1. INTRODUCTION

1.1 Purpose of Site Monitoring

Clinical trials site monitoring is the act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirements. The Food and Drug Administration (FDA) requires that clinical investigations involving human subjects are periodically monitored (21 CFR 312.56, Review of Ongoing Investigations). In order to fulfill this regulatory requirement, the Division of Cancer Prevention (DCP) has contracted with a Contract Research Organization to provide qualified Clinical Research Associates (CRAs) to periodically visit the Protocol Lead Organization to verify that:

- The rights and well-being of human subjects are protected;
- The study data are of the highest quality and integrity; and
- The study is in compliance with the currently approved protocol/amendments, GCP, and other regulatory requirements.

1.2 Purpose of this Manual

Staff at DCP created the *Study Site Monitoring Manual (SSMM)* (hereafter referred to as the Manual) initially for Master Agreement Holder (MAH) institutions conducting DCP-sponsored Phase I and II chemoprevention studies to provide clinical study site staff with reference information about monitoring clinical research studies. Currently, there are other DCP constituencies who will refer to this Manual as well.

The user of this Manual should have a basic understanding of the clinical research process. The Manual does not replace protocol-specific instructions or procedures. This Manual will be posted to the Clinical Trials Management section (http://prevention.cancer.gov/clinicaltrials/management) of the DCP website and will be updated regularly.

The Manual provides general information about DCP's mission and organization and the following:

- Study staff roles and responsibilities are described;
- Participant enrollment and study record maintenance are outlined;
- Serious Adverse Events (SAEs) procedures are reviewed;
- Protocol deviation procedures are reviewed;
- Participant status changes are reviewed;
- The types of monitoring visits are delineated;
- The process for conducting the visits is explained; and
- A list of staff, key to the management of clinical trials, is provided.

1.2.1 Manual Feedback

Feedback about the Manual content and organization can be directed to the DCP Help Desk at nci-dcpmonitoring@westat.com.