

Section 33: Study Coordinators

The study coordinator is an integral part of the study team and works closely with the overall PI, the research nurse, and the QACT data analyst.

33.1 Roles and Responsibilities

The study coordinator position may also be referred to as “CRC”, “CRA” or “data manager.”

This section will provide an overview of the roles and responsibilities of a study coordinator. The specific roles and responsibilities may vary by institution. Please consult your supervisor for an institution-specific job description.

33.2 Protocol Management

These topics summarize the responsibilities involved in managing protocols.

Understanding the Protocol Document

The study coordinator should possess a complete understanding of the following protocol elements essential to running a trial and ensuring protocol compliance:

- Trial objectives
- Eligibility criteria and enrollment procedures
- Treatment procedures
- SAE reporting
- Measurement of trial outcomes
- Trial parameters (required tests and procedures)
- Drug formulation and procurement, if applicable
- Research samples (pharmacokinetics, blood, tissue, etc.)
- Required data/records to be maintained

Subject Enrollment

Often, the study coordinator plays a major role in the enrollment of trial participants. The following are procedures that must be followed to ensure that only those participants who meet the eligibility criteria are enrolled:

- *Screening:* Procedures that are to be performed as part of the practice of medicine and that would be done whether or not trial entry was contemplated, such as for diagnosis or treatment of

a disease or medical condition, may be performed and the results subsequently used for determining trial eligibility without first obtaining consent. Informed consent must be obtained prior to initiation of any clinical screening procedures that is performed solely for the purpose of determining eligibility for research.

- *Informed Consent:* Confirm the most current version of the informed consent document is being used. The expiration date is located on the footer of every informed consent document. Each time a new participant is to be consented, the consent form must be printed from OncPro.
- *Eligibility:* Verify the potential participant's eligibility by reviewing the criteria outlined in the IRB-approved protocol. Confirm that all required tests and screening have been performed. Eligibility checklists created by the QACT are posted on OncPro with other trial-related materials. Refer to the protocol eligibility checklist documents required by the sponsor/cooperative group. Refer to the protocol document for specific instructions for additional registration or enrollment procedures.
- *Registration:* Once a participant is determined to be eligible for enrollment, registration must be completed with the QACT and the sponsor or any cooperative group, if applicable, prior to the participant beginning study treatment.

33.3 Data Management

These topics describe some of the documents and procedures involved in data management.

Source Documents

The International Conference on Harmonization (ICH) guidelines define source documentation as "original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subject's diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, X rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial)."

(Source: ICH GCP Guideline 1.52)

The information captured in source documentation is extracted and transcribed onto the trial's case report forms (CRFs). It generally falls to the study coordinator to collect and manage this data collection and abstraction. The study coordinator is responsible for submitting the data in a timely fashion.

Case Report Forms (CRFs)

CRFs (electronic or paper) capture all research data necessary to assess the outcomes in clinical trials. CRFs for each participant enrolled in the trial are completed, maintained, and then submitted to the sponsor throughout the trial at intervals specified in the protocol document. All data transcribed onto the CRF must correspond accurately with the source documentation. Discrepancies will be scrutinized and clarification sought through a query process.

The design of the CRFs depends on the trial's sponsor. The QACT designs CRFs for PI-initiated, in-house trials. In these cases, all original CRFs should be submitted to the assigned data analyst at the QACT for each participant. Sponsors, such as pharmaceutical companies and cooperative groups create CRFs for trials being conducted at DF/HCC, and data for these trials will be submitted as outlined in the protocol document.

Errors are sometimes identified on CRFs. Corrections on electronic CRFs should be made according to the sponsor's guidelines. When corrections need to be made to a paper CRF, draw a single line through the error and write the correct value next to the error. Do not obscure the original entry. Each correction must be initialed and dated. If the CRF was already submitted and the error is found and corrected later, please make the correction to the copy of the CRF, write "correction" at the top of the CRF with the correction highlighted, and resubmit the CRF to the appropriate office. Whiteout must *never* be used on a CRF or any other medical record.

Query Resolution

All trials typically are monitored and/or audited. Often a trial sponsor may send a monitor to review their data. The auditing team in the QACT also performs this function. There may be discrepancies between the CRFs and the source documents requiring clarification or correction. This is called the "query resolution process."

Serious Adverse Event (SAE) Reporting

SAEs experienced by trial participants must be reported *promptly* to the IRB and appropriate federal, state, and sponsoring agencies. Guidelines for SAE reporting are typically outlined in the protocol document. Sponsors/cooperative groups will also have their own standards for SAE reporting that may differ from the DFCI IRB. All reporting requirements *must be met*. The study coordinator is responsible for drafting the report, which is then reviewed and signed by the reporting investigator. The signed SAE report is then submitted to the IRB and other relevant groups. For the DFCI IRB specific reporting requirements, see the [Serious Adverse Event \(SAE\) Reporting Policy](#) section of this guide.

Research Files

Research files contain copies of source documentation for each participant.

Study Diaries and Questionnaires

As part of the protocol activities, the participant may be required to record drug administrations or other trial experiences in a study diary. Participants may also be asked to complete a questionnaire while on trial. A study coordinator may be responsible for administering the study questionnaires at the proper times specified by protocol and retrieving these materials for documentation purposes.

33.4 Drug Accountability

The study monitor performs drug accountability. This is done at the time of the monitoring visit with the investigational pharmacist. A study coordinator may be responsible for scheduling visits with pharmacy staff.

33.5 Regulatory Submissions

The study coordinator assists the PI with correspondence to regulatory agencies, such as the IRB, and/or the sponsor/cooperative group to ensure that all regulatory requirements have been met. The study coordinator may be responsible for completing these documents/forms:

- **New Submissions:** Please refer to Protocol Submission, Review, and Activation for a list of the basic elements of an IRB submission.
- **Continuing Reviews:** Regulations mandate that all research trials must be reviewed at least once per year. The study coordinator may assist the PI in preparing the continuing review for submission to the IRB.
- **Amendments:** During the course of a trial, components of the research are amended. Such changes require IRB review and approval prior to initiation. The study coordinator may oversee this process as well.
- **Violations/deviations:** Violations of or deviations from the protocol procedures must be reported to the DFCI IRB. The study coordinator may be responsible for gathering the appropriate information and completing the forms.

33.6 The Regulatory Binder

The study coordinator is responsible for maintaining the regulatory binder, which includes documentation of everything that has happened to a particular trial from the time of submission to completion. Generally, the sponsor of an industry-sponsored trial will provide binders to house study-specific regulatory documents. Sections within a regulatory binder may include, but are not limited to:

- **IRB Submission Track Sheet:** All items sent to the IRB for review and the subsequent approval dates should be listed and initialed on this sheet.
- **IRB Initial Approval:** This section includes the IRB application, all IRB correspondence pertaining to the initial approval of the trial, any responses submitted by the PI, and the IRB approval and activation memos. Radiation and/or biosafety committee correspondence, NCI approvals, and pathology committee correspondence and approvals also are included within this section.
- **IRB Continuing Reports:** This includes the continuing review report, any relevant IRB correspondence, and the IRB continuing review approval memo.
- **IRB Amendment Approvals:** Copies of all amendment forms, IRB review memos, and IRB approvals are incorporated in this section.
- **Pharmacy Correspondence:** Any pharmacy-related correspondence is included in this section.
- **Other Committee Correspondence (if applicable):** Copies of any violation/deviation forms and exception requests are incorporated here.
- **Legal/administrative (if applicable):** This section includes any documentation relating to the budget, contract with the sponsor, and FDA forms (1571 and 1572).
- **General Correspondence:** This section includes any correspondence among the study team and between the study team and other departments relating to the trial.
- **SAE Reports:** All SAE and IND/IDE safety reports, IRB responses, and any other relevant correspondence are included in this section.
- **Master Protocol:** The current versions of the protocol and consent documents are located in this

section.

QACT audit reports should be filed separately, not in the regulatory binder. See the [Monitoring and Audit Preparation](#) section below.

33.7 Research Sampling

Many trials involve the procurement of research samples from trial participants. Examples of research samples are tissue, urine, and blood.

In terms of sample collection, the study coordinator may be responsible for making sure that:

- Samples are drawn at the times specified by the protocol
- The correct tubes are used by phlebotomy/nursing
- All samples are labeled properly and the correct paperwork is completed
- Samples are stored at correct temperature or sent out to the proper recipients

Refer to the protocol for a list of specific sample collection requirements and procedures.

33.8 Monitoring and Audit Preparation

During the life of a trial, routine monitoring and auditing visits should be expected. Depending on the type of trial, the types of monitoring visits and audits will vary. However, their intent is the same – to ensure the best and most accurate data are being collected.

Sponsors representatives will visit a research site on a regular basis to monitor the trial progress or perform an audit of the trial. The sponsor may also send an independent firm to perform a quality assurance (QA) audit.

Federal regulatory agencies, such as the FDA and the NCI also may audit the research site, the investigator, or the research trial.

The QACT also audits trials conducted within DF/HCC. The QACT audits ongoing trials, including in-house trials, each year on a random basis.

For sponsored trials, a study coordinator acts as a liaison between the PI and the pharmaceutical company, CRO, or cooperative group.

The study coordinator may be responsible for:

- Coordinating visits with the sponsor/cooperative group and other DF/HCC sites, if applicable
- Coordinating times for the PI to meet with trial representatives
- Ensuring CRFs are completed
- Making medical records readily available
- Resolving previous follow-up issues

- Coordinating pharmacy monitoring visits
- Updating regulatory files

Important things to keep in mind during the monitoring visit:

1. Do not make any changes to AE pages (especially the relationship section) without discussing with PI.
2. Do not allow monitors to make photocopies of medical records.
3. If you are uncertain about something, refer it to the PI or your manager.

33.9 Checklist for Monitoring and Auditing Visit

The QACT has a checklist to help a study coordinator prepare for a monitoring or auditing visit. (Refer to Appendix A of the [DF/HCC Clinical Trials Audit Manual](#).) This checklist is suitable for visits performed by internal as well as external monitors and auditors.