**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 (but typically needs only 5,000 characters), should be written in layperson’s terms, and may repeat some of the information in the Research Strategy.

**Note:** This field matches a ClinicalTrials.gov field (Detailed Description).

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.

##### **4.1.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.)

**Note:** This field matches a ClinicalTrials.gov field (Primary Purpose).

##### **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.

**Note:** This field matches a ClinicalTrials.gov field. (Interventions, including Intervention Type and Intervention Name(s)).

**For more information** on how to answer this question for behavioral research trials, refer to the relevant FAQ on the Applying Electronically FAQ page.

##### **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).

**For more information** on how to answer this question for devices or behavioral interventions, refer to the relevant FAQ on the Applying Electronically FAQ page.

##### **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)

**Note:** This field matches a ClinicalTrials.gov field (Interventional Study Model).

**For more information:** Definitions of intervention models may be found in ClinicalTrials.gov’s Glossary of Common Site Terms or in the ClinicalTrials.gov’s description of Study Design.

##### **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

**Note:** This field matches a ClinicalTrials.gov field (Masking).

##### **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

**Note:** This field matches a ClinicalTrials.gov field (Allocation).

### **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.

**NIH-Defined Phase III Clinical Trials:** If the proposed research includes an NIH-Defined Phase III Clinical Trial, then outcomes for required analyses by sex/gender, race, and ethnicity should be entered.

Additional information about valid analysis is available on the NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research page.

**Note:** This field matches a ClinicalTrials.gov field (e.g., Primary Outcome Measure Information, which includes Title, Description, and Time Frame).

**For more information:** Refer to the relevant FAQ for question 4.2 Outcome Measures on the Applying Electronically FAQ page.

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### **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. This attachment’s typical length is approximately 3,000 characters.

**Content:**

Provide a summary describing the availability of study agents and support for the acquisition and administration of the study agent(s). Please indicate, if applicable, the IND/IDE status of the study agent, including whether a clinical investigation is exempt from the IND/IDE requirement. Also indicate whether the investigators have had any interactions with the FDA (e.g., indicate if the FDA has stated that research may proceed). If the study agent currently has an IND/IDE number, provide that information. Do not include the IND/IDE application, manufacturer’s product specifications, study protocol, or protocol amendments in this attachment.

Additional information such as FDA letters or correspondence with the FDA may be requested in the FOA.

**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 study is an applicable clinical trial (ACT) under the Food and Drug Administration Amendments Act (FDAAA).

**For more information**:

NIH Glossary’s definition of an applicable clinical trial

FAQs on the ClinicalTrials.gov & FDAAA

ClinicalTrials.gov FAQs

### **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).