2. DCP ORGANIZATIONAL OVERVIEW, DESCRIPTION OF PREVENTION TRIALS, AND SUMMARY OF CONTRACTOR RESPONSIBILITIES

2.1 Overview

The National Cancer Institute (NCI) coordinates the National Cancer Program, which conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients (http://www.cancer.gov/aboutnci/overview/mission). The Institute has six divisions, each specializing in a different aspect of cancer research. DCP is the primary unit of the NCI devoted to cancer prevention research. The mission of DCP is to plan, direct, implement, and monitor cancer research and training that is focused on early detection, cancer risk, chemoprevention, and supportive care. More information about the work of DCP is available at the following website: http://prevention.cancer.gov/about/mission.

2.2 Prevention Trials

Projects within DCP address the need to identify where a person is in the process of carcinogenesis, and to determine ways to actively intervene to stop it from becoming invasive cancer. Varied approaches are supported, from pre-clinical discovery and development of biomarkers and chemoprevention agents, including pharmaceuticals and micronutrients, to Phase III clinical testing. Programs are harmonized with other NCI divisions, NIH institutes, and federal and state agencies (http://prevention.cancer.gov/about/mission).

There are three types of prevention trials: screening, control, and intervention.

- **Screening Trials:** The goals of screening trials are to develop tools for detecting cancer or precancers before an individual becomes symptomatic and to see if early detection and treatment of disease improves the outcome. Screening can include:
  - Imaging tests (e.g., x-rays) that produce images of internal organs and tissues in the body;
  - Biological tests of the blood, urine, other bodily fluids, and tissues to find indicators of disease processes; and
  - Genetic tests that look for inherited genetic markers linked to certain types of cancers (e.g., BRCA1 gene mutation).

- **Control Trials:** A cancer-control trial assesses the effect of an intervention on cancer symptoms, side effects of cancer treatment, or the participant's quality of life. As with other clinical trials supported by DCP, the intervention can be pharmaceutical, nutriceutical, dietary, or behavioral.

- **Intervention trials:** These trials generally take one of two forms. Behavioral studies focus on finding out whether actions people take, such as exercise or smoking cessation, can prevent cancer. Agent studies focus on examining whether taking certain medicines, vitamins, minerals, or food supplements (or a combination of them), can prevent cancer.

- **Chemoprevention Trials:** Chemoprevention trials are a type of intervention trial. They may be Phase I, II, or III studies.

  - Phase I chemoprevention trials are the first studies in participants that evaluate how new agents should be given (i.e., by mouth, applied to the skin), how often, and what dose is safe. A Phase I trial usually enrolls only a small number of participants.

  - Phase II chemoprevention trials are conducted in larger groups of participants who are at high risk for certain cancers. While these trials continue to study the safety of the agent, they also evaluate the efficacy of the new agent usually by measuring the effect of the agent on biomarkers thus interrupting the process of carcinogenesis. Phase II studies usually focus on a particular type of cancer. Frequently these trials are conducted using a placebo-controlled group.

  - Phase III chemoprevention trials are conducted either in populations at high risk for specific cancers or in participants from the general population. These studies test new agents, a combination of agents, or a new surgical procedure in comparison to the current standard or to a placebo. A participant is usually randomly assigned to one of the groups defined in the protocol, which could include an investigational intervention, a standard intervention, or placebo. Phase III trials often enroll large numbers of participants to provide the sample size needed to address the research question and may require 5 to 10 years to complete. Phase III trials may be conducted at a variety of clinical settings nationwide such as physicians' offices, clinics, hospitals, or cancer centers.

2.3 DCP Organization

Peter Greenwald, M.D., Dr. PH is the Director of DCP. Leslie Ford, M.D., is the Acting Deputy Director and Associate Director for Clinical Research. DCP is organized into a number of specific groups and project teams. The DCP Protocol Information Office (PIO) is the coordinating office for cancer prevention studies. All protocol activity from protocol development to final report submission is

coordinated through the PIO. The PIO works closely with the Organ System Research Groups, the Chemopreventive Agent Development Research Group (CADRG), and the Community Oncology and Prevention Trials Research Group (COPTRG) to facilitate the research process for Principal Investigators conducting cancer prevention trials. A list of names, email addresses, and telephone numbers of DCP staff is available in Appendix A and also through the DCP website (http://prevention.cancer.gov/about/staff).

2.4 Prevention Protocol Management

There are three primary areas of protocol management:

- Protocol Development;
- Regulatory Affairs; and
- Study Site Monitoring.

DCP has enlisted the support of several contractors to assist with these activities. The DCP Regulatory Contractor assists with protocol development and regulatory affairs. The DCP Monitoring Contractor manages the study site monitoring, data management, and informatics activities.

The DCP Regulatory Contractor is responsible for assisting the PIO, Research Group personnel, and study site staff with protocol development and management of regulatory issues during the conduct of a study. The DCP Regulatory Contractor also provides technical assistance with drafting, revising, and managing investigational new drug (IND) packages, and DCP-sponsored New Drug Application (NDA) documents. Regulatory documents are described in Chapter 5, Study Record Maintenance.

The DCP Monitoring Contractor consists of staff with clinical trials monitoring experience, data management, education and training experience, and clinical trials database informatics experience. Through their existing contract, the DCP Monitoring Contractor will:

- Enhance the existing database, DCP Enterprise System Knowledgebase (DESK), and develop software applications to collect, analyze, and report the study data;
- Standardize site monitoring processes; and
- Provide consistent education and training to site staff about the conduct and management of clinical research trials.

A glossary of terms in Appendix B is provided to assist site staff and other readers with definitions of DCP prevention terminology.