

SAMPLE PROTECTION OF HUMAN SUBJECTS

1. RISKS TO HUMAN SUBJECTS

Human Subjects Involvement, Characteristics, and Design

[Describe the proposed involvement of human subjects in the work outlined in the Research Strategy section]

[Describe the characteristics of the subject population, including their anticipated number, age range, and health status.] – a table is nice here, exclude gender or race since those are included in the other sections, consider presenting data on age, health status, education, income for each accrual site.

[Describe and justify the sampling plan, including retention strategies and the criteria for inclusion or exclusion of any subpopulation]

[Identify the criteria for inclusion and exclusion of any subpopulation.]

[Explain rationale for the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals or others who may be considered vulnerable.]

[If relevant to the proposed research, describe procedures for assignment to a study group. As related to human subjects protection, describe and justify the selection of an intervention's dose, frequency, and administration.]

[List any collaborating sites where human subjects research will be performed and describe the role of those sites and collaborating investigators in performing the proposed research. Explain how data from the site(s) will be obtained, managed, and protected.]

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 from human subjects involved in the project.]

[Indicate who will have access to individually identifiable private information about human subjects.]

[Provide information about how the specimens, records, or data are collected, managed, and protected as well as whether material or data that include individually identifiable private information will be collected specifically for your proposed research project.]

Potential Risks

[Describe all the potential risks to subjects posed by participation in the research (physical, psychological, social, legal, and other), and assess their likelihood and seriousness to the subjects.]

[Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits of the alternative treatments and procedures to participants in the proposed research.]

2. ADEQUACY OF PROTECTION AGAINST RISKS

Recruitment and Informed Consent

[Describe plans for the recruitment of subjects 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. If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver. Informed consent document(s) need not be submitted to the PHS agencies unless requested]

Protections Against Risk

[Described planned procedures for protecting against or minimizing potential risks, including risks to privacy of individuals or confidentiality of data, and assess their likely effectiveness.]

[Research involving vulnerable populations, as described in the HHS regulations, Subparts B-D must include additional protections. Refer to HHS regulations, and OHRP guidance:

- Additional Protections for Pregnant Women, Human Fetuses and Neonates: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartb>
- Additional Protections for Prisoners: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc>
- OHRP Subpart C Guidance: <http://www.hhs.gov/ohrp/policy/index.html#prisoners>
- Additional Protections for Children: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd>
- OHRP Subpart D Guidance: <http://www.hhs.gov/ohrp/policy/index.html#children>

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 (See definition of "clinical trial" under Part III.3) must include a general description of the plan for data and safety monitoring of the clinical trials and adverse event reporting to the IRB, the DSMB (if one has been established for the trial), the NIH and others, as appropriate, to ensure the safety of subjects.]

3. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO HUMAN 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.]

[Please note that financial compensation of subjects is not considered to be a benefit of participation in research.]

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.]

5. DATA AND SAFETY MONITORING PLAN

[See Data and Safety Monitoring Plan sample]; will be uploaded as a separate document for proposals submitted after May 25, 2016.

6. CLINICALTRIALS.GOV REQUIREMENTS

[NIH encourages registration of ALL clinical trials whether required under the law or not. On January 28, 2015, NCI published a policy requiring the reporting of final trial results in a publicly accessible manner within 12 months of the trials primary completion date. NIH is considering a policy to require all NIH supported trials to be registered and final data reported in ClinicalTrials.gov; any final policy about this will be published in the NIH Guide for Grants and Contracts.]

[Include a note regarding whether or not your proposed research will require registration with ClinicaTrials.gov, and that if applicable and if funded, the project will be registered.]

INCLUSION OF WOMEN AND MINORITIES (uploaded to the grants.gov package as a separate document)

Address, at a minimum, the following four points:

1. Complete the targeted/planned enrollment table.
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.
3. A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group.
4. A description of proposed outreach programs for recruiting sex/gender and racial/ethnic group members as subjects.

INCLUSION OF CHILDREN (children are defined as under the age of 18; uploaded to the grants.gov package as a separate document)

[Provide either a description of the plans to include children or, if children will be excluded, you must present an acceptable justification for the exclusion.]

Address, at a minimum, the following five points:

- Describe the age(s) or age range of all individuals to be included in the proposed study.
- Specifically discuss whether children under the age of 18 (as a whole or a subset of individuals under 18) will be included or excluded.
- 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 working 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.
- 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 under the Protections Against Risk subheading (4.1.2.b).

[If children are NOT included, include a rationale for not selecting a specific age range of children is required.]