All applications that involve human subjects research or clinical trials must include a Human Subjects Research and Clinical Trials Information section that contains the information outlined below.

This document is based on the PHS Human Subjects and Clinical Trials Information Form. Only those sections and fields applicable to the Resident and Fellow Research Funds and not found elsewhere on the application are included. If your research involves human specimens and/or data, please refer to the NIH Research Involving Private Information or Biological Specimens flowchart to determine if your project is considered human subjects research. For more detailed information about the PHS form, please review this guidance from NIH or the annotated form.

1) **Study Population Characteristics**

   a. Describe the following information:
      - Characteristics of subject population (number, age range, and health status)
      - Eligibility criteria, inclusion/exclusion criteria, and age limits
      - Inclusion of women, minorities and children
      - Recruitment and retention plan, recruitment status, and study timeline

   b. Enrollment Table – Report the numbers of subjects you are targeting to recruit into each category. If you are using an existing dataset for your research, report the number of subjects in each category you plan to analyze.

<table>
<thead>
<tr>
<th>Racial Categories</th>
<th>Ethnic Categories</th>
<th>Not Hispanic or Latino</th>
<th>Hispanic or Latino</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
<td>Female</td>
<td>Male</td>
<td>Female</td>
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<tr>
<td>American Indian/Alaska Native</td>
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<tr>
<td>Asian</td>
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<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
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<tr>
<td>Black or African American</td>
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<tr>
<td>White</td>
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<tr>
<td>More than One Race</td>
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<tr>
<td>Total</td>
<td></td>
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</tbody>
</table>

2) **Protection and Monitoring Plans**

   a. Protection of Human Subjects
      - Description and justification for the proposed involvement of human subjects
      - Rationale for involvement of vulnerable populations (e.g. fetuses, pregnant women, children, prisoners, institutionalized individuals, others)
      - Role of collaborating sites where research will be performed
      - Description and justification of research procedures (including dosage, frequency, etc. of intervention)
      - Description of what research material, data, and information will be collected
      - Access to personally identifiable information collected and retained
      - Management and protection of materials and information
      - All potential risks to subjects (physical, psychological, financial, legal, or other) including likelihood and seriousness
      - Any alternative treatments or procedures
b. Protection Against Risks
   • How subjects will be recruited
   • Description of informed consent, parental permission and assent
   • Waiver for any elements of consent
   • How risks described previously, including privacy and confidentiality, will be minimized
   • Description of incentives offered and protection against undue influence
   • Additional protections for vulnerable populations
   • Ensuring necessary medical/professional intervention for adverse events

c. Potential Benefits of the Proposed Research to Human Subjects and Others (in Relation to Potential Risks)

d. Importance of the Knowledge to be Gained (in Relation to Potential Risks)

e. Data and Safety Monitoring Plan (for Clinical Trials)
   • Include who will be responsible for monitoring and the process by which Adverse Events (AEs) and Unanticipated Problems (UP) will be reported to all relevant regulatory bodies.
   • A Data and Safety Monitoring Board (DSMB) for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally for Phase III clinical trials.

3) Protocol Synopsis

a. Statistical Design and Power

b. Will the study use an FDA-regulated intervention? If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status.