**Protection of Human Subjects**

**Instructions**: Remove all blue text after completing this attachment. Upload this attachment as a PDF to Kuali.

Do not use the “Protection of Human Subjects” attachment to circumvent the page limits of the Research Strategy.

For Human Subjects Research Claiming Exemptions:

If you are claiming that your human subjects research falls under any exemptions, justify why the research meets the criteria for the exemption(s) that you have claimed. This justification should explain how the proposed research meets the criteria for the exemption claimed. Do not merely repeat the criteria or definitions themselves.

For Studies that involve Non-Exempt Human Subjects Research:

For any proposed nonexempt study involving human subjects, NIH requires a Protection of Human Subjects attachment that is commensurate with the risks of the study, its size, and its complexity. Organize your attachment into four sections, following the headings and specified order below, and discuss each of the points listed below.

Start each section with the appropriate section heading:

Risks to Human Subjects  
Adequacy of Protection Against Risks  
Potential Benefits of the Proposed Research to Research Participants and Others  
Importance of the Knowledge to be Gained.   
Also include any additional information requested in the FOA.

**Content**:

1. **Risks to Human Subjects**
   1. Human Subjects Involvement, Characteristics, and Design
      1. Briefly describe the overall study design.
      2. Describe the subject population(s) to be included in the study; the procedures for assignment to a study group, if relevant; and the anticipated numbers of subjects for each study group.
      3. 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.
   2. Study Procedures, Materials, and Potential Risks
      1. Describe all planned research procedures (interventions and interactions) involving study subjects; how research material, including biospecimens, data, and/or records, will be obtained; and whether any private identifiable information will be collected in the proposed research project.
2. **Adequacy of Protection Against Risks a. Informed Consent and Assent**
   1. Describe the process for obtaining informed consent. 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. When appropriate, describe how potential adult subjects’ capacity to consent will be determined and the plans for obtaining consent from a legally authorized representative for adult subjects not able to consent.
      1. **For research involving children:** If the proposed studies will include children, describe the process for meeting HHS regulatory requirements for parental permission and child assent (45 CFR 46.408). See the HHS page on Research with Children FAQs and the NIH page on Requirements for Child Assent and Parent/Guardian Permission.
   2. If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver. Do not submit informed consent document(s) with your application unless you are requested to do so.
   3. Protections Against Risk
      1. Describe planned strategies for protecting against or minimizing all potential risks identified, including strategies to manage and protect the privacy of participants and confidentiality of research data.
      2. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects on participants.
      3. Describe plans for handling incidental findings, such as those from research imaging, screening tests, or paternity tests.
   4. Vulnerable Subjects, if relevant to your study
      1. Explain the 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 populations. 'Prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers).
      2. Pregnant Women, Fetuses, and Neonates or Children
         1. If the study involves vulnerable subjects subject to additional protections under Subparts B and D (pregnant women, fetuses, and neonates or children), provide a clear description of the risk level and additional protections necessary to meet the HHS regulatory requirements.
      3. Prisoners
         1. If the study involves vulnerable subjects subject to additional protections under Subpart C (prisoners), describe how proposed research meets the additional regulatory requirements, protections, and plans to obtain OHRP certification for the involvement of prisoners in research.
3. **Potential Benefits of the Proposed Research to Research Participants and Others**
   1. Discuss the potential benefits of the research to research participants and others.
   2. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.
      1. Note: Financial compensation of subjects should not be presented as a benefit of participation in research.
4. **Importance of the Knowledge to be Gained**
   1. Discuss the importance of the knowledge to be gained as a result of the proposed research.
   2. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.