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| ***A close up of a sign  Description automatically generated*** | NIH Protocol Summary For Studies Proposing Clinical Trials |

# **NIH Protocol Summary Template**

The UCLA Clinical and Translational Science Institute (CTSI) Grants Submission Unit has created this protocol summary template as a tool to facilitate the development of required components for NIH applications involving Clinical Trials. Each section contains requirements from the NIH and these guidelines should be removed before finalizing. Please be aware of components for which [Text Field rules apply](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/rules-for-text-fields.htm) and their character limitations. It is not meant to replace your review of all applicable notices, guidelines, and updates from the NIH related to the specific funding opportunity being responded to. Investigators and research administration staff should continue to refer to NIH’s official policies and guidelines available here: <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general-forms-h.pdf>.

This template refers only to those sections of FORMS-H related to human subjects and clinical trials for applications on or after January 25th, 2023; it does not cover the entirety of the SF424 or other portions of the grant application process. Investigators should always remember to refer to the specific Funding Opportunity Announcement (FOA) for any submission-specific information, including whether clinical trials are allowed and other FOA-specific requirements that may not be reflected on this form.

Questions? Contact the UCLA CTSI Grants Submission Unit at gsu@mednet.ucla.edu or (310) 267-4258.

# **Section 1. Basic Information**

* 1. **Study Title** **(600 character limit):**

For additional studies within the same application, fill out this form separately each with its own unique study title.

# **Section 2. Study Population Characteristics**

**2.1 Conditions or Focus of Study** (Additional guidelines available [here](https://ctsi.ucla.edu/funding/files/view/docs/gsu/2.1_Conditions_or_Focus_of_the_Study.docx).)

Minimum 1 required, max 20. ***255 characters each***. 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 Subject Headings (MeSH)](https://meshb.nlm.nih.gov/MeSHonDemand). Include an entry for each condition separately. Text field rules apply.

**Condition 1:**

*Add more Conditions, if applicable.*

**2.2 Eligibility Criteria** (Additional guidelines available [here](https://ctsi.ucla.edu/funding/files/view/docs/gsu/2.2_Eligibility_Criteria_Guidelines.docx).)

***Limited to 15,000 characters***. List inclusion and exclusion criteria. Further explanation or justification should be included in the Recruitment and Retention plan. Text field rules apply.

**Inclusion Criteria:**

**Exclusion Criteria:**

**2.3 Age Limits:** Minimum Age:       Choose an item. Maximum Age:       Choose an item.

**2.3.a. Inclusion of Individuals Across the Lifespan** (Additional guidelines available [here](https://ctsi.ucla.edu/funding/files/view/docs/gsu/2.3a_Inclusion_of_Individuals_Across_the_Lifespan_Guidelines.docx).)

1. Justify exclusions of specific age or age range groups, if applicable
2. Specifically discuss whether there will be included/excluded across the lifespan (including children and older adults)
3. If included, include rationale for selected specific age range across the lifespan, if relevant
4. If excluded, provide rationale for exclusion
5. If children will be included, include a description of the expertise of the investigative team for working with children of the ages included, of the appropriateness of available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.
6. When children are involved in research, the Additional Protections for Children Involved as Subjects in Research apply and must be addressed in the Protection of Human Subjects attachment

**2.4 Inclusion of Women and Minorities** (Additional guidelines available [here](https://ctsi.ucla.edu/funding/files/view/docs/gsu/2.4_Inclusion_of_Women_Minorities_Guidelines.docx).)

### **Inclusion of Women and Minorities**

**If Recruitment is Planned**

1. Describe planned distribution of subjects by sex/gender, race, and ethnicity.
2. Describe rationale for selection of sex/gender, racial, and ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.
3. Describe proposed outreach programs for recruiting sex/gender, racial and ethnic group members. This is particularly important if difficulty recruiting certain groups is anticipated.
4. Inclusion of Excluded Groups: Provide a reason for limiting inclusion of any group by sex/gender, racial, and/or ethnicity. Cost and geographic location are not acceptable reasons.

**If Using Existing Datasets or Resources**

1. Include all of the above and,
2. Justify the details as appropriate to the scientific goals of the proposed study

**If study is NIH-Defined Phase III CT:**

1. Include all of the above and,
2. Provide plans for how sex/gender, race, and ethnicity will be taken into consideration in the design and valid analysis of the trial
3. Additional information about valid analysis
4. Plan to test for differences in effect among sex/gender, racial, and/or ethnic groups

**2.5 Recruitment and Retention Plan** (Additional guidelines available [here](https://ctsi.ucla.edu/funding/files/view/docs/gsu/2.5_Recruitment_and_Retention_Plan_Guidelines.docx).)

1. **Recruitment**
	1. Describe how you will recruit participants in your study (incl. planned recruitment activities)
2. **Retention**
	1. Describe how you will retain participants in your study
		1. Address proposed engagement strategies for retention
		2. OR justify why retention is not needed (i.e. only 1 interaction)
3. Include additional explanation or justification of Eligibility Criteria (inclusion and/or exclusion)

**2.6 Recruitment Status**: Choose an item.

**2.7 Study Timeline** (Additional guidelines available [here](https://ctsi.ucla.edu/funding/files/view/docs/gsu/2.7_Study_Timeline_Guidelines.docx).)

1. Provide a description or diagram describing the study timeline.
2. The timeline should be general (e.g. “one year after notice of award”), and should not include specific dates.
3. Timeline should be described in detail taking into account:
	1. Start-Up activities
	2. Anticipated rate of enrollment
	3. Planned follow-up assessment
	4. Timeline must be feasible and well justified
	5. If applicable, project incorporates efficiencies and existing resources (CTSAs, networks, EMRs, databases, and patient registries) to increase efficiency of patient enrollment
	6. Address potential challenges and correspondent solutions (i.e. strategies re: enrollment shortfalls)

**2.8 Enrollment of First Participant** (enter date as MM/DD/YYYY):

Click or tap to enter a date. Choose an item.

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

1) Inclusion Enrollment Report Title (600 characters:

2) Using an Existing Dataset or Resources? 

3) Enrollment Location Type: 

4) Enrollment Country(ies):

5) Enrollment Location(s):

6) Comments (Up to 500 characters):

**Planned.** Planned enrollment information is required and system enforced when answer to “Using an Existing Dataset or Resources” question is No. System enforcement relaxed if Comment is provided.

|  |  |
| --- | --- |
| **Racial Categories** | **Ethnic Categories** |
| Not Hispanic or Latino | Hispanic or Latino | **Total** |
| **Female** | **Male** | **Female** | **Male** |  |
| American Indian/Alaska Native |  |  |  |  |  |
| Asian |  |  |  |  |  |
| Native Hawaiian or Other Pacific Islander |  |  |  |  |  |
| Black or African American |  |  |  |  |  |
| White |  |  |  |  |  |
| More than Once race |  |  |  |  |  |
| **Total** |  |  |  |  |  |

**Cumulative (Actual).** Cumulative (Actual) enrollment information is required and system enforced when answer to “Using an Existing Dataset or Resource” is Yes. System enforcement relaxed if Comments is provided.

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| --- | --- |
| **Racial Categories** | **Ethnic** **Categories** |
| Not Hispanic or Latino | Hispanic or Latino | Unknown/Not Reported Ethnicity | **Total** |
| **Female** | **Male** | **Unknown/ Not Reported** | **Female** | **Male** | **Unknown/ Not Reported** | **Female** | **Male** | **Unknown/ Not Reported** |  |
| American Indian/Alaska Native |  |  |  |  |  |  |  |  |  |  |
| Asian |  |  |  |  |  |  |  |  |  |  |
| Native Hawaiian or Other Pacific Islander |  |  |  |  |  |  |  |  |  |  |
| Black or African American |  |  |  |  |  |  |  |  |  |  |
| White |  |  |  |  |  |  |  |  |  |  |
| More than Once race |  |  |  |  |  |  |  |  |  |  |
| Unknown or Not Reported |  |  |  |  |  |  |  |  |  |  |
| **Total** |  |  |  |  |  |  |  |  |  |  |

**Section 3. Protection and Monitoring Plans**

**3.1 Protection of Human Subjects** (Additional guidelines available [here](https://ctsi.ucla.edu/funding/files/view/docs/gsu/3.1_Protection_of_Human_Subjects_Guidelines.docx).)

1. **Risks to Human Subjects**
	1. **Human Subjects Involvement, Characteristics, and Design**

Briefly describe the overall study design.

Describe the subject population(s) to be included in the study; the procedures for assignment to a study group, if relevant; and the anticipated numbers of subjects for each study group.

List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research.

**No Forms H Updates for this section**.

* 1. **Study Procedures, Materials, and Potential Risks**

Describe all planned research procedures (interventions and interactions) involving study subjects; how research material, including biospecimens, data, and/or records, will be obtained; and whether any private identifiable information will be collected in the proposed research project.

For studies that will include the use of previously collected biospecimens, data or records, describe the source of these materials, whether these can be linked with living individuals, and who will be able to link the materials.

Describe all the potential risks to subjects associated with each study intervention, procedure or interaction, including physical, psychological, social, cultural, financial, and legal risks; risks to privacy and/or confidentiality; or other risks. Discuss the risk level and the likely impact to subjects.

Where appropriate, describe alternative treatments and procedures, including their risks and potential benefits. When alternative treatments or procedures are possible, make the rationale for the proposed approach clear.

**No Forms H Updates for this section**.

1. **Adequacy of Protection Against Risks**
	1. **Informed Consent and Assent**

Describe the process for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. When appropriate, describe how potential adult subjects’ capacity to consent will be determined and the plans for obtaining consent from a legally authorized representative for adult subjects not able to consent.

**For research involving children:** If the proposed studies will include children, describe the process for meeting HHS regulatory requirements for parental permission and child assent (45 CFR 46.408). See the HHS page on Research with Children FAQs and the NIH page on Requirements for Child Assent and Parent/Guardian Permission.

If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver. Do not submit informed consent document(s) with your application unless you are requested to do so.

**No Forms H Updates for this section**.

* 1. **Protections Against Risk**

Describe planned strategies for protecting against or minimizing all potential risks identified, including strategies to manage and protect the privacy of participants and confidentiality of research data.

Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects on participants.

Describe plans for handling incidental findings, such as those from research imaging, screening tests, or paternity tests.

**No Forms H Updates for this section**.

* 1. **Vulnerable Subjects, if relevant to your study**

Explain the rationale for the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. 'Prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers).

*Pregnant Women, Fetuses, and Neonates or Children*

If the study involves vulnerable subjects subject to additional protections under Subparts B and D (pregnant women, fetuses, and neonates or children), provide a clear description of the risk level and additional protections necessary to meet the HHS regulatory requirements.

*Prisoners*

If the study involves vulnerable subjects subject to additional protections under Subpart C (prisoners), describe how proposed research meets the additional regulatory requirements, protections, and plans to obtain OHRP certification for the involvement of prisoners in research.

**No Forms H Updates for this section**.

1. **Potential Benefits of the Proposed Research to Research Participants and Others**

Discuss the potential benefits of the research to research participants and others.

Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.

Note: Financial compensation of subjects should not be presented as a benefit of participation in research.

**No Forms H Updates for this section**.

1. **Importance of the Knowledge to be Gained**

Discuss the importance of the knowledge to be gained as a result of the proposed research.

Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

**No Forms H Updates for this section**.

**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?**  

**If Yes, Describe a single IRB Plan:** (Additional guidelines available [here](https://ctsi.ucla.edu/funding/files/view/docs/gsu/3.2_Single_IRB_Plan_sIRB_Guidelines.docx).)

**NOTE**: THIS QUESTION IS **NOT** REQUIRED FOR NIH APPLICATIONS, ONLY AHRQ. IRB of record will be required during Just-in-Time.

1. Describe how you will comply with the NIH Policy on the use of sIRB for multi-site research.
2. Provide the name of the IRB that will serve as the sIRB of Record (Reviewing IRB Institution).
3. Indicate that all identified participating sites have agreed to rely on the proposed sIRB and that any sites added afterward will rely on the sIRB.
4. Briefly describe how communications between sites will, prior to initiating the study, sign an authorization/reliance agreement that will clarify the roles and responsibilities of the sIRB and participating sites.
5. Indicate which institution or entity will maintain records of the authorization/reliance agreements and of the communication plan.
6. Note: Do NOT include the authorization/reliance agreements or communication plan(s).

*Contact UCLA IRB Reliance for guidance before completing:* *irbreliance@research.ucla.edu*

**3.3 Data and Safety Monitoring Plan** (Additional guidelines available [here](https://ctsi.ucla.edu/funding/files/view/docs/gsu/3.3_Data_and_Safety_Monitoring_Plan_Guidelines.docx).)

DSMP must be commensurate with the risks of the trial and its size and complexity. Provide a description of the proposed DSMP.

1. Describe overall framework for safety monitoring and what information will be monitored.
2. State the frequency of monitoring, including any plans for interim analysis and stopping rules (if applicable).
3. Describe the process by which Adverse Events (AEs), including Serious Adverse Events (SAEs) such as deaths, hospitalizations, and life threatening events and Unanticipated Problems (UPs), will be managed and reported as required to the Institutional Review Board (IRB), the person or group responsible for monitoring, the funding IC, the NIH Office of Biotechnology Activities (OBA; http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines), and the Food and Drug Administration (FDA; http://www.fda.gov/).
4. State the individual(s) or group that will be responsible for trial monitoring and advising the appointing entity. Because the monitoring plan will depend on potential risks, complexity, and the nature of the trial, a number of options for monitoring are possible. These include, but are not limited to, monitoring by a:
	1. PD/PI: While the PD/PI must ensure that the trial is conducted according to the protocol, in some cases (e.g., low risk trials, not blinded), it may be acceptable for the PD/PI to also be responsible for carrying out the DSMP.
	2. Independent safety monitor/Designated medical monitor: a physician or other expert who is independent of the study.
	3. Independent Monitoring Committee or Safety Monitoring Committee: A small group of independent investigators and biostatisticians.
	4. Data and Safety Monitoring Board (DSMB): a formal independent board of experts including investigators and biostatisticians. As noted in Part II Section 5.3, NIH requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally for Phase III clinical trials. Although Phase I and Phase II clinical trials may also need DSMBs, smaller clinical trials may not require this oversight format, and alternative monitoring plans may be appropriate.
		* If a DSMB is used, please describe the general composition of the Board without naming specific individuals (see Contacts above for established DSMBs, if needed).

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

**3.5 Overall Structure of the Study Team** (Additional guidelines available [here](https://ctsi.ucla.edu/funding/files/view/docs/gsu/3.5_Overall_Structure_Study_Team_Guidelines.docx).)

1. Provide a brief overview of the organizational structure of the study team including:
	1. Administrative sites
	2. Data Coordinating sites
	3. Enrollment/participating sites
	4. Any separate laboratory or testing centers
2. Note: Do NOT include study team member’s individual professional experiences (i.e. biosketch information)

# **Section 4. Protocol Synopsis**

**4.1 Study Design**

**4.1.a Detailed Description** (Additional guidelines available [here](https://ctsi.ucla.edu/funding/files/view/docs/gsu/4.1.a_Detailed_Description_Guidelines.docx).)

**Limited to 32,000 characters.** Enter a narrative description of the protocol, including more technical information. Do NOT include the entire protocol. Do NOT duplicate information elsewhere (i.e. Eligibility Criteria, Outcomes). Describe your plans for assignment of participants. Describe your plans for delivery of interventions. 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. See <https://researchmethodsresources.nih.gov/> for additional guidance. Text field rules apply.

Enter Detailed Description Here:

**4.1.b Primary Purpose**: Choose an item.

**4.1.c Interventions** (Additional guidelines available [here](https://ctsi.ucla.edu/funding/files/view/docs/gsu/4.1.c_Interventions_Guidelines.docx).)

Minimum 1 required, Maximum 20 allowed. Complete for each intervention to be used in your proposed protocol. Specify the intervention(s) associated with each arm or group. For observational studies, specify the intervention(s)/exposure(s) of interest. If an arm of the study to which subjects will be assigned includes more than one intervention, complete this section for each intervention. Text field rules apply.

**Name:** Must be unique within each Study Record; must not be proprietary**.**

**Description:** Provide details that can be made public about the intervention sufficient to distinguish interventions from one another.

Note: Interventions involving drugs may include dosage form dosage, frequency, and duration.

**Intervention 1**

**Intervention Type:** **Select from dropdown.**

**Name (200 characters):**

**Description (1,000 characters):**

*Add more Interventions, if applicable.*

**4.1.d Study Phase:** Choose an item.(Additional guidelines available [here](https://ctsi.ucla.edu/funding/files/view/docs/gsu/4.1.d_Study_Phase_Guidelines.docx).)

**If OTHER, provide a description (255 characters max):**

**Is this an NIH-defined Phase III clinical trial? **

**4.1.e Intervention Model**: **Select from dropdown.**

**4.1.f Masking?** ****

**If YES, check all that apply**: Participant [ ]  Care Provider [ ]  Investigator [ ]  Outcomes Assessor [ ]

**4.1.g Allocation**: **Select from dropdown.**

**4.2 Outcome Measures** (Additional guidelines available [here](https://ctsi.ucla.edu/funding/files/view/docs/gsu/4.2_Outcomes_Measures_Guidelines.docx).)

Minimum 1 required, max 50. Complete for all Primary, Secondary and other important measures.

**Name:** Must be unique within each Study Record

**Type:** Choose from drop-down options

**Primary:** Measures specified in the protocol that are of great importance (typically the outcome(s) used in the power calculation)

**Secondary:** Measures specified in the protocol that are of lesser importance

**Other:** Additional measures used to evaluate the intervention

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

Must be specific to the outcome measure

Note: The specific duration of time over which each participant is assessed is usually not the overall duration of the study

**Brief Description:** Describe the metric used to characterize the outcome, if not already included in the name

*Text field rules apply.*

**Outcome Measures 1**

**Name (255 characters):**

**Type: Select from dropdown.**

**Time Frame (255 characters):**

**Brief Description (999 characters):**

*Add more Outcomes, if applicable.*

**4.3 Statistical Design and Power** (Additional guidelines available [here](https://ctsi.ucla.edu/funding/files/view/docs/gsu/4.3_Statistical_Design_and_Power_Guidelines.docx).)

Specify expected number of subjects, the expected effect size, the power, and the statistical methods to be used with respect to each outcome measure you listed in 4.3 Outcome Measures. 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.*

**4.4 Subject Participation Duration (255 character limit)**:

**4.5 Will the study use an FDA-Regulated Intervention?**  ****

## **4.5.a If YES, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) Status.** (Additional guidelines available [here](https://ctsi.ucla.edu/funding/files/view/docs/gsu/4.5_FDA_Regulated_Interventions_Guidelines.docx).)

## Describe availability of study agents and support for the acquisition and administration of study agent(s) Indicate IND/IDE status of study agent, if applicable, and whether investigators have had interactions with the FDA. If 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.

Contact ctsiora@mednet.ucla.edu for additional guidance.

**4.6 Is this an applicable clinical trial (ACT) under FDAAA?** ****(If you are unsure, complete the *ClinicalTrials.gov Checklist for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial (ACT)* form here: <https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf>)

**4.7 Dissemination Plan** (Additional guidelines available [here](https://ctsi.ucla.edu/funding/files/view/docs/gsu/4.7_Dissemination_Plan_Guidelines.docx).)

Only one plan per application is allowed; this is true even if this project has multiple studies and/or interventions.

1. Explain briefly your plan for the dissemination of NIH-funded clinical trial information and address how the expectations of the policy will be met.
2. The plan must contain sufficient information to assure the following:
	1. 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 and according to the specific timelines stated in the policy;
	2. Informed consent documents for the clinical trial(s) will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov;
	3. The recipient institution has an internal policy in place to ensure that clinical trials registration and results reporting occur in compliance with policy requirements.
3. Do not include informed consent documents in your application.

**Note:** Below is **suggested** language to include in NIH grant applications regarding UCLA’s registration process. There is no one-size fits all dissemination plan, this can be considered an outline what PIs and/or study staff should do at a minimum:

*Dissemination of study results through ClinicalTrials.gov registration and reporting at a minimum will include the following components:*

*X (insert name or role, can be a designee) will be responsible for handling ClinicalTrials.gov requirements for this project under the PI’s oversight. S/he will register the trial prior to enrolling the first subject. Once a record is established, s/he will confirm accuracy of record content; resolve problems; and maintain records including content update and modifications. S/he will also be responsible for aggregate results reporting and AE reporting at the conclusion of the project.*

* 1. *Add specifics related to this trial.*

# **Section 5. Other Clinical Trial-Related Information**

*Do not complete this section unless instructed by the FOA.*