Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001 and 0925-0002
Expiration Date: 03/31/2020

* Always required field

Section 1 - Basic Information

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

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 Add Attachment | Delete Attachment | View Attachment

2.5. Recruitment and Retention Plan Add Attachment | Delete Attachment | View Attachment

2.6. Recruitment Status

2.7. Study Timeline Add Attachment | Delete Attachment | View Attachment

2.8. Enrollment of First Subject

Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects Add Attachment | View Attachment | Delete 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

If yes, describe the single IRB plan Add Attachment View Attachment Delete Attachment

3.3. Data and Safety Monitoring Plan Add Attachment View Attachment Delete Attachment

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

☐ Yes ☐ No

3.5. Overall structure of the study team Add Attachment View Attachment Delete Attachment

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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

Intervention Type	
Name	
Description	

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. Outcomes or Measures

Name	
Type	
Time Frame	
Brief Description	

4.4. Statistical Design and Power Add Attachment View Attachment Delete Attachment

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

Add Attachment View Attachment Delete Attachment

4.7. Dissemination Plan Add Attachment View Attachment Delete Attachment

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Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments Add Attachments Delete Attachments View Attachments