

# UCSF Human Research Protection Program

## Responsibilities for Research Involving Human Subjects Information Sheet for Clinical Research Coordinators

**THE CLINICAL RESEARCH COORDINATOR (CRC) WORKS WITH AND UNDER THE DIRECTION OF THE PRINCIPAL INVESTIGATOR (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 investigational 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 [CHR required human subjects protection training](#) (in addition to any other sponsor-required training).
- ✓ Complying with all CHR decisions, conditions, and requirements.
- ✓ Capturing and [reporting adverse events](#) to the study PI, the CHR and the study sponsor.
- ✓ Ensuring that [protected health information \(PHI\)](#) will not be reused or disclosed to any parties other than those described in the CHR-approved protocol, except as required by law.
- ✓ Making sure that all studies have current [CHR approvals](#) before any study is initiated, [continued beyond the period of initial approval](#) (usually one year), or [modified](#) 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 [CHR](#).
- ✓ Preparing documents for submission to the [Office of Sponsored Research](#).
- ✓ 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 according to [CHR guidelines](#).
- ✓ Working with the sponsor and/or CHR on (informed) consent form wording issues.
- ✓ Translating consent forms into other languages when necessary.
- ✓ When indicated in the CHR Application, conducting the [informed consent process](#) with potential participant (or a potential participant's duly authorized legal representative).
  - Providing potential participants with the [Experimental Subject's Bill of Rights](#);
  - 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!!!***

**MANAGING STUDY CONDUCT.** This may include:

- ✓ [Recruiting](#) 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 (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.