**NIH Grant Human Subjects Section (Protocol Synopsis)**

**Section 4 – Protocol Synopsis**

Who must complete "Section 4 - Protocol Synopsis:" If you answered "Yes" to all the questions in the "[Clinical Trial Questionnaire](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#1.4):" All the questions in the "Protocol Synopsis" section are required.

### **4.1 Study Design**

##### 4.1.a. Detailed Description

Enter a narrative description of the protocol. Studies differ considerably in the methods used to assign participants and deliver interventions. Describe your plans for assignment of participants and delivery of interventions. You will also need to show that your methods for sample size and data analysis are appropriate given those plans. For trials that randomize groups or deliver interventions to groups, special methods are required; additional information is available at the [Research Methods Resources](https://researchmethodsresources.nih.gov/) webpage.

The narrative description is limited to 32,000 characters.

For more information about formatting text entry fields, see NIH's [Rules for Text Fields](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/rules-for-text-fields.htm) page.

##### 41.b. Primary Purpose

Enter or select from the dropdown menu a single "Primary Purpose" that best describes the clinical trial. Choose from the following options:

* Treatment
* Prevention
* Diagnostics
* Supportive Care
* Screening
* Health Services Research
* Basic Science
* Device Feasibility
* Other (If you select "Other," provide a description in the space provided. Your response is limited to 255 characters.)

##### 4.1.c. Interventions

Complete the "Interventions" fields for each intervention to be used in your proposed protocol. If an arm of the study to which subjects will be assigned includes more than one intervention (e.g., drug plus educational intervention), complete this section for each intervention. You can add up to 20 interventions.

**Intervention Type:** Enter or select from the dropdown menu the intervention type the clinical trial will administer during the proposed award. Choose from the following options:

* 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)
* Dietary Supplement (e.g., vitamins, minerals)
* [Combination Product](https://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm118332.htm)
* Diagnostic Test
* Other

**Name:** Enter the name of the intervention. The name must be unique within each study record. The name is limited to 200 characters.

**Description:** Enter a description of the intervention. The description is limited to 1,000 characters.

##### 4.1.d. Study Phase

Enter or select from the dropdown menu a "[Study Phase](https://prsinfo.clinicaltrials.gov/definitions.html#StudyPhase)" that best describes the clinical trial. If your study involves a device, choose "Other."

Choose from the following options:

* Early Phase 1 (or Phase 0)
* Phase 1
* Phase 1/2
* Phase 2
* Phase 2/3
* Phase 3
* Phase 4
* Other (provide a description in the space provided. Your response is limited to 255 characters)

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

Select "Yes" or "No" to indicate whether the study includes an [NIH-defined Phase III clinical trial](https://grants.nih.gov/grants/glossary.htm#NIHDefinedPhaseIIIClinicalTrial).

##### 4.1.e. Intervention Model

Enter or select from the dropdown menu a single "Intervention Model" that best describes the clinical trial. If you select "Other," provide a description in the space provided. Choose from the following options:

* Single Group
* Parallel
* Cross-Over
* Factorial
* Sequential
* Other (provide a description in the space provided, response limited to 255 characters)

##### 4.1.f. Masking

Select "Yes" or "No" to indicate whether the protocol uses [masking](https://clinicaltrials.gov/ct2/about-studies/glossary#masking-or-blinding). Note that masking is also referred to as "blinding."

If you answered "Yes" to the "Masking" question, select one or more types of masking that best describes the protocol. Choose from the following options:

* Participant
* Care Provider
* Investigator
* Outcomes Assessor

##### 4.1.g. Allocation

Enter or select from the dropdown menu a single "Allocation" that best describes how subjects will be assigned in your protocol. If allocation is not applicable to your clinical trial, select "N/A" (e.g., for a single-arm trial). Choose from the following options:

* N/A
* Randomized
* Non-randomized

### **4.2. Outcome Measures**

Complete the "Outcome Measures" fields for each primary, secondary, and other important measures to be collected during your proposed clinical trial. You may have more than one primary outcome measure, and you can add up to 50 outcome measures.

**Name:** Enter the name of the individual outcome measure. The outcome measure must be unique within each study record.

**Type:** Enter or select from the dropdown menu the type of the outcome measure. Choose from the following options:

* Primary - select this option for the outcome measures specified in your protocol that are of greatest importance to your study
* Secondary - select this option for outcome measures specified in your protocol that are of lesser importance to your study than your primary outcomes
* Other - select this option for additional key outcome measures used to evaluate the intervention.

**Time Frame:** Indicate when a measure will be collected for analysis (e.g., baseline, post-treatment).

**Brief Description:** Describe the metric used to characterize the outcome measure if the metric is not already included in the outcome measure name. Your description is limited to 999 characters.

### **4.3. Statistical Design and Power**

#### Format:

Attach this information as a PDF file. See NIH's [Format Attachments](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) page.

#### Content:

Specify the number of subjects you expect to enroll, the expected effect size, the power, and the statistical methods you will use with respect to each outcome measure you listed in outcome measures.

You will need to show that your methods for sample size and data analysis are appropriate given your plans for assignment of participants and delivery of interventions. For trials that randomize groups or deliver interventions to groups, special methods are required; additional information is available at the [Research Methods Resources](https://researchmethodsresources.nih.gov/) webpage.

### **4.4 Subject Participation Duration**

Enter the time (e.g., in months) it will take for each individual participant to complete all study visits. If the participation duration is unknown or not applicable, write "unknown" or "not applicable." The subject participation duration is limited to 255 characters.

### **4.5 Will the study use an FDA-regulated intervention?**

Select "Yes" or "No" to indicate whether the study will use an FDA-regulated intervention (see the definition of "FDA Regulated Intervention" under the [Oversight](https://prsinfo.clinicaltrials.gov/definitions.html#oversight) section of the [ClinicalTrials.gov Protocol Registration Data Element Definitions for Interventional and Observational Studies](https://prsinfo.clinicaltrials.gov/definitions.html) page).

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

This attachment is required if you answered "Yes" to the "Will the study use an FDA-regulated intervention?" question.

#### Format:

Attach this information as a PDF file. See NIH's [Format Attachments](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) page.

#### Content:

Describe the availability of study agents and support for the acquisition and administration of the study agent(s). Please indicate the IND/IDE status of the study agent, if applicable, and whether the investigators have had any interactions with the FDA. If the study agent currently has an IND/IDE number, provide that information. **Note:** The awarding component may request consultation with the FDA and the IND/IDE sponsor about the proposed clinical trial after peer review and prior to award.

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### **4.6 Is This an applicable clinical trial under FDAAA?**

### Select "Yes" or "No" to indicate whether the trial meets the FDAAA requirements. See <https://clinicaltrials.gov/ct2/manage-recs/fdaaa>

### **4.7 Dissemination Plan**

#### Format:

Attach this information as a PDF file. See NIH's [Format Attachments](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) page.

Although one Dissemination Plan per application is sufficient, you must include a file for each study within your application. All file names within your application must be unique. You may either attach the same Dissemination Plan to different studies or attach a file that refers to the Dissemination Plan in another study within your application. For example, you may attach a file that says "See Dissemination Plan in the 'My Unique Study Name' study."

#### Content:

Explain briefly your plan for the dissemination of NIH-funded clinical trial information and address how the expectations of the policy will be met. The plan must contain sufficient information to assure the following:

* the applicant will ensure that clinical trial(s) under the award are registered and results information is submitted to ClinicalTrials.gov as outlined in the [policy](https://grants.nih.gov/policy/clinical-trials/reporting/understanding/nih-policy.htm) and according to the specific timelines stated in the policy;
* informed consent documents for the clinical trial(s) will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov; and
* the recipient institution has an internal policy in place to ensure that clinical trials registration and results reporting occur in compliance with policy requirements.

**Note:** Do not include informed consent documents in your application.

**Note:** If your human subjects study meets the definition of "[Delayed Onset](https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy)," include the dissemination plan in the [delayed onset study justification](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#Justification).

#### For more information:

See the [NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html).

See the [NIH Grants Policy Statement, Section 4.1.3.1 NIH Policy on Dissemination of NIH-Funded Clinical Trial Information](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1_public_policy_requirements_and_objectives.htm?tocpath=4%20Public%20Policy%20Requirements%2C%20Objectives%20and%20Other%20Appropriation%20Mandates%7C4.1%20Public%20Policy%20Requirements%20and%20Objectives%7C4.1.3%20Clinical%20Trials%20Registration%20and%20Reporting%20in%20ClinicalTrials.gov%20Requirement%7C_____1#4.1.3.1_NIH_Policy_on_Dissemination_of_NIH-Funded_Clinical_Trial_Information).