PI Roles and Responsibilities and Submitting and Managing Change in PI Amendment Applications

Linda Fox, CIP

Objectives

- Define the role, responsibilities, qualifications, authority, and accountability of individuals interested in serving in the role of PI
- Describe the actions required when a PI has a temporary leave of absence or permanent leave of absence
- Describe the actions required within the iStar application when there is a change in PI

Principal Investigator Responsibilities

- The PI is responsible for all aspects of IRB approved research including the ethical conduct, design, and reporting of the research, oversight of the informed consent process, fiscal management of the research, determining whether there are adequate resources available to execute the study, supervision and oversight of all study personnel, maintaining compliance with the protocol and all applicable federal, state, and local laws, as well as institutional policies (including CHLA, CHLA IRB, HSPP policies and procedures), compliance with all requirements for identifying and reporting new information that requires prompt reporting to the IRB, data safety monitoring reports, etc.
- The PI can delegate tasks to members of his/her study team; however, the ultimate responsibility and accountability for the conduct of the research study is with the PI alone. Any deviation from this responsibility can lead to noncompliance and potential study misconduct.

Principal Investigator Responsibilities (Continued)

- The IRB holds the PI of the study responsible for ensuring that:
  - Risks to subjects are minimized by using procedures which are consistent with sound research design.
  - Risks to subjects are reasonable in relation to anticipated benefits (if any) to the subject.
  - Selection of subjects is equitable.
  - Individuals are adequately informed of the risks and benefits of participation and the procedures involved, and that informed consent will be sought and appropriately documented.
  - Where appropriate, there is routine monitoring of the data collected to ensure the safety of human research subjects.
  - The privacy of human subjects is protected and the confidentiality of the data is maintained.
  - Additional safeguards are included in the study to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence.

Principal Investigator Responsibilities Continued

- The PI of an approved research study is responsible for:
  - Promptly responding to all requests for information or materials solicited by the IRB.
  - Timely submission of annual continuing review applications, amendment applications, updated protocols, updated IBs, DSMB reports, etc. Reminder: Only the PI can submit an IB amendment.
  - Ensuring that all personnel assisting in the conduct of the research study are appropriately informed of (i) the study procedures; (ii) informed consent requirements; (iii) the potential adverse events associated with study participation and the steps to be taken to reduce potential risks; (iv) reportable new information requirements; and (v) data collection and record-keeping criteria.
  - Conducting the research in accordance with the IRB approved protocol.
  - Ensuring that human research subjects are fully informed of any new information that may affect their willingness to continue to participate in the research study.
  - Maintaining adequate research subject records.

How many research studies should a PI oversee?

- The CHLA IRB has not established specific parameters on the total number of research studies for which an individual may serve in the role of PI. However, there are several factors to take into consideration before deciding to step into the role of PI.
- The prospective PI should ask themself whether they have the time, resources, and ability to maintain adequate oversight over the conduct of multiple research studies simultaneously.

How many research studies should a PI oversee (continued)?

- When evaluating the feasibility of serving in the role of PI of a new research study, the prospective PI should consider the following items:
  - Total number of open studies for which the individual is already currently serving in the role of PI
  - Enrollment status of existing studies
  - Total number of subjects to be enrolled in those existing studies
  - Complexity and risk level of existing studies
  - Whether the PI is serving as Co-I on other research studies and their level of involvement in those studies
  - Availability of research staff to help the prospective PI conduct the research
  - Etc.

PI Eligibility Requirements

- It is strongly suggested that the PI of a human subjects research study have an appointment or position that meets one of the following:
  - Professor, Associate Professor, or Assistant Professor at USC with a CHLA faculty appointment
  - MD/DO licensed physician (includes attendings, fellows, residents) at CHLA or an MD/DO physician that has an appointment as member of the CHLA medical staff (*Note: Fellows and residents must have a CHLA faculty advisor appointed to the study in order to serve in the role of PI)
  - Medical student with an MD/DO license and has training or experience in the conduct of research
  - Student without an MD/DO license but has training or experience in the conduct of research (*Note: Students much also have a CHLA faculty advisor. Students may not be PI of studies involving greater than minimal risk)
  - NOTE: The IRB holds students in the role of PI to the same standards as human subjects research conducted by faculty or staff.
  - Employed clinician other than an MD/DO with training or experience in the conduct of research
  - Employed CHLA non-clinician with training or experience in the conduct of human subjects research

PI Qualifications

- An individual's qualifications to serve as PI will be assessed based on the following criteria:
  - Maintain current CITI human subjects research certification
  - Maintain current CITI good clinical practice (GCP) certification for studies that are greater than minimal risk
  - Maintain current CITI GCP certification for NIH-funded clinical trial studies
  - Maintain current conflict of interest in human subjects research disclosure
  - Demonstrate no known restrictions to serve in the role of PI

  NOTE:

  -The department/divisional reviewer will also review the application and attest to whether the PI is qualified by training and experience to serve in the role of PI

  -The IRB will assess the individual's qualifications to serve in the role of PI

Stepping Down as PI

- An investigator serving in the role of PI on one or more research studies may need to step down as PI either temporarily or on a permanent basis.
- The following slides will describe recommendations that may be applicable to a PI's leave of absence. Please note that temporary leave of absences are assessed on a case by case basis.

Temporary Leave of Absence

- If the PI's leave of absence is temporary, the current PI must plan to temporarily transfer conduct and oversight of their study to a Co-Investigator on the study who will need to agree to serve in the role of PI on a temporary basis. This should be someone who has the time and expertise to temporarily assume the role of PI.
- If the temporary leave of absence is 21 consecutive days or less and the PI will assume their duties as PI upon their return, it is acceptable for the Co-I to take over the PI role temporarily in the short interim period of 21 days or less without a formal change of PI amendment submission in iStar.
- If the temporary leave of absence is greater than 21 consecutive days and the PI will assume their duties as PI upon return, the current PI must inform the IRB about the temporary transfer of PI change via submission of an amendment . The amendment application must be submitted prior to and in advance of the PI's temporary leave of absence date.
- If the current PI must take a temporary leave of absence that is 3 consecutive months or greater, the current PI must inform the IRB about this temporary transfer of PI change via submission of an amendment. Changes to documents (i.e. protocol, recruitment documents, consent forms, etc.) will be required.

Permanent Leave of Absence from CHLA

- 2 courses of action are available for the current PI of a study to take once they know they are permanently leaving CHLA.
- Option 1: Have the study remain open at CHLA, but the current PI who is permanently leaving will need to designate a new PI who is currently at CHLA to serve in the role of PI of the study. The new PI must have access to all the current and previous regulatory documentation and study files.
- Option 2: The PI leaving CHLA chooses to close out the study at CHLA and does not want to transfer the study over to a new CHLA PI.
- With both options, the PI who is leaving CHLA must inform the IRB about the transfer as soon as possible and plan for the timely submission of their amendment application prior to and in advance of their CHLA departure date.

What is needed in the iStar Application to capture a temporary PI change?

- For a temporary PI change, an amendment application must be submitted and will need to reflect a temporary PI change. The amendment must include an explanation of who the PI is changing from, that the change in PI is temporary, explain why this is temporary, describe how long the temporary leave of absence is expected to last and an approximate return date, include a statement that the PI will return to their full PI duties upon their return, and describe how subjects will be informed of the temporary PI change.
- AM1.1 “Identifier for this Amendment” – Enter “Temporary change of PI”
- AM1.2 – Select “Study Personnel” and “Other”
- AM1.2.3 – If ‘Other’ type of amendment, please specify: Enter “Temporary change of PI”
- AM15 – Describe each of the changes you wish to make to the previously approved study and provide a rationale for the change: Example - Dr. X will need to step down as PI temporarily because he will be out on medical leave starting 9/14/2023. Dr. X is expected to return to his role as PI in about 2 months after his 9/14/2023 temporary departure date. In the interim, Dr. Y will serve as temporary PI until Dr. X returns. Those subjects who are still being seen or are still having their data collected will be informed verbally of this temporary PI change (including being given contact information for this temporary PI) and given a research information sheet with this information as well.

What is needed in the iStar Application to capture a temporary PI change? (continued)

- Item 2.1 – Remove the PI who is going on temporary leave from item 2.1, and instead add the old PI in the role of Co-I for the time being. In item 2.1, add the new temporary PI in the role of PI. When the original PI returns, a PI change amendment will be required to change item 2.1 of the application back to the original PI.
- If the temporary PI change is 3 months or greater, changes to documents (e.g. protocol, recruitment documents, consent forms, data safety monitoring plans, etc.) will be required. When the PI returns, a new PI change amendment will be required to revert the application back to the original PI.

What is needed in the iStar application for a permanent PI change?

- For a permanent PI change, an amendment application must be submitted and will need to reflect a permanent PI change. The amendment must include an explanation of who the PI is changing form, and that the change in PI is permanent due to the original PI leaving CHLA. Be sure to describe how subjects will be informed of the permanent PI change.
- AM1.1 “Identifier for this Amendment” – Enter “Permanent change of PI”
- AM1.2 – Select “Study Personnel” and “Other”
- AM1.2.3 – If ‘Other’ type of amendment, please specify: Enter “Permanent change of PI”
- AM15 – Please describe each of the changes you wish to make to the previously approved study and provide a rationale for the change: Example - Dr. X will need to step down as PI at CHLA permanently because he will be leaving CHLA on 12/30/2023. Dr. Y will serve as the new permanent PI at CHLA. Those subjects who are still being seen or are still having their data collected will be informed verbally of this permanent PI change and given an information sheet describing the permanent PI change. Subjects who are no longer being seen but whom we continue to collect data about will be sent an information sheet describing the permanent PI change.

What is needed in the iStar application for a permanent PI change? (continued)

- Item 2.1 –
  - Remove the PI who is permanently leaving CHLA and no longer affiliated with CHLA from the role of PI in item 2.1.
  - Add the new PI to item 2.1. This reflects who the new permanent PI will be at CHLA.
- Changes to documents (i.e. protocol, recruitment documents, consent forms, repository worksheets, data safety monitoring plans, etc.) will be required.