



Clinical Research Coordinators Study-Related Tasks (last updated June 3, 2011)

Clinical Research Coordinator (CRC)

Job Responsibilities for a CRC

Study-Related Tasks that May Be Delegated by the Investigator to the CRC

- Evaluating New Protocols for Feasibility
- Preparing the Site for Study Conduct
- Managing the Study Conduct Research
- Post Approval Reporting Requirements
- Closing Out the Study

References

Clinical Research Coordinator (CRC)

Although the Principal Investigator (PI) is responsible for *all* aspects of the research study, the Clinical Research Coordinator (CRC) also has a critical role in facilitating, supporting and coordinating daily clinical research study activities. The CRC works under the direction of the PI who will delegate specific clinical research study related tasks.

Job Responsibilities for a CRC

One of the primary responsibilities of the CRC is to protect the rights and welfare of the human research participants in the studies. In order to do so the CRC must:

- **Complete** the required UCLA Office of Human Research Protection Program (OHRPP) human research subjects' training Collaborative Institutional Training Initiative (CITI) and the HIPAA Clinical Research Course before initiation of any clinical research related activities.
- **Understand** regulatory, institutional, sponsor and protocol requirements for the study.
- **Comply** with all IRB decisions, conditions and requirements.
- **Ensure** all studies have current IRB approval before any study related activities begin.
- **Coordinate** with the PI and other key research personnel to assure that clinical research activities are performed in accordance with federal/state and institutional regulations, policies and procedures.
- **Ensure** that Protected Health Information (PHI) will not be disclosed to any parties other than those described in the OHRPP IRB approved protocol, except as required by law.

Study-Related Tasks that May Be Delegated by the Investigator to the CRC

The job duties of the CRC will vary with each PI and research team. Under the guidance and supervision of the PI the duties of the CRC *may* include some or all of the following:

Evaluating New Protocols for Feasibility:

- **Review** the protocol and other study related materials (i.e. Investigator's Brochure) to understand study procedures.
- **Assist** the PI in study in assessing study feasibility.
- **Review** the protocol and other study related materials (i.e. Investigator's Brochure) to understand study procedures.
- **Assist** the PI in assessing the logistical requirements and resources necessary to conduct the study.
- **Assist** the PI in reviewing study participant eligibility requirements and determining if those participants would be available in sufficient numbers to achieve study enrollment goals.

Preparing the Site for Study Conduct:

- **Submit** the protocol and informed consent to the [UCLA webIRB](#) and other regulatory submissions documents as required by the protocol.
- **Set up** and organize study files (i.e., regulatory binder).
- **Design and maintain** organizational tools that will aid in the conduct of the study (i.e., consent process checklists).
- **Review** study-specific CRFs or source documents.
- **Collaborate** with other units within (i.e., UCLA Pharmaceutical Services, the Medical Radiation Safety Committee, the Conflict of Interest Review Committee) as necessary.
- **Attend** the investigator start-up meeting.
- **Schedule** and facilitate a site-initiation visit with the study sponsor.
- **Collect** documents needed to initiate the study and submit to the sponsor.
- **Assist** the PI in assuring that all key research personnel in the clinical research project have met [UCLA training requirements](#) in accordance with federal, state, UC/UCLA policies and regulations and sponsoring agency policies and procedures.
- **Assist** the PI in training other key research personnel in understanding and implementing the protocol.

Managing the Study Conduct Research:

- **Assist** PI in the registration (if required) of the study in [Clinicaltrials.gov](#) before enrolling subjects.
- **Assist** the PI in [recruiting](#) and screening potential participants.
- **Ensure** adherence according to the specific inclusion/exclusion criteria in the IRB approved protocol.

- **Review** that all necessary signatures and dates are on the current IRB approved consent form, and that the subject received the [California Experimental Subjects' Bill of Rights](#) in the subject's appropriate language and documenting the consent process.
- **Ensure** the subject signs the [University of California Permission to Use PHI for Research Forms](#) (if applicable) in the subject's appropriate language.
- **Assist** the PI in ensuring that the consent process is ongoing and continues throughout the study.
- **Assist** the PI in assuring amended consent forms are appropriately implemented and signed.
- **Schedule** and coordinate participants visits and tests, (i.e. ensuring that all appropriate study procedures are completed and documented).
- **Manage** laboratory procedures (i.e., draw blood samples).
- **Collect** data as required by the protocol and complete case report forms and reviews for completeness.
- **Meet** and maintain study timelines.
- **Maintain** study files in accordance with sponsor requirements and UCLA policies and procedures including but not limited to informed consent forms, source documentation, and investigational material accountability forms.
- **Maintain** effective and ongoing communication with the PI, sponsor, and research participants during the course of the study.
- **Schedule** and facilitate sponsor monitoring visits.
- **Work** with the PI to manage the day-to-day activities of the study including problem solving and protocol management.

Post Approval Reporting Requirements:

Sponsors and/or other oversight entities (i.e., Data Safety Monitoring Boards, FDA), reporting requirements **may be different** from the UCLA IRB. For a summary of the UCLA IRB post approval reporting requirements, please review the [Summary Sheet of Post-Approval Reporting Requirements for Investigators](#) .

- Report unexpected events to the PI.
- Assist the PI in reporting adverse events to the study sponsor, **according to the sponsor reporting requirements**.
- Assist the PI in reporting to the IRB following the [Guidance and Procedure: Post Approval Reporting Requirements](#).
- Assists the PI in promptly reporting any [unanticipated problems](#) involving risks to research participants or others to the IRB and sponsor. These problems go beyond adverse event reporting and include reporting of violations and incidents as well as subject complaints.

Closing Out the Study:

All types of clinical research studies need to be closed out. The UCLA IRB and the sponsor requirements may differ.

- To close out a study please follow the OHRPP guidance: [Closure of Human Subjects Research Studies](#) . UCLA IRB-approved studies should be closed out within thirty days of the end of the study. Be sure and read the caveats about when **not** to close a study.
- If the study sponsor wants to have access to study data that identifies subjects by name, according to FDA restrictions the study cannot be closed out.
- If you close out a study and later find you may need to reopen the study, it is possible to do so. Contact the office at mirb@research.ucla.edu for information about how to reopen a study.

References

[FDA Regulations and Good Clinical Practice Guidelines](#)

[SOCRA \(Society of Clinical Research Associates\)](#)

[Investigator Responsibilities](#)

[Post Approval Reporting Guidelines](#)

[OHRPP Learn at Lunch Training Sessions](#)