Complete human subjects section of R&R Other Project Information form prior to completing this form.

PHS Human Subjects and Clinical Trials Information

Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.

The following items are taken from the Research & Related Other Project Information form and displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project Information form and may impact the data items you are required to complete on this form.

- Are Human Subjects Involved? [ ] Yes [ ] No
- Is the Project Exempt from Federal regulations? [ ] Yes [ ] No
- Exemption number: [1 2 3 4 5 6 7 8]

If No to Human Subjects

Does the proposed research involve human specimens and/or data? [ ] Yes [ ] No

If Yes, provide an explanation of why the application does not involve human subjects research.

Add Attachment [ ] Delete Attachment [ ] View Attachment [ ]

Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.

If Yes to Human Subjects

Add a record for each proposed Human Subject Study by selecting ‘Add New Study’ or ‘Add New Delayed Onset Study’ as appropriate. Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide the study name and a justification for omission of human subjects study information.

Other Requested Information

Only provide an Other Requested Information attachment when specifically requested in the funding opportunity announcement text or application guide.

Study Record(s)

Attach human subject study records using unique filenames.

1) Please attach Human Subject Study 1

Delayed Onset Study(ies)

Study Title
Anticipated Clinical Trial?
Justification

Required and system enforced for each delayed onset study. Up to 600 characters. Study title must be unique within the application. First 150 characters of title will show in application bookmark.

If Anticipated Clinical Trial box is checked, funding opportunity announcement must allow clinical trials. When multiple studies are included in the same delayed onset record, select Yes if it is anticipated that any study will be a clinical trial.

Required and system enforced for each delayed onset study. In addition to justification, must include information regarding how the study will comply with the NIH single Institutional Review Board (sIRB) policy prior to initiating any multi-site study, as well as, a plan for the dissemination of NIH-funded clinical trial information.

Updated: April 18, 2019
Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 03/31/2020

* Always required field

Section 1 - Basic Information

1.1. * Study Title (each study title must be unique)

Required and system enforced. Up to 600 characters. Study title must be unique within the application. First 150 characters of title will show in application bookmark.

1.2. * Is this Study Exempt from Federal Regulations?

[ ] Yes [ ] No

Answer required and system enforced.

If Study Exempt is Yes, must provide exemption number. Exemptions 7 and 8 can be used for due dates on/after January 25, 2019.

1.3. Exemption Number

[ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ] 6 [ ] 7 [ ] 8

1.4. * Clinical Trial Questionnaire

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

1.4.a. Does the study involve human participants?

[ ] Yes [ ] No

1.4.b. Are the participants prospectively assigned to an intervention?

[ ] Yes [ ] No

1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?

[ ] Yes [ ] No

1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

[ ] Yes [ ] No

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

Required and system enforced unless study is exemption 4. Up to 20 conditions at 255 characters each.

2.2. Eligibility Criteria

Required and system enforced unless study is exemption 4 or otherwise noted in opportunity.

Age limits are required and system enforced unless study is exemption 4 or otherwise noted in opportunity.

2.3. Age Limits

Minimum Age [ ] Dropdown Years [ ] Dropout Months Maximum Age [ ] Dropout

2.4. Inclusion of Women, Minorities, and Children

Required and system enforced unless study is exemption 4.

2.5. Recruitment and Retention Plan

Required and system enforced unless study is exemption 4, 1.4.a = No, or otherwise noted in opportunity.

2.6. Recruitment Status

Required and system enforced unless study is exemption 4, 1.4.a = No, or otherwise noted in opportunity.

2.7. Study Timeline

Required and system enforced unless study is exemption 4, 1.4.a = No, or otherwise noted in opportunity.

2.8. Enrollment of First Subject

Date: MM/DD/YYYY.

Required and system enforced unless study is exemption 4, 1.4.a = No, or otherwise noted in opportunity.

Inclusion Enrollment Report(s)

Inclusion Enrollment Reports required and system enforced unless study is exemption 4 or otherwise noted in opportunity.

Add Inclusion Enrollment Report

Up to 20 Inclusion Enrollment Reports can be added.

* Fellowship (F) and Career Development (K) applications to FOAs that do not allow clinical trials cannot propose independent clinical trial studies led by applicant PD/PI. However, proposing studies under the leadership of a sponsor/mentor that allows for clinical trials research experience is encouraged. Answering Yes to all four Clinical Trial Questionnaire questions will not flag the study as a clinical trial. These studies must include HS information, but will receive a system error if information is included in study fields in sections 4 or 5 of form.
Inclusion Enrollment Report

1. * Using an Existing Dataset or Resource
   - Yes
   - No
   Answer required and system enforced.

2. * Enrollment Location Type
   - Domestic
   - Foreign
   Answer required and system enforced. Do not mix domestic and foreign enrollment data on the same inclusion enrollment report.

3. Enrollment Country(ies)
   Multi-select from list of countries.

4. Enrollment Location(s)

5. Comments
   Up to 500 characters.

Planned enrollment information is required and system enforced when answer to "Using an Existing Dataset or Resource" question is No. System enforcement relaxed if Comment is provided.

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<th>Ethnic Categories</th>
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<td>Male</td>
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<td>0</td>
</tr>
<tr>
<td>Total</td>
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<td>0</td>
</tr>
</tbody>
</table>
Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects

Add Attachment  Delete Attachment  View Attachment

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  N/A

Answer required and system enforced. "N/A" is only a valid option for fellowship, and career development applications OR if study is exempt from federal regulations (i.e., Question 1.2a is Yes).

If yes, describe the single IRB plan

Add Attachment  Delete Attachment  View Attachment

Required and system enforced if Yes. Can attach same plan (unique filenames) in multiple studies.

3.3. Data and Safety Monitoring Plan

Add Attachment  Delete Attachment  View Attachment

Required and system enforced for CT study. Optional for HS study.

3.4. Will a Data and Safety Monitoring Board be appointed for this study?

Yes  No

Answer required and system enforced for CT study unless otherwise noted in opportunity. Optional for HS study.

3.5. Overall Structure of the Study Team

Add Attachment  Delete Attachment  View Attachment

Optional.

Section 4 - Protocol Synopsis

You are not allowed to complete fields in Section 4 (i.e., will receive system error) if FOA does not allow clinical trials and/or you answered No to one of the Clinical Trial Questionnaire questions in Section 1.

4.1. Brief Summary

Up to 5000 characters. Required and system enforced for CT studies unless otherwise noted in opportunity.

4.2. Study Design

All Study Design fields (4.2.a thru 4.2.g) are required and system enforced for CT studies unless otherwise noted in opportunity.

4.2.a. Narrative Study Description

Up to 32,000 characters.

4.2.b. Primary Purpose

Dropdown list: Treatment; Prevention; Diagnostics; Supportive Care; Screening; Health Services Research; Basic Science; Device Feasibility; and Other

4.2.c. Interventions

Up to 20 Interventions allowed.

<table>
<thead>
<tr>
<th>Intervention Type</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
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<tr>
<td>Basic Science</td>
<td></td>
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</tr>
<tr>
<td>Device Feasibility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug (including placebo); Device (including sham); Biological/Vaccine; Procedure/Surgery; Radiation; Behavioral (e.g., Psychotherapy, Lifestyle Counseling); Genetic (including gene transfer, stem cell and recombinant DNA); and Dietary Supplement (e.g., vitamins, minerals)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.2.d. Study Phase

Dropdown list: Early Phase 1 (or Phase 0); Phase 1; Phase 1/2; Phase 2; Phase 2/3; Phase 3; Phase 4; and Other

Is this an NIH-defined Phase III clinical trial?

Yes  No

4.2.e. Intervention Model

Dropdown list: Single Group; Parallel; Cross-Over; Factorial; Sequential; and Other.

4.2.f. Masking

Yes  No

Participant  Care Provider  Investigator  Outcomes Assessor

If Masking is Yes, you must select at least 1 of the Participant/Care Provider/Investigator/Outcomes Assessor check boxes.

Updated: April 18, 2019

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4.2.g. Allocation

Dropdown list: N/A; Randomized; and Non-randomized

Non-randomized

4.3. Outcome Measures

At least one Outcome Measure required and system enforced for CT studies unless otherwise noted in opportunity. Up to 50 Outcome Measures allowed.

<table>
<thead>
<tr>
<th>Name</th>
<th>Up to 255 characters</th>
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<tbody>
<tr>
<td>Type</td>
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<tr>
<td>Time Frame</td>
<td>Up to 255 characters</td>
</tr>
<tr>
<td>Brief Description</td>
<td>Up to 999 characters</td>
</tr>
</tbody>
</table>

4.4. Statistical Design and Power

Required and system enforced for CT study unless otherwise noted in opportunity.

4.5. Subject Participation Duration

Up to 255 characters. Required and system enforced for CT studies unless otherwise noted in opportunity.

4.6. Will the study use an FDA-regulated intervention?

☐ Yes  ☐ No

Answer required and system enforced for CT study unless otherwise noted in opportunity.

4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status

Required and system enforced if Yes.

4.7. Dissemination Plan

Required and system enforced for CT study. Generally one Dissemination Plan per application is sufficient. Can attach same plan (unique filenames) in multiple studies.

Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments

Form supports up to 10 attachments. Attachments only allowed for CT studies. Only include attachments requested in opportunity.