Human Subjects Study Record At-a-Glance

FULL GUIDANCE from section G. 500 – PHS Human Subjects and Clinical Trials Information*

Of the GENERAL APPLICATION GUIDE FOR NIH AND OTHER PHS AGENCIES (rev. 10/16/20)

**contains links to additional info and resources for each section*

Section 1: Basic Information

1.1 Title – unique PER study (600 characters)
1.2 Exempt?
1.3 Exemption Number
1.4 Clinical Trial Questionnaire (a-d) to determine if meets the definition of a clinical trial
1.5 Clinical Trial Identifier

Section 2 - Study Population Characteristics (*not required if using existing data only)

2.1 Conditions or Focus: refers to primary condition/disease being studied
(up to 20/255 char. per condition)
2.2 Eligibility Criteria: provide a brief description of inclusion and exclusion criteria
(500 – 15,000 characters*)
2.3. Age limits (min/max)
2.3.a. Inclusion Across the Lifespan **ATTACHMENT**
2.4 Inclusion of Women & Minorities **ATTACHMENT**
2.5 Recruitment and Retention Plan **ATTACHMENT** *(not required if exempt for #4)*
2.6 Recruitment Status (drop box) *(not required if exempt for #4)*
2.7 Study Timeline **ATTACHMENT** (optional if exempt for #4)
2.8 Enrollment of First Participant (date field*) (not required if exempt for #4 or using existing dataset)*
2.9 Inclusion Enrollment Report(s) **FORM** w/tables; minimum of one IER required PER study (unless exempt #4)

- Not required if using EXISTING datasets
- Completed for target/planned enrollment
- Location and racial categories are collected
- Individual and cumulative info
- Detailed descriptions/definitions provided in guidance

Section 3 – Protection and Monitoring Plans

3.1 Protection of Human Subjects **ATTACHMENT** ***(detailed outline on page 4)***
Risks; Adequacy of Protections; Potential Benefits; Importance of Knowledge to be Gained
3.2 Multi/single-site IRB plan (Y/N - **ATTACHMENT** if Yes)
3.3 Data and Safety Monitoring Plan **ATTACHMENT** (required if clinical trial; optional if not)
3.4. Data and Safety Monitoring Board appointed? (Y/N)

3.5 Study Team structure/qualifications (optional) **ATTACHMENT**

Section 4 – Protocol Synopsis

If "No" to any question in the "Clinical Trial Questionnaire:" Do not complete.

If "Yes" to all the questions in the "Clinical Trial Questionnaire:" then "Protocol Synopsis" section is required.

4.1 Study Design Description – fields (5000 –32,000)
4.2 Outcome Measures (fields/drop boxes) (up to 50 with up to 999 characters each)
4.3 Statistical Design and Power (ATTACHMENT)
4.4 Participation Duration (field)
4.5 FDA-regulated Intervention? (Y/N; ATTACHMENT if yes)
4.6. FDAAA Clinical Trial (field)
4.7 Dissemination Plan (ATTACHMENT PER study)

Section 5 – other clinical trial-related ATTACHMENT(S)

- Complete this section ONLY if specified as a requirement in the FOA; and only if your project meets the definition of a clinical trial (item 1.4)
- If required by FOA, there may be special additional requirements for the TYPE of proposal (career development, training, fellowship, etc.)
- If requested/required by FOA, be sure to use the requested filenames as instructed.

Detailed ATTACHMENT info/outlines:

2.3.a. Inclusion Across the Lifespan *- exclusion of any specific age or age range group (e.g., children or older adults) should be justified in this section. Discuss whether individuals will be excluded based on age and provide a rationale for the minimum and maximum age of study participants, if applicable. Additionally, if individuals will be excluded based on age, provide a scientific or ethical rationale for their exclusion. Include a description of the expertise of the investigative team for working with individuals of the ages included, the appropriateness of the available facilities to accommodate individuals in the included age range, and how the age distribution of participants will contribute to a meaningful analysis relative to the purpose of the study.*

2.4 Inclusion of Women & Minorities - *Discuss each of the points listed below and include any additional information requested in the FOA:*

- *Describe the planned distribution of subjects by sex/gender, race, and ethnicity.*
- *Describe the rationale for selection of sex/gender, racial, and ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.*
- *Describe proposed outreach programs for recruiting sex/gender, racial, and ethnic group members.*
- *Inclusion and Excluded Groups: Provide a reason for limiting inclusion of any group by sex/gender, race, and/or ethnicity. In general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of particular groups.*
- *If you will use an existing dataset, resource, or samples that may have been collected as part of a different study, you must address inclusion, following the instructions above. Generally, you must provide details about the sex/gender, race, and ethnicity of the existing dataset/resource and justify the details as appropriate to the scientific goals of the proposed study.*
- *If the proposed research includes an NIH-Defined Phase III Clinical Trial, the "Inclusion of Women and Minorities" attachment MUST address plans for how sex/gender, race, and ethnicity will be taken into consideration in the design and valid analysis of the trial.*

2.5 Recruitment & Retention Plan - *Describe how you will recruit and retain participants in your study. You should address both planned recruitment activities as well as proposed engagement strategies for retention.*

2.7 Study Timeline *(required only for clinical trial or if exempt by #4)* *- Provide a description or diagram describing the study timeline. The timeline should be general (e.g., "one year after notice of award"), and should not include specific dates.*

3.1 Protection of Human Subjects - D*o 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 non-exempt 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, and Importance of the Knowledge to be Gained. Also include any additional information requested in the FOA*

1. Risks to Human Subjects

a. Human Subjects Involvement, Characteristics, and Design

- Briefly describe the overall study design.
- 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.
- 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.

b. Study Procedures, Materials, and Potential Risks

- 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.
- For studies that will include the use of previously collected biospecimens, data or records, describe the source of these materials, whether these can be linked with living individuals, and who will be able to link the materials.
- Describe all the potential risks to subjects associated with each study intervention, procedure or interaction, including physical, psychological, social, cultural, financial, and legal risks; risks to privacy and/or confidentiality; or other risks. Discuss the risk level and the likely impact to subjects.
- Where appropriate, describe alternative treatments and procedures, including their risks and potential benefits. When alternative treatments or procedures are possible, make the rationale for the proposed approach clear.

2. Adequacy of Protection Against Risks

a. Informed Consent and Assent

- 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.
- For research involving children**:** If the proposed studies will include children, describe the process for meeting HHS regulatory requirements for parental permission and child. If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver.

b. Protections Against Risk

- 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.
- Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects on participants.
- Describe plans for handling incidental findings, such as those from research imaging, screening tests, or paternity tests.

c. Vulnerable Subjects, if relevant to your study

- 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).
- *Pregnant Women, Fetuses, and Neonates or Children* - 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.
- *Prisoners* - 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

- Discuss the potential benefits of the research to research participants and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.
- **Note:** Financial compensation of subjects should not be presented as a benefit of participation in research.

4. Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge 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.

3.2. Multi-site IRB Plan *(if project is multi-site and required by agency)*

- Describe how you will comply with the single IRB review requirement under the Revised Common Rule at 45 CFR 46.114 (b) (cooperative research). If available, provide the name of the IRB that you anticipate will serve as the sIRB of record.
- Indicate that all identified participating sites will agree to rely on the proposed sIRB and that any sites added after award will rely on the sIRB.
- Briefly describe how communication between sites and the sIRB will be handled.
- Indicate that all participating sites will, prior to initiating the study, sign an authorization/reliance agreement that will clarify the roles and responsibilities of the sIRB and participating sites.
- Indicate which institution or entity will maintain records of the authorization/reliance agreements and of the communication plan.
- Note: Do not include the authorization/reliance agreement(s) or the communication plan(s) documents in your application.
- Note: If you anticipate research involving human subjects but cannot describe the study at the time of application, include information regarding how the study will comply with the single Institutional Review Board (sIRB) requirement prior to initiating any multi-site study in the delayed onset study justification.

3.3 Data & Safety Monitoring Plan - For human subjects research that does not involve a clinical trial: Your study, although it is not a clinical trial, may have significant risks to participants, and it may be appropriate to include a data and safety monitoring plan. If you choose to include a data and safety monitoring plan, you may follow the content criteria listed below, as appropriate. For AHRQ Applicants, Data and Safety Monitoring (DSM) plans are required in all non-exempt research applications when support is sought to study the effect of a health-related intervention on outcomes in human subjects where there is greater than minimal risk. DSMP should be commensurate with the risks of the trial, its size, and its complexity.

- Indicate how many people and what type of entity will provide the monitoring. Include such details as whether a single person, multiple people, or a data safety monitoring board will provide monitoring. Also indicate what type of entity will provide the monitoring
- The overall framework for safety monitoring and what information will be monitored.
- The frequency of monitoring, including any plans for interim analysis and stopping rules
- The process by which Adverse Events (AEs), including Serious Adverse Events (SAEs) such as deaths, hospitalizations, and life threatening events and Unanticipated Problems (UPs), will be managed and reported, as required, to the IRB, the person or group responsible for monitoring, the awarding IC, the NIH Office of Biotechnology Activities, and the Food and Drug Administration.
- The individual(s) or group that will be responsible for trial monitoring and advising the appointing entity. Because the DSMP will depend on potential risks, complexity, and the nature of the trial, a number of options for monitoring are possible.

3.5 Study Team Structure/Qualifications (optional) - Provide a brief overview of the organizational/administrative structure and function of the study team, particularly the administrative sites, data coordinating sites, enrollment/participating sites, and any separate laboratory or testing centers. The attachment may include information on study team composition and key roles (e.g., medical monitor, data coordinating center), the governance of the study, and a description of how study decisions and progress are communicated and reported. **Note:** Do not include study team members' individual professional experiences (i.e., biosketch information).