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

Add Attachment  Delete Attachment  View Attachment

Click here to extract the Human Subject Study Record Attachment

Study Record(s)

Attach human subject study records using unique filenames.

1) Please attach Human Subject Study 1

Add New Study

Delayed Onset Study(ies)

<table>
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<tr>
<th>Study Title</th>
<th>Anticipated Clinical Trial?</th>
<th>Justification</th>
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Add New Delayed Onset Study
Study Record: PHS Human Subjects and Clinical Trials Information

Section 1 - Basic Information

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

1.2. * Is this Study Exempt from Federal Regulations?  [ ] Yes  [ ] No

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

2.2. Eligibility Criteria

2.3. Age Limits  Minimum Age  [ ]  [ ]  [ ] Maximum Age  [ ]  [ ]  [ ]

2.4. Inclusion of Women, Minorities, and Children

2.5. Recruitment and Retention Plan

2.6. Recruitment Status

2.7. Study Timeline

2.8. Enrollment of First Subject

Inclusion Enrollment Report(s)

Add Inclusion Enrollment Report
# Inclusion Enrollment Report

1. * Using an Existing Dataset or Resource
   - [ ] Yes
   - [ ] No

2. * Enrollment Location Type
   - [ ] Domestic
   - [ ] Foreign

3. **Enrollment Country(ies)**
   - [X]
   - Add New Country

4. **Enrollment Location(s)**

5. **Comments**

## Planned

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Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects

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
   If yes, describe the single IRB plan

3.3. Data and Safety Monitoring Plan

3.4. Will a Data and Safety Monitoring Board be appointed for this study?
   □ Yes  □ No

3.5. Overall Structure of the Study Team

Section 4 - Protocol Synopsis

4.1. Brief Summary

4.2. Study Design

4.2.a. Narrative Study Description

4.2.b. Primary Purpose

4.2.c. Interventions

<table>
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<th>Intervention Type</th>
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4.2.d. Study Phase

Is this an NIH-defined Phase III clinical trial?  □ Yes  □ No

4.2.e. Intervention Model

4.2.f. Masking
   □ Yes  □ No
   □ Participant  □ Care Provider  □ Investigator  □ Outcomes Assessor
4.2.g. Allocation

4.3. Outcome Measures

<table>
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<tr>
<th>Name</th>
<th>Type</th>
<th>Time Frame</th>
<th>Brief Description</th>
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Add New Outcome

4.4. Statistical Design and Power

4.5. Subject Participation Duration

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

☐ Yes ☐ No

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

4.7. Dissemination Plan

Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments