**National Institutes of Health**

**National Cancer Institute**

**Division of Cancer Prevention**

**US-Latin American-Caribbean HIV/HPV Cancer Prevention Clinical Trials Network (ULACNet)**

**PROTOCOL TEMPLATE FOR ANCILLARY STUDIES**

INSTRUCTIONS

In ULACNet, a study deemed as an ‘Ancillary Study’ will have the following characteristics:

* must extend knowledge of diseases being studied by parent study investigators under a defined protocol, or study diseases and conditions outside of the original scope of the parent study but within the research areas and mission of NCI
* must abide by the procedures established by the parent study
* may focus on additional data or sample collection from human subjects,
* may not interfere with the primary objectives of the parent study

Note: An Ancillary Study Protocol may focus on a study that may—in and of itself-- not meet the NIH definition of a [clinical trial](file:///C%3A%5CUsers%5Chousem%5CDesktop%5Cclinical%20trial) (see: <https://grants.nih.gov/policy/clinical-trials/definition.htm>), although it will be nested within (or linked to) the parent study that, by virtue of being supported in ULACNet, will be a NIH-defined clinical trial.

Numbering of Ancillary Study Protocols:

* Ancillary study protocols in ULACNet will be assigned a study number by adding a lowercase letter to the parent study number. For example, ULACNet-101a, ULACNet-101b.
* If a proposed study (regardless of meeting the NIH definition of a clinical trial) requires additional participant accrual, and/or specimen collection purely for research (i.e., not as part of a standard of care visit), it will be considered a new parent study and be given a new number.

Please modify all sections of the template as necessary to meet the scientific aims of the study and development of the protocol.

1. An “administratively complete” initial protocol submission must include the following components:
	1. **ULACNet Protocol Submission Worksheet (PSW):** This document contains prompts for required administrative information. The PSW is required for all protocol submissions including the original protocol, revisions, and amendments. It must match the version and date of the other documents submitted.
	2. **Protocol:** The template document attached to these instructions provides standard language plus instructions and prompts for information required in each ULACNet ancillary protocol.
	3. **Informed Consent/Assent Form(s):** If additional Informed Consent or Assent is required for this ancillary study, please use the templates provided by DCP ([ULACNet Instructions, Forms, and Templates](https://prevention.cancer.gov/clinical-trials/clinical-trials-management/ulacnet-instructions-forms)) as a guideline. Only the English version is required. Note: The Consent Forms and Protocol must have the same date and version number.
	4. **IRB/Ethics Board Approval:** IRB approvals for the ancillary study must be submitted if the ancillary study is not IRB exempt. This may be pending during first protocol submission, but the award prohibits expending human subject funds before IRB approval.
	5. **Recruitment Materials:** Collection is for recruitment repository only. They will not be translated. NCI review will not occur.
	6. **Additional Study-Related Documents as applicable.**
2. All subsequent submissions (protocol revisions and amendments) must include:
3. **Protocol Submission Worksheet (PSW)**
4. **Cover Letter** (including a point-by-point response to each item listed in the concurrence review or requested amendments)
5. **Tracked Changes Version of Protocol/Consent (if applicable)**
6. **Clean Copy Version of Protocol/Consent (if applicabl**e)
7. **Updated Additional Study-Related Documents (if applicabl**e)

“Administratively Incomplete” submissions will be returned to the Partnership Center for completion. The review process will begin following receipt of an administratively complete submission.

1. Formatting
2. *All Protocol Template instructions and prompts are in italics*. *Italicized information should be deleted prior to submitting the protocol to DCP.*
3. Please note that the Protocol Template has built-in styles for headings levels 1–4 (Level 1 Heading – Level 4 Heading). These heading styles will automatically update the Table of Contents (TOC) and convert to Bookmarks in a final PDF protocol document. **Please retain the heading styles and do not edit the TOC manually.**
4. Indicate changes using the ‘tracked changes’ function, highlighting, or underlining new or modified text in protocol revisions or amendments to facilitate the review process.
5. Wherever possible, please use the date format: day month year and write out the month (e.g., 05 June 2020).
6. Please update the header of this template document before submission with the protocol number and protocol version number and date. Please delete the footer (ULACNet Ancillary Protocol Template version and date) but retain the page numbers.
7. DCP terminology for changes to protocol:
	1. Changes made prior to the initial DCP study approval are “**Revisions**”. Each submission of the protocol prior to DCP approval is documented with a whole number for the version number (i.e., 1.0, 2.0, 3.0).
	2. Changes made after DCP approval are “**Amendments**”. Each amendment is documented with a decimal number with the base version number that was approved (i.e., 3.1, 3.2, 3.3).
8. Submission:

All document submissions must be sent electronically ***both*** to the DCP Protocol Information Office mailbox (NCI\_DCP\_PIO@mail.nih.gov) ***and*** the ULACNet mailbox (ULACNet@mail.nih.gov). Documents submitted elsewhere will not be accepted for review.

**Questions:** Contact ULACNet at (240) 276-7532 or e-mail ULACNet@mail.nih.gov

**US-Latin American-Caribbean HIV/HPV-Cancer Prevention Clinical Trials Network (ULACNet)**

**DCP Protocol #:**

**DCP Parent Protocol #:**

**Local Protocol #:**

**Ancillary Protocol Title:**

**ULACNet Partnership Center Name:**

**Lead Academic Organization (LAO):** *Name of Organization (add CTEP code)*

**Contact Principal Investigator:** *Name of Contact Principal Investigator of the Partnership Center*

*Division/Department*

 *Address*

 *Address*

 *Telephone (+country code – area code – phone number)*

 *E-mail address*

**US/LAC Affiliate Organization (AO):** *Name of Organization (select US or LAC) (add CTEP code)*

**Protocol Principal Investigator:** *Name of Protocol Principal Investigator*

 *Division/Department*

 *Address*

 *Address*

 *Telephone (+country code – area code – phone number)*

 *E-mail address*

**Funding Sponsor Organization:**National Cancer Institute

**Program Scientist:**  Vikrant Sahasrabuddhe, MBBS, MPH, DrPH

 Division of Cancer Prevention

 9609 Medical Center Drive, 5E-338

 Rockville, MD, 20850, USA

 +1-240-276-7332

 vikrant.sahasrabuddhe@nih.gov

 ULACNet@mail.nih.gov

**Investigational Agent(s):** *Investigational Agent(s) Name(s) or N/A if not applicable*

**Supplier**: *Supplier Name or N/A if not applicable*

**IND/IDE Sponsor:** *IND/IDE Sponsor or N/A if not applicable*

**IND/IDE Number:**  *IND/IDE Number* *or N/A if not applicable*

**NIH Grant Number:** U54CAXXXXXX

Parent Protocol: ULACNet-XXX

Other sources of funding: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Protocol Version and Date:** Version X, dated DD-Month-20YY

# TABLE OF CONTENTS

*NOTE: The page numbers in the TOC should update as you incorporate text into the protocol. If the numbers do not automatically update, follow these steps:*

 *1. Select the TOC by highlighting it.*

 *2. Right-click on the highlighted TOC. You will see a dialogue box asking if you want to update the whole table or just the page numbers.*

 *3. Choose update page numbers.*

[TABLE OF CONTENTS 2](#_Toc84409780)

[1. INTRODUCTION 3](#_Toc84409781)

[1.1 Background and Rationale 3](#_Toc84409782)

[1.2 Study Objectives 3](#_Toc84409783)

[2. PARTICIPANTS 3](#_Toc84409784)

[2.1 Eligibility 3](#_Toc84409785)

[2.2 Recruitment and Retention 3](#_Toc84409786)

[2.3 Accrual and Feasibility 3](#_Toc84409787)

[3. RESEARCH DESIGN AND METHODS 4](#_Toc84409788)

[3.1 Summary of Study Plan 4](#_Toc84409789)

[3.2 Specimen management (if applicable) 4](#_Toc84409790)

[3.3 Informed Consent 4](#_Toc84409791)

[4. EVALUATIONS AND ANALYSIS PLAN 5](#_Toc84409792)

[4.1 Study Evaluations 5](#_Toc84409793)

[4.2 Analysis Plan 5](#_Toc84409794)

[4.3 Statistical Considerations 5](#_Toc84409795)

[5. REGULARTORY CONSIDERATIONS 5](#_Toc84409796)

[5.1 Institutional Review Board 5](#_Toc84409797)

[5.2 NCI Registration and Credential Repository (RCR) 5](#_Toc84409798)

[5.3 ClinicalTrials.gov 5](#_Toc84409799)

[6. REFERENCES 5](#_Toc84409800)

# INTRODUCTION

## 1.1 Background and Rationale

*Include brief information on the study disease and approach. Include relevant literature review and/or data to support conduct of the ancillary study. Clearly state the hypotheses for the objective(s). Justify selection of target population, approach, and choice of techniques, assessments, and measurements. Describe the contributions that the proposed study will make to the current knowledge base.*

*Include how this ancillary study relates to the parent study but there is no need to describe the parent study in detail.*

## Study Objectives

*Study objectives are concise statements of clinical and statistical questions that the study is designed to answer. Each objective should be stated as specifically and succinctly as possible. Number the objectives in order of priority if there are multiple.*

# PARTICIPANTS

## 2.1 Eligibility

*Explain which participants will be eligible from the parent study or the eligibility criteria if additional participants will be recruited. Include Inclusion and Exclusion Criteria.*

## 2.2 Recruitment and Retention

*Provide a plan for selecting a subset of participants from the parent study or additional study groups (if applicable) including:*

* Enrollment rate (e.g., number of participants meeting eligibility criteria for enrollment per month) and timeline/milestone plans for accrual.
* Procedures to monitor enrollment and track/retain participants for follow-up assessments (if applicable).
* Discussion of potential recruitment delays or challenges and alternative strategies that can be implemented if there are enrollment delays or shortfalls.
* Strategies to ensure the study population has scientifically appropriate diversity and representativeness.

## 2.3 Accrual and Feasibility

*Specify the planned sample size and accrual rate (*e.g*., participants/month). Describe how the total sample size (including sex and minority considerations) and sampling strategy are justified for testing the study hypotheses.*

***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:**

(*Please* *provide tables for each international country separately and together. Puerto Rico is considered Domestic in this network.)*

**Domestic (including Puerto Rican participants) Planned Enrollment Report**

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

# RESEARCH DESIGN AND METHODS

## 3.1 Summary of Study Plan

*Provide a brief synopsis of the following points:*

* *Study design*
* *Number of participants to be enrolled (total number and number per arm)*
* *Brief description of the study population*
* *Study intervention plan, if applicable*
* *Time points for performing study assessments*
* *Description of measurements taken to meet study objectives*
* *Duration of study*

*Optional: Include a study schedule or schema*

## 3.2 Specimen management (if applicable)

*Include information on laboratories, collection and handling procedures, biohazard containment, shipping instructions, specimen repository, if applicable*

## 3.3 Informed Consent

*State if the study is IRB exempt. If not, describe how informed consent will be collected. Use the ULACNet Informed Consent Template and submit as an additional document with the protocol..*

# EVALUATIONS AND ANALYSIS PLAN

## 4.1 Study Evaluations

*Delineation of endpoints to meet study objectives, methods for measuring or evaluating, and timing of endpoint ascertainment should be described here.*

## 4.2 Analysis Plan

*Include your analysis plan.*

*Address the following, as appropriate:*

* *If known, indicate the prevalence of the marker*
* *Specify how any cut points will be determined*
* *Specify the statistical power of the correlative study for the endpoint chosen*
* *If relevant, indicate what corrections will be made for multiple comparisons*
* *If appropriate, indicate relevant clinical endpoint, and a plan for how this endpoint will be correlated with the target(s) or marker(s).*

## 4.3 Statistical Considerations

*Describe relevant statistical considerations, if applicable*

# REGULARTORY CONSIDERATIONS

## 5.1 Institutional Review Board

*Include the IRB information or if the study is IRB exempt.*

##  NCI Registration and Credential Repository (RCR)

*Partnership Centers will be collecting regulatory documents and per institutional standards and NIH requirements. All persons participating in any NCI-sponsored clinical trial are required to register and renew their registration annually: https://ctep.cancer.gov/investigatorResources/default.htm*

*See ClinRegs, a public resource for country-specific clinical research regulatory information at https://clinregs.niaid.nih.gov.*

## Delegation of Tasks Logs

*Any accruing sites must submit a Delegation of Task Logs using the ULACNet DTL form. Sites must submit a new DTL for the ancillary study even if the staff are the same as the parent study, Refer to the guidance document.*

## 5.3 ClinicalTrials.gov (if appliable)

In an effort to make information about clinical trials widely available to the public, the US Department of Health and Human Services issued The Final Rule (42 CFR Part 11) that clarifies and expands the regulatory requirements and procedures for submitting registration and results information for certain trials to ClinicalTrials.gov, in accordance with FDAAA 801. In addition, NIH has issued a complementary policy for registering and submitting summary results information to ClinicalTrials.gov for all NIH-funded clinical trials, including those not subject to the final rule. The Partnership Center is responsible for ensuring adherence to these policies when submitting and updating ClinicalTrials.gov.

The Partnership Center is required to register each clinical trial in ClincalTrials.gov within 21 days of enrollment of the first participant. Protocols must be submitted to the NCI Clinical Trials Reporting Office no later than 12 months after the primary completion date. The Partnership Center will post the most recent IRB-approved model consent form to ClinicalTrials.gov within 60 days of the study status changing to “Closed to Accrual and Treatment.” Clinical trials result information must be submitted no later than 12 months after the trial’s primary completion date.

# REFERENCES

*Please provide the citations for any publications referenced in the text.*