

3. DCP STUDY STAFF ROLES AND RESPONSIBILITIES

The study site research team usually includes the following members: Principal Investigator (PI), Study Coordinator or Research Nurse, and Pharmacist. Members of the research team at DCP include the Medical Monitor and/or Scientific Monitor, Organ System Research Group Nurse Specialist, PIO staff, Contracting Officer, and Contracting Specialist.

The National Institutes of Health (NIH) mandates education on human subject protection for all investigators and research team members who apply for or receive NIH funds for research involving human subjects. Each research team member must document completion of training in human subject protection and this documentation must be maintained at the site. This documentation must also be submitted to DCP prior to initiating a clinical trial. An online continuing education program is utilized by the NCI to fulfill this requirement. The educational program, Human Participant Protections Education for Research Teams, is available online at the following website: <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>. This online educational link may be used by sites that do not have a local training program.

The following sections describe the roles of various research team members and tasks that are often performed by them or delegated to them. Though select tasks are delegated to the Study Coordinator, Research Nurse, or pharmacist, the PI is ultimately responsible for the research conducted at the site.

3.1 Principal Investigator

The PI is responsible for the overall conduct of research activities at the site. The PI is expected to comply with the Code of Federal Regulations (CFR) and the International Conference on Harmonisation Guidelines for Good Clinical Practice (ICH/GCP). By signing the Form FDA 1572, the PI agrees to:

- Conduct the study(ies) in accordance with the relevant, current protocol(s) and will make changes in a protocol only after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects;
- Personally conduct or supervise the described investigation(s);

- Inform any participants, or any persons used as controls, that the agents are being used for investigational purposes and will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met;
- Report to the sponsor any adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64;
- Read and understand the information in the investigator's brochure, including the potential risks and side effects of the agent;
- Ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments;
- Maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68;
- Ensure that the IRB complies with the requirements of 21 CFR Part 56 and will be responsible for the initial and continuing review and approval of the clinical investigation;
- Promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others;
- Make no changes in the research protocol without obtaining prior DCP and IRB approval except in extenuating circumstances to minimize immediate threats to the safety of human subjects; and
- Agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

NOTE: Refer to Section 9 of Form FDA 1572 for complete information on investigator responsibilities. The instructions for completing the form are located at this link: <http://www.fda.gov/cder/forms/1571-1572-help.html>. The form can be found at <http://www.fda.gov/opacom/morechoices/fdaforms/default.html>. See Appendix C for a sample of the form.

3.2 Study Coordinator or Research Nurse

A well-implemented protocol is often attributable to an organized, responsible Study Coordinator or Research Nurse. The PI may delegate some or all of the following tasks to the Study Coordinator or Research Nurse. Under the PI's guidance, this person may:

- Submit protocol and amendments, informed consent, protocol submission worksheet, Data Safety Monitoring Plan, and Case Report Forms (CRFs) to the DCP PIO for review;
- Prepare regulatory documentation;
- Ensure the study is conducted in compliance with protocol requirements;
- Maintain IRB correspondence and regulatory documentation;
- Recruit potentially eligible participants for clinical trials enrollment;
- Meet with study participants to review the details of study enrollment;
- Evaluate study participants for protocol eligibility;
- Ensure that informed consent has been obtained from the participants before initiating research-related activities;
- Instruct and educate participants regarding study interventions and anticipated side effects and their management;
- Develop strategies to retain study participants in a clinical trial;
- Schedule tests and appointments for participants within timeframes required by the protocol;
- Identify abnormal laboratory results and obtain repeat evaluations as required by the protocol;
- Send the investigator-signed prescriptions for study agent to the pharmacist;
- Provide guidance to the PI, pharmacist, and participant on dose adjustments based on protocol dose modification section;
- Inform the pharmacist about any dose changes (as prescribed by the study investigator(s));
- Collect returned study agent;
- Monitor participant dosing compliance;

- Maintain source documentation for each study participant in accordance with the protocol;
- Complete CRFs accurately and retain a copy in the CRF notebook or folder;
- Perform quality assurance on aspects of data collection that were completed by other study staff;
- Identify and document Adverse Events (AEs) and SAEs;
- Initiate SAEs and obtain the PI's signature within the proper timeframes, notify appropriate individuals stated in the protocol, and submit reports according to DCP procedures;
- Identify, document, and submit protocol deviations in accordance with DCP procedures;
- Enter study data from paper CRFs to electronic systems (if available);
- Respond to data queries in a timely manner;
- Monitor study progress at participating organizations (as designated by NCI/DCP);
- Conduct monitoring visits at participating sites;
- Prepare for site monitoring visits by sponsor-designated clinical research associates or auditors;
- Contact the appropriate DCP Organ System Nurse Specialist with questions regarding study implementation; and
- Update the PI on study status.

3.3 Pharmacist

The pharmacist or designated qualified staff member is accountable for:

- Study agent supply, receipt, storage, preparation, dispensation, and disposal or return;
- Accountability of records and record security, including retention of:
 - Instructions for ordering study agent;
 - Shipping receipts and return records;
 - NCI Drug Accountability Record Forms (DARFs); and
 - Transfer forms;

- Agent administration record;
- Maintenance of blinded study integrity; and
- Instruction to the care provider on the proper method of agent administration.

NOTE: All study agents and records in the investigational pharmacy must be accessible only to specified pharmacy staff.

3.4 DCP Medical Monitor

The Medical Monitor is a physician or other licensed clinician who is a member of the DCP staff who belongs to one of the Research Groups within DCP. The Medical Monitor's responsibilities include:

- Managing scientific portfolios of grants, contracts, and other long-term projects in a distinct area of cancer prevention science;
- Reviewing protocols;
- Ensuring the quality and scientific integrity of protocol design, implementation, and data;
- Ensuring that the protocol is conducted safely and according to GCP and regulatory requirements;
- Reviewing SAE reports, deviations, and all clinical data; and
- Serving as a resource to study PIs and site staff for protocol-specific clarification.

3.5 Organ System Research Group Nurse Specialist

The Organ System Research Group Nurse Specialist is a registered nurse with advanced knowledge in the conduct of clinical research studies. The Nurse Specialist's responsibilities include:

- Serving as a resource and liaison to site staff conducting cancer prevention research;
- Participating in the management of cancer prevention research protocols;
- Participating in and leading DCP project teams and work groups; and
- Updating the DCP Medical Monitor on study status.

3.6 Contracting Officer

The Contracting Officer is a staff member who is responsible for the performance of pre-award and post-award contracting functions with NCI. The Contracting Officer is the only representative authorized by the United States Government to enter into contracts (i.e., commit Federal funds) and administer them. The Contracting Officer's acts are binding and responsibilities include the following:

- Providing guidance and technical assistance to program personnel who are involved in the planning and development of specifications, descriptions, and statements of work;
- Reviewing and evaluating requests for acquisitions, recommending and/or making revisions, analyzing requirements, and determining adequacy and completeness of requests;
- Recommending or deciding on the types of contracts;
- Coordinating the establishment of a peer review of proposals;
- Analyzing proposals through evaluating technical, cost/price data, proposal feasibility, and other factors; and
- Working with DCP officials to develop negotiation strategies.

3.7 Clinical Research Associate (CRA)

The CRA is qualified by training and experience, and is responsible for ensuring that clinical trials are conducted according to the CFR and the ICH/GCP. The CRA is an employee of the DCP Monitoring Contractor and represents DCP in the monitoring process. The CRA is responsible for verifying/assuring the following:

- The acceptability and accuracy of the investigator's and site staff's qualifications;
- The acceptability of the agent storage facilities;
- The initial and ongoing acceptability of the investigational site facilities;
- Investigational agents are supplied only to participants who are eligible to receive them, and in accordance with the dosing specified in the protocol;
- Participants are given the necessary instructions on properly using, handling, storing, and returning the study agent;
- The receipt, use, and return of the investigational agents at the sites are controlled and documented accurately;

- The study site research team complies with the protocol, applicable regulatory requirements, GCPs, and DCP policies;
- Informed consent was obtained prior to each participant's involvement in the trial;
- Study site staff are adequately informed and receive all trial documents and supplies to enable them to properly conduct the trial;
- The PI has appropriately delegated his or her authority;
- The PI is randomizing only eligible participants;
- Accurate reporting of the enrollment rate for the protocol;
- Accurate, complete, and current source documents and trial records are maintained;
- The PI provides all the required reports, notifications, applications, and IRB submissions, and that these documents are accurate, complete, timely, legible, and dated;
- The accuracy and completeness of the CRF relative to the source;
- Appropriate reporting of AEs and SAEs;
- Protocol changes/deviations are documented and reported to DCP and the IRB;
- Protocol deviations are reported to the PI, and the site has taken appropriate action to prevent the recurrence of the identified deviations;
- Data are entered appropriately and in a timely manner in a research database; and
- Data queries are addressed as appropriate to the coordinating center or as defined by the research database operations.

3.8 Protocol Information Office (PIO)

The DCP PIO is the central office for all protocol-related information management for DCP sponsored trials. The mission of the PIO is to coordinate all administrative aspects related to clinical trial development to assure that quality protocols are developed in the most expeditious and efficient manner possible. PIO personnel work closely with DCP and site staff assigned to this protocol to facilitate the research process for the Principal Investigator(s). The DCP PIO is responsible for the following:

- Coordinating all protocol activity from protocol development to final report submission; and

Collecting, processing, and tracking all protocol-related information between DCP, the study staff, the DCP Monitoring Contractor, and the DCP Regulatory Contractor.