Details only required if the proposal falls under Scenario B: Non-exempt Human Subjects Research

Detailed information available at: <http://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf#4_1_protection_of_human_subject>

**Protection of Human Subjects**

Note: The proposed project falls under Scenario B: Non-Exempt Human Subjects Research

***Human Subjects Involvement, Characteristics, and Design***

**Justification for involvement of human subjects**

NIH Standard: *Describe and justify the proposed involvement of human subjects in the work outlined in the Research Strategy Section*

**Subject population**

NIH Standard: *Describe the characteristics of the subject population, including the anticipated number, age range, and health status where relevant*.

**Sampling plan, retention strategies, and inclusion/exclusion criteria**

NIH Standard: *Describe and justify the sampling plan, including retention strategies and the criteria for inclusion or exclusion of any subpopulation.*

**Vulnerable populations**

*e.g., Fetuses, neonates, Children <17, pregnant and/or nursing women/ institutionalized persons/prisoners/homeless individuals.*

NIH Standard: *Explain the rationale for the involvement of special vulnerable populations as noted above or others who may be considered vulnerable populations. Note that prisoners includes* all *subjects involuntary incarcerated (e.g., in detention centers) as well as subjects who become incarcerated* after *the study begins*.

**Study groups (if relevant)**

NIH Standard: *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.*

**Sites**

NIH Standard: *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***

**Research material**

NIH Standard: *Describe the research material obtained from* living *individuals in the form of specimens, records, or data.*

**Data collected**

NIH Standard: *Describe any data that will be collected from human subjects for the project(s) described in the application.*

**Access to Identifiable Private Information**

NIH Standard: *Indicate who will have access to individually identifiable private information about human subjects.*

**Data collection, management, and protection**

NIH Standard: *Provide information regarding method for specimen, record, and/or data collection, management, and protection as well as whether material or data including individually identifiable private information will be collected specifically for the proposed research project.*

***Potential Risks***

**All potential risks**

NIH Standard: *Describe all the potential risks to subjects posed by participation in the research (e.g., physical, psychological, financial, legal, or other), and assess their likelihood and seriousness to the human subjects.*

**Alternative treatments or procedures**

NIH Standard: *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*.

**Adequacy of Protection Against Risk**

***Recruitment and Informed Consent***

**Recruitment strategies**

NIH Standard: *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.*

**Informed Consent and Waiver**

NIH Standard: *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***

**Protecting against/minimizing potential risks**

NIH Standard: *Describe planned procedures for protecting against or minimizing potential risks, including risks to privacy of individuals or confidentiality of data, and assess their likely effectiveness.*

**Protections for vulnerable populations**

NIH Standard: *Research involving vulnerable populations must include additional protections as described in (control-click to follow links):*

* [*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)
* [*Additional protections for children*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd)

*Guidance is also available for OHRP Subparts* [*C (prisoners)*](http://www.hhs.gov/ohrp/policy/index.html#prisoners) *and* [*D (children).*](http://www.hhs.gov/ohrp/policy/index.html#children)

**Medical/professional intervention**

NIH Standard: *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  *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.*

***Potential Benefits of the Proposed Research***

**Potential benefits**

NIH Standard: *Discuss the potential benefits of the research to research participants and others.*

**Reasonableness of risks**

NIH Standard: *Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others*.

**NOTE: Financial compensation of subjects is not considered to be a benefit of participation in research**

***Importance of the Knowledge to be Gained***

**Importance of the knowledge to be gained**

NIH Standard: *Discuss the importance of the knowledge to be gained as a result of the proposed research.*

**Risk to subjects compared to the importance of knowledge**

NIH Standard: *Discuss why the risks to subjects are reasonable in relation to the importance of knowledge that reasonably may be expected to result.*

**NOTE: Test articles (e.g., investigational new drugs, devices, or biologics) must be named, whether or not they will be used for purposes or administered by routes that have not been approved for general use by the FDA. Additional requirements apply in these cases.**

***Data Safety and Monitoring Plan***

Only required if the proposed research includes a clinical trial.

NIH Standard: *Provide a general description of a monitoring plan to be established as the overall framework for data and safety monitoring.*