PHS Human Subjects and Clinical Trials Information

* Always required field

1. * **Study Title (must be unique):**

2. * **Delayed Onset Study?:** ○ Yes ◉ No

3. * **Is the Study Exempt from Federal Regulations?:** ○ Yes ◉ No

4. * **Exemption Number:**

5. * **Clinical Trial Questionnaire:**

5.a. Does the study involve human participants?	◉ Yes	○ No
5.b. Are the participants prospectively assigned to an intervention?	◉ Yes	○ No
5.c. Is the study designed to evaluate the effect of the intervention on the participants?	◉ Yes	○ No
5.d. Is the effect that will be evaluated a health-related, biomedical, or behavioral outcome?	◉ Yes	○ No

If study is not delayed onset, the following sections are required:

Section 1 - Study Population Characteristics

1.1. Conditions or Focus of Study:

Add New Condition

1.2. Inclusion Criteria:

1.3. Exclusion Criteria:

1.4. Age Limits: **Minimum Age:** **Maximum Age:**

1.5. Inclusion of Women, Minorities and Children: Add Attachment

1.6. Recruitment and Retention Plan: Add Attachment

1.7. Recruitment Status:

1.8. Study Timeline: Add Attachment

Inclusion Enrollment Report(s): Add New IER Report

« 1 2 3 4 5 ... 12 »

Entry #	Enrollment Location Type	Enrollment Location	Actions
1	Domestic	Enrollment Location 1	Edit Remove View
2	Foreign	Enrollment Location 2	Edit Remove View
3	Domestic	Enrollment Location 3	Edit Remove View
4	Domestic	Enrollment Location 4	Edit Remove View
5	Domestic	Enrollment Location 5	Edit Remove View

Section 2 - Protection and Monitoring Plans

2.1. Protection of Human Subjects: Add Attachment

2.2. 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 the single IRB plan: Add Attachment

2.3. Will a data and safety monitoring board be appointed for this study? (•) Yes ( ) No

2.4. Data and Safety Monitoring Plan: MonitoringPlan.pdf Replace Attachment Delete Attachment View Attachment

2.5. Overall structure of the study team:

Section 3 - Clinical Trial Synopsis

3.1. Objective:

3.2. Study Design:

3.2.a. Narrative Study Description:

3.2.b. Primary Purpose:

3.2.c. Interventions:

Intervention Type	
Name	
Description	

Add New Intervention

3.2.d. Study Phase:

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

3.2.e. Intervention Model:

3.2.f. Masking: [ ] Participant [ ] Care Provider [ ] Investigator [ ] Outcomes Assessor [ ] No Masking

3.2.g. Allocation:

3.3. Outcomes or Measures:

Name	
Type	
Time Frame	

Brief Description	

Add New Outcome

3.4. Statistical Design and Power: Add Attachment

3.5. Subject Participation Duration:

3.6. Will use an FDA regulated intervention?: (•) Yes ( ) No

3.6.a. If yes, Availability of Investigational Product (IP) and IND/IDE Status:

3.7. Dissemination Plan : Add Attachment

Section 4 - Other Clinical Trial-related Attachments

4.1. Other Trial Related Attachments: Add Attachment

Attachment File Name	Delete On Save	Update Attachment	View Attachment
Attachment 1.pdf	☐	Update	View
Attachment 2.pdf	☐	Update	View

Section 5 - Clinical Trial Milestone Plan

5.1. Have there been any anticipated or unanticipated serious adverse events? ( ) Yes (•) No ( ) Not applicable

5.2. Have adverse events occurred with greater than 5 percent frequency within any area of the clinical trial? ( ) Yes (•) No ( ) Not applicable

5.3. Study Start Date: MM/DD/YYYY

5.4. Study Primary Completion Date: MM/DD/YYYY

5.5. Study Final Completion Date: MM/DD/YYYY

5.6. Finalization of clinical protocol (with program agreement, if applicable): MM/DD/YYYY

5.7. Registration of clinical trial in ClinicalTrials.gov: MM/DD/YYYY

5.8. Completion of regulatory approvals: MM/DD/YYYY

5.9. Enrollment of the first subject: MM/DD/YYYY

5.10. Enrollment and randomization:

25% of planned enrollment recruited by: MM/DD/YYYY

50% of planned enrollment recruited by: MM/DD/YYYY

75% of planned enrollment recruited by: MM/DD/YYYY

100% of planned enrollment recruited by: MM/DD/YYYY

5.11. Completion of data collection time period: MM/DD/YYYY

5.12. Completion of primary endpoint data analyses: MM/DD/YYYY

5.13. Completion of secondary endpoint data analyses: MM/DD/YYYY

5.14. Completion of final study report: MM/DD/YYYY

5.15. Reporting of results in ClinicalTrials.gov: MM/DD/YYYY

5.16. Provide the ClinicalTrials.gov identifier (e.g. NCT00654321) for this trial :

5.17. Is this an applicable clinical trial under FDAAA? (•) Yes ( ) No

5.18. Clinical Trials Registration & Reporting Certification:

Assurance is hereby provided that the recipient and all investigators conducting NIH-funded clinical trials are in compliance with NIH policy on Dissemination of NIH-Funded Clinical Trial Information and that any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov. If not registered at the time of this submission, the clinical trial will be registered not later than 21 days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the primary completion date, even if the primary completion date occurs after the period of performance.

(•) Agree ( ) Disagree

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