entire article should be submitted as a PDF attachment. • **Manuscripts published but an online journal link is not available:** The entire article should be submitted as a PDF attachment. 6. List patents, copyrights, trademarks, invention reports and other printed materials, if any, that resulted from the Phase I or describe patent status, trade secrets or other demonstration of IP protection. 7. Describe the technology developed from this SBIR/STTR, its intended use and who will use it. 8. Describe the current status of the product (e.g., under development, commercialized, in use, discontinued). 9. If applicable, describe the status of FDA approval for your product, process, or service (e.g., continuing pre-IND studies, filed an IND, in Phase I (or II or III) clinical trials, applied for approval, review ongoing, approved, not approved). 10. Describe how your company has benefited from the program and/or the technology developed (e.g., firm's growth, follow-on funding, increased technical expertise, licensing agreements, spin-off companies, public offering [include stock exchange and symbol]). 11. List of the generic and/or commercial name of product, process, or service, if any, that resulted from SBIR/STTR funding. If applicable, indicate the number of products sold. 12. Provide the current number of employees (total full time equivalents [FTEs]). **Phase II portion of a Fast-Track application:** For Fast-Track applications, the Phase I Final Progress Report is submitted to the awarding component after Phase I is awarded and the Phase I research proposed is completed. The report should be a presentation of the accomplishments of the Phase I effort. See the Phase II instructions above for specific details. While the Phase II portion of a Fast-Track application

Field Name	Instructions
	will not include the Phase I Final Progress Report, you may use this space to further explain the Phase I feasibility measures and milestones to be met. **Phase II Competing Renewal applications:** If the renewal or resubmission/revision application involves clinical research, then you must report on the enrollment of research subjects and their distribution by ethnicity/race and sex/gender. See "What Form Should PDs/PIs Use for Population Tracking? (New Versus Old)" for more detailed instructions on which Target and Enrollment Report or Table to use. In the Progress Report for the renewal and revision applications, the publications portion and/or any Target and Enrollment Reports/Tables are not included in the 25-page limit. **Six to eight pages are recommended** for the narrative portion of this section. Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.
5. Research Design and Methods	**Phase I and Phase II Applications:** Include a detailed description of the Phase I or Phase II R/R&D plan. The plan should indicate what will be done, where it will be done, and how the R/R&D will be carried out to address the objectives in the Specific Aims section. As part of this section, provide a tentative sequence or timetable for the project. For Phase I applications, discuss the *criteria that will be used to determine that feasibility has been demonstrated*. Discuss in detail the experimental design, procedures and protocols to be used to achieve each objective or task, and the means by which the data will be analyzed and interpreted. Describe any new methodology and its advantage over existing methodologies. Describe any novel concepts, approaches, tools, or technologies for the proposed studies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised. Unless addressed separately in Item 14, include how the data will be collected, analyzed, and interpreted as well as the data-sharing plan as appropriate. **SBIR and STTR Fast-Track Applications:** Create two separate sections, entitled "Phase I Research Design and Methods" and "Phase II Research Design and Methods." Follow the instructions above for each phase. Although no specific number of pages is recommended for the Research Design and Methods section, be as succinct as possible. There is no

Field Name	Instructions
	requirement that all pages allotted for items 2-5 be used. Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.

Human Subjects Sections

Field Name	Instructions
6. Protection of Human Subjects	This section covers only the initial information regarding the Protection of Human Subjects. Follow the instructions in Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan. See separate sections below for other human subjects related sections that may apply. Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open. Unless an explanation is necessary, if Human Subjects research is not involved, and you have checked the box marked "No" on the Other Project Information Component, you need not include any additional information in this section.
7. Inclusion of Women and Minorities	To determine if Inclusion of Women and Minorities applies to this application, follow the instructions in Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan. Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.
8. Targeted/Planned Enrollment Table	If this application involves the Inclusion of Women and Minorities, complete the Targeted/Planned Enrollment Table. Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.
9. Inclusion of Children	To determine if Inclusion of Children applies to this application, follow the instructions in the Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan. Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.
10. Data and Safety Monitoring Plan	To determine if the Data and Safety Monitoring Plan section applies to this application, follow the instructions in Part II, Supplemental

Field Name	Instructions
	Instructions for Preparing the Human Subjects Section of the Research Plan. Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.

Other Sections

Field Name	Instructions
11. Vertebrate Animals	If you indicated that Vertebrate Animals are involved in this project, address the following five key points. In addition, when research involving vertebrate animals will take place at collaborating site(s) or other performance site(s), provide this information before discussing the five points. Although no specific page limitation applies to this section of the application, be succinct. 1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Design and Methods section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work. 2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers. 3. Provide information on the veterinary care of the animals involved. 4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury. 5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations. Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.
	For those applicants familiar with the PHS398, please note that the Literature Cited section of the Research Plan is now called “Bibliography & References Cited.” Refer to Item 8 in the Other Project Information Component for instructions.

Field Name	Instructions
Select Agents	Select Agents are hazardous biological agents and toxins that have been identified by HHS or USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. CDC maintains a list of these agents. See http://www.cdc.gov/od/sap/docs/salist/pdf. If the activities proposed in your application involve only the use of a strain(s) of Select Agents which has been excluded from the list of select agents and toxins as per 42 CFR 73.4(f)(5), the Select Agent requirements do not apply. Use this section to identify the strain(s) of the Select Agent that will be used and note that it has been excluded from this list. The CDC maintains a list of exclusions at http://www.cdc.gov/od/sap/sap/exclusion.htm. If the strain(s) is not currently excluded from the list of select agents and toxins but you have applied or intend to apply to HHS for an exclusion from the list, use this section to indicate the status of your request or your intent to apply for an exclusion and provide a brief justification for the exclusion. If any of the activities proposed in your application involve the use of Select Agents at any time during the proposed project period, either at the applicant organization or at any other performance site, address the following three points for each site at which Select Agent research will take place. Although no specific page limitation applies to this section, be succinct. 1. Identify the Select Agent(s) to be used in the proposed research. 2. Provide the registration status of all entities* where Select Agent(s) will be used. • If the performance site(s) is a foreign institution, provide the name(s) of the country or countries where Select Agent research will be performed. *An "entity" is defined in 42 CFR 73.1 as "any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity." 3. Provide a description of all facilities where the Select Agent(s) will be used. • Describe the procedures that will be used to monitor possession, use and transfer of Select Agent(s). • Describe plans for appropriate biosafety, biocontainment, and security of the Select Agent(s). If you are responding to a specific funding opportunity announcement (e.g., PA or RFA), address any requirements specified by the solicitation. Reviewers will assess the information provided in this Section, and any questions associated with Select Agent research will need to be addressed

Field Name	Instructions
	prior to award. Until a separate PDF attachment becomes available, when Select Agent Research is involved, create a separate section and use the Consortium/Contractual Arrangements upload below. If your application includes both Select Agent Research and Consortium/Contractual Arrangements, combine the two sections into a single file. Save this file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.
Multiple PD/PI Leadership Plan	NIH Implementation of multiple PDs/PIs is still in pilot stage. Therefore, multiple PDs/PIs may only be designated on applications in response to specific announcements where multiple PDs/PIs have been indicated. For applications proposing multiple PIs, a leadership plan is required. The governance and organizational structure should be described, including communication plans and procedures for resolving conflicts. The shared administrative, technical, and scientific responsibilities for the project or program should be delineated for the PIs. Until a separate PDF attachment becomes available, when multiple PDs/PIs are proposed, create a separate section and use the Consortium/Contractual Arrangements upload below. If your application includes both Multiple PDs/PIs and Consortium/Contractual Arrangements, combine the two sections into a single file. Save this file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.
12. Consortium/Contractual Arrangements	Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee. **SBIR** **Phase I SBIR Applications:** Normally, a minimum of two-thirds or 67% of the research or analytical effort must be carried out by the small business concern. The total amount of all consultant and contractual arrangements to third parties for portions of the scientific and technical effort generally may not exceed 33% of the total amount requested (direct, F&A/indirect, and fee). The signature of the official signing for the application organization on the SF424 (R&R) cover component (Item 18) of the application signifies that the applicant and all proposed consortium participants understand and agree to the following statement: The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the NIH consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.

Field Name	Instructions
	Phase II SBIR Applications: Normally, a minimum of one-half or 50% of the research or analytical effort must be carried out by the small business concern. The total amount of consultant and contractual arrangements to third parties for portions of the scientific and technical effort generally may not exceed 50% of the total Phase II amount requested (direct, F&A/indirect, and fee). The basis for determining the percentage of work to be performed by each of the cooperative parties in Phase I or Phase II will be the total requested costs attributable to each party, unless otherwise described and justified in Item 12, Consortium/Contractual Arrangements, of the PHS 398 Research Plan component. **Fast-Track SBIR Applications:** Create two separate sections entitled "Phase I Consortium/Contractual Arrangements" and "Phase II Consortium/Contractual Arrangements", and complete the sections following the instructions provided above for each phase. **STTR** **Phase I and Phase II STTR Applications:** At least 40% of the work must be performed by the small business concern and at least 30% of the work must be performed by the single partnering research institution. The basis for determining the percentage of work to be performed by each of the cooperative parties will be the total of the requested costs (direct and F&A/indirect costs and fee) attributable to each party, unless otherwise described and justified in Item 12, Consortium/Contractual Arrangements, of the PHS 398 Research Plan component. Certification showing the cooperative R&D arrangement between the small business concern and the research institution will be requested prior to an award. The single partnering research institution must certify at the time of application that at least 30% of the work of the STTR project will be performed by the research institution. This 30% requirement applies to the single collaborating organization identified as the "research institution." The requisite signature, printed name, title, and date of signature of the duly authorized representative of the research institution affirming certifications made by the research institution must be included in a letter stating: "The small business concern and the research institution certify jointly that: (1) the proposed STTR project will be conducted jointly by the small business concern and the research institution in which not less than 40 percent of the work will be performed by the small business concern and not less than 30 percent of the work will be performed by the research institution ("cooperative research and development"); (2) the proposed STTR project is a cooperative research or research and development effort to be conducted jointly by the small business concern and the research institution in which not less than 40 percent of the work will be performed by the small business concern and not less than 30 percent of the work will be performed by the research institution ("performance of research and analytical work"); and (3) regardless of the

Field Name	Instructions
	proportion of the proposed project to be performed by each party, the small business concern will be the primary party that will exercise management direction and control of the performance of the project. If the research institution is a contractor-operated Federally Funded Research and Development Center (FFRDC), the duly authorized representative of the contractor-operated Federally funded research and development center certifies, additionally, that it: (4) is free from organizational conflicts of interests relative to the STTR program; (5) did not use privileged information gained through work performed for an STTR agency or private access to STTR agency personnel in the development of this STTR grant application; and (6) used outside peer review, as appropriate, to evaluate the proposed project and its performance therein." The applicant small business concern should convert the letter from the partnering research institution into a PDF attachment, and include it as part of Item 12, Consortium/Contractual Arrangements, of the PHS 398 Research Plan component. **Fast-Track STTR Applications:** Create two separate sections entitled "Phase I Consortium/Contractual Arrangements" and "Phase II Consortium/Contractual Arrangements", and complete the sections following the instructions provided above for each phase. Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.
13. Letters of Support	Attach appropriate letters here from all individuals confirming their roles in the project and rate/charge for consulting services. **Phase I, Phase II, and Fast-Track SBIR/STTR Applications:** Involvement of consultants in the planning and research stages of the project is permitted. If such involvement is intended, it should be described in detail. Include with the application appropriate letters from each individual confirming his or her role in the project. Following is guidance for such documentation: The letter should be prepared on the letterhead of the consultant and addressed to the Small Business Concern (SBC). *One page is recommended.* At a minimum, each letter should (1) verify the consultant's commitment to the project; (2) refer to the specific project by name, acknowledging the PD/PI as the lead on the project; and (3) specify what assets or services the consultant will contribute (e.g. expertise, number of hours/ percent of effort) as well as the consultant's remuneration. Also include biographical sketches for each consultant. Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.

Field Name	Instructions
14. Resource Sharing Plan(s)	This section includes the Data Sharing Plan, when applicable, and Sharing Model Organisms. *These descriptions are not included in the Research Plan page limits.* 1) *Data Sharing Plan*: Investigators seeking $500,000 or more in direct costs in any year are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible. Specific funding opportunity announcements may also require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the specific opportunity carefully and discuss their data-sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. See Data-Sharing Policy or http://grants.nih.gov/grants/policy/data_sharing/index.htm. (2) *Sharing Model Organisms*: Regardless of the amount requested, all applications where the development of model organisms is anticipated are to include a description of a specific plan for sharing and distributing unique model organism research resources or state appropriate reasons why such sharing is restricted or not possible. Note unlike the data sharing requirement above, this requirement is for all applications where the development of model organisms is anticipated. See Sharing Model Organisms Policy. If model organisms are not planned as part of the research proposal, omit this section. Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.

15. Appendix	Only one copy of appendix material is necessary. Use the add attachments button to the right of this field to complete this entry. A maximum of 10 PDF attachments is allowed. If more than 10 are needed, combine the remaining information into attachment #10.
	
	New, resubmission, renewal, and revision applications **may** include the following materials in the Appendix:
	
	• Submit up to 10 publications or manuscripts **accepted** for publication. *Do not include abstracts, unpublished theses, or manuscripts **submitted** for publication*.
	
	  • **Publications in press:** Include only a publication list with a link to the publicly available on-line journal article or the NIH PubMed Central (PMC) submission identification number. Do not include the entire article.
	  • **Manuscripts accepted for publication but not yet published:** The entire article should be submitted as a PDF attachment.
	  • **Manuscripts published but an online journal link is not available:** The entire article should be submitted as a PDF

Field Name	Instructions
	attachment. • Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents. • Photographs or color images of gels, micrographs, etc., provided that the image (may be reduced in size) is also included within the 25-page limit of Items 2 - 5 of the Research Plan. No images may be included in the Appendix that are not also represented within the Research Plan. Do not use the Appendix to circumvent the page limitations of the Research Plan. An application that does not observe these limitation will be withdrawn from review. These Appendix limitations may not apply to specialized grant applications. Request and follow the additional instructions for those applications. Specific appendix requirements may also be listed in a specific funding opportunity announcement. The Appendix will be sent only to certain members of the Scientific Review Group who will serve as the primary reviewers of the application. **Phase I SBIR/STTR Applications:** Do not include appendices unless specifically solicited by NIH.

Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

5.5 Checklist Component

PHS 398 Checklist

OMB Number: 0925-0001
Expiration Date: 9/30/2007

1. Application Type:

From SF 424 (R&R) Cover Page. The responses provided on the R&R cover page are repeated here for your reference, as you answer the questions that are specific to the PHS398.

* Type of Application:

☐ New ☐ Resubmission ☐ Renewal ☐ Continuation ☐ Revision

Federal Identifier:

2. Change of Investigator / Change of Institution Questions

☐ Change of principal investigator / program director

Name of former principal investigator / program director:

Prefix:
* First Name:
Middle Name:
* Last Name:
Suffix:

☐ Change of Grantee Institution

* Name of former institution:

3. Inventions and Patents (For renewal applications only)

* Inventions and Patents: Yes ☐ No ☐

If the answer is "Yes" then please answer the following:

* Previously Reported: Yes ☐ No ☐

1. Application Type

Field Name	Instructions
Type of Application	This field is pre-populated from the SF 424 (R&R) Cover Component. Corrections to this field must be made in that component.
Federal Identifier	This field is pre-populated from the SF 424 (R&R). Corrections to this field must be made in that component. For New applications this field will be blank.

2. Change of Investigator/Change of Institution Questions

Field Name	Instructions
Change of Principal Investigator/Program Director	Check this box if this application reflects a change in PD/PI from the one who was indicated on a previous application. This is not generally applicable to a "New" application.
Prefix	If this application reflects a change in PD/PI, enter the name prefix (for example, Mr., Mrs., Rev.) of the former PD/PI.
First Name	If this application reflects a change in PD/PI, enter the first name of the former PD/PI.
Middle Name	If this application reflects a change in PD/PI, enter the middle name of the former PD/PI.
Last Name	If this application reflects a change in PD/PI, enter the last name of the former PD/PI.
Suffix	If this application reflects a change in PD/PI, provide the suffix (for example, Jr., Sr., PhD) of the former PD/PI.
Change of Grantee Institution	Check this box if this application reflects a change in grantee institution from the one that was indicated on a previous application. This is not generally applicable to a "New" application.
Name of Former Institution	If this application reflects a change in grantee institution, enter the name of the former institution.

3. Inventions and Patents (For renewal applications only)

Field Name	Instructions
Inventions and Patents	This block need only be completed if submitting an R&R "Renewal" application. If no inventions were conceived or reduced to practice during the course of work under this project, check the No box. The remaining parts of the item are then not applicable. If any inventions were conceived or reduced to practice during the previous period of support, check the Yes box. **SBIR and STTR Applications:** This block needs to be completed for Phase II SBIR/STTR applications only (not Phase I or Fast-Track).
Previously Reported	If you checked the Yes box for Inventions and Patents, above, indicate whether this information has been reported previously to the PHS or to the applicant organization official responsible for patent matters.

OMB Number. 0925-0001
Expiration Date: 9/30/2007

4. Program Income

Is program income anticipated during the periods for which the grant support is requested?

☐ Yes ☐ No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

5. Assurances/Certifications (see instructions)

In agreeing to the assurances/certification section 18 on the SF424 (R&R) form, the authorized organizational representative agrees to comply with the following policies, assurances and/or certifications when applicable. Descriptions of individual assurances/certifications are provided at: http://grants.nih.gov/grants/funding/phs398/PolAssurDef.doc

*Human Subjects; *Research Using Human Embryonic Stem Cells; *Research on Transplantation of Human Fetal Tissue; *Women and Minority Inclusion Policy; *Inclusion of Children Policy; *Vertebrate Animals; *Debarment and Suspension; *Drug- Free Workplace (applicable to new [Type 1] or revised [Type 1] applications only) ; *Lobbying; *Non-Delinquency on Federal Debt; *Research Misconduct; *Civil Rights (Form HHS 441 or HHS 690); *Handicapped Individuals (Form HHS 641 or HHS 690); *Sex Discrimination (Form HHS 639-A or HHS 690); *Age Discrimination (Form HHS 680 or HHS 690); *Recombinant DNA and Human Gene Transfer Research; *Financial Conflict of Interest (except Phase I SBIR/STTR); *Prohibited Research; *Select Agents; *Smoke-Free Workplace; *STTR ONLY: Certification of Research Institution Participation.

If unable to certify compliance, where applicable, provide an explanation and attach below.

Explanation: [ ] Add Attachment | Delete Attachment | View Attachment

4. Program Income

NIH policy requires applicants for research grants to include in their grant applications an estimate of the amount and source of program income (defined below) expected to be generated as a result of the project for which funding is being sought. The specific policies that govern the treatment of program income

under research grants are set forth in the *NIH Grants Policy Statement* (http://grants.nih.gov/grants/policy/nihgps_2003/index.htm).

Program Income is defined as gross income earned by the applicant organization that is directly generated by a supported activity or earned as a result of the award. The *PHS Grants Policy Statement* or *NIH Grants Policy Statement* contains a detailed explanation of program income, the ways in which it may be generated and accounted for, and the various options for its use and disposition.

Examples of program income include:

- Fees earned from services performed under the grant, such as those resulting from laboratory drug testing;
- Rental or usage fees, such as those earned from fees charged for use of computer equipment purchased with grant funds;
- Third party patient reimbursement for hospital or other medical services, such as insurance payments for patients when such reimbursement occurs because of the grant-supported activity;
- Funds generated by the sale of commodities, such as tissue cultures, cell lines, or research animals;
- Patent or copyright royalties (exempt from reporting requirements); and
- Registration fees generated from grant-supported conferences.

Generally, SBIR/STTR grantee organizations that earn program income are authorized to have such income added to the grant account and used to further the objectives of the research project under the expanded authorities stated in the Notice of Award.

Field Name	Instructions
Is program income anticipated during the periods for which the grant support is requested?	If program income is anticipated during the periods for which the grant support is requested, check the Yes box, and then complete the section below. If no program income is anticipated, check the No box and leave the following section blank.
Budget Period	If program income is anticipated, enter the budget periods. If the application is funded, the Notice of Award will provide specific instructions regarding the use of such income.
Anticipated Amount ($)	If program income is anticipated, enter the amount anticipated for each budget period listed.
Source(s)	If program income is anticipated, enter the source for each budget period listed.

5. Assurances/Certifications (see instructions)

In agreeing to the assurances/certification section 18 of the SF424 (R&R) form, the authorized organizational representative agrees to comply with the following policies, assurances and certifications when applicable. Descriptions of individual assurances/certifications are provided in Part III: Policies, Assurances, Definitions, and Other Information.

Human Subjects Research; Research on Transplantation of Human Fetal Tissue; Research Using Human Embryonic Stem Cells; Women and Minority Inclusion Policy; Inclusion of Children Policy;

Vertebrate Animals; Debarments and Suspension; Drug Free Workplace; Lobbying; Non-Delinquency of Federal Debt; Research Misconduct; Civil Rights; Handicapped Individuals; Sex Discrimination; Age Discrimination; Recombinant DNA, including Human Gene Transfer Research; Financial Conflict of Interest; Smoke-Free Workplace; Prohibited Research; Select Agent Research; Principal Investigator Assurance

If you are unable to certify compliance with the applicable policies, assurances, and certifications listed, please provide an explanation in a separate file. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.

Once all data have been entered, click the "Close Form" button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

5.6 Completing SBIR/STTR Information Component

In conjunction with the SF424 (R&R) components and the PHS398 components, NIH, CDC, and FDA SBIR/STTR grant applicants must also complete and submit the "SBIR/STTR Information" component.

SBIR/STTR Information

OMB Number: 0925-0001
Expiration Date: 09/30/2007

*** Program Type (select only one)**

☐ SBIR ☐ STTR

☐ Both *(See agency-specific instructions to determine whether a particular agency allows a single submission for both SBIR and STTR)*

*** SBIR/STTR Type (select only one)**

☐ Phase I ☐ Phase II

☐ Fast-Track *(See agency-specific instructions to determine whether a particular agency participates in Fast-Track)*

Questions 1-7 must be completed by all SBIR and STTR Applicants:

☐ Yes ☐ No	* 1. Do you certify that at the time of award your organization will meet the eligibility criteria for a small business as defined in the funding opportunity announcement?
☐ Yes ☐ No	* 2. Does this application include subcontracts with Federal laboratories or any other Federal Government agencies? * If yes, insert the names of the Federal laboratories/agencies:
☐ Yes ☐ No	* 3. Are you located in a HUBZone? To find out if your business is in a HUBZone, use the mapping utility provided by the Small Business Administration at its web site: http://www.sba.gov
☐ Yes ☐ No	* 4. Will all research and development on the project be performed in its entirety in the United States? If no, provide an explanation in an attached file. * Explanation: Add Attachment Delete Attachment View Attachment
☐ Yes ☐ No	* 5. Has the applicant and/or Program Director/Principal Investigator submitted proposals for essentially equivalent work under other Federal program solicitations or received other Federal awards for essentially equivalent work? * If yes, insert the names of the other Federal agencies:
☐ Yes ☐ No	* 6. Disclosure Permission Statement: If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?
	* 7. Commercialization Plan: If you are submitting a Phase II or Phase I/Phase II Fast-Track Application, include a Commercialization Plan in accordance with the agency announcement and/or agency-specific instructions. * Attach File: Add Attachment Delete Attachment View Attachment

1. Certification of Small Business Eligibility

If you certify that at the time of award, your organization will meet the eligibility criteria for a small business as defined in the FOA, check the Yes box. Otherwise, check the No box. A selection is required.

2. Subcontracts

If this application includes subcontracts with Federal laboratories or any other Federal Government agencies, check the Yes box and insert the name of the Federal laboratories/agencies in the space provided. Otherwise, check the No box. A selection is required.

3. HUBZone

If you are located in a HUBZone, check the Yes box. To find out if your business is in a HUBZONE, use the mapping utility provided by the Small Business Administration at its web sit: http://www.sba.gov. Otherwise, check the No box. A selection is required.

4. R&D Performance

If all research and development on the project will be performed in its entirety in the United States, check the Yes box. Otherwise, check the No box and provide an explanation in an attached file. A selection is required.

5. Essentially Equivalent Work

If the applicant and/or PD/PI has submitted proposals for essentially equivalent work under other Federal program solicitations or received other Federal awards for essentially equivalent work, check the Yes box and insert the names of the other Federal agencies in the space provided. Otherwise, check the No box. A selection is required.

6. Disclosure Permission Statement

If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and email address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)? Check either the "Yes" or "No" box. A selection is required.

7. Commercialization Plan

(Applicable to all Phase II applications and Phase I/ Phase II Fast-Track Applications.)

All Phase II applications and Fast-Track applications must include a succinct Commercialization Plan. The Commercialization Plan is limited to 15 pages. Be succinct. There is no requirement for applicants to use the maximum allowable pages allotted to the Commercialization Plan.

Create a section entitled, "Commercialization Plan," and provide a description in each of the following areas:

a. ***Value of the SBIR/STTR Project, Expected Outcomes, and Impact.*** Describe, in layperson's terms, the proposed project and its key technology objectives. State the product, process, or service to be developed in Phase III. Clarify the need addressed, specifying weaknesses in the current approaches to meet this need. In addition, describe the commercial applications of the research and the innovation inherent in this application. Be sure to also specify the potential societal, educational, and scientific benefits of this work. Explain the non-commercial impacts to the overall significance of the project. Explain how the SBIR/STTR project integrates with the overall business plan of the company.

b. ***Company.*** Give a brief description of your company including corporate objectives, core competencies, present size (annual sales level and number and types of employees), history of previous Federal and non-Federal funding, regulatory experience, and subsequent commercialization, and any current products/services that have significant sales. Include a short description of the origins of the company. Indicate your vision for the future, how you will grow/maintain a sustainable business entity, and how you will meet critical management functions as your company evolves from a small technology R&D business to a successful commercial entity.

c. ***Market, Customer, and Competition.*** Describe the market and/or market segments you are targeting and provide a brief profile of the potential customer. Tell what significant advantages your innovation will bring to the market, e.g., better performance, lower cost, faster, more efficient or effective, new capability. Explain the hurdles you will have to overcome in order to gain market/customer acceptance of your innovation.

   Describe any strategic alliances, partnerships, or licensing agreements you have in place to get FDA approval (if required) and to market and sell your product.

Briefly describe your marketing and sales strategy. Give an overview of the current competitive landscape and any potential competitors over the next several years. *(It is very important that you understand and know the competition.)*

d. ***Intellectual Property (IP) Protection***. Describe how you are going to protect the IP that results from your innovation. Also note other actions you may consider taking that will constitute at least a temporal barrier to others aiming to provide a solution similar to yours.

e. ***Finance Plan.*** Describe the necessary financing you will require to commercialize the product, process, or service, and when it will be required. Describe your plans to raise the requisite financing to launch your innovation into Phase III and begin the revenue stream. Plans for this financing stage may be demonstrated in one or more of the following ways:

- Letter of commitment of funding.
- Letter of intent or evidence of negotiations to provide funding, should the Phase II project be successful and the market need still exist.
- Letter of support for the project and/or some in-kind commitment, e.g., to test or evaluate the innovation.
- Specific steps you are going to take to secure Phase III funding.

f. ***Production and Marketing Plan.*** Describe how the production of your product/process/service will occur (e.g., in-house manufacturing, contract manufacturing). Describe the steps you will take to market and sell your product/process/service. For example, explain plans for licensing, Internet sales, etc.

g. ***Revenue Stream.*** Explain how you plan to generate a revenue stream for your company should this project be a success. Examples of revenue stream generation include, but are not limited to, manufacture and direct sales, sales through value added resellers or other distributors, joint venture, licensing, service. Describe how your staffing will change to meet your revenue expectations.

Applicants are encouraged to seek commitment(s) of funds and/or resources from an investor or partner organization for commercialization of the product(s) or service(s) resulting from the SBIR/STTR grant. Place relevant letters following letters from consultants and collaborators.

Your Phase III funding may be from any of a number of different sources including, but not limited to: SBIR/STTR firm itself; private investors or “angels”; venture capital firms; investment companies; joint ventures; R&D limited partnerships; strategic alliances; research contracts; sales of prototypes (built as part of this project); public offering; state finance programs; non SBIR-funded R&D or production commitments from a Federal agency with the intention that the results will be used by the United States government; or other industrial firms.

SBIR/STTR Information

OMB Number: 0925-0001
Expiration Date: 09/30/2007

SBIR-Specific Questions:

Questions 8 and 9 apply only to SBIR applications. If you are submitting ONLY an STTR application, leave questions 8 and 9 blank and proceed to question 10.

☐ Yes ☐ No	* 8. Have you received SBIR Phase II awards from the Federal Government? If yes, provide a company commercialization history in accordance with agency-specific instructions using this attachment. * Attach File: Add Attachment Delete Attachment View Attachment
☐ Yes ☐ No	* 9. Will the Project Director/Principal Investigator have his/her primary employment with the small business at the time of award?

STTR-Specific Questions:

Questions 10 and 11 apply only to STTR applications. If you are submitting ONLY an SBIR application, leave questions 10 and 11 blank.

☐ Yes ☐ No	* 10. Please indicate whether the answer to BOTH of the following questions is TRUE: (1) Does the Project Director/Principal Investigator have a formal appointment or commitment either with the small business directly (as an employee or a contractor) OR as an employee of the Research Institution, which in turn has made a commitment to the small business through the STTR application process; AND (2) Has the Project Director/Principal Investigator devoted at least 10% effort to the proposed project?
☐ Yes ☐ No	* 11. In the joint research and development proposed in this project, does the small business perform at least 40% of the work and the research institution named in the application perform at least 30% of the work?

SBIR-Specific Questions:

8. Prior SBIR Phase II Awards

If you have received SBIR Phase II awards from the Federal Government (including NIH), check the Yes box. Attach a file that includes either: (1) a statement indicating that the applicant small business *has not received* more than 15 SBIR Phase II awards from the Federal Government during the preceding five fiscal years; or (2) a company commercialization history if you *have received* more than 15 Phase II SBIR awards from the Federal Government during the preceding five fiscal years. The history must document the extent to which the company was able to secure Phase III funding to develop concepts resulting from previous Phase II SBIR awards, and for each Phase II award the history must include: (1) name of awarding agency; (2) award number and date; (3) amount of award; (4) title of project; (5) source, date, and amount of Phase III funding agreement; and (6) commercialization status of each Phase II award.

If you have not received SBIR Phase II awards, then check the No box.

9. PD/PI Primary Employment

If the PD/PI will have his/her primary employment with the small business at the time of award, check the Yes box. Otherwise, check the No box. A selection is required.

STTR-Specific Questions:

10. PD/PI Commitment

Check the Yes box **only** if **both** of the following conditions is true:

(1) The PD/PI has a formal appointment or commitment either with the small business directly (as an employee or a contractor) OR as an employee of the Research Institution, which in turn has made a commitment to the small business through the STTR application process; and

(2) The PD/PI devoted at least 10% effort to the proposed project.

Check the No box if either of these two conditions (or both) is false.

11. Joint Research and Development Proposed

If in the joint research and development proposed in this project, the small business will perform at least 40% of the work and the research institution named in the application will perform at least 30% of the work, check the Yes box. Otherwise, check the No box.

Once all data have been entered, click the "Close Form" button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

6. Peer Review Process

A description of what happens to your research project grant application after it is received for peer review can be found at the following location: http://cms.csr.nih.gov/ResourcesforApplicants/Submission+And+Assignment+Process.htm.

Overview

Most applications submitted to the PHS will be reviewed through a two-tier system. The first level of review will be performed by a Scientific Review Group (SRG), often called a "study section" or "review committee." The purpose of the SRG is to evaluate the scientific and technical merit of applications. The SRG does not make funding decisions. Additional detailed information on review procedures for scientific review group meetings is located at: http://www.csr.nih.gov/guidelines/proc.pdf. The complete listing of Rosters for NIH Scientific Review Groups (SRGs) is available at http://era.nih.gov/roster/index.cfm.

Streamlining

The initial scientific peer review of most research applications also will include a process in which only those applications deemed by the reviewers to have the highest scientific merit, generally the top half of the applications under review, will be discussed at the SRG meeting, assigned a priority score, and receive a second level review. Applications in the lower half are not discussed or scored at the SRG meetings. This process allows the reviewers to focus their discussion on the most meritorious applications.

SRG members will be instructed to evaluate research applications by addressing five review criteria (see below) and assigning a single, global score for each scored application. The score will reflect the overall impact that the proposed research could have on the field. Requests for Applications (RFAs) and other types of funding opportunities may have different and/or additional review criteria.

As part of the initial merit review and regardless of whether an application is scored or unscored (streamlined), all applicants will receive a written critique, called a "Summary Statement." The Summary Statement represents a combination of the reviewers' written comments and, for non-streamlined applications, includes the SRA's summary of the members' discussion during the study section meeting as well as the recommendations of the study section, a recommended budget, and administrative notes of special considerations.

Information about charters and membership of SRGs, Councils, and Boards may be obtained from the appropriate agency.

Research Project Evaluation Criteria

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Approach: Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well-integrated, well-reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

In conducting an evaluation of the scientific assessment of Approach criterion, SRGs will also evaluate the involvement of human/animal subjects, the proposed plans for inclusion of minorities and members of both sexes/genders. The evaluation will be factored into the overall score for scientific and technical merit of the application.

Innovation: Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches or methodologies, tools, or technologies for this area?

Investigator: Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the PD/PI and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

While these review criteria are intended for use primarily with unsolicited research project applications (e.g., R01 or P01), to the extent reasonable, they will also form the basis of the review of solicited applications and non-research activities. However, for some activities (e.g., construction grants), use of these criteria as stated may not be feasible.

Note: In addition to the above criteria, the following items will be considered in the determination of scientific merit and the priority score.

Protection of Human Subjects: In conducting peer review for scientific and technical merit, SRGs also will evaluate the involvement of human subjects and proposed protections from research risk relating to their participation in the proposed non-exempt Research Plan according to the following five review criteria: (1) Risk to subjects, (2) Adequacy of protection against risks (3) Potential benefits of the proposed research to the subjects and others; (4) Importance of the knowledge to be gained; and (5) Data and safety monitoring for clinical trials.

When human subjects are involved in research that involves one of the six categories of research that are exempt under 45 CFR Part 46, the SRG will evaluate the justification for the exemption and (1) Human Subjects Involvement and Characteristics, and (2) Sources of Materials.

Inclusion of Women, Minorities, and Children: When human subjects are involved in the proposed clinical research, the SRG will also evaluate the proposed plans for inclusion of minorities and members of both sexes/genders, as well as the inclusion of children in clinical research, as part of the scientific assessment of Approach criterion.

Vertebrate animals: As part of the peer review process, the SRG will evaluate the proposed involvement and protection of vertebrate animals as part of the scientific assessment of Approach and Environment criteria and according to the following five points: (1) detailed description of the proposed use of the animals; (2) justification for the use of animals and for the appropriateness of the species and numbers proposed; (3) adequacy of proposed veterinary care; (4) procedures for limiting pain and distress to that which is unavoidable; and (5) methods of euthanasia.

Dual-Level Peer Review

The second level of review will usually be performed by the Advisory Council or Board of the potential awarding component (Institute, Center, or other unit). Council or Board recommendations are based not only on considerations of scientific merit, as judged by the SRGs, but also on the relevance of the proposed study to an Institute/Center's mission, programs, and priorities.

PART II

Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan

Preparing the Human Subjects Research Section of the Research Plan

In the Human Subjects Research section of the Research Plan, you must provide sufficient information for reviewers to determine that the proposed research meets (1) the requirements of the HHS regulations to protect human subjects from research risks (45 CFR Part 46), (2) the requirements of NIH policies for data and safety monitoring of clinical trials, and (3) the requirements of NIH policies on inclusion of women, minorities, and children. See Instructions Pertaining to Non-Exempt Human Subjects Research.

If the research is exempt from the requirements in the Federal regulations, you must provide a justification for the exemption with sufficient information about the involvement of the human subjects to allow a determination by peer reviewers and NIH staff that claimed exemption(s) is/are appropriate. See Exempt Human Subjects Research.

Applications must comply with this requirement; if not, application processing may be delayed or the application may be returned to the applicant without review.

For all research involving human subjects, a part of the peer review process will include careful consideration of protections from research risks, as well as the appropriate inclusion of women, minorities, and children. The Scientific Review Group (SRG) will assess the adequacy of safeguards of the rights and welfare of research participants, and the appropriate inclusion of women, minorities, and children, based on the information in the application.

To assist you in completing the Research Plan (Human Subjects Research), we have provided six possible scenarios. All research will fall into one of these six scenarios. Determining which scenario best matches your proposed research depends on your answers to the following five questions:

Question 1: Does your proposed research involve human subjects?

Question 2: Does your proposed human subjects research meet the criteria for one or more of the exemptions in the HHS regulations (45 CFR Part 46)?

Question 3: Does your proposed research meet the definition of clinical research?

Question 4: Does your proposed research include a Clinical Trial?

Question 5: Does your proposed research meet criteria for an NIH-Defined Phase III Clinical Trial?

Click on the questions and when you can answer the five questions, select the scenario that best matches your responses, and then follow the instructions provided for the scenario you choose.

Decision Table for Human Subjects Research, Protection and the Inclusion of Women, Minorities, and Children

	Criteria and Answers to Questions 1 thru 5				
Scenarios with linked instructions	1. Human Subjects Research	2. Exempt from HHS Human Subjects Regulations	3. Clinical Research	4. Clinical Trial	5. NIH-Defined Phase III Clinical Trial
A No Human Subjects	No	N/A	N/A	N/A	N/A
Requirements for Scenario A: If Human Subjects is "Yes," see Scenarios B-F below.					
B Human Subjects/E-4	Yes	Yes Exemption: 4	No	N/A	N/A
Requirements for Scenario B: - Indicate Exemption 4 (E-4) and include justification that E-4 is appropriate.					
C Human Subjects/ Other Exemptions	Yes	Yes Exemptions: 1, 2, 3, 5, 6	Yes	N/A	N/A
Requirements for Scenario C: - Indicate Exemption number(s) and include justification that the designated exemption(s) is appropriate. - Address "Inclusion of Women and Minorities" - Address "Inclusion of Children"					
D Clinical Research	Yes	No	Yes	No	N/A
Requirements for Scenario D: - Address Protection of Human Subjects - Address "Inclusion of Women and Minorities" - Address "Inclusion of Children" "Targeted/Planned Enrollment Table(s)" for each new study/ protocol (New applications; Competing Renewal applications; Competing Supplements) - "Inclusion Enrollment Report Table(s)" (Competing Renewals; Competing Revisions (Supplements))					
E Clinical Trials	Yes	No	Yes	Yes	No
Requirements for Scenario E: - All requirements in Scenario D - Data and Safety Monitoring Plan - Note: Some trials may require a Data and Safety Monitoring Board, based on risk					

	Criteria and Answers to Questions 1 thru 5				
Scenarios with linked instructions	1. Human Subjects Research	2. Exempt from HHS Human Subjects Regulations	3. Clinical Research	4. Clinical Trial	5. NIH-Defined Phase III Clinical Trial
F NIH-Defined Phase III Clinical Trial	Yes	No	Yes	Yes	Yes
Requirements for Scenario F: - All requirements in Scenario E Increased requirements for Inclusion of Women and Minorities in Clinical Research					

HUMAN SUBJECTS RESEARCH

Question 1: Does your proposed research involve human subjects?

The first thing you must determine is whether or not your research involves human subjects, either at the applicant organization or at any other performance site or collaborating institution (e.g., subcontractors, consultants).

The research described in your application may include more than one research project; thus the application may include individual projects that meet the requirements for non-exempt or exempt human subjects research, or are not defined as human subjects research.

If research activities involving human subjects are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution, then your answer is "Yes" even if the research is exempt from regulations for the protection of human subjects.

The HHS regulations "Protection of Human Subjects" (45 CFR Part 46, administered by OHRP) define a human subject as a living individual about whom an investigator conducting research obtains:

- data through *intervention* or *interaction* with the individual or
- identifiable *private information*

Research that involves obtaining private information or human biological specimens (such as blood and tissue samples) that can be linked by the investigator(s) to living individuals is considered human subjects research.

Research that involves only coded private information/data or coded human biological specimens may or may not constitute human subjects research under the HHS human subjects regulations (45 CFR 46).

Investigator: The OHRP considers the term investigator to include anyone involved in conducting the research. OHRP does not consider the act of solely providing coded private information or specimens (for example, by a tissue repository) to constitute involvement in the conduct of the research. However, if the individuals who provide *coded* information or specimens also collaborate on other activities related to the conduct of the research with the investigators who receive such information or specimens, they will be considered to be involved in the conduct of the research. [OHRP's Coded Specimen Guidance]

Research: HHS regulations define *research* at 45 CFR 46.102(d) as follows:
Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Obtains: In its guidance for use of coded specimens, OHRP has determined that under the definition of human subject at 45 CFR 46.102(f), *obtaining* identifiable private information or identifiable specimens for research purposes constitutes human subjects research. *Obtaining* means receiving or accessing identifiable private information or identifiable specimens for research purposes. OHRP interprets *obtaining* to include an investigator's use, study, or analysis for research purposes of *identifiable private information* or identifiable specimens already in the possession of the investigator.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. (45 CFR 46.102(f))

Interaction includes communication or interpersonal contact between investigator and subject. (45 CFR 46.102(f))

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). Private information must be *individually identifiable* (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. (45 CFR 46.102(f))

Individually Identifiable Private Information: According to its guidance for use of coded specimens, OHRP generally considers private information or specimens to be *individually identifiable* as defined at 45 CFR 46.102(f) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through *coding* systems. Conversely, OHRP considers private information or specimens not to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

Research Using Human Specimens or Data: Regulatory requirements (Federal and state) to protect human subjects apply to a much broader range of research than many investigators realize, and researchers using *human specimens and/or data* are often unsure about how regulations apply to their research. Regulatory obligations to protect human subjects would apply, for example, to research that uses –

- Bodily materials, such as cells, blood or urine, tissues, organs, hair or nail clippings, from living individuals who are individually identifiable to the investigator(s), even if these materials were collected by others;
- Residual diagnostic specimens from living individuals that are individually identifiable to the investigator(s), including specimens obtained for routine patient care that would have been discarded if not used for research;
- Private information, such as medical information, about living individuals that is individually identifiable to the investigator(s), even if the information was not specifically collected for the study in question. This includes research on genetic information that can be readily associated by the investigator(s) with identifiable living individuals.

The definition of "human subject" includes, but is not limited to, human organs, tissues, and body fluids from living individuals, well as private graphic, written, or recorded information about living individuals, if (1) there is interaction or intervention with a living individual to obtain the specimens or data for research purposes, or (2) the identity of the subjects can be readily ascertained by the investigator or other members of the research team.

Research that involves only *coded* private information/data or coded human biological specimens may not constitute human subjects research under the HHS human subjects regulations (45 CFR Part 46) if:

- the specimens and/or private information were not collected specifically for the currently proposed research project through an interaction/intervention with living individuals AND
- the investigator(s) (including collaborators) on the proposed research cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain (e.g., the researcher's access to subject identities is prohibited by written repository procedures and policies and/or through an agreement signed between the recipient researcher and the repository providing the specimens and/or data). [See definitions below and the following guidance from the Office for Human Research Protections (OHRP) for additional information and examples: http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf.]

Individuals who provide *coded* information or specimens for proposed research and who also collaborate on the research involving such information or specimens are considered to be involved in the conduct of human subjects research.

Coded: With respect to private information or human biological specimens, *coded* means that:

1. Identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol or combination thereof (i.e., the code); and
2. A key to decipher the code exists, enabling linkage of the identifying information with the private information or specimens.

You may find it helpful to consult the following guidance from OHRP:

- OHRP Decision Charts: http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm
- OHRP Policy on Coded Specimens and Data: http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf
- OHRP Guidance on Repositories: http://www.hhs.gov/ohrp/humansubjects/guidance/reposit.htm; http://www.hhs.gov/ohrp/humansubjects/guidance/guid1223.pdf

With regard to the engagement of performance sites in proposed human subjects research, you may find it helpful to consult the following:

- OHRP Memo on Engagement: http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm

The decisions about when research involving human specimens and/or data from subjects is considered human subjects research are complex. The OHRP recommends that institutions have policies in place that designate the individual or entity authorized to determine whether proposed research is exempt from regulatory requirements to protect human subjects and that determinations should be made by someone other than the investigator.

You need to be aware that the involvement of human subjects in non-exempt research must be approved by your IRB prior to award.

The NIH Office of Extramural Research Human Subjects website contains additional information and Frequently Asked Questions that may help investigators understand how these regulations and Guidance documents apply to their research. See http://grants.nih.gov/grants/policy/hs/index.htm.

How can you determine whether research that involves only the use of specimens and/or data from pathology archives or a specimen bank and/or data repository is human subjects research?

The research described in your application may include more than one research project; thus the application may include separate projects that meet the requirements for either human subjects research, exempt human subjects research, or are not defined as human subjects research. Examples are provided below:

- If the specimens and/or data were obtained specifically for the currently proposed research project through intervention or interaction with a living individual, then your research is human subjects research.
- If you receive or have access to individually identifiable specimens or data from living individuals (e.g., pathology or medical records), your proposed research is human subjects research.

- If you receive or have access to existing individually identifiable private information or identifiable specimens from living individuals (e.g., pathology or medical records), but you as the investigator or your collaborator record the information in such a manner that you cannot subsequently access or obtain direct or indirect identifiers that are linked to the subjects the research project that you conduct using data recorded in this manner meets the requirements of Exemption 4. If you will retain or can access any identifiers, the research project is not exempt under Exemption 4.
- If you are using specimens and/or data and neither you nor your collaborators can identify the subjects from whom the specimens and/or data were obtained either directly or indirectly through coding systems, the HHS human subjects regulations (45 CFR Part 46) do not apply at all.
- If your research involves only coded private information/data or coded specimens, OHRP does not consider this research to involve human subjects as defined under the HHS Protection of Human Subjects Regulations (45 CFR Part 46.102(f)) *if* the following conditions are *both* met:
  - the private information/data or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; *and*
  - the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
    - (a) the key to decipher the code is destroyed before the research begins;
    - (b) the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased;
    - (c) there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or
    - (d) there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

What is not human subjects research under HHS regulations at 45 CFR Part 46?

- Research that does not involve intervention or interaction with living individuals, or identifiable private information is not human subjects research (see definitions),
- Research that only proposes the use of cadaver specimens is not human subjects research, because human subjects are defined as "living individuals." The use of cadaver specimens is not regulated by 45 CFR Part 46, but may be governed by other Federal, state and local laws.

Guidance and Additional Instructions

If you answered "No" to Question 1, then proceed to Scenario A.

If you answered "Yes" to Question 1, then you may need to determine whether your research meets the criteria for an exemption from the Human Subjects Protection requirements. Proceed to Question 2.

If you need to consider an alternative scenario, return to the Decision Table.

EXEMPT HUMAN SUBJECTS RESEARCH

Question 2: Does your proposed human subjects research meet the criteria for one or more of the exemptions in the HHS regulations (45 CFR Part 46)?

Some human subjects research is exempt from the HHS regulations (45 CFR Part 46). OHRP guidance states that Exemptions should be independently determined (http://www.hhs.gov/ohrp/humansubjects/guidance/irb71102.pdf). Institutions often designate their IRB to make this determination. Because NIH does not require IRB approval at time of application, the exemptions designated in item 4a often represent the opinion of the PD/PI, and the justification provided for the exemption by the PD/PI is evaluated during peer review.

The research described in your application may include more than one research project; thus the application may include individual projects that meet the requirements for non-exempt or exempt human subjects research, or are not defined as human subjects research.

If research activities involving human subjects are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution, then your answer is "Yes" to Question 1 "Does your proposed research involve human subjects" even if the research is exempt from regulations for the protection of human subjects.

Research involving individuals who are or who become prisoners cannot be exempt under any exemption categories (see **45 CFR Part 46 Subpart C**).

Your human subjects research is exempt if all of the proposed research meets the criteria for one or more of the following six exemptions.

Exemption 1: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exemption 2: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Exemption 2 for research involving survey or interview procedures or observation of public behavior, does not apply to research with children (see **45 CFR Part 46, Subpart D**), except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Exemption 3: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Exemption 4: Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the

information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

The humans subjects regulations decision charts (http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm) from the Office of Human Research Protection (OHRP) will help you to see whether your research falls under the human subjects regulations and if so, whether it meets the criteria for Exemption 4. See also the information contained at: Exemption 4 Guidance and Information.

The NIH Office of Extramural Research website also contains information that is helpful for determining whether your human subjects research meets the criteria for Exemption 4. See http://grants.nih.gov/grants/policy/hs/index.htm.

Research that meets the criteria for Exemption 4 is not considered "clinical research" as defined by NIH. Therefore the NIH policies for inclusion of women, minorities and children in clinical research do not apply to research projects covered by Exemption 4.

Exemption 5: Research and demonstration projects that are conducted by or subject to the approval of Department or Agency heads and that are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs (ii) procedures for obtaining benefits or services under those programs (iii) possible changes in or alternatives to those programs or procedures or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

Exemption 6: Taste and food quality evaluation and consumer acceptance studies (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Guidance and Additional Instructions

If you answered "Yes" to Question 2, then your research meets the criteria for an exemption.

- If your research meets the criteria for Exemption 4, then follow the instructions for Scenario B and read the information contained in Exemption 4 Guidance and Information.
- If your research meets the criteria for any of the other five exemptions, follow the instructions for Scenario C.

Remember that you need to identify which exemption(s) you believe is applicable to your research, and provide a justification for the exemption(s) with sufficient information about the involvement of human subjects to allow a determination by peer reviewers and NIH staff that the claimed exemption(s) is appropriate.

If you answered "No" to Question 2, then your research does not qualify for one of the exemptions, and your research is not exempt from full IRB review. Proceed to Question 3.

If you need to consider an alternative scenario, return to the Decision Table.

CLINICAL RESEARCH

Question 3: Does your proposed research meet the definition of clinical research?

The NIH defines Clinical Research as:

(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies.

(2) Epidemiologic and behavioral studies.

(3) Outcomes research and health services research.

Clinical research that does not meet the criteria for a clinical trial or an NIH-defined Phase III clinical trial must follow the instructions in **Scenario D**.

Research projects that meet the criteria for Exemption 4 are not considered "clinical research." Investigators who propose research that meets the criteria for Exemption 4 must follow the instructions provided in **Scenario B**.

Guidance and Additional Instructions

If you answered "Yes" to Question 3, then proceed to Question 4 and Question 5 to determine whether your research meets the criteria for a clinical trial or an NIH-defined Phase III clinical trial.

If you answered "No," then you need to consider an alternative Scenario. Return to the Decision Table.

CLINICAL TRIAL

Question 4: Does your proposed research include a clinical trial?

The NIH defines a *clinical trial* as a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).

Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective.

Behavioral human subjects research involving an intervention to modify behavior (diet, physical activity, cognitive therapy, etc.) fits these criteria of a clinical trial.

Human subjects research to develop or evaluate clinical laboratory tests (e.g. imaging or molecular diagnostic tests) might be considered to be a clinical trial if the test will be used for medical decision-making for the subject or the test itself imposes more than minimal risk for subjects.

Biomedical clinical trials of experimental drug, treatment, device or behavioral intervention may proceed through four phases:

> ***Phase I*** clinical trials test a new biomedical intervention in a small group of people (e.g., 20-80) for the first time to evaluate safety (e.g., to determine a safe dosage range, and to identify side effects).
>
> ***Phase II*** clinical trials study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety.
>
> ***Phase III*** studies investigate the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.
>
> ***Phase IV*** studies are conducted after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

Guidance and Additional Instructions

If you answered "Yes" to Question 4, then you will need to provide a general description of a Data and Safety Monitoring Plan. See Scenario E.

Also continue to Question 5 to determine whether your research meets the criteria for an NIH-defined Phase III clinical trial.

If you answered "Yes" to Question 3 (Clinical Research) and "No" to Question 4 (Clinical Trial), then follow the instructions for Scenario D.

If you answered "No" to Question 4, you will need to consider an alternative scenario. Return to the Decision Table.

NIH-DEFINED PHASE III CLINICAL TRIAL

Question 5: Does your proposed research meet criteria for an NIH-Defined Phase III Clinical Trial?

An *NIH-Defined Phase III Clinical Trial* is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of either evaluating an experimental intervention in comparison with a standard or control intervention or of comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

If your research meets the above criteria, then in addition to providing a Data and Safety Monitoring Plan, you will be expected to address whether you expect to find clinically important sex/gender and/or race/ethnicity differences in the intervention effect. The discussion may include supporting evidence and/or data derived from prior animal studies, clinical observations, metabolic studies, genetic studies, pharmacology studies, and observational, natural history, epidemiology, and other relevant studies.

You will be expected to provide a Research Plan that must include one of the following plans:

- Plans to conduct valid analyses to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR
- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups. (Representation of sex/gender and racial/ethnic groups is not required as subject selection criteria, but inclusion is encouraged.), OR
- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Guidance and Additional Instructions

If you answered “Yes” to Question 5, then follow the instructions for Scenario F.

If you answered “No,” then you need to consider an alternative Scenario. Return to the Decision Table.

EXEMPTION 4 GUIDANCE AND INFORMATION

Research that meets the criteria for Exemption 4 is Human Subjects Research, but it is not considered clinical research.

Exemption 4 includes research projects involving the collection or study of *existing* data, documents, records, pathological specimens, or diagnostic specimens, if these sources are *publicly available* or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through *identifiers* linked to the subjects.

What is meant by "existing" data or specimens?

Exemption 4 applies to retrospective studies of specimens and/or data that have already been collected. The materials must be "on the shelf" (or in the freezer) at the time the protocol is submitted to the IRB or other designated officials at your institution to determine whether the research is indeed exempt. Research that involves the ongoing collection of specimens and/or data does not meet the criteria for Exemption 4.

What is meant by "publicly available sources"?

This language in the regulation was intended to apply to public sources of data, such as census data. Its meaning with respect to human tissue specimens is widely debated. Although there are organizations that make human cells and tissues broadly accessible to the research community, these materials are not usually available to the public at large and are not generally considered to be publicly available.

What is meant by "identifiers linked to the subjects"?

Identifiers, such as names, social security numbers, medical record numbers, or pathology accession numbers, or other codes that permit specimens to be linked to living individuals and perhaps also to associated medical information.

How can I determine whether my research meets the criteria for Exemption 4?

The humans subjects regulations decision charts (http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm) from the Office of Human Research Protection (OHRP) will help you to see whether your research falls under the human subjects regulations and if so, whether a research project meets the criteria for Exemption 4.

OHRP advises that investigators should not have the authority to make an independent determination that research involving human subjects is exempt. OHRP guidance states that Exemptions should be independently determined (http://www.hhs.gov/ohrp/humansubjects/guidance/irb71102.pdf). Institutions often designate their IRB to make this determination. Because NIH does not require IRB approval at time of application, the exemptions designated in item 4a often represent the opinion of the PD/PI, and the justification(s) provided by the PD/PI for the exemption(s) is/are evaluated during peer review.

Information is also available on the NIH Office of Extramural Research website at http://grants.nih.gov/grants/policy/hs/index.htm.

How can you determine whether research that involves only the use of specimens and/or data from pathology archives or a specimen bank and/or data repository is human subjects research?

The research described in your application may include more than one research project; thus the application may include separate projects that meet the requirements for either human subjects research, exempt human subjects research, or are not defined as human subjects research. Examples are provided below:

- If the specimens and/or data were obtained specifically for the currently proposed research project through intervention or interaction with a living individual, then your research is human subjects research.
- If you receive or have access to individually identifiable specimens or data from living individuals (e.g., pathology or medical records), your proposed research is human subjects research.
- If you receive or have access to existing individually identifiable private information or identifiable specimens from living individuals (e.g., pathology or medical records), but you as the investigator or your collaborator record the information in such a manner that you cannot subsequently access or obtain direct or indirect identifiers that are linked to the subjects the research project that you conduct using data recorded in this manner meets the requirements of Exemption 4. If you will retain or can access any identifiers, the research project is not exempt under Exemption 4.
- If you are using specimens and/or data and neither you nor your collaborators can identify the subjects from whom the specimens and/or data were obtained either directly or indirectly through coding systems, the HHS human subjects regulations (45 CFR Part 46) do not apply at all.
- If your research involves only coded private information/data or coded specimens, OHRP does not consider this research to involve human subjects as defined under the HHS Protection of Human Subjects Regulations (45 CFR Part 46.102(f)) *if* the following conditions are *both* met:
    - the private information/data or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; *and*
    - the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
        (a) the key to decipher the code is destroyed before the research begins;
        (b) the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased;
        (c) there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or
        (d) there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

Guidance and Additional Instructions

If your research meets the criteria for Exemption 4, refer to Scenario B.

If you need to consider an alternative scenario, return to the Decision Table.

INSTRUCTIONS PERTAINING TO NON-EXEMPT HUMAN SUBJECTS RESEARCH

In your application narrative (PHS398 Research Plan Component), attach a section entitled "6. Human Subjects Research." Although no specific page limitation applies to this section of the application, be succinct. Scientific Review Groups will assess each application as being "acceptable" or "unacceptable" with regard to the protection of human subjects.

As the first entry, create a heading entitled "Protection of Human Subjects." Use subheadings to address the issues listed under items 1-4 below.

If your research includes a clinical trial, separately address item 10, "Data and Safety Monitoring Plan" of the PHS398 Research Plan Component.

Protection of Human Subjects

1. RISKS TO THE SUBJECTS

a. ***Human Subjects Involvement and Characteristics***

- Describe the proposed involvement of human subjects in the work outlined in the Research Design and Methods section.
- Describe the characteristics of the subject population, including their anticipated number, age range, and health status.
- Identify the criteria for inclusion or exclusion of any subpopulation.
- Explain the rationale for the involvement of special classes of subjects, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. Note that 'prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers) as well as subjects who become incarcerated after the study begins.
- List any collaborating sites where human subjects research will be performed, and describe the role of those sites in performing the proposed research.

b. ***Sources of Materials***

- Describe the research material obtained from living human subjects in the form of specimens, records, or data.
- Describe any data that will be recorded on the human subjects involved in the project.
- Describe the linkages to subjects, and indicate who will have access to subject identities.
- Provide information about how the specimens, records, or data are collected and whether material or data will be collected specifically for your proposed research project.

c. ***Potential Risks***

- Describe the potential risks to subjects (physical, psychological, social, legal, or other), and assess their likelihood and seriousness to the subjects.
- Where appropriate, describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures to participants in the proposed research.

2. ADEQUACY OF PROTECTION AGAINST RISKS

a. ***Recruitment and Informed Consent***

- Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.
- Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. Informed consent document(s) need not be submitted to the PHS agencies unless requested.

b. ***Protection Against Risk***

- Describe planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
- Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Studies that involve clinical trials (biomedical and behavioral intervention studies) must include a description of the plan for data and safety monitoring of the research and adverse event reporting to ensure the safety of subjects.

3. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS

- Discuss the potential benefits of the research to the subjects and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

4. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

NOTE: Test articles (investigational new drugs, devices, or biologicals) including test articles that will be used for purposes or administered by routes that have not been approved for general use by the Food and Drug Administration (FDA) must be named. State whether the 30-day interval between submission of applicant certification to the FDA and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the Food and Drug Administration, and/or the status of requests for an IND or IDE covering the proposed use of the test article in the Research Plan.

5. DATA AND SAFETY MONITORING PLAN

- If your research includes a clinical trial, create a heading entitled "Data and Safety Monitoring Plan."
- Provide a general description of a monitoring plan that you plan to establish as the overall framework for data and safety monitoring. Describe the entity that will be responsible for monitoring and the process by which Adverse Events (AEs) will be reported to the Institutional Review Board (IRB), the funding I/C, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA) in accordance with Investigational New Drug (IND) or Investigational Device Exemption (IDE) regulations. Be succinct. Contact the FDA (http://www.fda.gov/) and also see the following websites for more information related to IND and IDE requirements:

http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr312_01.html (IND)
http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr812_01.html (IDE)

- The frequency of monitoring will depend on potential risks, complexity, and the nature of the trial; therefore, a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:
    a. PD/PI (required)
    b. Independent individual/Safety Officer
    c. Designated medical monitor
    d. Internal Committee or Board with explicit guidelines
    e. Data and Safety Monitoring Board (DSMB). NIH specifically requires the establishment of Data and Safety Monitoring Boards (DSMBs) for *multi-site* clinical trials involving interventions that entail potential *risk* to the participants, and generally for Phase III clinical trails. Although Phase I and Phase II clinical trials may also use DSMBs, smaller clinical trials may not require this oversight format, and alternative monitoring plans may be appropriate.
    f. Institutional Review Board (IRB - required)
- A detailed Data and Safety Monitoring Plan must be submitted to the applicant's IRB and subsequently to the funding IC for approval prior to the accrual of human subjects (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html). For additional guidance on creating this Plan, see the above reference.

Guidance and Additional Instructions

Proceed to Inclusion of Women and Minorities.

INCLUSION OF WOMEN AND MINORITIES

Create a section heading entitled "Inclusion of Women and Minorities" and place it immediately following the "Protection of Human Subjects" section. Although no specific page limitation applies to this section of the application, be succinct.

Scientific Review Groups will assess each application as being "acceptable" or "unacceptable" with regard to the protection of human subjects.

In this section of the Research Plan, address, at a minimum, the following four points:

1. The targeted/planned distribution of subjects by sex/gender and racial/ethnic groups for each proposed study or protocol using the format in the Targeted/Planned Enrollment Table (http://grants.nih.gov/grants/funding/424/SF424R-R_enrollment.doc). (Instructions for completing this table are provided below.) If you are using existing specimens and/or data that does not meet the criteria for Exemption 4 and you do not have access to information on the distribution of women and minorities, so state and explain the impact on the goals of the research as part of the rationale that inclusion is inappropriate (item 3 below). Alternatively, you may describe the women and minority composition of the population base from whom the specimens and/or data will be obtained. Include the Targeted/Planned Enrollment Table in this section.
2. A description of the subject selection criteria and rationale for selection of sex/gender and racial/ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.
3. A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group (see examples below).
4. A description of proposed outreach programs for recruiting sex/gender and racial/ethnic group members as subjects.

Examples of acceptable justifications for exclusion of:

A. ***One gender:***

1. One gender is excluded from the study because:
   - inclusion of these individuals would be inappropriate with respect to their health;
   - the research question addressed is relevant to only one gender;
   - evidence from prior research strongly demonstrates no difference between genders;
   - sufficient data already exist with regard to the outcome of comparable studies in the excluded gender, and duplication is not needed in this study.
2. One gender is excluded or severely limited because the purpose of the research constrains the applicant's selection of study subjects by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or overriding factors dictate selection of subjects, such as matching of transplant recipients, or availability of rare surgical specimens).
3. Gender representation of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens, or data-sets with incomplete gender documentation are used), and this does not compromise the scientific objectives of the research.

B. ***Minority groups or subgroups:***

1. Some or all minority groups or subgroups are excluded from the study because:
   - Inclusion of these individuals would be inappropriate with respect to their health;
   - The research question addressed is relevant to only one racial or ethnic group;
   - Evidence from prior research strongly demonstrates no differences between racial or ethnic groups on the outcome variables;
   - A single minority group study is proposed to fill a research gap;
   - Sufficient data already exists with regard to the outcome of comparable studies in the excluded racial or ethnic groups and duplication is not needed in this study.
2. Some minority groups or subgroups are excluded or poorly represented because the geographical location of the study has only limited numbers of these minority groups who would be eligible for the study, and the investigator has satisfactorily addressed this issue in terms of:
   - The size of the study;
   - The relevant characteristics of the disease, disorder or condition;
   - The feasibility of making a collaboration or consortium or other arrangements to include representation.
3. Some minority groups or subgroups are excluded or poorly represented because the purpose of the research constrains the applicant's selection of study subjects by race or ethnicity (e.g., uniquely valuable cohorts, stored specimens or existing datasets are of limited minority representation, very small numbers of subjects are involved, or overriding factors dictate selection of subjects, such as matching of transplant recipients or availability of rare surgical specimens).
4. Racial or ethnic origin of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens or data sets with incomplete racial or ethnic documentation are used) and this does not compromise the scientific objectives of the research.

Additional Instructions and Requirements When NIH-Defined Phase III Clinical Trials Are Proposed

If your proposed research includes an NIH-Defined Phase III Clinical Trial, the section on Inclusion of Women and Minorities also must address whether you expect to find clinically important sex/gender and/or race/ethnicity differences in the intervention effect. The discussion may include supporting evidence and/or data derived from prior animal studies, clinical observations, metabolic studies, genetic studies, pharmacology studies, and observational, natural history, epidemiology and other relevant studies. Your discussion of expected sex/gender and/or race/ethnicity differences in intervention effect must include selection and discussion of one of the following analysis plans:

- Plans to conduct valid analyses to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, *or*
- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups. (Representation of sex/gender and racial/ethnic groups is not required as subject selection criteria, but inclusion is encouraged.), *or*

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Instructions for Completing the Targeted/Planned Enrollment Tables for Reporting Race and Ethnicity Data for Subjects in Clinical Research

A. New Applications and Clinical Research Studies begun after January 10, 2002:

All new clinical research studies should collect and report information on participants with respect to two categories of ethnicity and five categories of race. The new Inclusion Enrollment Report Table (http://grants.nih.gov/grants/funding/424/SF424R-R_enrollmentreport.doc) for reporting summary data on participants to NIH includes two categories of ethnicity and five categories of race and is based on recent changes by the Office of Management and Budget (OMB) regarding standards for data on race and ethnicity. Investigators should review the instructions and Frequently Asked Questions about using the new Enrollment Table format at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html.

When reporting these data in the aggregate, investigators should report: (a) the number of respondents in each ethnic category; (b) the number of respondents who selected only one category for each of the five racial categories; (c) the total number of respondents who selected multiple racial categories reported as the "number selecting more than one race," and (d) the number of respondents in each racial category who are Hispanic or Latino. Investigators may provide the detailed distributions, including all possible combinations, of multiple responses to the racial designations as additional information. However, more detailed items should be designed in a way that they can be aggregated into the required categories for reporting purposes.

For new applications and clinical research studies begun after January 10, 2002, use the Targeted/Planned Enrollment Table format ((http://grants.nih.gov/grants/funding/424/SF424R-R_enrollment.doc)).

Provide the study title.

The "Total Planned Enrollment" means the number of subjects that are expected to be enrolled during the entire period of the study and are needed to evaluate the research question The "Total Planned Enrollment" will be reported in two ways in the table: by "Ethnic Category" and by "Racial Categories."

"Ethnic Category": Provide the numeric distribution of the Total Planned Enrollment according to ethnicity and sex/gender in the top part of the table.

"Racial Categories": Provide the numeric distribution of the Total Planned Enrollment, this time by racial categories and sex/gender, in the bottom part of the table. Note that Hispanic is not a racial category.

If there is more than one study/protocol, provide a separate table for each.

List any proposed racial/ethnic subpopulations below the table.

How should I report race and ethnicity data when my research involves a foreign population?

Investigators are encouraged to design their data collection instruments in ways that allow respondent self-identification of their racial and ethnic affiliation. However, these items should be designed in a way that they can be aggregated into the required categories. Also, the investigator can report on any racial/ethnic subpopulations by listing this information in an attachment to the required table. This may be particularly useful when distinctive subpopulations are relevant to the scientific hypotheses being studied.

When completing the tables, investigators should asterisk and footnote the table indicating that data includes foreign participants. If the aggregated data only includes foreign participants, the investigator should provide information in one table with an asterisk and footnote. However, if the study includes both

domestic and foreign participants, the investigator should complete two separate tables – one for domestic data and one for foreign data, with an asterisk and footnote accompanying the table with foreign data.

B. Clinical Research Studies begun before January 10, 2002:

If the proposed research uses existing data, then use the formats below for competing continuations (now known as "Renewals") and competing supplements (now known as "Revisions"). Investigators should review the instructions and Frequently Asked Questions about using the new Enrollment Table format at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html.

Competing Continuations (now known as "Renewals"):

For renewal applications involving the collection of new/additional clinical data, use the "Targeted/Planned Enrollment Table" and the instructions above. *Note:* If you choose to report information with the new Targeted/Planned Enrollment Table, you must continue to use this format for the remaining years of the project.

For renewal applications involving studies begun before January 10, 2002 that do not involve the collection of new/additional clinical data, the data on ethnicity/race and sex/gender may be presented in EITHER the Targeted/Planned Enrollment Table OR the 4/98 Version of the Inclusion Table. If data were originally collected from study subjects using two questions (one about ethnicity and one about race) and subjects were given the option of selecting more than one race, then use the Targeted/Planned Enrollment Table. Otherwise, use the 4/98 Version of the Inclusion Table, which uses a combined race/ethnicity format with five categories.

Competing Supplements (now known as "Revisions"):

For revision applications involving studies begun before January 10, 2002, investigators may report ethnicity/race and sex/gender composition using EITHER the Inclusion Enrollment Report OR the 4/98 Version of the Inclusion Table. If data are being collected using two questions (one about ethnicity and one about race) and subjects were given the option of selecting more than one race, then use the Targeted/Planned Enrollment Table. *Note:* If you choose to report information with the new Targeted/Planned Enrollment Table, you must continue to use this format for the remaining years of the project.

If data are being collected using one question that combines ethnicity and race, use the 4/98 Version of the Inclusion Table. For previously funded studies that used the 4/98 Version of the Inclusion Table the earlier reporting format is NOT directly transferable to the format.

C. What Inclusion/Enrollment Table Should PDs/PIs Use for Reporting Accrual Data to NIH? (New versus Old Table)

The following instructions apply to progress reports, whether submitted as part of a non-competing or competing application.

Guidelines for choosing the new Inclusion Enrollment Report Table versus the old Inclusion Table are as follows:

New Inclusion Enrollment Report (http://grants.nih.gov/grants/funding/424/SF424R-R_enrollmentreport.doc)

- Studies begun after January 10, 2002, must be designed to ask participants two questions, one about their ethnicity and one about their race, and investigators must use the new Inclusion Enrollment Report table format for reporting summary data to NIH.
- PDs/PIs who started a study prior to January 10, 2002 using the old Inclusion Table format for reporting summary data to NIH may switch to the new Inclusion Enrollment Report format if

they choose to do so, but they must also change their data collection methods to ask two questions (one about ethnicity and another about race) rather than one question (that combined race and ethnicity) for all participants enrolled in the study from that point on.

- For studies that began prior to January 10, 2002: When the study is submitted for renewal and plans to collect new/additional data, the PD/PI is required to change to the new standards for collecting data and use the new Inclusion Enrollment Report format for reporting data to NIH. In some cases, this will mean that PDs/PIs will need to re-ask study participants about their race and ethnicity using the new two-question format. Note: PDs/PIs should not ask again about race and ethnicity if the subjects are no longer participating in the study.

Old Inclusion Table (4/98 Version) (http://grants.nih.gov/grants/funding/424/SF424R-R_Inclusion498version.doc)

- Studies begun prior to January 10, 2002 (and now in their non-competing Type 5 period) that were structured with one question about race and ethnicity may continue to report enrollment/accrual data to NIH based on the old form, i.e., using five categories of race/ethnicity. However, when they come in for competitive renewal (Type 2), they will need to change to the new standards/new form for any additional data collection.
- PDs/PIs should not switch to the new form if only one question about race and ethnicity is used in data collection.

Investigators who have questions about these choices should contact NIH program staff for advice.

Guidance and Additional Instructions

After you have completed the Inclusion of Women and Minorities section, proceed to Inclusion of Children.

INCLUSION OF CHILDREN

- Create a section entitled "Inclusion of Children" and place it immediately following the last entry in the Inclusion of Women and Minorities section.
- For the purpose of implementing these guidelines, a *child* is defined as an individual under the age of 21 years (for additional information see http://grants.nih.gov/grants/funding/children/children.htm and http://grants.nih.gov/grants/guide/notice-files/not98-024.html).
- Provide either a description of the plans to include children or, if children will be excluded from the proposed research, application, or proposal, then you must present an acceptable justification (see below) for the exclusion.
- If children are included, the description of the plan should include a rationale for selecting a specific age range of children. The plan also must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.
- Scientific Review Groups will assess each application as being "acceptable" or "unacceptable" with regard to the age-appropriate inclusion or exclusion of children in the research project.
- When children are involved in research, the Additional Protections for Children Involved as Subjects in Research (45 CFR Part 46 Subpart D) apply and must be addressed in the "Human Subjects Research and Protection from Risks" subheading.

Justifications for Exclusion of Children

For the purposes of this policy, all individuals under 21 are considered children; however, exclusion of any specific age group, such as individuals under 18, should be justified in this section.

It is expected that children will be included in all clinical research unless one or more of the following exclusionary circumstances can be fully justified:

1. The research topic to be studied is not relevant to children.
2. There are laws or regulations barring the inclusion of children in the research.
3. The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be needlessly redundant. Documentation of other studies justifying the exclusions should be provided. NIH program staff can be contacted for guidance on this issue if the information is not readily available.
4. A separate, age-specific study in children is warranted and preferable. Examples include:
    a. The condition is relatively rare in children, as compared to adults (in that extraordinary effort would be needed to include children, although in rare diseases or disorders where the applicant has made a particular effort to assemble an adult population, the same effort would be expected to assemble a similar child population with the rare condition); or
    b. The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
    c. Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages or different age-related metabolic processes). While this situation may represent a

justification for excluding children in some instances, consideration should be given to taking these differences into account in the study design and expanding the hypotheses tested, or the interventions planned, to allow inclusion of children rather than excluding them.

5. Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). Although children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis.
6. Study designs are aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children).
7. Other special cases can be justified by the investigator and found acceptable to the review group and the Institute Director.

Guidance and Additional Instructions

After you have completed this section of the application, proceed to Vertebrate Animals.

See Policy on Inclusion of Children.

SCENARIO A: NO HUMAN SUBJECTS RESEARCH PROPOSED

Criterion

If you are uncertain as to whether your research involves Human Subjects please read: Question 1: Does your proposed research involve human subjects?

Instructions

Check the box marked "No" on the Other Project Information Component, Item 1.

In your application narrative, create a heading labeled "Human Subjects Research" and place it immediately after the last entry in the Research Design and Methods section. Include the following statement below the heading: "No Human Subjects Research is proposed in this application."

If your proposed research involves human specimens and/or data from subjects, please provide a justification for your claim that no human subjects are involved. (See guidance under Question 1. Does your proposed research involve human subjects?)

Guidance and Additional Instructions

The material that you provide will be used by reviewers as part of their evaluations on the research design and methods of your proposed research.

Do not follow the instructions for Scenario A if research activities involving human subjects are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution. You will need to consider an alternative scenario.

If you need to consider an alternative scenario return to the Decision Table.

or

After you have completed this section of the application, proceed to Vertebrate Animals.

SCENARIO B: HUMAN SUBJECTS RESEARCH CLAIMING EXEMPTION 4

Criteria	
Human Subjects Research	Yes
Exemption	4
Clinical Research	No
Clinical Trial	N/A
NIH-Defined Phase III Clinical Trial	N/A

Instructions and Required Information

Although no specific page limitation applies to this section of the application, be succinct in your responses.

Check the box marked "Yes" on the Other Project Information Component, Item 1. Check "Yes" if activities involving human subjects are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution. "Yes" should be checked even if the research is exempt from requirements in the Federal regulations for the protection of human subjects (45 CFR Part 46).

Indicate that you are claiming Exemption 4 in Item 1a and enter "NA" for the Human Subject Assurance Number, since no assurance is needed.

In your application narrative, create a heading entitled "Human Subjects Research" and place it immediately after the last entry in the Research Design and Methods section. Include the following statement below the heading: "This Human Subjects Research falls under Exemption 4."

Address the following three items in this new section:

1. Human Subjects Involvement and Characteristics:

a. Describe the proposed involvement of human subjects in the work outlined in the Research Design and Methods section.

b. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. If the characteristics of the population are not available, then the applicant should indicate that the information is unknown.

c. Identify the criteria for inclusion or exclusion of any subpopulation.

d. Explain the rationale for the involvement of vulnerable populations, such as fetuses, neonates, pregnant women, children, institutionalized individuals, or others who may be considered vulnerable populations. Exemptions 1-6 do not apply to research involving prisoners or subjects who become prisoners (see 45 CFR Part 46 Subpart C). Although Exemptions 1 and 3-6 apply to research involving children (see 45 CFR Part 46 Subpart D), Exemption 2 can only be used for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

e. List any collaborating sites where human subjects research will be performed and describe the role of those sites in performing the proposed research.

2. Sources of Materials:

a. Describe the research material obtained from living human subjects in the form of specimens, records, or data.

b. Describe any data that will be recorded on the human subjects involved in the project.

c. Describe the linkages to subjects, and indicate who will have access to subject identities.

d. Provide information about when the specimens, records, or data were collected and whether new material or data will need to be collected specifically for your proposed research project.

3. Justification for Exemption:

a. Indicate that you are claiming Exemption 4.

b. Provide a justification for why your research meets the criteria for Exemption 4.

Guidance and Additional Instructions

The material that you provide will be used by reviewers as part of their evaluations on the research design and methods of your proposed research.

What types of research meet the criteria for Exemption 4? Research projects involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. Determining the appropriateness of Exemption 4 for research using specimens and data can be complex.

Note: Prospective collection of additional specimens does not meet the criteria for Exemption 4.

If you are uncertain as to whether your research meets the criteria for Exemption 4, refer to Exemption 4 Guidance and Information.

If you need to consider an alternative scenario, return to the Decision Table.

After you have completed this section of the application, proceed to Vertebrate Animals.

SCENARIO C: HUMAN SUBJECTS RESEARCH CLAIMING EXEMPTION 1, 2, 3, 5, OR 6

Criteria	
Human Subjects Research	Yes
Exemption Claimed	1, 2, 3, 5, 6
Clinical Research	Yes
Clinical Trial	N/A
NIH-Defined Phase III Clinical Trial	N/A

Instructions and Required Information

Although no specific page limitation applies to this section of the application, be succinct.

Check the box marked "Yes" on the Other Project Information Component, Item 1, enter the exemption number that you are claiming in Item 1a. Enter "NA" for the Human Subject Assurance Number, since no OHRP assurance number is needed for exempt research.

Although your research may be exempt from the IRB oversight provisions, it is still human subjects research, and you need to follow the instructions that are identified for each of the following topics and provide the information that is requested.

In your application narrative, create a heading entitled "Human Subjects Research" and place it immediately after the last entry in the Research Design and Methods section. Address the following items in this new section. Include the following statement below the heading: "This Human Subjects Research falls under Exemption(s) … ."

1. Human Subjects Involvement and Characteristics:

a. Describe the proposed involvement of human subjects in the work outlined in the Research Design and Methods section.

b. Describe the characteristics of the subject population, including their anticipated number, age range, and health status.

c. Identify the criteria for inclusion or exclusion of any subpopulation (e.g., men, women, children).

d. Explain the rationale for the involvement of vulnerable populations, such as fetuses, neonates, pregnant women, children, institutionalized individuals. Please note that research involving prisoners is not exempt under any category (see 45 CFR Part 46 Subpart C).

e. List any collaborating sites where human subjects research will be performed and describe the role of those sites in performing the proposed research.

2. Sources of Materials:

a. Describe the sources of the research material obtained from living human subjects in the form of specimens, records, or data.

b. Describe any data that will be recorded on the human subjects involved in the project.

c. Describe the linkages to subjects and indicate who will have access to subject identities.

d. Provide information about when the specimens, records, or data were collected and whether new material or data will need to be collected specifically for your proposed research project.

3. Justification for Exemption(s):

In this section, identify which exemption(s) (1, 2, 3, 5, or 6) you are claiming. (If you are claiming Exemption 4 please refer to Scenario B and the appropriate instructions.) Justify why your research is appropriate for the exemption(s) that you have claimed.

4. Inclusion of Women and Minorities *(click and follow instructions)*

The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design appropriate to the scientific objectives of the study.

Create a section entitled "Inclusion of Women and Minorities" and place it immediately following the last entry in the "Human Subjects Research" section.

Describe the composition of the proposed study population in terms of sex/gender and racial/ethnic group, and provide a rationale for selection of such subjects. Such a plan should contain a description of the proposed outreach programs for recruiting women and minorities as participants. See http://grants.nih.gov/grants/funding/women_min/women_min.htm.

Include the Targeted/Planned Enrollment Table here.

5. Inclusion of Children *(click and follow instructions)*

For the purpose of implementing these guidelines, a *child* is defined as an individual under the age of 21 years. (For additional information see http://grants.nih.gov/grants/funding/children/children.htm and http://grants.nih.gov/grants/guide/notice-files/not98-024.html.)

Guidance and Additional Instructions

The material that you provide will be used by reviewers as part of their evaluations on the research design and methods of your proposed research.

If you are uncertain as to whether your research meets the criteria for an exemption please read: Question 2: Does your proposed human subjects research meet the criteria for one or more of the exemptions in the HHS regulations?

If you need to consider an alternative Scenario, return to the Decision Table.

After you have completed this section of the application, proceed to Vertebrate Animals.

SCENARIO D: CLINICAL RESEARCH

Criteria

Human Subjects Research	Yes
Exemption	No
Clinical Research	Yes
Clinical Trial	No
NIH-Defined Phase III Clinical Trial	No

Instructions and Required Information

Although no specific page limitation applies to this section of the application, be succinct.

Check the box marked "Yes" on the Other Project Information Component, Item 1, and enter your OHRP assurance number in Item 1a.

In your application narrative, create a section entitled "Human Subjects Research" immediately following the last entry in the Research Design and Methods section. Include the following statement below the heading: "This Human Subjects Research meets the definition of 'Clinical Research.'"

Create a subheading for each of the following items, follow the instructions that are identified for each topic, and provide the information that is requested:

- Protection of Human Subjects (click and follow instructions)
- Inclusion of Women and Minorities (click and follow instructions)
  Targeted/Planned Enrollment Table
- Inclusion of Children (click and follow instructions)

If your application involves collaborating sites, provide the information identified above for each participating site.

Guidance and Additional Instructions

Research that meets the criteria for Exemption 4 is not considered clinical research.

Research that uses *existing (archived)* specimens or data that *can* be linked to living individuals must address the inclusion of women, minorities and children as identified above, unless the investigator does not have access to the information.

The material that you provide will be used by reviewers as part of their evaluations on the research design and methods of your proposed research.

If you are uncertain as to whether your research meets the criteria for clinical research, read: Question 3: Does your proposed research meet the definition of Clinical Research?

If you need to consider an alternative scenario, return to the Decision Table.

After you have completed this section of the application, proceed to Vertebrate Animals.

SCENARIO E. CLINICAL TRIALS

Criteria

Human Subjects Research	Yes
Exemption	No
Clinical Research	Yes
Clinical Trial	Yes
NIH-Defined Phase III Clinical Trial	No

Instructions and Required Information

Check the box marked "Yes" on the Other Project Information Component, and enter your OHRP assurance number for Item 1a.

In your application narrative, create a section entitled "Human Subjects Research" immediately following the last entry in the Research Design and Methods section. Include the following statement below the heading: "This Human Subjects Research meets the definition of a clinical trial." Create a subheading for each of the following items, follow the instructions that are identified for each topic, and provide the information that is requested:

- Protection of Human Subjects (click and follow instructions)
- Data and Safety Monitoring Plan (click and follow instructions)
- Inclusion of Women and Minorities (click and follow instructions)
  Targeted/Planned Enrollment Table
- Inclusion of Children (click and follow instructions)

If your application involves collaborating sites, provide information for each of the issues identified above for each participating site.

Guidance and Additional Instructions

The material that you provide will be used by reviewers as part of their evaluations on the research design and methods of your proposed research. If you are uncertain as to whether your research includes a clinical trial please read: Question 4: Does your proposed research include a clinical trial?

If you need to consider an alternative scenario, return to the Decision Table.

After you have completed this section of the application, proceed to Vertebrate Animals.

SCENARIO F. NIH DEFINED PHASE III CLINICAL TRIAL

Criteria

Human Subjects Research:	Yes
Exempt:	No
Clinical Research:	Yes
Clinical Trial:	Yes
NIH-Defined Phase III Clinical Trial:	Yes

Instructions and Required Information

Check the box marked "Yes" on the Other Project Information Component, and enter your OHRP assurance number for Item 1a.

In your application narrative, create a section entitled "Human Subjects Research" immediately following the last entry in the Research Design and Methods section. Include the following statement below the heading: "This Human Subjects Research is an NIH-Defined Phase III Clinical Trial."

Follow the instructions that are identified for each of the following topics and provide the information that is requested:

- Protection of Human Subjects (click and follow instructions)
- Data and Safety Monitoring Plan (click and follow instructions)
- Inclusion of Women and Minorities (click and follow instructions)
  Targeted/Planned Enrollment Table
- Inclusion of Children (click and follow instructions)

If your application involves collaborating sites, provide the information identified above for each participating site.

Guidance and Additional Instructions

The material that you provide will be used by reviewers as part of their evaluations on the research design and methods of your proposed research. If you are uncertain as to whether your research includes clinical research, read Question 5: Does your proposed research meet criteria for an NIH-Defined Phase III Clinical Trial?

If you need to consider an alternative scenario, return to the Decision Table.

After you have completed this section of the application, proceed to Vertebrate Animals.

HUMAN SUBJECTS RESEARCH DEFINITIONS

Autopsy Materials. The use of autopsy materials is governed by applicable Federal, state and local law and is not directly regulated by 45 CFR Part 46.

Child. The NIH Policy on Inclusion of Children defines a child as an individual under the age of 21 years. The intent of the NIH policy is to provide the opportunity for children to participate in research studies when there is a sound scientific rationale for including them, and their participation benefits children and is appropriate under existing Federal guidelines. Thus, children must be included in NIH conducted or supported clinical research unless there are scientific and ethical reasons not to include them.

HHS Regulations (45 CFR Part 46, Subpart D, Sec.401-409) provide additional protections for children involved as subjects in research, based on this definition: "Children are persons who have not attained the legal age for consent to treatments or procedures involved in research, under the applicable law of the jurisdiction in which the research will be conducted." Generally, state laws define what constitutes a "child." Consequently, the age at which a child's own consent is required and sufficient to participate in research will vary according to state law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

Clinical Research. NIH defines human clinical research as: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are *in vitro* studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research. Note: Studies falling under Exemption 4 for human subjects research are not considered clinical research by this definition.

Clinical Trial. The NIH defines a *clinical trial* as a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).

Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective.

Behavioral human subjects research involving an intervention to modify behavior (diet, physical activity, cognitive therapy, etc.) fits this definition of a clinical trial.

Human subjects research to develop or evaluate clinical laboratory tests (e.g. imaging or molecular diagnostic tests) might be considered to be a clinical trial if the test will be used for medical decision making for the subject or the test itself imposes more than minimal risk for subjects.

Biomedical clinical trials of experimental drug, treatment, device or behavioral intervention may proceed through four phases:

> ***Phase I*** clinical trials test a new biomedical intervention in a small group of people (e.g., 20-80) for the first time to evaluate safety (e.g., to determine a safe dosage range and to identify side effects).
>
> ***Phase II*** clinical trials study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety.
>
> ***Phase III*** studies investigate the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.

Phase IV studies are conducted after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

NIH-Defined Phase III Clinical Trial. For the purpose of the Guidelines an NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or controlled intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

Data and Safety Monitoring Plan. NIH requires a data and safety monitoring plan for each clinical trial that will provide oversight and monitoring to ensure the safety of participants and the validity and integrity of the data. The level of monitoring should be commensurate with the risks and the size and complexity of the clinical trial. A detailed data and safety monitoring plan must be submitted to the applicant's IRB and subsequently to the funding IC for approval prior to the accrual of human subjects. The reporting of Adverse Events must be reported to the IRB, the NIH funding Institute or Center, and other required entities. This policy requirement is in addition to any monitoring requirements imposed by 45 CFR Part 46.

Data and Safety Monitoring Board (DSMB). NIH requires the establishment of a Data and Safety Monitoring Board (DSMB) for multi-site clinical trials involving interventions that entail potential risk to the participants, *and generally for Phase III clinical trials*.

Gender. Refers to the classification of research subjects into either or both of two categories: women and men. In some cases, representation is unknown, because gender composition cannot be accurately determined (e.g., pooled blood samples or stored specimens without gender designation).

Human Subjects. The HHS regulations "Protection of Human Subjects" (45 CFR 46, administered by OHRP) define a ***human subject*** as a living individual about whom an *investigator* conducting *research obtains*:

- data through *intervention* or *interaction* with the individual or
- *identifiable private information*

Investigator. The OHRP considers the term investigator to include anyone involved in conducting the research. OHRP does not consider the act of solely providing coded private information or specimens (for example, by a tissue repository) to constitute involvement in the conduct of the research. However, if the individuals who provide *coded* information or specimens also collaborate on other activities related to the conduct of the research with the investigators who receive such information or specimens, they will be considered to be involved in the conduct of the research. [OHRP's Coded Specimen Guidance]

Research. HHS regulations define *research* at 45 CFR 46.102(d) as follows:
Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Obtains. In its guidance for use of coded specimens, OHRP has determined that under the definition of human subject at 45 CFR 46.102(f), *obtaining* identifiable private information or identifiable specimens for research purposes constitutes human subjects research. *Obtaining* means receiving or accessing

identifiable private information or identifiable specimens for research purposes. OHRP interprets *obtaining* to include an investigator's use, study, or analysis for research purposes of *identifiable private information* or identifiable specimens already in the possession of the investigator.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. (45 CFR 46.102(f))

Interaction includes communication or interpersonal contact between investigator and subject. (45 CFR 46.102(f))

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). Private information must be *individually identifiable* (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. (45 CFR 46.102(f))

Individually Identifiable Private Information. According to its guidance for use of coded specimens, OHRP generally considers private information or specimens to be *individually identifiable* as defined at 45 CFR 46.102(f) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through *coding* systems. Conversely, OHRP considers private information or specimens not to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

Coded. With respect to private information or human biological specimens, *coded* means that:

(1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol or combination thereof (i.e., the code); and

(2) a key to decipher the code exists, enabling linkage of the identifying information with the private information or specimens.

Research that involves only coded private information/data or coded human biological specimens may not constitute human subjects research under the HHS human subjects regulations (45 CFR 46) if:

- the specimens and/or information/data are not obtained from an interaction/intervention with the subject specifically for the research; and
- the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain (e.g., the researcher's access to subject identities is prohibited).

(See the following guidance from the Office for Human Research Protections (OHRP) for additional information and examples: http://www.hhs.gov/ohrp/humansubjects/guidance/cdeiol.pdf.)

Significant Difference. For purposes of NIH policy, a "significant difference" is a difference that is of clinical or public health importance, based on substantial scientific data. This definition differs from the commonly used "statistically significant difference," which refers to the event that, for a given set of data, the statistical test for a difference between the effects in two groups achieves statistical significance. Statistical significance depends upon the amount of information in the data set. With a very large amount of information, one could find a statistically significant, but clinically small difference that is of very little clinical importance. Conversely, with less information one could find a large difference of potential importance that is not statistically significant.

Valid Analysis. This term means an unbiased assessment. Such an assessment will, on average, yield the correct estimate of the difference in outcomes between two groups of subjects. Valid analysis can and should be conducted for both small and large studies. A valid analysis does not need to have a high statistical power for detecting a stated effect. The principal requirements for ensuring a valid analysis of the question of interest are: allocation of study participants of both sexes/genders (males and females) and from different racial/ethnic groups to the intervention and control groups by an unbiased process such as randomization; unbiased evaluation of the outcome(s) of study participants; and use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects among the gender and racial/ethnic groups.

HUMAN SUBJECTS RESEARCH POLICY

Human Subjects Research Policy includes Federal regulations for the protection of human subjects and the following NIH policies related to human subjects research.

Protection of Human Subjects

The Department of Health and Human Services (HHS) regulations for the protection of human subjects provide a systematic means, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the HHS. The regulations stipulate that an applicant organization, whether domestic or foreign, bears responsibility for safeguarding the rights and welfare of human subjects in HHS-supported research activities. The regulations require that applicant organizations proposing to involve human subjects in nonexempt research, provide written Assurance of Compliance with the Office for Human Research Protections (OHRP), that they will comply with requirements set forth in the HHS regulations to protect human subjects. These regulations, 45 CFR Part 46, Protection of Human Subjects, are available from OHRP, Department of Health and Human Services, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852 or by contacting OHRP at ohrp@osophs.dhhs.gov; Telephone: 1-866-447-4777 or (301) 496-7005.

Under HHS regulations to protect human subjects from research risks, certain research areas are exempt. However, if an applicant makes inappropriate designations of the noninvolvement of human subjects or of exempt categories of research, this may result in delays in the review of an application or the return of the application without review. The PHS will make a final determination as to whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the Research Plan. When in doubt, consult with the Office for Human Research Protections (OHRP), Department of Health and Human Services by accessing their website http://www.hhs.gov/ohrp/ for guidance and further information.

No non-exempt research involving human subjects can be conducted under a HHS award unless that organization is operating in accord with an approved Assurance of Compliance and provides verification that an Institutional Review Board (IRB) that is registered under the specific Assurance has reviewed and approved the proposed activity in accordance with the HHS regulations. No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the HHS regulations. Foreign applicant organizations must also comply with the provisions of the regulations.

In addition to the HHS human subjects regulations, FDA regulations (21 CFR part 50; 21 CFR part 56) may also apply to your research. FDA regulations generally apply to biomedical research involving an unapproved drug, device or biologic and may apply to certain studies of approved products. Researchers proposing such research should consult with their IRB and the FDA to determine whether and how the FDA regulations may apply. Additional information on FDA regulations is available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm.

Studies that involve the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into human research participants (known as “human gene transfer” or “gene therapy”) are subject to the oversight and biosafety requirements outlined in the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) when these studies are conducted at, or sponsored by, an institution that receives any NIH support for recombinant DNA research. These requirements, which include review by an Institutional Biosafety Committee and submission to the NIH for review by the Recombinant DNA Advisory Committee, are described in Section III-C-1 and Appendix M of the NIH Guidelines (accessible at: http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html). Additional information on the special

requirements that pertain to human gene transfer can be found in a series of Frequently Asked Questions at: http://www4.od.nih.gov/oba/RAC/RAC_FAQs.htm.

Federal requirements to protect human subjects apply to most research on human specimens (such as cells, blood, and urine), residual diagnostic specimens and medical information. Research involving the collection or study of existing data, documents, records, pathological specimens, diagnostic specimens, or tissues that are individually identifiable is considered "research involving human subjects." The NIH Office of Extramural Research Human Subjects website contains additional information and Frequently Asked Questions that is available to help investigators understand how these Federal requirements apply to their research. See http://grants.nih.gov/grants/policy/hs/index.htm.

The HHS regulations also require "Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency" (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.120). This independent evaluation is conducted at the NIH through the peer review system and NIH staff review, and, as required, will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. On the basis of this evaluation, the NIH may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

Vulnerable Populations

Investigators who conduct research involving pregnant women, human fetuses and neonates, prisoners, or children must follow the provisions of the regulations in Subparts B, C, and D of 45 CFR Part 46, respectively, which describe the additional protections required for these populations. Note that 'prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers) as well as subjects who become incarcerated after the study begins. Relevant information may be obtained at the OHRP website (http://www.hhs.gov/ohrp/policy/index.html).

REMINDER: HHS regulations at **45 CFR Part 46, subpart C** describe requirements for additional protections for research involving prisoners as subjects or individuals who become prisoners after the research has started. Refer to: http://www.hhs.gov/ohrp/humansubjects/guidance/prisoner.htm for complete instructions.

Exemptions 1-6 do not apply to research involving prisoners or subjects who become prisoners (see Subpart C). Although Exemptions 1 and 3-6 apply to research involving children (see Subpart D), Exemption 2 can only be used for educational tests or research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Data and Safety Monitoring Plans for Clinical Trials

For each proposed clinical trial, NIH requires a data and safety monitoring plan that describes oversight and monitoring to ensure the safety of participants and the validity and integrity of the data. The level of monitoring should be commensurate with the risks and the size and complexity of the clinical trial. A detailed data and safety monitoring plan must be submitted to the applicant's IRB and subsequently to the funding IC for approval prior to the accrual of human subjects. The reporting of Adverse Events must be reported to the IRB, the NIH funding Institute or Center, and other required entities. This policy requirement is in addition to any monitoring requirements imposed by 45 CFR Part 46. NIH requires the establishment of a Data and Safety Monitoring Board (DSMB) for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally for Phase III clinical trials.

Research on Transplantation of Human Fetal Tissue

When verifying the submitted application in the eRA Commons, the duly authorized representative of the applicant organization certifies that if research on the transplantation of human fetal tissue is conducted, the applicant organization will make available, for audit by the Secretary, HHS, the physician statements and informed consents required by section 498A (b)(2) and (c) of the Public Health Service Act, 42 U.S.C. 289g (b)(2) and (c), or ensure HHS access to those records, if maintained by an entity other than the applicant organization.

Research Using Human Embryonic Stem Cells

http://stemcells.nih.gov/index.asp

When verifying the submitted application in the eRA Commons, the duly authorized representative of the applicant organization certifies that if research using human embryonic stem cells is proposed, the applicant organization will be in compliance with the "Notice of Extended Receipt Date and Supplemental Information Guidance for Applications Requesting Funding that Proposes Research with Human Embryonic Stem Cells" (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-006.html).

IRB Approval

NIH does not require certification of IRB approval of the proposed research prior to NIH peer review of an application. See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-031.html.

Following NIH peer review, applicants and their institutions will be notified of the need for review and approval of the proposed research by an OHRP-registered IRB. See http://www.hhs.gov/ohrp/ to register an IRB. Documentation of IRB approval must be sent to the Grants Management Office identified in the notice requesting certification. This IRB certification must include: the PHS application number, title of the project, name of the PD/PI, date of IRB approval, and appropriate signatures. You may also use the optional form "Protection of Human Subjects - Assurance Identification/IRB Certification/Declaration of Exemption (Common Rule) (OMB Form No. 0990-0263) to meet this requirement: http://www.hhs.gov/ohrp/humansubjects/assurance/OF310.rtf

An institution is automatically considered to be engaged in human subjects research when it receives an NIH award to support nonexempt human subjects research. All institutions engaged in human subjects research must obtain a Federal Wide Assurance (FWA) from OHRP. Instructions for applying for a Federal Wide Assurance (FWA) are available from the OHRP website at http://www.hhs.gov/ohrp/assurances/assurances_index.html.

Any modifications in the Research Plan section of the application, required by either NIH or by the IRB must be submitted with the follow-up certification of IRB approval to the NIH before the competing award is made. It is the responsibility of the PD/PI and the applicant organization to submit the follow-up certification.

If more than a year will have elapsed between the initial IRB review date and the anticipated award date, the awarding unit staff shall require re-review by the IRB prior to award.

Required Education in the Protection of Human Research Participants

NIH requires education on the protection of human research participants for all individuals identified as Key Personnel before funds are awarded for applications or contract proposals involving human subjects. For information relating to this requirement, see the following see the following notices (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html and http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-061.html), and Frequently Asked Questions found at: http://grants.nih.gov/grants/policy/hs_educ_faq.htm. Prior to award, applicants will be required

to provide a description of education completed in the protection of human subjects for all Key Personnel involved in human subjects research. Although NIH does not endorse programs, there are curricula available that can provide guidance or that can be modified to provide training in this area. See http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp for computer-based training developed for NIH that can be downloaded at no charge. For information on facilitating education and developing curricula, see http://www.nih.gov/sigs/bioethics.

Relevant Policies and Information

PROCEDURES FOR SUBMISSION OF COMPLIANCE DOCUMENTS TO THE HUMAN PLURIPOTENT STEM CELL REVIEW GROUP FOR THE RESEARCH USE OF HUMAN EMBRYONIC GERM CELLS	NOTICE: NOT-OD-02-049 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html
GUIDANCE FOR INVESTIGATORS AND INSTITUTIONAL REVIEW BOARDS REGARDING RESEARCH INVOLVING HUMAN EMBRYONIC STEM CELLS, GERM CELLS AND STEM CELL-DERIVED TEST ARTICLES	NOTICE: NOT-OD-02-044 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-044.html
IMPLEMENTATION ISSUES FOR HUMAN EMBRYONIC STEM CELL RESEARCH - FREQUENTLY ASKED QUESTIONS	NOTICE: NOT-OD-02-014 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-014.html
FEDERAL GOVERNMENT CLEARANCES FOR RECEIPT OF INTERNATIONAL SHIPMENT OF HUMAN EMBRYONIC STEM CELLS	NOTICE: NOT-OD-02-013 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-013.html
NOTICE OF EXTENDED RECEIPT DATE AND SUPPLEMENTAL INFORMATION GUIDANCE FOR APPLICATIONS REQUESTING FUNDING THAT PROPOSES RESEARCH WITH HUMAN EMBRYONIC STEM CELLS	NOTICE: NOT-OD-02-006 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-006.html
NOTICE OF CRITERIA FOR FEDERAL FUNDING OF RESEARCH ON EXISTING HUMAN EMBRYONIC STEM CELLS AND ESTABLISHMENT OF NIH HUMAN EMBRYONIC STEM CELL REGISTRY	NOTICE: NOT-OD-02-005 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html
NIH FUNDING OF RESEARCH USING SPECIFIED EXISTING HUMAN EMBRYONIC STEM CELLS	NOTICE: NOT-OD-01-058 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-059.html

NIH Policy on the Inclusion of Women and Minorities in Clinical Research

It is the policy of NIH that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving clinical research unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of an Institute/Center Director based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research.

All NIH-supported biomedical and behavioral research involving human subjects is defined as clinical research. This policy applies to research subjects of all ages.

The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design appropriate to the scientific objectives of the study. The Research Plan should describe the composition of the proposed study population in terms of sex/gender and racial/ethnic group, and provide a rationale for selection of such subjects. Such a plan should contain a description of the proposed outreach programs for recruiting women and minorities as participants. See http://grants.nih.gov/grants/funding/women_min/women_min.htm.

NIH Policy on Inclusion of Children

(See Definition of "child.")

Research involving children must comply with the NIH Policy and Guidelines on the Inclusion of Children in Clinical Research. The following excerpts provide the key policy statements. Investigators should obtain full copies of the Policy and Guidelines from NIH staff, or from the NIH grants Web site under http://grants.nih.gov/grants/funding/children/children.htm.

NIH policy requires that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH unless there are clear and compelling reasons not to include them. Therefore, proposals for clinical research must include a description of plans for including children. If children will be excluded from the research, the application or proposal must present an acceptable justification for the exclusion.

In addition, the involvement of children as subjects in research must be in compliance with all applicable subparts of 45 CFR Part 46 as well as with other pertinent Federal laws and regulations.

Additionally, IRBs have special review requirements to protect the well-being of children who participate in research. These requirements relate to risk, benefit, parental/guardian consent, and assent by children, and to research involving children who are wards of the state or of another institution. The local IRB approves research that satisfies the conditions set forth in the regulations.

NIH Policy on Reporting Race and Ethnicity Data: Subjects in Clinical Research

The Office of Management and Budget (OMB) (http://www.whitehouse.gov/omb/fedreg/ombdir15.html) defines minimum standards for maintaining, collecting and presenting data on race and ethnicity for all Federal reporting agencies (including NIH). The categories in this classification are social-political constructs and should not be interpreted as being anthropological in nature. The standards were revised in 1997 and now include two ethnic categories, "Hispanic or Latino" and "Not Hispanic or Latino." There are five racial categories: American Indian or Alaska Native; Asian; Black or African American; Native Hawaiian or Other Pacific Islander; and White. Reports of data on race and ethnicity shall use these categories. NIH is required to use these definitions to allow comparisons to other Federal databases, especially the census and national health databases. The following definitions apply to the minimum standards for the ethnic and racial categories.

Ethnic Categories:

> **Hispanic or Latino:** A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino."
>
> **Not Hispanic or Latino**

Racial Categories:

American Indian or Alaska Native: A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.

Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

Black or African American: A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."

Native Hawaiian or Other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

White: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Ethnic/Racial Subpopulations: In addition to OMB ethnic and racial categories, NIH uses the following definition for ethnic/racial subpopulations:

Subpopulations: Each ethnic/racial group contains subpopulations that are delimited by geographic origins, national origins, and/or cultural differences. It is recognized that there are different ways of defining and reporting racial and ethnic subpopulation data. The subpopulation to which an individual is assigned depends on self-reporting of specific origins and/or cultural heritage. Attention to subpopulations also applies to individuals who self identify with more than one race. These ethnic/racial combinations may have biomedical, behavioral, and/or social-cultural implications related to the scientific question under study. (http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm).

Guidance on Collecting Race and Ethnicity Data from Study Subjects

When an investigator is planning to collect data on ethnicity and race, the categories identified above should be used. The collection of greater detail is encouraged, for example on ethnic/racial subpopulations. However, any collection that uses more detail must be designed in a way that data can be aggregated into these minimally required categories. Use self-report or self-identification to collect this information by asking two separate questions – one on ethnicity and one on race. Collect ethnicity information first followed by the question on race and provide subjects with the option to select more than one racial category.

See NIH Policy on Inclusion of Women and Minorities.

Collecting Data on Foreign Populations: If you are conducting clinical research outside of the US, you should design culturally sensitive and appropriate data collection items and instruments that allow subjects to self-identify their ethnic and racial affiliation in a culturally appropriate manner. These items, however, should be designed in a way that allow you, the investigator, to aggregate the information into the OMB minimally required ethnic and racial categories when reporting the information to NIH.

Submitting Applications or Proposals Using Existing Data in Clinical Research with No Plans for Collecting New/Additional Data:

Investigators are instructed to provide plans for the total number of subjects proposed for the study and to provide the distribution by ethnic/racial categories and sex/gender. Under these circumstances, investigators are not required to re-contact subjects solely to comply with the newly revised categories. If the existing data on ethnicity and race allow accurate correspondence with the new categories, the investigator can use the format in the Targeted/Planned Enrollment table. However, if the existing data do not allow accurate correspondence with the new categories, information may be reported using the former categories and according to the format in the 4/98 Version of the Inclusion Table.

Annual Progress Reports (Type 5 applications) and Competing Supplement Applications

In annual Progress Reports, investigators conducting clinical research are required to provide the cumulative total enrollment of subjects to-date, showing the distribution by ethnic/racial categories and sex/gender on EITHER the new Inclusion Enrollment Report OR the format in the former 4/98 Version of the Inclusion Table.

For competing supplement applications, any proposed additions to the Targeted/Planned Enrollment Table should be provided, in addition to the current Inclusion Enrollment Table.

If Data Collection is Ongoing, Such that New Subjects Will be Enrolled and/or Additional Data Will be Collected from Human Subjects:

Investigators may choose to report ethnicity/race and sex/gender sample composition using EITHER the new Inclusion Enrollment Report OR the format in the former 4/98 Version of the Inclusion Table.

[Note: If investigators with on-going data collection choose to report information using the new Inclusion Enrollment Report, they must continue to use this format for the remaining years of the project.]

If Data Collection is Complete, Such that No New/Additional Subject Contact is Planned:

Investigators may EITHER continue to report using the former categories and according to the 4/98 Version of the Inclusion Table, OR, if data allow accurate correspondence with the new categories, use the format in the new Inclusion Enrollment Report.

Additional Information

Additional information on NIH policy regarding the Inclusion of Women and Minorities in Clinical Research can be found at the website http://grants.nih.gov/grants/funding/women_min/women_min.htm.

PART III

Policies, Assurances, Definitions, and Other Information

I. Policy

A. Applications That Include Consortium/Contractual Facilities and Administrative Costs

See: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-004.html.

NIH broadens the scope of Notice OD-04-040 to apply to all applications involving consortium/contractual facilities and administrative (F&A) costs, regardless of budget amount or budget format (e.g., modular and non-modular).

This policy applies to all solicited and investigator-initiated applications. For solicited applications, this policy change now applies to all currently active announcements (Request for Applications and Program Announcements), regardless of the announcement issue date.

This policy is particularly relevant to all applications that include a limitation on direct costs. While consortium F&A costs will continue to be requested and awarded, applicants will now separate these costs when determining if a budget exceeds a direct cost limit.

This policy impacts eligibility to submit a modular budget. The modular budget format continues to be used for applications requesting $250,000 or less in direct costs per year. However consortium/contractual F&A costs are no longer factored into this direct cost limit. They may be requested in addition to the $250,000.

The policy also impacts applications requesting a budget of $500,000 or more direct costs for any year. These applications continue to require prior approval from Institute/Center staff; however this limit is now exclusive of any consortium F&A costs.

Note: The implications of this policy do not affect the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs since the statutory budget guidelines are based on total costs, not direct costs.

B. Resubmission of Unpaid RFA Applications and Resubmission of Applications with a Changed Grant Activity Mechanism

See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-019.html.

The majority of grant applications submitted to NIH each year are investigator-initiated. However, the Institutes and Centers of NIH also solicit grant applications on specific topics through the use of Requests for Applications (RFAs). Resubmissions of grant applications fall into the following categories:

1. Applications that were originally submitted in response to an RFA and then resubmitted as an investigator-initiated application.
2. Applications that were originally submitted as investigator-initiated applications and subsequently resubmitted in response to an RFA.
3. Applications that were originally submitted using one grant mechanism and subsequently resubmitted using a different grant mechanism (for example, an application that was originally an R01 and then is resubmitted as an R21).

Since an RFA often has special considerations of eligibility, scientific scope, and review criteria, it is felt that most unfunded applications should be resubmitted as **new** applications. Similarly, a change of grant

mechanism (from an R01 to an R21 or from an R03 to an R01, for example) usually involves a change of eligibility criteria, application characteristics, dollar limits, time limits, or review criteria. This also suggests that consideration as a new application is the most appropriate course. Because the application will be new, it will be easier to conform to the new application requirements, which should be an advantage to the applicant in the review process. Additionally, submission of a new application will allow the applicant to benefit fully from the NIH policy that allows an applicant to submit two resubmissions (see http://grants.nih.gov/grants/policy/amendedapps.htm).

NEW APPLICATIONS: The new application must be submitted on the scheduled due dates for new applications (see http://grants.nih.gov/grants/funding/submissionschedule.htm). It must not include an Introduction describing the changes and improvements made and the text must not be marked to indicate the changes. Although the investigator may still benefit from the previous review, the applicant should not explicitly address reviewers' comments. The reviewers will not be provided with the previous Summary Statement. The investigator will be allowed to submit the new application and up to two resubmissions of this application, should that be necessary.

POLICY: This general policy on application resubmission, stated below, applies to all grant mechanisms that might be solicited via an RFA and to instances where there is a change in mechanism. There may, however, be exceptions to this policy, which will be clearly identified in the original RFA or in a follow-up RFA.

1. When an application that was submitted in response to an RFA is not funded and the investigator wishes to resubmit an application on this topic as an investigator-initiated application, it is to be submitted as a **new** application, unless provisions for a resubmission are clearly delineated in the RFA. In addition, if a subsequent RFA specifically solicits resubmissions of unfunded applications from a previous RFA, the instructions in the second RFA should be followed. In all other cases, applications submitted in response to an RFA and then resubmitted as an investigator-initiated application must be submitted as a **new** application.
2. When a previously unfunded application, originally submitted as an investigator-initiated application is to be submitted in response to an RFA, it is to be prepared as a **new** application.
3. When an unfunded application that was reviewed for a particular research grant mechanism (for example, R01) is to be submitted for a different grant mechanism (for example, R03), it is to be prepared as a **new** application.

C. Revised NIH Policy on Submission of a Revised (Amended) Application

See: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-041.html.

The NIH will not consider a third resubmission (A3) or higher resubmission to an application for extramural support. There is no longer a time limit for the submission of the first and second resubmissions (A1 and A2). This policy applies to all NIH extramural funding mechanisms.

In submitting a resubmission application, it is worth noting that a lengthy hiatus after the initial submission may be marked by significant advances in the scientific field and the comments of the reviewers may no longer be relevant. PDs/PIs and their institutions need to exercise their best judgment in determining the advisability of submitting a resubmission application after several years have elapsed.

The policy limiting the number of resubmissions was established following analysis of data indicating that investigators who receive initial funding for a resubmission application have a lower success rate in obtaining support for a follow-on renewal application. The likelihood of subsequent success decreased

with an increasing number of resubmissions. After three reviews, it was felt that it was time for investigators to take a fresh approach to their research proposals.

Investigators who have submitted three versions of an application and have not been successful often ask NIH staff how different the next application submitted has to be to be considered a new application. It is recognized that investigators are trained in a particular field of science and are not likely to make drastic changes in their research interests; however, a new application following three reviews is expected to be substantially different in content and scope with more significant differences than are normally encountered in a resubmission application. Simply re-wording the title and/or Specific Aims or incorporating minor changes in response to comments in the previous Summary Statement does not constitute a substantial change in scope or content. Changes to the Research Plan should produce a significant change in direction and approach for the research project. Thus, a new application would include substantial changes in all sections of the Research Plan, particularly the Specific Aims and the Research Design and Methods sections.

In the referral process, NIH staff look at all aspects of the application, not just the title and Description (abstract). Requesting review by a different review committee does not affect the implementation of this policy. When necessary, previous applications are analyzed for similarities to the present one. Thus, identical applications or those with only minor changes will not be accepted for review.

D. Policy on the Acceptance for Review of Unsolicited Applications That Request $500,000 or More in Direct Costs

Applicants must seek agreement to accept assignment from Institute/Center staff at least six weeks prior to the anticipated submission of any application requesting $500,000 or more in direct costs for any year. Note for the purposes of determining whether or not this policy applies, this $500,000 limit now excludes any consortium F&A costs.

The NIH supports research projects with large budgets but needs to consider such awards as early as possible in the budget and program planning process. Regardless of the merit of the application or the budget justification, unanticipated requests for unusually high amounts of direct costs are difficult for NIH to manage. It is in the best interest of all parties if applicants anticipating large direct costs contact the appropriate NIH program staff as early as possible to ensure that an Institute/Center (IC) would be willing to accept the application.

Applicants must seek agreement from IC staff at least six weeks prior to the anticipated submission of any application requesting $500,000 or more in direct costs for any year. Note for the purposes of determining whether or not this policy applies, this limit now excludes any consortium F&A costs. If the proposed budget excluding consortium F&A costs equals or exceeds the $500,000 level, then prior approval is required. If staff is contacted less than six weeks before submission, there may be insufficient time to make a determination about assignment prior to the intended submission date. If the requested dollars are significantly greater than $500,000, then approval should be sought even earlier.

This prior acceptance policy does not apply to applications submitted in response to RFAs or in response to other Announcements that include specific budgetary limits. Such applications must be responsive to any budgetary limits specified; however, any specified budgetary limit now excludes consortium F&A costs.

PROCEDURES

- An applicant planning to submit a grant application with $500,000 or more in direct costs for any year (excluding consortium F&A costs) is required to contact in writing or by telephone NIH IC program staff. This contact should be made during the development process of the application but no later than six weeks before the anticipated submission date. If the IC is willing to accept assignment of the application for consideration of funding, the staff will notify the Center for Scientific Review before the application is submitted.
- The PD/PI must include a cover letter with the application. That cover letter must identify the program staff member contacted and the Institute/Center that has agreed to accept assignment of the application.
- An application received without indication of prior staff concurrence and identification of program staff contacted will be returned to the applicant without review. Therefore, NIH strongly encourages applicants to contact appropriate IC staff at the earliest possible time.

For additional information about this policy, contact the program staff at any Institute/Center. Applicants who are uncertain about which IC may have the greatest interest in the research for which support is sought should contact the NIH CSR Receipt and Referral Office at (301) 435-0715.

SBIR/STTR applicants are NOT required to obtain pre-approval to submit an application if the budget exceeds $500K in direct costs per year. The $500K Policy does not apply to applications submitted in response to RFAs or other solicited applications, and SBIR/STTRs are solicited applications. In addition, the budget levels set for SBIR/STTRs are statutory guidelines, not caps.

However, applicants are very strongly encouraged to contact Institute/Center Program Staff before submitting an application in which the budget and/or project period deviates from the SBIR or STTR statutory guidelines. While the Phase I and Phase II award levels are guidelines that allow for applicants to propose a budget and project period appropriate for completion of the research project, deviations from the guidelines should be discussed with appropriate NIH staff listed in the Awarding Component/Agency Contact Information Table (http://grants.nih.gov/grants/funding/sbirsttr1/SBIR_STTR_ContactInfo.pdf) prior to submission of the application.

E. Resource Sharing

1) Data Sharing Policy: All investigator-initiated applications with direct costs of $500,000 or greater in any single year will be expected to address data-sharing in their application. Applicants are encouraged to discuss their data-sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application as described at http://grants.nih.gov/grants/guide/ notice-files/NOT-OD-02-004.html.

Applicants are reminded that agreement to accept assignment of applications $500,000 or greater must be obtained at least six weeks in advance of the anticipated submission date. Instructions related to the data-sharing policy as it is applied to applications and proposals responding to a specific Request for Application (RFA) or Request for Proposals (RFP) will be described in the specific solicitation. In some cases, Program Announcements (PA) may request data-sharing plans for applications that are less than $500,000 direct costs in any single year. Reviewers will not factor the proposed data-sharing plan into the determination of scientific merit or priority score. Program staff will be responsible for overseeing the data-sharing policy and for assessing the appropriateness and adequacy of the proposed data-sharing plan.

NIH recognizes that data-sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule. As NIH stated in the March 1, 2002 draft data-sharing statement (http://grants.nih.gov/grants/guide/notice-

files/NOT-OD-02-035.html), the rights and privacy of people who participate in NIH-sponsored research must be protected at all times. Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects. When data-sharing is limited, applicants should explain such limitations in their data-sharing plans.

Under the Small Business Act, SBIR grantees may withhold their data for 4 years after the end of the award. The Small Business Act provides authority for NIH to protect from disclosure and nongovernmental use all SBIR data developed from work performed under an SBIR funding agreement for a period of 4 years after the closeout of either a Phase I or Phase II grant unless NIH obtains permission from the awardee to disclose these data. The data rights protection period lapses only upon expiration of the protection period applicable to the SBIR award, or by agreement between the small business concern and NIH.

For more information on data-sharing, please see our website at http://grants.nih.gov/grants/policy/data_sharing/.

2) Sharing Model Organisms: All applications where the development of model organisms is anticipated are to include a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources or state appropriate reasons why such sharing is restricted or not possible. Model organisms include but are not restricted to mammalian models, such as the mouse and rat; and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

The adequacy of plans for sharing model organisms will be considered by the reviewers when a competing application is evaluated. Reviewers will be asked to describe their assessment of the sharing plan in an administrative note, and, normally, will not include their assessment in the overall priority score.

Note unlike the data sharing requirement above, this requirement is for **all** applications.

For additional information on this policy, see the NIH Model Organism for Biomedical Research Website at: http://www.nih.gov/science/models/ and NIH Guide Notices OD-04-042: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html, and OD-04-066: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-066.html.

F. Inventions and Patents

According to NIH Grants Policy and Federal law, NIH recipient organizations must promptly report all inventions that are either conceived or first actually reduced to practice using NIH funding. Invention reporting compliance is described at http://www.iedison.gov. Grantees are encouraged to submit reports electronically using Interagency Edison (http://www.iedison.gov). Information from these reports is retained by the NIH as confidential and submission does not constitute any public disclosure. Failure to report as described at 37 CFR Section 401.14 is a violation of 35 U.S.C. 202 and may result in loss of the rights of the recipient organization. Inquiries or correspondence should be directed to: Division of **Extramural Inventions and Technology Resources, Office of Policy for Extramural Research Administration, OER, NIH, 6705 Rockledge Drive, Suite 310, MSC 7980, Bethesda, MD 20892-7980, Telephone: (301) 435-1986.**

G. Just-In-Time Policy

Several elements of an application are no longer required at the time the application is submitted. Instead, this information will be requested later in the review cycle (i.e., "just-in-time") to ensure that it is current. The information eligible for just-in-time submission includes:

- **Current Other Support**: See Other Support section for policy information. For all Key Personnel, provide details on how you would adjust any budgetary, scientific, or effort overlap if this application is funded.
- For **Career Development Award** applicants, information on all active support for the candidate, sponsor(s), co-sponsor(s), and Key Personnel may be requested by the awarding component prior to award.
- Certifications:
- If human subjects are involved, provide the assurance type and number (if not previously provided) and the Certification of IRB Review and Approval. Pending or out-of-date approvals are not acceptable.
- If vertebrate animals are involved and this information was not previously provided on the Research & Related Other Project Information Component of the application, provide assurance number, verification of IACUC approval with date, and any IACUC-imposed changes. Pending or out-of-date approvals are not acceptable.
- **Human Subjects Education:** For grants involving Human Subjects, provide certification that each person identified under Key Personnel involved in the design or conduct of research involving human subjects has completed an educational program in the protection of human subjects. For further information refer to the separate section on Required Education in the Protection of Human Research Participants.

In addition, applicants for **Research Career Development Awards** will be asked to provide detailed, categorical budget and narrative justification pages prior to award.

Applicants are advised to submit this information (countersigned by an authorized business official) only when requested by the awarding component. Guidance for submitting this information will be provided at the time of the request. Alternatively, this information may now be submitted using the Just-In-Time feature of the eRA Commons found in the **Status** section. For information on the Commons see: https://commons.era.nih.gov/ commons/index.jsp.

H. Other Support

Do not submit information on Other Support with the application beyond that required in the biographical sketch. If this information is included at the time of application, processing may be delayed or the application may be returned to the applicant without review.

Information on Other Support is required for all applications that are to receive grant awards; NIH will request complete and up to date information from applicants at an appropriate time *after peer review*. The Institute/Center scientific program and grants management staff will review this information prior to award.

Don't confuse "Research Support" with "Other Support." Though they sound similar, these parts of the application are very different. As part of the biosketch section of the application, "Research Support"

highlights your accomplishments, and those of your colleagues, as scientists. It is used by reviewers for the "investigator" review criterion. In contrast, "Other Support" information is required for all applications that are selected to receive grant awards. NIH staff will request complete and up-to-date "other support" information from you *after* peer review. This information will be used to check that the proposed research has not already been Federally-funded.

Other Support Policy

Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts are not included.

Information on Other Support assists awarding agency staff in the identification and resolution of potential overlap of support. Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. The goals in identifying and eliminating overlap are to ensure that sufficient and appropriate levels of effort are committed to the project; that there is no duplication of funding for scientific aims, specific budgetary items, or an individual's level of effort; and that only funds necessary to the conduct of the approved project are included in the award.

Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salary) are requested in an application but are already provided for by another source.

Commitment overlap occurs when a person's time commitment exceeds 100 percent, whether or not salary support is requested in the application. While information on other support is only requested for Key Personnel (excluding consultants), no individuals on the project may have commitments in excess of 100 percent.

Scientific overlap occurs when: (1) substantially the same research is proposed in more than one application or is submitted to two or more different funding sources for review and funding consideration, or (2) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more applications or awards, regardless of the funding source. Potential scientific overlap is to be addressed by the SRG *only* by its identification in an Administrative Note in the Summary Statement.

Resolution of Overlap. Resolution of overlap occurs at the time of award in conjunction with applicant institution officials, the PD/PI, and awarding agency staff.

Other Support Information

Information on Other Support should be submitted ONLY when requested by the NIH Institute/Center (IC).

There is no form page for Other Support. Follow the sample format provided below. The sample is intended to provide guidance regarding the type and extent of information requested.

The following instructions should be followed in completing the information:

- Information on active and pending Other Support is required for Key Personnel, excluding consultants. For individuals with no active or pending support, indicate "None." Neither the application under consideration nor the current PHS award for this project should be listed as Other Support. Do not include Other Support for individuals listed as "Other Significant Contributors" unless their involvement has changed so that they now meet the definition of "key personnel."

- If the support is provided under a consortium/subcontract arrangement or is part of a multiproject award, indicate the project number, PD/PI, and source for the overall project, and provide all other information for the subproject only.

Instructions for Selected Items

Project Number: If applicable, include a code or identifier for the project.

Source: Identify the agency, institute, foundation, or other organization that is providing the support.

Major Goals: Provide a brief statement of the overall objectives of the project, subproject, or subcontract.

Dates of Approved/Proposed Project: Indicate the inclusive dates of the project as approved/proposed. For example, in the case of NIH support, provide the dates of the approved/proposed competitive segment.

Annual Direct Costs: In the case of an active project, provide the current year's direct cost budget. For a pending project, provide the proposed direct cost budget for the initial budget period.

Percent Effort/Person Months: For an active project, provide the level of actual effort in person months (even if unsalaried) for the current budget period. Person months should be classified as academic, calendar and/or summer. For a pending project, indicate the level of effort in person months as proposed for the initial budget period. In cases where an individual's appointment is divided into academic and summer segments, indicate the proportion of each devoted to the project.

Overlap: After listing all support, summarize for each individual any potential overlap with the active or pending projects and this application in terms of the science, budget, or an individual's committed effort.

Sample Format for Other Support

OTHER SUPPORT

Format

NAME OF INDIVIDUAL
ACTIVE/PENDING

Project Number (PD/PI) Source Title of Project *(or Subproject)* The major goals of this project are…	Dates of Approved/Proposed Project Annual Direct Costs	Person Months (Cal/Acad/ Summer)

OVERLAP *(summarized for each individual)*

Samples

ANDERSON, R.R.
ACTIVE

2 R01 HL 00000-13 (Anderson) 3/1/1997 – 2/28/2002 3.60 calendar
NIH/NHLBI $186,529
Chloride and Sodium Transport in Airway Epithelial Cells
The major goals of this project are to define the biochemistry of chloride and sodium transport in airway epithelial cells and clone the gene(s) involved in transport.

5 R01 HL 00000-07 (Baker) 4/1/1994 – 3/31/2002 1.20 calendar
NIH/NHLBI $122,717
Ion Transport in Lungs
The major goal of this project is to study chloride and sodium transport in normal and diseased lungs.

R000 (Anderson) 9/1/1996 – 8/31/2002 1.20 calendar
Cystic Fibrosis Foundation $43,123
Gene Transfer of CFTR to the Airway Epithelium
The major goals of this project are to identify and isolate airway epithelium progenitor cells and express human CFTR in airway epithelial cells.

PENDING

DCB 950000 (Anderson) 12/01/2002 – 11/30/2004 2.40 calendar
National Science Foundation $82,163
Liposome Membrane Composition and Function
The major goals of this project are to define biochemical properties of liposome membrane components and maximize liposome uptake into cells.

OVERLAP

There is scientific overlap between aim 2 of NSF DCB 950000 and aim 4 of the application under consideration. If both are funded, the budgets will be adjusted appropriately in conjunction with agency staff.

RICHARDS, L.
NONE

HERNANDEZ, M.
ACTIVE

5 R01 CA 00000-07 (Hernandez) 4/1/1995 – 3/31/2002 3.60 academic
NIH/NCI
Gene Therapy for Small Cell Lung Carcinoma
The major goals of this project are to use viral strategies to express the normal p53 gene in human SCLC cell lines and to study the effect on growth and invasiveness of the lines.

5 P01 CA 00000-03 (Chen)	7/1/2000 – 6/30/2002	1.80 academic
NIH/NCI	$104,428 (sub only)	3.00 summer

Mutations in p53 in Progression of Small Cell Lung Carcinoma
The major goals of this subproject are to define the p53 mutations in SCLC and their contribution to tumor progression and metastasis.

BE 00000 (Hernandez)	9/1/1996 – 8/31/2002	1.80 academic
American Cancer Society	$86,732	

P53 Mutations in Breast Cancer
The major goals of this project are to define the spectrum of p53 mutations in human breast cancer samples and correlate the results with clinical outcome.

OVERLAP
Potential commitment overlap for Dr. Hernandez between 5 R01 CA 00000-07 and the application under consideration. If the application under consideration is funded with Dr. Hernandez committed at 3.60 person months, Dr. Hernandez will request approval to reduce her months on the NCI grant.

BENNETT, P.
ACTIVE

Investigator Award (Bennett)	9/1/1999 – 8/31/2002	9.00 calendar
Howard Hughes Medical Institute	$581,317	

Gene Cloning and Targeting for Neurological Disease Genes
This award supports the PD/PI's program to map and clone the gene(s) implicated in the development of Alzheimer's disease and to target expression of the cloned gene(s) to relevant cells.

OVERLAP: None

I. Graduate Student Compensation

The maximum amount awarded by the NIH for the support of a graduate student on a research grant or a cooperative agreement is tied to the National Research Service Award (NRSA) zero-level stipend in effect at the time the grant award is issued. The schedule for NRSA stipends can be found at http://grants.nih.gov/training/nrsa.htm. Consistent with cost principles for educational institutions described in Office of Management and Budget (OMB) Circular A-21 at section J.41.b (http://www.whitehouse.gov/omb/ circulars/a021/a021.html), the compensation of graduate students supported by research grants must be reasonable. These operating principles associated with the compensation of students performing necessary work on NIH funded research projects are described in detail in the *NIH Grants Policy Statement* at http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part6.htm. As before, the amount provided for compensation includes salary or wages, fringe benefits, and tuition remission.

These guidelines apply to graduate students at the grantee institution who are supported by NIH research grants and cooperative agreements and not to individuals supported by NRSA training grants and fellowships. NIH has separate appropriations to support research training under the NRSA authorization at Section 487 of the Public Health Service Act.

The stipends provided to recipients of NRSA support offset the cost-of-living during the period of training and are not considered equivalent to salaries or other forms of compensation provided to individuals supported on research grants. Nevertheless, the entry-level postdoctoral NRSA stipend provides a useful benchmark for an award amount that approximates a reasonable rate of compensation for graduate students. Anticipated escalations in NRSA stipends (see http://grants.nih.gov/training/nas_report/NIHResponse.htm) in future years should permit annual increases in the maximum award amount for such individuals.

For all new and competing grant and cooperative agreement awards, the NIH will provide reasonable amounts for graduate compensation, consistent with the requested budget for the position(s) and up to the currently effective NRSA zero postdoctoral stipend level. NIH staff will review the compensation requested for graduate students on competing and cooperative agreement applications for which a detailed budget is submitted. NIH will neither request nor accept budgets for those applications using a modular budget format solely for the purpose of reviewing graduate student compensation. However, applicants should use this policy when estimating the number of modules.

When submitting detailed budgets that request support for a graduate student, grantees are reminded to request actual institutional-based compensation and to provide information justifying the requested compensation level. If this information is not provided, NIH staff will obtain this information from the institution's business office for any request that appears excessive.

NIH institutes and centers will review the requested compensation level and, if considered reasonable, will award the actual amount requested, up to a maximum equal to the NRSA zero level postdoctoral stipend. Revised budgets submitted solely to adjust requested levels for graduate students will not be accepted.

Institutions may continue to rebudget funds to charge more than the awarded amount provided that OMB cost principles requiring reasonable compensation are observed. In general, graduate student compensation will not be considered reasonable if in excess of the amount paid to a first-year postdoctoral scientist at the same institution performing comparable work.

J. DUNS Number

Applicant organizations **must have** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. Form Page 1 includes a field for the organization's DUNS number. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An authorized organizational official should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an authorized organizational official should complete the US D&B D-U-N-S Number Request Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual PDs/PIs do not need to register for a DUNS.

K. Public Access Policy

Since May 2, 2005, NIH-funded investigators are requested to submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript upon acceptance for publication, resulting from research supported, in whole or in part, with direct costs from NIH. The author's final manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process.

This policy applies to all research grant and career development award mechanisms, cooperative agreements, contracts, Institutional and Individual Ruth L. Kirschstein National Research Service

Awards, as well as NIH intramural research studies. The policy is intended to: 1) create a stable archive of peer-reviewed research publications resulting from NIH-funded research to ensure the permanent preservation of these vital published research findings; 2) secure a searchable compendium of these peer-reviewed research publications that NIH and its awardees can use to manage more efficiently and to understand better their research portfolios, monitor scientific productivity, and ultimately, help set research priorities; and 3) make published results of NIH-funded research more readily accessible to the public, health care providers, educators, and scientists.

Additional information can be found at: http://publicaccess.nih.gov/policy.htm.

L. NIH Plans to Transition to the SF424 (R&R) Application and Electronic Submission through Grants.gov

As first announced in August 2005 (See NOT-OD-05-067), NIH is transitioning from the PHS398 application to the SF424 (R&R) application and electronic submission through Grants.gov. This transition is being done by grant mechanism. Applicants should refer to the Timeline to determine when a particular mechanism has transitioned to the new form and electronic submission. Information on Transition Strategy and Timeline can be found at: http://era.nih.gov/ElectronicReceipt/strategy_timeline.htm.

As part of the ongoing effort to keep the PHS398 and the SF424 (R&R) synchronized, changes in terminology are being implemented throughout the PHS398 instructions. Specifically, you will see dual references to types of applications:

- "Competing Continuation" is now termed "Renewal"
- "Revision" or "Amendment" is now termed "Resubmission"
- "Competing Supplement" is now termed "Revision"

During this transition period, both terms are being used together; i.e., "Competing Continuation/Renewal."

For more information on NIH's transition plans, see the website for Electronic Submission of Grant Applications: http://era.nih.gov/ElectronicReceipt/.

II. Assurances and Certifications

Each application to the PHS requires that the following assurances and certifications be verified by the Authorized Organizational Representative (a.k.a. Signing Official) for the Applicant Organization on the SF424 (R&R) cover component (Item 18) of the application.

PI and SO Verification

After the PI and SO successfully submit an application, they will receive an automatically generated email requesting them to view and verify (or reject) the application on-line in the Commons. To do this, the PI and SO need to:

1. Make sure they can log onto the NIH eRA Commons. Before they receive the email, they should be sure to know their Commons account names and passwords.
2. Verify the electronic grant application via the NIH eRA Commons. Complete instructions on the verification process are in the Applicant Package.

The assurances listed and explained below may or may not be applicable to your project, program, or type of applicant organization. There are a number of additional public policy requirements with which applicants and grantees must comply. Contact your institution's research grant administrative office or consult the *NIH Grants Policy Statement* for additional information. A copy of the NIH Grants Policy Statement may be obtained from the NIH website (http://grants.nih.gov/grants/policy/ policy.htm). When verifying the submitted application in the eRA Commons, the duly authorized representative of the applicant organization certifies that the applicant organization will comply with the following policies, assurances and/or certifications:

A. Human Subjects Research

(Also see Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan.)

The DHHS regulations for the protection of human subjects provide a systematic means, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the DHHS. The regulations stipulate that an applicant organization, whether domestic or foreign, bears responsibility for safeguarding the rights and welfare of human subjects in DHHS-supported research activities. The regulations require that applicant organizations proposing to involve human subjects in non-exempt research file a written Assurance of Compliance with the Office for Human Research Protections (OHRP), establishing appropriate policies and procedures for the protection of human subjects. These regulations, 45 CFR Part 46, Protection of Human Subjects, are available from the OHRP, Department of Health and Human Services, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20854, 1-866-447-4777 or (240) 453-6900.

No non-exempt research involving human subjects can be conducted under a DHHS-sponsored award unless that organization is operating in accordance with an approved Assurance of Compliance and provides verification that an appropriate Institutional Review Board (IRB) has reviewed and approved the proposed activity in accordance with the DHHS regulations. An award will not be made to an applicant unless that applicant is affiliated with an assured organization that accepts responsibility for compliance with the DHHS regulations. Foreign applicant organizations must also comply with the provisions of the regulations as cited in section 46.101(h).

The Center of Biologics Evaluation and Research (CBER) at FDA regulates the use of biological products in humans, at the investigational and marketing phases, including somatic cell therapies and gene

therapies. If your work involves these areas or preclinical research that will support later work in these areas, please see the Office of Recombinant DNA Activities Web site at http://www4.od.nih.gov/oba/.

Note: Under HHS regulations to protect human subjects from research risks, certain research areas are exempt. (See Exemption Categories). Nonetheless, with the exception of research projects that meet the criteria for Exemption 4, studies that are exempt from the human subjects regulations must still address the inclusion of women and minorities and children in the study design. Therefore, applications will be evaluated for compliance with this policy. Research involving the collection or study of existing data, documents, records, pathological specimens, diagnostic specimens, or tissues that can be linked by the investigator(s) to living individuals is considered human subjects research.

Federal requirements to protect human subjects apply to research on human specimens (such as cells, blood, and urine), residual diagnostic specimens and/or medical information, when these specimens and/or medical information are from living individuals who are individually identifiable to the investigator(s).

Vulnerable Populations

Investigators who conduct research involving pregnant women, human fetuses and neonates, prisoners, or children must follow the provisions of the regulations in Subparts B, C, and D of 45 CFR Part 46, respectively, which describe the additional protections required for these populations. Relevant information may be obtained at the OHRP website (http://www.hhs.gov/ohrp/policy/index.html).

REMINDER: HHS regulations at **45 CFR Part 46, subpart C** describe requirements for additional protections for research involving prisoners as subjects or individuals who become prisoners after the research has started. Refer to: http://www.hhs.gov/ohrp/humansubjects/guidance/prisoner.htm for complete instructions.

Exemptions 1-6 (See Human Subjects Research Supplement) do not apply to research involving prisoners or subjects who become prisoners (see Subpart C). Although Exemptions 1 and 3-6 apply to research involving children (see Subpart D), Exemption 2 can only be used for research involving educational testing or observations of public behavior of children when the investigator(s) do not participate in the activities being observed.

Data and Safety Monitoring

NIH requires oversight and monitoring of all human intervention studies to ensure the safety of participants and the validity and integrity of the data. A data and safety monitoring plan is required for each clinical trial. This policy is in addition to any monitoring requirements imposed by 45 CFR Part 46.

The detailed data and safety monitoring plans should be submitted to the applicant's IRB and must subsequently be provided to the funding IC for approval prior to the accrual of human subjects. The level of monitoring should be commensurate with the risks and the size and complexity of the clinical trial. The establishment of data safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risk to the participants. A DSMB also may be appropriate for clinical trials if the studies have multiple clinical sites, are blinded (masked), or employ high-risk interventions or involve vulnerable populations.

Summary reports of adverse events must be provided to the NIH funding institute/center and to individual IRBs in order for them to address reports related to the site for which they have responsibility. Grantees should address questions on this subject to the NIH Program Official.

Further information concerning these requirements is contained in several *NIH Guide for Grants and Contracts* notices (http://grants.nih.gov/grants/guide/notice-files/not98-084.html) and (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html).

Required Education in the Protection of Human Research Participants

NIH requires education on the protection of human research participants for all individuals identified as Key Personnel who will be involved in the design or conduct of human subjects research before funds are awarded for applications or contract proposals involving human subjects. For information relating to this requirement, see the following notices: (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html and http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-061.html), and Frequently Asked Questions (http://grants.nih.gov/grants/policy/hs_educ_faq.htm). Prior to award, applicants will be required to provide a description of education completed in the protection of human subjects for all Key Personnel. While NIH does not endorse specific programs, there are curricula available that can provide guidance or that can be modified to provide training in this area. See http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp for computer-based training developed for NIH that can be downloaded at no charge. For information on facilitating education and developing curricula, see http://www.nih.gov/sigs/bioethics.

B. Research on Transplantation of Human Fetal Tissue

When verifying the submitted application in the eRA Commons, the duly authorized representative of the applicant organization certifies that if research on the transplantation of human fetal tissue is conducted, the applicant organization will make available, for audit by the Secretary, DHHS, the physician statements and informed consents required by section 498A (b)(2) and (c) of the Public Health Service Act, 42 U.S.C. 289g (b)(2) and (c), or ensure DHHS access to those records, if maintained by an entity other than the applicant organization.

C. Research Using Human Embryonic Stem Cells

http://stemcells.nih.gov/index.asp

When verifying the submitted application in the eRA Commons, the duly authorized representative of the applicant organization certifies that if research using human embryonic stem cells is proposed, the applicant organization will be in compliance with the "Notice of Extended Receipt Date and Supplemental Information Guidance for Applications Requesting Funding that Proposes Research with Human Embryonic Stem Cells" (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-006.html).

D. NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research

It is the policy of NIH that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving clinical research unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of an Institute/Center Director based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. All NIH-supported biomedical and behavioral research involving human subjects is defined as clinical research. This policy applies to research subjects of all ages.

The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design appropriate to the scientific objectives of the study. The Research Plan should describe the composition of the proposed study population in terms of sex/gender and racial/ethnic group, and provide a rationale for selection of such subjects. Such a plan should contain a description of the proposed outreach programs for recruiting women and minorities as participants. See http://grants.nih.gov/grants/funding/women_min/women_min.htm.

NIH Policy On Reporting Race And Ethnicity Data: Subjects In Clinical Research

Also see "**Guidance on Reporting Ethnicity/Race and Sex/Gender in Clinical Research"** in Human Subjects Research Supplemental Instructions**.**

The NIH has adopted the 1997 Office of Management and Budget (OMB) revised minimum standards for maintaining, collecting, and presenting data on race and ethnicity for all grant, contract, and intramural proposals and for all active research grants, cooperative agreements, contracts, and intramural projects. The minimum standards are described in the 1997 OMB Directive 15, http://www.whitehouse.gov/omb/fedreg/ombdir15.html.

The 1997 OMB revised minimum standards include two ethnic categories (Hispanic or Latino, and Not Hispanic or Latino) and five racial categories (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White). The categories in this classification are social-political constructs and should not be interpreted as being anthropological in nature. Using self-reporting or self-identification to collect an individual's data on ethnicity and race, investigators should use two separate questions with ethnicity information collected first followed by the option to select more than one racial designation.

Collection of this information and use of these categories is required for research that meets the NIH definition of clinical research.

Revised Minimum Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity

The following are the ethnic and racial definitions for the minimum standard categories (1997 OMB Directive 15):

Ethnic Categories:

Hispanic or Latino: A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term "Spanish origin" can also be used in addition to "Hispanic or Latino."

Not Hispanic or Latino

Racial Categories:

American Indian or Alaska Native: A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment.

Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

Black or African American: A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."

Native Hawaiian or Other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

White: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Using respondent self-report or self-identification to collect an individual's data on ethnicity and race, investigators should use two separate questions with ethnicity information collected first followed by the option to select more than one racial designation.

When reporting these data in the aggregate, investigators should report: (a) the number of respondents in each ethnic category; (b) the number of respondents who selected only one category for each of the five racial categories; (c) the total number of respondents who selected multiple racial categories reported as the "number selecting more than one race"; and (d) the number of respondents in each racial category who are Hispanic or Latino. Investigators may provide the detailed distributions, including all possible combinations, of multiple responses to the racial designations as additional information. However, more detailed items should be designed in a way that they can be aggregated into the required categories for reporting purposes. NIH is required to use these definitions to allow comparisons to other Federal databases, especially the census and national health databases. Federal agencies will not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

E. NIH Policy on Inclusion of Children

(See definition of "child.")

Research involving children must comply with the NIH Policy and Guidelines on the Inclusion of Children in Clinical Research. The following excerpts provide the key policy statements. Investigators should obtain full copies of the Policy and Guidelines from NIH staff, or from the NIH grants Web site under http://grants.nih.gov/grants/funding/children/children.htm.

NIH policy requires that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH unless there are clear and compelling reasons not to include them. Therefore, proposals for clinical research must include a description of plans for including children. If children will be excluded from the research, the application or proposal must present an acceptable justification for the exclusion.

In addition, the involvement of children as subjects in research must be in compliance with all applicable subparts of 45 CFR Part 46 as well as with other pertinent Federal laws and regulations.

Additionally, IRBs have special review requirements to protect the well-being of children who participate in research. These requirements relate to risk, benefit, parental/guardian consent, and assent by children, and to research involving children who are wards of the state or of another institution. The local IRB approves research that satisfies the conditions set forth in the regulations.

F. Vertebrate Animals

NIH no longer requires Institutional Animal Care and Use Committee (IACUC) approval of the proposed research **before NIH peer review** of an application (http://grants.nih.gov/ grants/guide/notice-files/NOT-OD-02-064.html).

In August, 2002 NIH announced an IACUC "just-in-time" process for applications submitted for the October 1, 2002 deadline or other deadlines where the applications had a May/June 2003 Council review. The PHS policy requirement that no award may be made without an approved Assurance and without verification of IACUC approval remains in effect. The new policy gave institutions flexibility in the timing of IACUC review relative to the submission of an application and the verification of IACUC review. The policy does not require that IACUC approval be deferred. Institutional officials retain the discretion to require IACUC approval prior to NIH peer review in circumstances of their choosing if

deemed necessary. As part of the NIH peer review process, the scientific review group will continue to address the adequacy of animal usage and protections in the review of an application and will continue to raise any concerns about animal welfare issues. Verification of IACUC approval will be required in a "just-in-time" fashion prior to award.

The PHS *Policy on Humane Care and Use of Laboratory Animals* requires that applicant organizations proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office of Laboratory Animal Welfare (OLAW), establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by the PHS. The PHS policy stipulates that an applicant organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS-supported research activities. This policy implements and supplements the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training* and requires that institutions use the *Guide for the Care and Use of Laboratory Animals* as a basis for developing and implementing an institutional animal care and use program. This policy does not affect applicable state or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act as amended (7 USC 2131 et sec.) and other Federal statutes and regulations relating to animals. These documents are available from the Office of Laboratory Animal Welfare, National Institutes of Health, Bethesda, MD 20892, (301) 496-7163.

The PHS policy defines "animal" as "any live, vertebrate animal used or intended for use in research, research training, experimentation or biological testing or for related purposes."

No PHS award for research involving vertebrate animals will be made to an applicant organization unless that organization is operating in accordance with an approved Animal Welfare Assurance and provides verification that the IACUC has reviewed and approved the proposed activity in accordance with the PHS policy. Applications may be referred by the PHS back to the IACUC for further review in the case of apparent or potential violations of the PHS policy. No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the PHS policy. Foreign applicant organizations applying for PHS awards for activities involving vertebrate animals are required to comply with PHS policy or provide evidence that acceptable standards for the humane care and use of animals will be met.

G. Debarment and Suspension

Executive Order 12549, "Debarment and Suspension," mandated development of a Government-wide debarment and suspension system for nonprocurement transactions with Federal agencies. Executive Order 12689 and Section 2455 of the Federal Acquisition Streamlining Act of 1994 further required Federal agencies to establish regulations for reciprocal Government-wide effect across procurement and nonprocurement debarment and suspension actions. This reciprocity rule is effective for any debarment, suspension or other Government-wide exclusion initiated on or after August 25, 1995.

DHHS regulations implementing Executive Orders 12549 and 12689 and Section 2455 of the Federal Acquisition Regulation are provided in 45 CFR 76, "Government-wide Debarment and Suspension (Nonprocurement)." Changes in this Government-wide requirement (adopted in the November 26, 2003 Federal Register Notice) now implement this as a term and condition of an award.

H. Drug-Free Workplace

DHHS regulations implementing the Drug-Free Workplace Act of 1988 (Public Law 100-690, Title V, Subtitle D) are now provided in 45 CFR 82, "Government-wide Requirements for Drug-Free Workplace

(Financial Assistance)." Changes in this Government-wide requirement (adopted in the November 26, 2003 Federal Register Notice) now implement this as a term and condition of an award.

I. Lobbying

Title 31, United States Code, Section 1352, entitled "Limitation on Use of Appropriated Funds to Influence Certain Federal Contracting and Financial Transactions," generally prohibits recipients of Federal grants and cooperative agreements from using Federal (appropriated) funds for lobbying the Executive or Legislative Branches of the Federal Government in connection with a specific grant or cooperative agreement. Section 1352 also requires that each person who requests or receives a Federal grant or cooperative agreement must disclose lobbying undertaken with non-Federal (nonappropriated) funds. These requirements apply to grants and cooperative agreements exceeding $100,000 in total costs. DHHS regulations implementing Section 1352 are provided in 45 CFR Part 93, "New Restrictions on Lobbying."

The complete Certification Regarding Lobbying is provided below.

"The undersigned (authorized official signing for the applicant organization) certifies, to the best of his or her knowledge and belief that:

"(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

"(2) If any funds other than Federally appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form LLL, "Disclosure of Lobbying Activities," in accordance with its instructions.

"(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

"This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure."

Standard Form LLL, "Disclosure of Lobbying Activities," its instructions, and continuation sheet are available from GrantsInfo, National Institutes of Health, email: GrantsInfo@nih.gov, (301) 435-0714.

J. Nondelinquency on Federal Debt

The Federal Debt Collection Procedure Act, 28 U.S.C. 3201 (e), provides that an organization or individual that is indebted to the United States, and has a judgment lien filed against it, is ineligible to receive a Federal grant. NIH cannot award a grant unless the authorized organizational official of the applicant organization (or individual as in the case of an individual Ruth L. Kirschstein National Research Service Award) certifies, by means of his/her signature on the application, that the organization is not delinquent in repaying any Federal debt. If the applicant discloses delinquency on a debt owed to the

Federal Government, NIH may not award the grant until the debt is satisfied or satisfactory arrangements are made with the agency to which the debt is owed.

K. Research Misconduct

Each institution that receives or applies for a research, research training, or research-related grant or cooperative agreement under the Public Health Service Act must certify that the institution has established administrative policies as required by (1) 42 CFR Part 50, Subpart A, "Responsibilities for PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science" and (2) 42 CFR 94, "Public Health Service Standards for the Protection of Research Misconduct Whistleblowers" (effective on the date set forth in the final rule).

The signature of the official signing for the applicant organization on the SF424 (R&R) cover component (Item 18) of the application serves as certification that:

1. The institution will comply with the requirements of the PHS regulations for dealing with reporting possible scientific misconduct under 42 CFR Part 50, Subpart A, and for protecting research misconduct whistleblowers under 42 CFR Part 94;
2. The institution has established policies and procedures incorporating the provisions set forth in 42 CFR Part 50, Subpart A, and 42 CFR Part 94;
3. The institution will provide its policies and procedures to the Office of Research Integrity upon request; and
4. The institution will submit an Annual Report on Possible Research Misconduct (Form 6349). A copy of Form 6349, covering the previous year, will be automatically sent to all PHS awardees by the Office of Research Integrity each January.

Research Misconduct is defined by the Public Health Service as "fabrication, falsification or plagiarism in proposing, performing, or reviewing research, or in reporting research results."

(a) Fabrication is making up data or results and recording or reporting them.

(b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

(d) Research misconduct does not include honest error or differences of opinion.

For further information, please contact:

U.S. Department of Health and Human Services
Office of Research Integrity
1101 Wootton Parkway, Suite 750
Rockville, MD 20852
AskORI@osophs.dhhs.gov
Phone: (240) 453-8200
Fax: (301) 443-5351.

L. Assurance of Compliance (Civil Rights, Handicapped Individuals, Sex Discrimination, Age Discrimination)

Before a grant award can be made, a domestic applicant organization must certify that it has filed with the DHHS Office for Civil Rights: an Assurance of Compliance (Form HHS 690) with Title VI of the Civil Rights Act of 1964 (P.L. 88352, as amended), which prohibits discrimination on the basis of race, color, or national origin; Section 504 of the Rehabilitation Act of 1973 (P.L. 93-112, as amended), which prohibits discrimination on the basis of handicaps; Title IX of the Education Amendments of 1972 (P.L. 92-318, as amended), which prohibits discrimination on the basis of sex; and the Age Discrimination Act of 1975 (P.L. 94-135), which prohibits discrimination on the basis of age.

The Assurance of Compliance Form HHS 690 is available from http://www.hhs.gov/ocr/ps690.pdf.

Assurance of Compliance Form HHS 690 is now used in lieu of individual assurances: Form HHS 441, Civil Rights; Form HHS 641, Handicapped Individuals; Form HHS 639-A, Sex Discrimination; and Form HHS 680, Age Discrimination.

M. Research Involving Recombinant DNA, including Human Gene Transfer Research

The *National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* apply to all projects (NIH-funded and non-NIH-funded) involving recombinant DNA molecules that are conducted at or sponsored by an institution that receives NIH support for recombinant DNA research. As defined by the *NIH Guidelines*, recombinant DNA molecules are either: (1) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; or (2) DNA molecules that result from the replication of those described in (1). The *NIH Guidelines* set forth principles and standards for safe and ethical conduct of recombinant DNA research and apply to both basic and clinical research studies. The *NIH Guidelines* should be carefully reviewed and implemented to ensure that proper biosafety and containment practices are employed for all projects involving recombinant DNA research, including review by an Institutional Biosafety Committee that meets the requirements of the *NIH Guidelines*. Further, the *NIH Guidelines* include special review and reporting requirements for the conduct of human gene transfer studies (under Appendix M). Failure to comply with the *NIH Guidelines* may result in suspension, limitation, or termination of NIH funds for recombinant DNA research at the organization or a requirement for NIH prior approval of any or all recombinant DNA projects at the organization. A copy of *the NIH Guidelines* is posted at the following URL: http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html and may be obtained from the NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, 301-496-9838.

N. Financial Conflict of Interest

NIH requires grantees and investigators (except Phase I SBIR/STTR applicants) to comply with the requirements of 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." These requirements promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an investigator.

The signature of the Authorized Organizational Representative on the SF424 (R&R) cover component (Item 18) of the application serves as certification of compliance with the requirements of 42 CFR Part 50, Subpart F, including that:

1. There is in effect at the organization a written and enforced administrative process to identify and manage, reduce, or eliminate conflicting financial interests with respect to research projects for which NIH funding is sought.
2. Prior to the expenditure of any NIH funds awarded under a new award, the organization will inform NIH of the existence of any conflicting financial interests of the type covered by 42 CFR 50.605 and assure that the interest has been managed, reduced, or eliminated in accordance with the regulations;
3. The Institution will continue to make similar reports on subsequently identified conflicts; and it will make information available to NIH, upon request, as to how identified conflicting interests have been handled.

O. Smoke- Free Workplace

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

P. PHS Metric Program

Consistent with Government-wide implementing regulations, 15 CFR Part 19, Subpart B and/or any other Government-wide requirements, PHS policy is to support Federal transition to the metric system and to use the metric system of measurement in all grants, cooperative agreements, and all other financial assistance awards. Likewise, measurement values in reports, publications, and other communications regarding grants will be in metric.

Q. Prohibition on Awards to 501(c)4 Organizations That Lobby

Organizations described in section 501(c)4 of the Internal Revenue Code of 1968 that engage in lobbying are not eligible to receive grant/cooperative agreement awards. This is not to be confused with 45 CFR Part 93, Section 1352, “New Restrictions on Lobbying” See “Lobbying.”

R. Prohibited Research

BAN ON FUNDING OF HUMAN EMBRYO RESEARCH (Section 510)

This section continues the current ban that prohibits NIH from using appropriated funds to support human embryo research. Grant, cooperative agreement, and contract funds may not be used for: “(a)…(1) the creation of a human embryo or embryos for research purposes; or (2)research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR Part 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). (b) For purposes of this section, the term `human embryo or embryos' includes any organism not protected as a human subject under 45 CFR Part 46 as of the date of

the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells."

The NIH has published final guidelines on the allowability of Federal funds to be used for research on existing human embryonic stem cell lines. The URL is http://stemcells.nih.gov/index.asp.

LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES (Section 511)

"(a) None of the funds made available in this Act may be used for any activity that promotes the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act (21 U.S.C.812). (b)The limitation in subsection (a) shall not apply when there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that Federally sponsored clinical trials are being conducted to determine therapeutic advantage."

RESTRICTION ON DISTRIBUTION OF STERILE NEEDLES (Section 505)

"Notwithstanding any other provision of this Act, no funds appropriated under this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug."

RESTRICTION ON ABORTIONS (Section 508)

"(a) None of the funds appropriated under this Act, and none of the funds in any trust fund to which funds are appropriated under this Act, shall be expended for any abortion."

S. Select Agent Research

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) is designed to provide protection against misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the United States homeland or other criminal acts. The Act was implemented, in part, through regulations published by CDC at 42 CFR 73 <http://www.cdc.gov/od/sap/docs/42cfr73.pdf>, Select Agents and Toxins.

As a term of award, grantees who conduct research involving Select Agents (see 42 CFR 73 for the list; and 7 CRF 331 and 9 CFR 121 for the relevant animal and plant pathogens) are reminded that they must complete registration with CDC (or USDA, depending on the agent) before using NIH funds. No funds can be used for research involving Select Agents if the final registration certificate is denied.

In addition to the above requirements, research involving **both select agents and recombinant DNA** molecules is also subject to the NIH Guidelines for Research Involving DNA Molecules (NIH Guidelines) (see Section M. Research Involving Recombinant DNA, including Human Gene Transfer Research in this subsection for applicability of these guidelines).

For additional information regarding Select Agent research, see the following websites maintained by NIH, CDC, and USDA:

NIH Office of Extramural Research Select Agent Information:
http://grants.nih.ov/grants/poliyc/select_agent/

Center for Disease Control Select Agent Program: http://www.cdc.gov/od/sap/index.htm

Center for Disease Control Select Agent Program Guidelines: http://www.cdc.gov/od/sap/guidelines.htm

Center for Disease Control Select Agent Program Public Laws and Regulations:
http://www.cdc.gov/od/sap/regulations.htm

Center for Disease Control Select Agent Program Related Links:
http://www.cdc.gov/od/sap/regulations.htm

Animal and Plant Health Inspection Service (APHIS) Select Agent Program:
http://www.aphis.usda.gov/programs/ag_selectagent/

T. Principal Investigator Assurance

The applicant organization agrees to secure and retain a written assurance from the Principal Investigator (PI) prior to submitting an application to the PHS. While this assurance is no longer required as part of the submitted application, it remains a compliance requirement. Therefore, organizations must retain a unique signature and date for each submitted application. This assurance must be available to the sponsoring agency or other authorized HHS or Federal officials upon request. Such an assurance must include at least the following certifications: 1) that the information submitted within the application is true, complete and accurate to the best of the PI's knowledge; 2) that any false, fictitious, or fraudulent statements or claims may subject the PI to criminal, civil, or administrative penalties; and 3) that the PI agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application. If multiple PIs are proposed in an application, this assurance must be retained for all named PIs.

U. Small Business Concern SBIR Verification Statement

Under the SBIR program, the statute requires that the applicant must be eligible at the time of the award. As the responsible Federal Official for administering funds, Grants Management Officials must verify eligibility prior to issuing a Notice of Grant Award. For eligibility clarification see the July 25, 2003, Notice in the *NIH Guide for Grants and Contracts* (NOT-OD-03-053) SMALL BUSINESS ELIGIBILITY REQUIREMENTS FOR APPLICANTS TO THE SMALL BUSINESS INNOVATION RESEARCH (SBIR) AND SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAMS. If the firm is affiliated with any other organization (domestic or foreign), see http://www.sba.gov/regulations/121.

If an application is selected for funding, no award will be issued until the NIH IC receives and accepts the following information, which may be provided in a format of your choosing or by completing a checklist as in the example below:

☐ 1 The above named organization is a for-profit United States small business concern that is at least 51% owned and controlled by one or more *individuals* who are citizens of, or permanent resident aliens in, the United States *or*
The above named organization is a for-profit business concern that is at least 51% owned and controlled by another (one) for-profit business concern that is at least 51% owned and controlled by one or more *individuals* who are citizens of, or permanent resident aliens in, the United States.

☐ 2 The above named organization is independently owned and operated, and has, including its affiliates, 500 or fewer employees.

☐ 3 The *research space* occupied by the above named organization is generally not shared with another organization and is under the control of the above named organization.

☐ 4 All research on the above referenced grant will be *performed in its entirety* in the United States.

☐ 5 The above named PD/PI's *primary employment* is with the above named organization and more than one-half of the above named PD/PI's time will be in the employ of the above named organization at the time of award and for the duration of the project.

☐ 6 It is understood that PHS will not support any *market research* under its SBIR program, as defined in the omnibus SBIR/STTR solicitation, or literature searches that will lead to a new or expanded statement of work, and that if an award is made, any such costs, if requested in the application, will be removed prior to award.

☐ 7 It is understood that if this project is funded, drawing down funds from the payment system serves as the certification that the above-named organization has in place written policies and procedures for financial and business management systems that comply with 45 C.F.R. 74 and the NIH Grants Policy Statement (12/03) and will follow those policies and procedures.

V. Small Business Concern STTR Verification Statement

Under the STTR program, the statute requires that the applicant must be eligible at the time of the award. As the responsible Federal Official for administering funds, Grants Management Officials must verify eligibility prior to issuing a Notice of Grant Award. For eligibility clarification see the July 25, 2003, Notice in the *NIH Guide for Grants and Contract*s (NOT-OD-03-053) SMALL BUSINESS ELIGIBILITY REQUIREMENTS FOR APPLICANTS TO THE SMALL BUSINESS INNOVATION RESEARCH (SBIR) AND SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAMS. If the firm is affiliated with any other organization (domestic or foreign), see http://www.sba.gov/regulations/121.

If an application is selected for funding, no award will be issued until the NIH IC receives and accepts the following information, which may be provided in a format of your choosing or by completing a checklist as in the example below:

☐ 1 The above named organization is a for-profit United States small business concern that is at least 51% owned and controlled by one or more *individuals* who are citizens of, or permanent resident aliens in, the United States (as the regulations currently require) and the above named organization *is not* a subsidiary of another company.

☐ 2 The above named organization is independently owned and operated, and has, including its affiliates, 500 or fewer employees.

☐ 3 The *research space* occupied by the above named organization is generally not shared with another organization and is under the control of the above named organization.

☐ 4 All research on the above referenced grant will be *performed in its entirety* in the United States.

☐ 5 The above named PD/PI has a formal appointment or commitment to the above named organization, which is characterized by an official relationship between the organization and the PD/PI, whose effort on this project will be not less than 10 percent of his or her total professional effort.

☐ 6 It is understood that PHS will not support any *market research* under its STTR program, as defined in the omnibus solicitation, or literature searches that will lead to a new or expanded statement of work, and that if an award is made, any such costs, if requested in the application, will be removed prior to award.

☐ 7 In conducting the joint research and development proposed in this project, the above named applicant will conduct not less than 40% of the work and the research institution named in the application will perform not less than 30% of the work.

☐ 8 It is understood that if this project is funded, drawing down funds from the payment system serves as the certification that the above-named organization has in place written policies and procedures for financial and business management systems that comply with 45 C.F.R. 74 and the NIH Grants Policy Statement (12/03) and will follow those policies and procedures.

III. Definitions

(See also Human Subjects Research Definitions.)

AIDS Related. Includes: (1) projects relating to the etiology, epidemiology, natural history, diagnosis, treatment, or prevention of AIDS; (2) various sequelae specifically associated with the syndrome; and (3) preparation and screening of anti-AIDS agents as well as vaccine development, including both preclinical and clinical studies. Not all applications examining various influences on T-lymphocytes or retroviruses will be appropriate for the expedited AIDS review process. Applications only indirectly related to AIDS will be evaluated by established Scientific Review Groups (SRGs) appropriate to the scientific discipline during regular NIH review cycles and should not be submitted in response to the expedited AIDS receipt dates. Applicants are urged to take note of the yearly NIH Plan for HIV-Related Research and indicate how their application addresses the NIH priorities set forth in that Plan. The Plan can be found on the NIH Office of AIDS Research homepage.

Affiliate. This term has the same meaning as set forth in 13 C.F.R. Part 121 – Small Business Size Regulations, §121.103, *"What is affiliation?"*

Animal. Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes at the applicant organization or any collaborating site or other performance site.

Applicant. The organizational entity that, at the time of award, will qualify as a Small Business Concern (SBC) and that submits a grant application for a funding agreement under the SBIR or STTR program.

Applicant Organization Types.

Federal: A cabinet-level department or independent agency of the Executive Branch of the Federal Government or any component part of such a department or agency that may be assigned the responsibility for carrying out a grant-supported program.

State: Any agency or instrumentality of a state government of any of the United States or its territories.

Local: Any agency or instrumentality of a political subdivision of government below the State level.

Nonprofit: An institution, corporation, or other legal entity no part of whose net earnings may lawfully inure to the benefit of any private shareholder or individual.

For profit: An institution, corporation, or other legal entity, which is organized for the profit or benefit of its shareholders or other owners. A "for profit" organization is considered to be a small business if it is independently owned and operated, if it is not dominant in the field in which research is proposed, and if it employs no more than 500 persons. Also see definition for Small Business Concern.

Small Business Concern: A small business concern is one that, at the time of award of Phase I and Phase II, meets **all** of the following criteria:

1. Is independently owned and operated, is not dominant in the field of operation in which it is proposing, has its principal place of business located in the United States, and is organized for profit.
2. Is at least 51% owned, or in the case of a publicly owned business, at least 51% of its voting stock is owned by United States citizens or lawfully admitted permanent resident aliens.
3. Has, including its affiliates, ***a number of employees not exceeding 500***, and meets the other regulatory requirements found in 13 CFR Part 121. Business concerns, other than investment companies licensed, or state development companies qualifying under the Small Business Investment Act of 1958, 15 U.S.C. 661, et seq., are affiliates of one another when either directly or indirectly, (a) one concern controls or has the power to control the other; or (b) a third-party/parties controls or has the power to control both.

Control can be exercised through common ownership, common management, and contractual relationships. The term "affiliates" is defined in greater detail in 13 CFR 121.3-2(a). The term "number of employees" is defined in 13 CFR 121.3-2(t).

Business concerns include, but are not limited to, any individual (sole proprietorship), partnership, corporation, joint venture, association, or cooperative. Further information may be obtained by contacting the Small Business Administration Size District Office at http://www.sba.gov/size/.

Socially and Economically Disadvantaged Small Business Concern: A socially and economically disadvantaged small business concern is one that is at least 51% owned by (a) an Indian tribe or a native Hawaiian organization, or (b) one or more socially and economically disadvantaged individuals; **and** whose management and daily business operations are controlled by one or more socially and economically disadvantaged individuals.

Women-Owned Small Business Concern: A small business concern that is at least 51% owned by a woman or women who also control and operate it. "Control" in this context means exercising the power to make policy decisions. "Operate" in this context means being actively involved in the day-to-day management.

Co-investigator. An individual involved with the PD/PI in the scientific development or execution of the project. The co-investigator (collaborator) may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement. This individual would typically devote a specific percent of effort to the project and would be identified as Key Personnel. The designation of a co-investigator, if applicable, does not affect the PD/PI's roles and responsibilities as specified in the *Grants Policy Statement*.

Collaborator. An individual involved with the PD/PI in the scientific development or execution of the project. These individuals would typically devote a specific percent of effort to the project and would be identified as Key Personnel. The collaborator may be employed by, or affiliated with, either the grantee organization or an organization participating in the project under a consortium or contractual agreement.

Commercialization. The process of developing markets and producing and delivering products for sale (whether by the originating party or by others). As used here, commercialization includes both government and private sector markets.

Consortium Agreement. A formalized agreement whereby a research project is carried out by the grantee and one or more other organizations that are separate legal entities. Under the agreement, the grantee must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties. These agreements typically involve a specific percent of effort from the consortium organization's PD/PI and a categorical breakdown of costs, such as personnel, supplies, and other allowable expenses, including Facilities and Administrative costs.

Consultant. An individual who provides professional advice or services for a fee, but normally not as an employee of the engaging party. In unusual situations, an individual may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee. To prevent apparent or actual conflicts of interest, grantees and consultants must establish written guidelines indicating the conditions of payment of consulting fees. Consultants may also include firms that provide paid professional advice or services.

Consulting fees. The fee paid by an institution to a salaried member of its faculty is allowable only in unusual cases and only if both of the following conditions exist: (1) the consultation crosses departmental lines or involves a separate operation; and (2) the work performed by the consultant is in addition to his or her regular workload.

In all other cases, consulting fees paid to employees of recipient or cost-type contractor organizations in addition to salary may be charged to PHS grant-supported projects only in unusual situations and when all

of the following conditions exist: (1) the policies of the recipient or contractor permit such consulting fee payments to its own employees regardless of whether Federal grant funds are received; (2) the consulting services are clearly outside the scope of the individual's salaried employment; and (3) it would be inappropriate or not feasible to compensate the individual for these services through payment of additional salary.

For additional clarification on the allowance and appropriateness of consulting fees, refer to the *NIH Grants Policy Statement*.

Contract. An award instrument establishing a binding legal procurement relationship between a funding agency and the recipient, obligating the latter to furnish an end product or service and binding the agency to provide payment therefore.

Cooperative Agreement. A financial assistance mechanism that will have substantial Federal scientific and/or programmatic involvement. Substantial programmatic involvement means that after award, scientific or program staff will assist, guide, coordinate, or participate in programmatic activities beyond the normal stewardship responsibility in the administration of grants. Proposed cooperative agreements will be published as policy announcements, Program Announcements, or Requests for Applications.

Employees. The number of employees of a firm is its average number of persons employed for each pay period over the firm's latest 12 months. Any person on the payroll must be included as one employee regardless of hours worked or temporary status. The number of employees of a firm in business under 12 months is based on the average for each pay period it has been in business.

Equipment. An article of tangible nonexpendable personal property that has a useful life of more than one year and an acquisition cost per unit that equals or exceeds the lesser of the capitalization threshold established by the organization or $5,000.

Essentially Equivalent Work. This term is meant to identify "scientific overlap," which occurs when (1) substantially the same research is proposed for funding in more than one contract proposal or grant application submitted to the same Federal agency; **or** (2) substantially the same research is submitted to two or more different Federal agencies for review and funding consideration; **or** (3) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more proposals or awards, regardless of the funding source.

Expanded Authorities. The operating authorities provided to grantees under certain research grant mechanisms that waive the requirement for NIH prior approval for specified actions. See the *NIH Grants Policy Statement* (http://grants.nih.gov/grants/policy/ nihgps_2003/NIHGPS_Part7.htm#_Toc54600128) and the NIH Guide Notice (http://grants.nih.gov/grants/ guide/notice-files/NOT-OD-01-070.html) which expanded the authorities (other than Phase I carry-over) to include Phase I SBIR/STTR.

Facilities and Administrative (Indirect) Costs. Facilities and Administrative (F&A) Costs are defined as costs that are incurred by a grantee for common or joint objectives and that, therefore, cannot be identified specifically with a particular project or program.

Feasibility. The extent to which a study or project may be done practically and successfully.

Foreign Component. The performance of any significant scientific element or segment of a project outside of the United States, either by the grantee or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities that would meet this definition include, but are not limited to: (1) the involvement of human subjects or animals; (2) extensive foreign travel by grantee project staff for the purpose of data collection, surveying, sampling, and similar activities; or (3) any activity of the grantee that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Foreign travel for consultation is not considered a foreign component.

Full-Time Appointment. The number of days per week and/or months per year representing full-time effort at the applicant/grantee organization, as specified in organizational policy. The organization's policy must be applied consistently regardless of the source of support.

Funding Agreement. Any grant, contract, or cooperative agreement entered into between any Federal agency and any small business concern for the performance of experimental, developmental, or research work, including products or services, funded in whole or in part by the Federal Government.

Grant. A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever the NIH Institute or Center anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities.

Grantee. For purposes of the SBIR and STTR programs, "grantee" means the organization awarded a grant by NIH that is responsible and accountable for the use of the funds provided and for the performance of the grant-supported project or activity. The grantee is the entity legally responsible and accountable to NIH for the performance and financial aspects of the grant-supported project or activity.

Historically Underutilized Business Zone (HUBZone). A small business concern meeting the following criteria:

1. Located in a "historically underutilized business zone" or HUBZone area located in one or more of the following:
    a. A qualified census tract (as defined in section 42(d)(5)(C)(i)(l) of the Internal Revenue Code of 1986; or
    b. A qualified "non-metropolitan county" (as defined in section 143(k)(2)(B) of the Internal Revenue Code of 1986) with a median household income of less than 80 percent of the state median household income or with an unemployment rate of not less than 140 percent of the statewide average, based on U.S. Department of Labor recent data; or
    c. Lands within the boundaries of Federally recognized Indian reservations.
2. Owned and controlled by one or more U.S. Citizens.
3. At least 35% of its employees must reside in a HUBZone.

Innovation. Something new or improved, including research for (1) development of new technologies, (2) refinement of existing technologies, or (3) development of new applications for existing technologies. For the purposes of PHS programs, an example of "innovation" would be new medical or biological products for improved value, efficiency, or costs.

Institutional Base Salary. The annual compensation that the applicant organization pays for an employee's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of duties to the applicant organization. Base salary may not be increased as a result of replacing institutional salary funds with NIH grant funds.

Some PHS grant programs are currently subject to a legislatively imposed salary limitation. Any adjustment for salary limits will be made at time of award. Applicants are encouraged to contact their offices of sponsored programs or see the *NIH Guide for Grants and Contracts* for current guidance on salary requirements.

Intellectual Property. The separate and distinct types of intangible property that are referred to collectively as "intellectual property," including but not limited to: patents, trademarks, copyrights, trade secrets, SBIR/STTR technical data (as defined in this section), ideas, designs, know-how, business, technical and research methods, and other types of intangible business assets, and including all types of

intangible assets either proposed or generated by an SBC as a result of its participation in the SBIR program.

Joint Venture. An association of concerns with interests in any degree or proportion by way of contract, express or implied, consorting to engage in and carry out a single specific business venture for joint profit, for which purpose they combine their efforts, property, money, skill, or knowledge, but not on a continuing or permanent basis for conducting business generally. A joint venture is viewed as a business entity in determining power to control its management.

Key Personnel. In addition to the PD/PI, Key Personnel are defined as individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested.

Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level should be included if their involvement meets the definition of Key Personnel. Consultants should also be included if they meet the definition of Key Personnel. Key Personnel must devote measurable effort to the project whether or not salaries are requested--"zero percent" effort or "as needed" are not acceptable levels for those designated as Key Personnel.

Other Significant Contributors. This category identifies individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort to the projects. These individuals are typically presented at "zero percent" effort or "as needed" (individuals with measurable effort cannot be listed as Other Significant Contributors). Consultants should be included if they meet this definition. This would also be an appropriate designation for mentors on Career awards.

Person Months. A metric for expressing the effort (amount of time) that PIs, faculty and other senior/key personnel devote to a specific project. Effort is expressed as a percentage of the total institutional appointment and is based on the organization's regular academic-year, summer or calendar-year.

Principal Investigator, Program Director, or Project Director (PD/PI). The individual(s) designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. The applicant organization may designate multiple individuals as principal investigators who share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple principal investigators are named, each is responsible and accountable to the grantee organization, or as appropriate, to a collaborating organization for the proper conduct of the project or program including the submission of all required reports.

Program Income. Gross income earned by the applicant organization that is directly generated by a supported activity or earned as a result of the award. The *PHS Grants Policy Statement* or *NIH Grants Policy Statement* contains a detailed explanation of program income, the ways in which it may be generated and accounted for, and the various options for its use and disposition.

Examples of program income include:

- Fees earned from services performed under the grant, such as those resulting from laboratory drug testing;
- Rental or usage fees, such as those earned from fees charged for use of computer equipment purchased with grant funds;
- Third party patient reimbursement for hospital or other medical services, such as insurance payments for patients when such reimbursement occurs because of the grant-supported activity;
- Funds generated by the sale of commodities, such as tissue cultures, cell lines, or research animals;

- Patent or copyright royalties (exempt from reporting requirements); and
- Registration fees generated from grant-supported conferences.

Prototype. A model of something to be further developed and includes designs, protocols, questionnaires, software, and devices.

Research or Research and Development (R/R&D). Any activity that is:

- A systematic, intensive study directed toward greater knowledge or understanding of the subject studied;
- A systematic study directed specifically toward applying new knowledge to meet a recognized need;
- A systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

Research Institution. A United States research organization that is:

- A nonprofit college or university or
- A nonprofit research institution, including nonprofit medical and surgical hospitals. (A "nonprofit institution" is defined as an organization that is owned and operated exclusively for scientific or educational purposes, no part of the net earnings of which inures to the benefit of any private shareholder or individual.) or
- A contractor-operated, Federally funded research and development center, as identified by the National Science Foundation in accordance with the Government-wide Federal Acquisition Regulation issued in accordance with section 35(c)(1) of the Office of Federal Procurement Policy Act (or any successor legislation thereto).

(Laboratories staffed by Federal employees do not meet the definition of "research institution" for purposes of the STTR program.)

SBIR/STTR Technical Data. All data generated during the performance of an SBIR/STTR award.

SBIR/STTR Technical Data Rights. The rights a small business concern obtains in data generated during the performance of any SBIR/STTR Phase I, Phase II, or Phase III award that an awardee delivers to the Government during or upon completion of a Federally-funded project, and to which the Government receives a license.

Socially and Economically Disadvantaged Individual. A member of any of the following groups: Black Americans; Hispanic Americans; Native Americans; Asian-Pacific Americans; Subcontinent Asian Americans; other groups designated from time to time by the Small Business Administration (SBA) to be socially disadvantaged; or any other individual found to be socially and economically disadvantaged by SBA pursuant to Section 8(a) of the Small Business Act, 15 U.S.C. 637(a).

Subcontract. Any agreement, other than one involving an employer-employee relationship, entered into by a Federal Government prime contractor calling for supplies or services required solely for the performance of the prime contract or another subcontract.

Summary Statement. The official agency record of the evaluation and recommendations made by peer review groups. It contains the essentially unedited, verbatim critiques of two or more individuals assigned to review the grant application.

United States. The 50 states, territories and possessions of the U.S., Commonwealth of Puerto Rico, Trust Territory of the Pacific Islands, and District of Columbia.

IV. General Information

A. Research Grant Mechanisms

The following table summarizes the major mechanisms NIH uses to fund research grants. For more detailed information, visit the OER Grants website http://grants.nih.gov/grants/oer.htm.

Over the next several years, NIH will transition all the mechanisms listed below to electronic submission through Grants.gov. Initial plans are announced in the NIH Guide Notice, OD-05-067: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-067.html. Additional notices will be posted in the Guide giving the community several months notice of the transition of a specific mechanism. Specific funding opportunity announcements will also be posted in the NIH Guide and on Grants.gov, Apply for Grants, when a particular mechanism is transitioned.

Type (Mechanism)	Description
Research Grants	
Basic Research Grant (R01)	**Basic Research Grants** are awarded to eligible institutions on behalf of a PD/PI to support a discrete project related to the investigator's area of interest and competence. These grants make up the largest category of NIH funding.
Small Research Grant (R03) http://grants.nih.gov/grants/funding/r03.htm	**Small Research Grants** support small research projects that can be carried out in a short period of time with limited resources for projects such as pilot or feasibility studies; secondary analysis of existing data; small, self-contained research projects; development of research methodology and/or development of new research technology. *Not all awarding components accept investigator-initiated R03 applications.* Applicants interested in the small research grant program of PHS-awarding components other than NIH should contact an official of the appropriate PHS-awarding component.
Academic Research Enhancement Award (AREA) (R15) http://grants.nih.gov/grants/funding/area.htm	**Academic Research Enhancement Awards** provide support to scientists at eligible domestic institutions for small-scale health-related research projects, such as pilot research projects and feasibility studies; development, testing, and refinement of research techniques; and similar discrete research projects that demonstrate research capability. This award is directed toward those smaller public and private colleges and universities that provide undergraduate training for a significant number of the U.S. research scientists.

Type (Mechanism)	Description
Exploratory/Developmental Research Grant (R21/R33) http://grants.nih.gov/grants/funding/r21.htm	**Exploratory/Developmental Research Grants** seek to broaden the base of inquiry in fundamental biomedical research by encouraging applications for research projects that involve an especially high degree of innovation and novelty. NIH provides pilot-scale support for potentially ground-breaking ideas, methods, and systems that meet the following criteria: they lack sufficient preliminary data for feasibility to be established, their successful demonstration would have a major impact on biomedical research, and they fall within the areas supported by the awarding I/C. *Not all awarding components accept R21/R33 applications.*
Small Business Innovation Research Grant (SBIR: R43/R44) **Small Business Technology Transfer Grant (STTR: R41/R42)** http://grants.nih.gov/grants/funding/sbir.htm	**SBIR and STTR grants** are made to eligible domestic for-profit small business concerns conducting innovative research that has the potential for commercialization. SBIR/STTR awards are intended to stimulate technological innovation, use small business to meet Federal research and development needs, increase private sector commercialization of innovations derived from Federal research and development, and foster and encourage participation by minority and disadvantaged persons in technological innovation.
Program Project Grant (P01)	**Program Project Grants** are more complex in scope and budget than the individual basic research (R01) grant. While R01s are awarded to support the work of one PD/PI who, with supporting staff, is addressing a scientific problem, program project grants are available to a group of several investigators with differing areas of expertise who wish to collaborate in research by pooling their talents and resources. Program project grants represent synergistic research programs that are designed to achieve results not attainable by investigators working independently. *Not all awarding components accept P01 applications.*
Research Center Grant (P50/P60)	**Research Center Grants** serve varying scientific and IC-specific purposes, but they have elements in common. The grants are multidisciplinary in scope and may focus more on an area or discipline of science than on a specific theme or goal. Independent investigators direct the projects and cores. Center grants offer a greater opportunity for scientific interactions and overall progress than with individually-funded projects. *Not all awarding components accept P50/P60 applications.*

Type (Mechanism)	Description
Scientific Meeting Support (R13) http://grants.nih.gov/grants/funding/r13/index.htm	Most NIH ICs provide support for scientific meetings, conferences, and workshops that are relevant to its scientific mission. Any U.S. institution or organization, including an established scientific or professional society, is eligible to apply. For more information and guidelines, see http://grants.nih.gov/grants/guide/pa-files/PAR-03-176.html. *Applicants must obtain IC approval prior to submission.*
Research Grants to Foreign Institutions and International Organizations	http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part12.htm#_Toc54600260.
Training, Fellowships and Career Development Programs	
NIH Institutional Ruth L. Kirschstein National Research Service Award (T32/T34/T35) http://grants.nih.gov/grants/guide/pa-files/PA-00-103.html	These awards are made to domestic institutions that have the facilities and faculty to provide for research training programs in scientific specialties. Grant funds may be used for personnel, equipment, supplies, trainee stipends (both pre- and postdoctoral), and related costs.
Individual Ruth L. Kirschstein National Research Service Award Fellowships) (NRSA: F30/F31/F32/F33) http://grants.nih.gov/training/nrsa.htm	These fellowships are awarded to qualified individuals at the predoctoral, postdoctoral, or senior investigator level to pursue full-time research training in designated biomedical or behavioral science areas**.** **NRSA APPLICANTS MUST USE PHS 416-1 FORMS/INSTRUCTIONS** (http://grants.nih.gov/grants/funding/416/phs416.htm)
Career Development Award (K Award) http://grants.nih.gov/training/careerdevelopmentawards.htm	Among NIH components, several types of career development awards are available to research and academic institutions on behalf of scientists who require additional independent or mentored experience in a productive scientific environment in order to further develop their careers in independent biomedical or behavioral research.
APPLICATIONS AVAILABLE FROM OTHER OFFICES	
International Research Fellowship Award Application (NIH 1541-1)	Fogarty International Center (FIC) (301) 496-1653
Nonresearch Training Grant Application (PHS 6025)	Health Resources and Services Administration (HRSA) (301) 443-6960
Health Services Project Application (5161-1)	Substance Abuse and Mental Health Services Administration (SAMHSA) (301) 436-8451

B. Government Use of Information Under Privacy Act

The Privacy Act of 1974 (5 U.S.C. 552a) is a records management statute and regulates the collection, maintenance, use, and dissemination of personal information by Federal agencies. In accordance with the Act, the PHS is required to provide the following notification to each individual whom it asks to supply information.

The PHS maintains applications and grant records pursuant to its statutory authority for awarding grants. The purpose of the information collection is to aid in the review, award, and administration of PHS programs. Provision of information is voluntary; however, a lack of sufficient information may hinder the ability of the PHS to review applications, monitor grantee performance, or perform overall management of grant programs.

The Privacy Act authorizes discretionary disclosure of this information within the Department of Health and Human Services and outside the agency to the public, as required by the Freedom of Information Act and the associated DHHS regulations (45 CFR 5), including the Congress acting within its legislative authority, the National Archives, the General Accounting Office, the Bureau of Census, law enforcement agencies, and pursuant to a court order. Information also may be disclosed outside the Department, if necessary, for the following purposes:

1. To a Congressional office at the request of the record subject;
2. To the Department of Justice as required for litigation;
3. To the cognizant audit agency for auditing;
4. To qualified experts not within the definition of Department employees as prescribed in Department Regulations (45 CFR 5b.2) for opinions as part of the application review/award process;
5. For an authorized research purpose under specified conditions;
6. To contractors for the purpose of processing, maintaining, and refining records in the system. Contractors will be required to maintain Privacy Act safeguards with respect to such records;
7. To a Federal agency, in response to its request, in connection with the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the records are relevant and necessary to the requesting agency's decision on the matter; and
8. To the applicant organization in connection with the review of an application or performance or administration under the terms and conditions of the award, or in connection with problems that might arise in performance or administration if an award is made.

C. Information Available to the PD(s)/PI(s)

Under the provisions of the Privacy Act, PDs/PIs may request copies of records pertaining to their grant applications from the PHS component responsible for funding decisions. PDs/PIs are given the opportunity under established procedures to request that the records be amended if they believe they are inaccurate, untimely, incomplete, or irrelevant. If the PHS concurs, the records will be amended.

D. Information Available to the General Public

The PHS makes information about awarded grants available to the public, including the title of the project, the grantee institution, the PD/PI, and the amount of the award. The Project Summary/Abstract, from Item 6 on the Other Project Information Component, of a funded research grant application is sent to the National Technical Information Service (NTIS), U.S. Department of Commerce, where the information is used for the dissemination of scientific information and for scientific classification and program analysis purposes. These descriptions are available to the public from the NTIS.

NIH also routinely places information about awarded grants, including project title, name of the PD/PI, and project description (abstract) in the CRISP system.

The Freedom of Information Act and implementing DHHS regulations (45 CFR Part 5) require the release of certain information about grants upon request, regardless of the intended use of the information. Generally available for release, upon request are: all funded grant applications and progress reports **including** their derivative funded **noncompeting supplemental** grant progress reports; pending and funded **noncompeting continuation** progress reports; progress reports of grantees; and final reports of any review or evaluation of grantee performance conducted or caused to be conducted by the DHHS. Generally **not** available for release to the public are: **competing** grant progress reports (new, resubmission, renewal, and revisions) for which awards have **not** been made; evaluative portions of site visit reports; and summary statements of findings and recommendations of review groups. Trade secrets and commercial, financial, or otherwise proprietary information may be withheld from disclosure. Information, which, if disclosed, would be a clearly unwarranted invasion of personal privacy, may also be withheld from disclosure. Although the grantee institution and the PD/PI will be consulted about any such release, the PHS will make the final determination. If a requested document contains both disclosable and nondisclosable information, the nondisclosable information will be deleted and the balance of the document will be released.

Access to Research Data

By regulation (45 CFR 74.36), grantees that are institutions of higher education, hospitals, or non-profit organizations are required to provide, in response to a FOIA request, the research data first produced under the award. The term “research data” is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings. It does not include preliminary analyses; drafts of scientific papers; plans for future research; peer reviews; communications with colleagues; physical objects (e.g., laboratory samples, audio or video tapes); trade secrets; commercial information; materials necessary to be held confidential to a researcher until publication in a peer-reviewed journal; information that is protected under the law (e.g., intellectual property); personnel and medical files and similar files, the disclosure of which would constitute an unwarranted invasion of personal privacy or information that could be used to identify a particular person in a research study.

These requirements do not apply to commercial organizations or to research data produced by state or local governments. However, if a state or local governmental grantee contracts with an educational institution, hospital or non-profit organization, and the contract results in covered research data, those data are subject to these disclosure requirements.