# ULACNet **Protocol Submission Worksheet** v4.0

**Protocol Information Office, DCP, NCI**

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*Submit documents electronically to:*

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## Section 1: Overview of Protocol Information

Partnership Center Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Partnership Center PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

ULACNet Protocol #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Local Protocol #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Protocol Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Protocol Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Protocol Principal Investigator Organization: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Study Phase □ 0 □ I □ I/II □ II □ N/A (for trials without phases)  
Is this a multi-institutional study: □yes □ no

*If yes, list the name of each participating site and investigators directly on the protocol title page(s).*

Will additional funding be used from other NIH funding mechanisms? □ yes □ no □ pending

*If yes, provide the Grant No.* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Are you receiving support from non-NIH sources (e.g., industry, American Cancer Society, etc.), for this study?

□ yes □ no □ pending

*If yes, specify the source and use of funds.* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Is this study monitored by a Data and Safety Monitoring Board (DSMB)? □ yes □ no

Does the study generate large-scale genomic data? □ yes □ no

*If yes, the Genomic Data Sharing (GDS) Policy is applicable (policy at* [*https://sharing.nih.gov/genomic-data-sharing-policy*](https://sharing.nih.gov/genomic-data-sharing-policy)).If the GDS Plan was not previously submitted (e.g., with the concept), it should be submitted now. *The Institutional Certifications (provisional and final) can be accessed at* [*https://sharing.nih.gov/genomic-data-sharing-policy/institutional-certifications/about-institutional-certifications*](https://sharing.nih.gov/genomic-data-sharing-policy/institutional-certifications/about-institutional-certifications) *and will be due at protocol submission (provisional certification) and 30 days post IRB approval (final certification). Note that final DCP approval will not be delayed for receipt of Final Institutional Certification.*

## Section 2: Purpose of Submission

|  |  |  |  |
| --- | --- | --- | --- |
| □ First submission to DCP PIO | | NCI Version Date: | Version Number: |
| □ Revised Protocol (changes made prior to NCI approval) | | NCI Version Date: | Version Number: |
| □ Amendment to Protocol (changes made after NCI approval) | | NCI Version Date: | Version Number: |
| □ Other, specify |  | NCI Version Date: | Version Number: |

Is this document submitted in response to a DCP review? □ yes □ no

*If yes, date of DCP review letter:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Section 3: Study Agent(s)

|  |  |  |
| --- | --- | --- |
| Agent Name: | Supplier: | CAS Registry Number®  *(if known)*: |
|  |  |  |
|  |  |  |

Will this study be conducted under an Investigational New Drug (IND)? □ yes □ no □ unknown

*If yes, IND Number:*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *IND sponsor:*

*□ Investigator (name):* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *□ Pharmaceutical Company (name):* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Section 4a: Accrual Information

Projected Study Start Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Planned Sample Size (#Evaluable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Target Enrollment: (Maximum #): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Projected Monthly Accrual Rate: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Projected completion date of accrual: \_\_\_\_\_\_\_\_\_\_\_\_\_

The Study Dates below must be the same dates entered in the Human Subjects System and ClinicalTrials.gov:

Actual Study Start Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Actual Study Start Date Definition: The date the first participant was enrolled.***

Anticipated Primary Completion Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Actual Primary Completion Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Primary Completion Date Definition: The date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated****.*

Anticipated Study Completion Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Section 4b: Planned Accrual Estimates

***Enter actual estimates, whole numbers only (percentages, fractions, or decimals are not acceptable). The total provided for Ethnicity must match the total given for Race.***

### Planned Accrual Estimates DOMESTIC (including Puerto Rican participants) PLANNED ENROLLMENT REPORT

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Racial Categories** | **Female**  (*not* Hispanic or Latino) | **Male**  (*not* Hispanic or Latino) | **Female** (Hispanic or Latino) | **Male** (Hispanic or Latino) | **TOTAL** |
| American Indian/Alaska Native |  |  |  |  |  |
| Asian |  |  |  |  |  |
| Native Hawaiian or Other Pacific Islander |  |  |  |  |  |
| Black or African American |  |  |  |  |  |
| White |  |  |  |  |  |
| More Than One Race |  |  |  |  |  |
| Total |  |  |  |  |  |

### INTERNATIONAL (including Canadian participants) PLANNED ENROLLMENT REPORT

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Racial Categories** | **Female**  (*not* Hispanic or Latino) | **Male**  (*not* Hispanic or Latino) | **Female** (Hispanic or Latino) | **Male** (Hispanic or Latino) | **TOTAL** |
| American Indian/Alaska Native |  |  |  |  |  |
| Asian |  |  |  |  |  |
| Native Hawaiian or Other Pacific Islander |  |  |  |  |  |
| Black or African American |  |  |  |  |  |
| White |  |  |  |  |  |
| More Than One Race |  |  |  |  |  |
| Total |  |  |  |  |  |

## Section 5: Name and Title of Person Completing Worksheet

|  |  |  |
| --- | --- | --- |
| Name: | Title: | |
| Email: | Telephone: | Date: |