Summary of decision tree figure:

The purpose of this decision tree is to assist in understanding what types of studies are subject to the NIH inclusion policy on sex/gender, race, and ethnicity. The first question is to determine whether human subjects are involved (yes or no). A hyperlink to the Code of Federal Regulations is provided. If no, then the inclusion policy does not apply. If yes, then individuals should proceed to the next question which is to determine whether the study qualifies for an IRB (institutional review board) exemption number four (yes or no). If yes, an IRB Exemption number four applies, and the study is not subject to the NIH inclusion policy. If no, then the next question is whether the study meets the NIH definition for clinical research. If no, then the inclusion policy does not apply. If yes, then the study is subject to the NIH inclusion policy. The next question is whether the study meets the NIH definition for a Phase III clinical trial. If no, then the inclusion policy applies and inclusion of individuals based on sex/gender, race, and ethnicity should be addressed in competing and non-competing NIH applications per the specific application instructions. If the answer is yes (the study is an NIH-defined Phase III clinical trial), there are additional requirements. Not only do applicants/investigators need to address inclusion of individuals based on sex/gender, race, and ethnicity in competing and non-competing NIH applications, but they also need to address requirements for a valid analysis in these applications.

Several hyperlinks are provided in the decision tree. These lead to resources and definitions including:

1. 45 CFR 46 which is the section of the Code of Federal Regulations that provides guidance on human subjects’ research and protections. The hyperlink address is <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

2. There is a link within the 45CFR46 to the definition of IRB Exemption 4. The hyperlink address is <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101>

The definition of research eligible for IRB Exemption 4 is “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.”

3. There is a hyperlink to the NIH definition for clinical research. The hyperlink address is <http://grants.nih.gov/grants/glossary.htm#C>

The NIH definition of clinical research is research with human subjects that is:

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. It includes: mechanisms of human disease, therapeutic interventions, clinical trials, and development of new technologies
2. Epidemiological and behavioral studies.
3. Outcomes research and health services research.

Studies falling under 45 CFR part 46.101(b) (4) (Exemption 4) are not considered clinical research by this definition.

4. There is a hyperlink to the NIH definition for a Phase III clinical trial. They hyperlink address is <http://grants.nih.gov/grants/glossary.htm#P>

The NIH definition for a Phase III clinical trial is a broadly based prospective Phase III clinical investigation (usually involving several hundred or more human subjects) to evaluate an experimental intervention in comparison with a standard or control intervention or to compare two or more existing treatments. 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 also are included. Go to [Clinical Trial](http://grants.nih.gov/grants/glossary.htm#C14).

5. There is a hyperlink to the NIH application instructions page. The hyperlink address is <http://grants.nih.gov/grants/forms.htm>

6. There is a hyperlink to the NIH website for inclusion on the basis of sex/gender, race, and ethnicity. The hyperlink is <http://grants.nih.gov/grants/funding/women_min/women_min.htm>