**HUMAN SUBJECTS FORM E**

The document below lists the various sections and questions that must be answered for Form E for NIH submissions. Please address all highlighted text.

**STUDY RECORD**

**Is this a delayed onset study?** Yes/No

* Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).
* If you believe you are submitting a delayed onset study, please contact grants administrator for more information.

**SECTION 1.**

* 1. **Study Title:** Enter study title (no more than 600 characters)
* **Is this study exempt from federal regulations?** YES/NO
	1. **If YES to 1.2, please provide exemption number:** 1, 2, 3, 4, 5, 6, 7 or 8
	2. **Clinical Trials Questionnaire.**
* **Does the study involve human participants?** YES/NO
* **Are the participants prospectively assigned to an intervention?** YES/NO
* **Is the study designed to evaluate the effect of the intervention on the participants?** YES/NO
* **Is the effect that will be evaluated a health-related biomedical or behavioral outcome?** YES/NO

If you answered yes to all 4 questions in 1.3, then this study meets the definition of a clinical trial. Please review the chart below for the sections you must fill out:

|  |  |  |
| --- | --- | --- |
| Form section | If you answered “yes “ to all the questions in the clinical trial questionnaire | If you answered “no” to any of the questions in the clinical trial questionnaire |
| Section 2 – Study population characteristics | Required | Required |
| Section 3 – Protection and monitoring plans | Required | Required  |
| Section 4 – protocol synopsis | Required | Do not complete |
| Section 5 – other clinical trial-related attachments | Required if specified in the FOA | Do not complete |

The sections/instructions below are only for those studies that are not considered clinical trial. If you are proposing a clinical trial, please contact the grants administrator for additional instructions and materials.

**SECTION 2**

**2.1 Conditions or focus of study:** List 1-20 entries. Identify names of diseases or conditions you are studying or the focus of the study

**2.2 Eligibility Criteria**

List Inclusion Criteria - you can use bullets. Max is 15,000 characters

List Exclusion Criteria - you can use bullets. Max is 15,000 characters

**2.3 Age limits**

* **Min Age:** enter age. If no limit, enter N/A
* **Max Age:** enter age. If no limit, enter N/A

**2.4 Inclusion of women, minorities, and children**

Prepare narrative according to the instructions below. You may attach as a separate PDF. Organize your attachment into two sections, following the headings and specified order below, and discuss each of the points listed below. Start each section with the appropriate section heading – “Inclusion of Women and Minorities” and “Inclusion of Children.” Also include any additional information requested in the FOA.

1. Inclusion of Women and Minorities:

Describe the following points:

* 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. See the Inclusion of Women and Minorities as Participants in Research Involving Human Subjects - Policy Implementation Page for more information.

Existing Datasets or Resources. 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. For more information about what is considered an existing dataset or resource for inclusion policy, see the NIH FAQs on Monitoring Inclusion When Working with Existing Datasets and/or Resources.

1. Inclusion of Children

For the purposes of the Inclusion of Children, individuals under 18 are defined as a child; however, exclusion of any specific age or age range group (e.g., older adults) should be justified in this section. In addition, address the following points:

* Children are expected to be included in all NIH-defined clinical research unless there are scientific or ethical reasons not to include them. Discuss whether children (as a whole or a subset of individuals under 18) will be included or excluded. If children will be included, include a rationale for selecting a specific age range of children, if relevant. If children will be excluded, provide a rationale for exclusion. See the NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects for additional information about circumstances that may justify the exclusion of children.
* Include a description of the expertise of the investigative team for working with children of the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.
* When children are involved in research, the policies under HHS’ 45 CFR 46, Subpart D - Additional Protections for Children Involved as Subjects in Research apply and must be addressed in the Protection of Human Subjects attachment.

For more information, see:

* [NIH's Policy Implementation Page on the Inclusion of Women and Minorities](https://grants.nih.gov/grants/funding/women_min/women_min.htm)
* [NIH’s Policy Implementation Page on the Inclusion of Children.](https://grants.nih.gov/grants/funding/lifespan/lifespan.htm)

**2.5 Recruitment and 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. You may attach a separate PDF or include here.

**2.6 Recruitment status: Select one of the following from the dropdown.** If any facility in a multi-site study has an individual site status of “recruiting,” then choose “recruiting” for this question. Only one selection is allowed. Choose

* Not yet recruiting
* Recruiting
* Enrolling by invitation
* Active, not recruiting
* Completed
* Suspended
* Terminated
* Withdrawn

**2.7 Study timeline**

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.

* 1. **Enrollment of first subject:** DD/MM/YY
* **Is this date anticipated or actual?** Anticipated/Actual

**Inclusion enrollment report**

Complete and attach planned inclusion enrollment report. You may complete and upload separately in the P30 pilot form. See <https://archives.nih.gov/asites/grants/04-13-2016/sites/default/files/PlannedEnrollmentReport_0.pdf> for blank template.

**Section 3**

**3.1 Protection of human subjects**

Please describe plan for protection of human subjects according to instructions below or provide separate attachment.

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. o 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.
* 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.

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).
1. 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.
1. 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 Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?** YES/NO

* **If yes, describe single IRB plan.**

**3.3 Data safety monitoring plan**

Please describe plan data safety monitoring plan according to instructions below or provide separate attachment.

For any proposed clinical trial, NIH requires a data and safety monitoring plan (DSMP) that is commensurate with the risks of the trial, its size, and its complexity. Provide a description of the DSMP, including:

* 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 (if applicable).
* 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. These include, but are not limited to, monitoring by a:
	+ PD/PI: While the PD/PI must ensure that the trial is conducted according to the approved protocol, in some cases (e.g., low risk trials, not blinded), it may be acceptable for the PD/PI to also be responsible for carrying out the DSMP.
	+ Independent safety monitor/designated medical monitor: a physician or other expert who is independent of the study.
	+ Independent Monitoring Committee or Safety Monitoring Committee: a small group of independent experts.
	+ Data and Safety Monitoring Board (DSMB): a formal independent board of experts including investigators and biostatisticians. NIH requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally, for all Phase III clinical trials, although Phase I and Phase II clinical trials may also need DSMBs. If a DSMB is used, please describe the general composition of the Board without naming specific individuals.

**3.4 Will a data and safety monitoring board be appointed for this study?** YES/NO

**3.5 Overall Structure of Study Team**

Provide a brief overview of the organizational structure of the study team, particularly the administrative sites, data coordinating sites, enrollment/participating sites, and any separate laboratory or testing centers. Note: Do not include study team members’ individual professional experiences (i.e., biosketch information).