Responsibilities of PIs and CRCs

Responsibilities of the PI

Responsibilities of a Clinical Research Coordinator

Responsibilities of the PI

The PI is ultimately responsible for all aspects of conducting the research study, including the supervising of all staff to whom study responsibilities are delegated. While the PI may delegate responsibilities as appropriate, it is the PI who is responsible for ensuring that all research activities are carried out correctly.

The PI must be qualified by education and training in the therapeutic area in which the research is being conducted. The PI must be familiar with the protocol and investigational articles being tested and must also comply with the applicable regulatory requirements Code of Federal Regulations, FDA Good Clinical Practice (GCP) and International Conference on Harmonization (ICH GCP Guidelines), state statues, other applicable federal regulations, and institutional policies and guidelines.

PIs are responsible for the following:

Protecting the safety and welfare of research participants

- Conducting the study in an ethical manner, including protecting the rights and welfare of human subjects who are involved in the research project.

- Ensuring that the resources necessary to protect participants are present before conducting the research study.
- Reporting unexpected or serious adverse events [1] to the IRB according the to the UCSF HRPP reporting guidance.
- Reporting protocol violations and research-related incidents [2] to the IRB according to the UCSF HRPP reporting guidance.
- Reporting any correspondence to or from a regulatory agency regarding matters of regulatory compliance [1] (e.g., FDA audit findings, PI audit response letter) to the IRB.
- Responding to participants? complaints/concerns or requests for information and reporting to the IRB any significant participant complaints/concerns [3].
- Designing and carrying out the research study with adequate data and safety monitoring [4], when appropriate.
- Assuring that the protected health information (PHI) [5] requested, if any, is the minimum necessary to meet the research objectives, and that PHI is not reused or disclosed to any parties other than those described in the IRB-approved protocol, except as required by law.

Training and supervising collaborating faculty and staff

- Ensuring that all participating faculty and research staff observe pertinent laws, regulations, and institutional policies and guidelines.
- Ensuring that key personnel performing the study are qualified, appropriately trained or re-trained and adhere to the provisions of the IRB-approved protocol.

Adherence to regulatory and IRB requirements and guidance

- Completing IRB-required human subjects protection training [6] (in addition to other sponsor-required training).
- Ensuring that all research involving human subjects receives IRB review and approval before commencement of the research [7], including screening or recruitment.
- Seeking IRB guidance when in doubt about whether proposed research requires IRB review [8].
- Complying with all IRB decisions, conditions and requirements.
- Obtaining IRB review and approval before changes are made to approved protocols or consent forms (IRB modification request [9]).
- Ensuring that no human subject is involved in the research prior to obtaining his or her consent [10].
- Ensuring the adequacy of the informed consent process [10].
- Ensuring that protocols receive continuing IRB review and approval [11] at the appropriate interval.
- Providing financial disclosure information or any other potential conflicts of interest [12] that might affect the relationship with the research participant or the outcome of the research.

Responsibilities of a Clinical Research Coordinator (CRC)

The CRC works with and under the direction of the PI. Although the PI is legally responsible

for all aspects of the research study, the CRC often handles the bulk of the daily study activities and plays a key role in the study conduct and management. The CRC is frequently responsible for organizing the documentation and files pertaining to a study and for coordinating the activities of the investigators and the study participants.

The responsibilities of the CRC will vary at each site, but may include the following:

Protecting the rights and welfare of human subjects

- Understanding the regulatory, institutional, sponsor and protocol requirements for the study.
- Completing IRB required human subjects protection training [6] (in addition to any other sponsor required training).
- Complying with all IRB decisions, conditions and requirements.
- Capturing and reporting adverse events [1] and protocol violations [2] to the study PI, the IRB and the study sponsor.
- Ensuring that PHI [5] will not be reused or disclosed to any parties other than those described in the IRB-approved protocol, except as required by law.
- Making sure that all studies have current IRB approvals before any study is initiated [7], continued beyond the period of current approval [11] (usually 1 or 3 years) or modified [9] in any way.

Important note: These responsibilities always apply regardless of research site or research setting.

Evaluating new protocols for feasibility

This may include:

- Reviewing the protocol and other materials (e.g., Investigator?s Brochure, data collection forms and sample consent forms) for practical procedures, safety issues and establishment of a study budget.
- Reviewing study participant eligibility requirements and determining if those participants would be available in sufficient numbers to achieve study enrollment goals.
- Assessing the logistical requirements and resources necessary to conduct the study.

Preparing the site for study conduct

This may include:

- Preparing documents for submission to the IRB.
- Preparing documents for submission to the Office of Sponsored Research [13].
- Setting up and organizing study files.
- Training all people involved in the study conduct (e.g., faculty, study staff, ancillary personnel, etc.).
- Collaborating with other departments (e.g.; laboratory, pharmacy, etc.) as indicated.
- Attending the investigator start-up meeting.

- Scheduling and facilitating a site-initiation visit with the study sponsor.
- Creating or reviewing study-specific source documents.
- Collecting the documents needed to initiate the study and sending them to the study sponsor.

Participating in the informed consent process

This may include:

- Writing study consent forms [14] according to IRB guidelines [10].
- Working with the sponsor and/or IRB on consent form wording issues [15].
- Obtaining translations of the consent forms [16] into other languages, when necessary.
- When indicated in the IRB Application, conducting the informed consent process [17] with potential participant (or a potential participant?s authorized legal representative or surrogate [18]).
    - Providing potential participants with the Experimental Subject?s Bill of Rights [19], when required;
    - Discussing all aspects of study participation;
    - Reviewing the consent form with the potential study participant;
    - Answering questions and assessing potential study participant?s comprehension;
    - Ensuring that all necessary signatures and dates are on the informed consent forms;
    - Documenting, distributing and filing signed informed consent forms appropriately;
    - Ensuring that all amended consent forms are appropriately implemented and signed;
    - Ensuring that the consent process is ongoing and continues throughout the duration of the study.

Important note: Informed consent is not just a signature on a document. It is an ongoing process [17].

Managing study conduct

This may include:

- Recruiting [20] and screening potential participants.
- Ensuring adherence to the study inclusion/exclusion criteria.
- Scheduling and managing study participant study visits (e.g., ensuring that all appropriate study procedures are done and documented).
- Managing laboratory procedures (drawing samples, processing, packaging and shipping).
- Reviewing case report form entries for completeness and correctness.
- Reviewing case report forms and source documents for adverse events [1] (AE).

Important Note: While it is a direct responsibility of the CRC to capture and report all AEs to the PI, CRCs are not allowed to determine the cause of an AE unless they are an appropriately licensed health care professional (i.e.; MD, PA or NP) who also holds investigator status on the study.

- Scheduling and facilitating sponsor monitoring visits.
- Ensuring that test article accountability is done correctly for each study participant and overall.

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Links
[1] https://irb.ucsf.edu/adverse-event
[2] https://irb.ucsf.edu/protocol-violation-or-incident
[3] https://irb.ucsf.edu/reporting-research-concerns-and-complaints
[4] https://irb.ucsf.edu/data-and-safety-monitoring-plans-and-boards
[5] https://irb.ucsf.edu/hipaa
[6] https://irb.ucsf.edu/citi-human-subjects-training
[7] https://irb.ucsf.edu/new-study
[8] https://irb.ucsf.edu/research-needing-irb-review
[9] https://irb.ucsf.edu/modification
[10] https://irb.ucsf.edu/consent-guidelines
[11] https://irb.ucsf.edu/continuing-review
[12] https://irb.ucsf.edu/conflicts-of-interest-research
[13] http://osr.ucsf.edu/
[14] https://irb.ucsf.edu/consent-and-assent-form-templates
[15] https://irb.ucsf.edu/consent-form-guidelines-and-suggested-wording
[16] https://irb.ucsf.edu/consenting-non-english-speakers
[17] https://irb.ucsf.edu/informed-consent-discussion-and-documentation
[18] https://irb.ucsf.edu/surrogate-consent
[19] https://irb.ucsf.edu/experimental-subjects-bill-rights
[20] https://irb.ucsf.edu/recruitment