Check Form for Errors | Save

# Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 02/28/2023

* Always required field

## Section 1 - Basic Information

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

This should match the title on your application.

**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

Section 2 is required for all Human Subjects Research. Please complete all fields.

**2.1. Conditions or Focus of Study**

At least 1 entry is *required*, and up to 20 entries are allowed (enter each entry on its own line). Each entry is limited to 225 characters.

Identify the name(s) of the disease(s) or condition(s) you are studying, or the focus of the study. If available, use appropriate descriptors from NLM's Medical Subjects Headings (MeSH) so the application can be categorized: https://meshb.nlm.nih.gov/search

**2.2. Eligibility Criteria**

List the study's inclusion and exclusion criteria. To provide a bulleted list, use a dash (or other character) followed by a space ("- ") at the start of each bullet. Be sure to check the format in the assembled application image. Further explanation or justification should be included in attachment 2.5 Recruitment and Retention Plan. Your text entry is limited to 15,000 characters (but typically needs only ~500 characters).

**2.3. Age Limits** **Minimum Age** **Maximum Age** Years

**2.3.a. Inclusion of Individuals Across the Lifespan** Add Attachment | Delete Attachment | View Attachment

**2.4. Inclusion of Women and Minorities** Add Attachment | Delete Attachment | View Attachment

**2.5. Recruitment and Retention Plan** This is required unless you selected *only* **Exemption 4** for question "1.3 Exemption Number." 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 Participant**

Do no complete this field if you are using an existing dataset or resource.
This is otherwise required unless you selected *only* **Exemption 4** for question "1.3 Exemption Number."

**2.9. Inclusion Enrollment Report(s)**

Add Inclusion Enrollment Report

An Inclusion Enrollment Report is required for all human subjects studies unless, on question "1.3 Exemption Number," you selected *only* **Exemption 4** and no other exemptions.
Each proposed study otherwise *must* contain at least one Inclusion Enrollment Report (IER). However, more than one IER per study is allowed (for example, Aim 1 includes focus group or interviews and Aim 2 includes a device study). Select "Add Inclusion Enrollment Report" to add a new IER.

**Section 3 - Protection and Monitoring Plans** Section 3 is required for all Human Subjects Research. Please complete all fields.

**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

**If yes, describe the single IRB plan** This attachment is **not** required. Add Attachment | Delete Attachment | View Attachment

**3.3. Data and Safety Monitoring Plan** This attachment is *only* required if you answered "Yes" to all 4 questions in Section "1.4 Clinical Trial Questionnaire." Add Attachment | Delete Attachment | View Attachment

**3.4. Will a Data and Safety Monitoring Board be appointed for this study?** If you answered "Yes" to all 4 questions in Section "1.4 Clinical Trial Questionnaire" please contact Jason Molony (jmolony@umass.edu) to determine safety oversight. Otherwise, select "No."

☐ Yes ☐ No

**3.5. Overall Structure of the Study Team** This attachment is *only* required if you answered "Yes" to all 4 questions in Section "1.4 Clinical Trial Questionnaire." Add Attachment | Delete Attachment | View Attachment

**Section 4 - Protocol Synopsis**

**4.1. Study Design**

**4.1.a. Detailed Description**

**4.1.b. Primary Purpose**

**4.1.c. Interventions**

| | |
|---|---|
| **Intervention Type** | |
| **Name** | |
| **Description** | |

**4.1.d. Study Phase**

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

**4.1.e. Intervention Model**

**4.1.f. Masking** ☐ Yes ☐ No

☐ Participant ☐ Care Provider ☐ Investigator ☐ Outcomes Assessor

**4.1.g. Allocation**

**4.2. Outcome Measures**

| | |
|---|---|
| **Name** | |
| **Type** | |
| **Time Frame** | |
| **Brief Description** | |

**4.3. Statistical Design and Power** Add Attachment | Delete Attachment | View Attachment

**4.4. Subject Participation Duration**

**4.5. Will the study use an FDA-regulated intervention?** ☐ Yes ☐ No

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

Add Attachment | Delete Attachment | View Attachment

**4.6. Is this an applicable clinical trial under FDAAA?** ☐ Yes ☐ No

**4.7. Dissemination Plan** Add Attachment | Delete Attachment | View Attachment

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**Section 5 - Other Clinical Trial-related Attachments**

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