

Principal Investigator:

HUMAN SUBJECTS

If your project does not involve human subjects, do not submit this form
No page limit, but please be succinct

If the project proposes the use of human subjects, specimens, tissues, fluids or primary cell cultures, this form must be submitted.

IRB approval is not required at the time of submission of the application.

(Double Click on Check Box, and change default value from “Not checked” to “Checked”)

This project has or will likely receive an exempt/non-exempt status from the IRB:

Exempt
Non-Exempt

A copy of a draft consent form (optional) has been included in the appendices:

Yes
No

If your research plan has been granted exempt status by an appropriate Institutional Review Board or there is an overwhelming likelihood that the IRB will grant such status when the proposal is reviewed in the future, please explain in item 1. Also, complete item 2 and item 3, if known. Mark other items “N/A”. If your research is non-exempt, please address all the applicable items below (bracketed instructions can be deleted before PDF conversion).

1. Detailed description of the proposed involvement of human subjects in the project:

2. Identify the sources of research material specimens, records or data:

[Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records or data.]

3. Characteristics of the subject population, especially underserved and under-researched populations:

[Describe the characteristics of the subject population, including its anticipated number, age range, and health status, if applicable. Include an appropriate demographics table, if applicable, in this section. Also explain the rationale for the involvement of special classes of subjects, if any, such as pregnant women, children, prisoners, other institutionalized individuals, or others who are likely to be vulnerable.]

4. Describe the plans for recruiting subjects and documenting consent:

[Describe the plans for recruiting subjects and the consent procedures to be followed, including: the circumstances under which consent will be sought and obtained, who will seek it; the nature of the information to be provided to the prospective subjects; and the method of documenting consent. Describe recruitment incentives, if applicable]

5. Describe any potential risks —physical/medical, psychological, social, legal, or other:

[Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.]

6. Describe the procedures for protecting against, or minimizing, any potential risks:

[Assess their likely effectiveness. Include risks to confidentiality. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects on the subjects. Also, where appropriate, describe the provision for monitoring the data collected to ensure the safety of subjects.]

7. Discuss why the risks are reasonable relative to the anticipated benefit:

[Benefit can be to the participants and/or the anticipated benefit and importance of knowledge that may reasonably be expected to result.]