3. DCP STUDY STAFF ROLES AND RESPONSIBILITIES

Members of the study site research team usually include at least one of the following: Principal Investigator, study coordinator or research nurse, and pharmacist. Members of the research team at DCP include the Medical Monitor, Organ System Research Group Nurse Specialist, PIO staff, and Contract Officer.

The National Institutes of Health (NIH) mandates education on human subject participation for all investigators and research team members who apply for or receive NIH funds for research involving people. 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 National Cancer Institute to fulfill this requirement. The Human Participants Protection Education for Research Teams course is available online at the following website: http://cme.nci.nih.gov.

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 Principal Investigator is ultimately responsible for the research conducted at the site.

3.1 Principal Investigator

The Principal Investigator (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 only make changes in a protocol 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 adverse experiences that occur in the course of the investigation(s) in accordance with 21 CRF 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 an IRB that complies with the requirements of 21 CFR Part 56 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 without DCP and IRB approval except where necessary to eliminate apparent immediate hazards to human subjects.
- 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 the 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 FDA 1572 can be found at http://forms.psc.gov/forms/FDA/fda.html or 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:

- 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.
- Develop strategies to retain study participants in a clinical trial.
- Schedule tests and appointments for participants within timeframes required by protocol.
- Validate participant height and weight for accurate dose determination.
- Send the prescriptions for study agent to the pharmacist.
- Complete Case Report Forms (CRFs) accurately, and retain a copy in the CRF Notebook.
- Maintain source documentation for each study participant in accordance with the protocol.
- Instruct and educate participants regarding study intervention modalities and anticipated side effects and their management.
- Provide guidance to the Principal Investigator, pharmacist, and participant on dose adjustments based on protocol dose modification section.
- Inform the pharmacist about any dose changes.
- Collect returned study agent and monitor participant dosing compliance.
- Identify abnormal laboratory results and obtain repeat evaluations as required by the protocol.
- Identify and document adverse events and serious adverse events.
- Initiate Serious Adverse Event Reports (SAEs) and obtain the PI's signature within the proper timeframes, notify proper individuals stated in the protocol, and fax report according to DCP procedures.
- Submit protocol and amendments, informed consent, protocol submission worksheet, Data Safety Monitoring Plan, and Case Report Forms to the DCP PIO for Review.

- Identify, document, and submit protocol deviations in accordance with DCP procedures.
- Respond to data queries in a timely manner.
- Contact appropriate DCP Organ System Research Nurse Specialist with questions regarding study implementation.
- Update PI on study status.

3.3 Pharmacist

The pharmacist or designated qualified staff member is accountable for:

- Study agent supply, storage, preparation, dispensation, and disposal;
- Accountability records and record security;

  Retain:

  1. Instructions for ordering study agent;
  2. Shipping receipts and return records;
  3. NCI Drug Accountability Record Forms (DARFs); and
  4. Transfer Forms.
- Agent administration record;
- Maintenance of blinded study integrity; and
- Instruction to the care provider on the proper method of agent administration.

3.4 DCP Medical Monitor

The Medical Monitor is usually a physician who is a member of the DCP staff. She or he belongs to one of the Organ System Research Groups or one of the Foundations of Prevention Research Groups. 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;

- Ensuring the quality and scientific integrity of protocol design, implementation, and data;
- Reviewing protocols;
- Reviewing Serious Adverse Events Reports and Deviations;
- Participating in the development of work statements; 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 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 DCP project teams and work groups; and
- Updating PI on study status.

3.6 Contract Officer

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

- 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, analyzing requirements, and determining adequacy and completeness of requests; recommending and/or making revisions;
- Recommending or deciding on the types of contracts;
- Coordinating the establishment of a peer review of proposals;

- Analyzing proposals, evaluating technical, cost/price data, and other factors, and determining reasonableness; and
- Working with DCP officials to develop negotiation strategies.

3.7 Clinical Research Associate

The Clinical Research Associate (CRA) is an appropriately qualified person, by training and experience, who is responsible for ensuring that clinical trials are conducted according to the Code of Federal Regulations and the International Conference on Harmonisation Guidelines for Good Clinical Practice. The CRA represents DCP in the monitoring process at the Lead Organization. The CRA is responsible for verifying/assuring:

- The acceptability and accuracy of the Investigator and site's qualifications;
- The acceptability of the agent storage facilities;
- Adequacy of clinical supplies;
- The initial and ongoing acceptability of the investigation site facilities;
- The investigational agents are supplied only to participants who are eligible to receive them, and according to 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 appropriate disposition of unused clinical trial supplies;
- The study site research team complies with the protocol, applicable regulatory requirements, and GCPs;
- Informed consent was obtained prior to each participant's participation 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 Principal Investigator has appropriately delegated his/her authority;
- The Principal Investigator is enrolling only eligible participants;

- Accurate reporting of the participant's enrollment rate;
- Accurate, complete, and current source documents and trial records are maintained;
- The Principal Investigator 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 Case Report Form (CRF) relative to the source documentation;
- Appropriate reporting of Adverse Events (AEs) and Serious Adverse Events (SAEs);
- Protocol changes/deviations are documented and reported to DCP and Institutional Review Board (IRB); and
- Significant protocol deviations are reported to the Principal Investigator, with appropriate action taken to prevent the recurrence of the detected deviations.