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1 ULACNet Change in Protocol Principal Investigator Process

1.1 Introduction

The purpose of this document is to establish the requirements and processes for a permanent or long-term temporary (≥ 3 months) change in ULACNet Protocol Principal Investigator (PI) regardless of IND or Non-IND status. This process document will:

1. Set a reporting process to NCI/DCP and appropriate governing bodies
2. Discuss compliance requirements to complete a change in PI
3. Establish Points of Contact (POCs) for the process

Note: this document does not discuss change in status of key personnel or effort changes in the U54 grant key personnel which is a separate process of 'NIH Prior Approval' handled directly with the NCI Office of Grants Administration and the NCI Program Official as outlined on https://www.cancer.gov/grants-training/manage-award/prior-approvals.

1.2 Definitions

Abbreviation	Definition
DCP	Division of Cancer Prevention
DTL	Delegation of Tasks Log
IND	Investigational New Drug Application
IRB	Institutional Review Board
LAO	Lead Academic Organization
LBR	Leidos Biomedical Research
NCI	National Cancer Institute
NIH	National Institutes of Health
PI	Principal Investigator
PIO	Protocol Information Office
RCR	Registration and Credential Repository
ULACNet	US-Latin America-Caribbean Network

1.3 Principal Investigator

In general, a Principal Investigator (PI) is an individual who conducts the clinical protocol at a clinical accruing site. The PI may be supported by a team of sub-investigators or other staff, but the PI remains the responsible party overseeing the conduct of the study and the team at their site.

The term PI may also encompass key personnel listed on the face sheet of the protocol at non-accruing organizations, such as at US based Lead Academic Organizations (LAO) and serve in some other capacity such as protocol chair, partnership center lead, or have an oversight function.

Of importance, there should be no lapse in PI coverage of the clinical study. If a PI associated with a clinical protocol separates from the conduct of the study either permanently or on a long-term temporary (≥ 3 months) basis, a replacement PI must be selected. The procedures in section 2 must be followed to ensure compliance with programmatic and federal requirements for carrying out the clinical study.

2 Change in Principal Investigator Process

2.1 Notification Requirements

If a change in PI is requested for any reason, the following steps and guidelines should be followed to ensure that the safety of human subjects is in place and to maintain compliance with programmatic procedures and practices:

a.) DCP should be notified as soon as a change in PI is known via the following pathways:

- Email Dr. Vikrant Sahasrabuddhe, NCI ULACNet Project Scientist at Vikrant.Sahasrabuddhe@nih.gov and the ULACNet mailbox at ULACNet@mail.nih.gov
- Submission of a Protocol Amendment, and as applicable, updates to the Informed Consent Form(s) via the standard Protocol Information Office (PIO) submission process
- During the next regularly scheduled study team call

b.) The applicable Institutional Review Board (IRB) and/or In-country Ethics boards and regulatory/oversight bodies should be notified once NCI/DCP has been made aware of the request.

- Please submit all copies of approval or acknowledgement notices from the IRBs and regulatory/oversight bodies to the ULACNet mailbox at ULACNet@mail.nih.gov and Leidos Biomedical Research (NCI regulatory and auditing contractor) at CMRPDDCPULACNetProjectTeam@mail.nih.gov.
- If the ICF was also modified, please forward a copy of the IRB or In-Country approval notice and the revised ICF
- Please update (as applicable) the DTL and all accompanying documentation needed to fulfill the requirements of the NCI Registration and Credential Repository (RCR)

c.) For studies that are ongoing, participants in the study that have previously been provided PI contact information should be notified if there are any changes to the contact information (phone numbers, emails, etc.).

2.2 Compliance Documentation

Compliance should be maintained with Human Subjects Protection Regulations (45 CFR 46) in mind. Of note, there should be no lapse in PI coverage of the clinical study.

The change in PI notification should include:

- The reason for the change in PI
- The name of the PI who will be on long-term temporary leave (with anticipated departure and return dates), or who will be permanently replaced (with anticipated departure date)
- The name of the PI who will be covering during long-term temporary leave, or who will be permanently replacing the protocol PI; the PI institution contact information; and the anticipated dates of coverage

The documentation required for the new PI will be uploaded into NCI RCR and includes:

- NCI biographical sketch of the proposed new PI:
  - Curriculum Vitae (CV)
  - Licensing information
  - List of Completed Certifications
- A completed and signed FDA Form 1572
- Completed Financial Disclosure Form (FDF)
- Good Clinical Practice (GCP) training certificate

(Details on NCI RCR are at: https://ctep.cancer.gov/investigatorresources/default.htm)

These forms are necessary not only for federal regulatory compliance, but the forms also encompass specific IND submission requirements for applicable protocols within ULACNet.

International sites should refer to their in-country regulatory, governing oversight bodies, or independent ethics committees to ensure compliance with country-specific reporting requirements.

2.3 Summary

The change in protocol PI request should be initiated as soon as DCP has been notified and completed in a timely manner, with adequate time to allow for a seamless transition between PIs. As the compliance and regulatory environment changes, and other unforeseen challenges arise, this policy document will be adjusted accordingly.

All questions should be addressed directly by DCP over regularly scheduled team calls, or by emailing the DCP mailbox: ULACNet@mail.nih.gov