# 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 Operation Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirements. The FDA requires that clinical investigations involving human subjects be periodically monitored (21 CFR 312.56, Review of Ongoing Investigations). In order to fulfill this regulatory requirement, the Division of Cancer Prevention (DCP) representative, which is the Westat Team, periodically visits the 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

DCP created the *Study Site Monitoring Manual* for Master Agreement Holders (MAH) of Phase I and II studies to provide clinical study site staff conducting DCP studies with reference information about monitoring clinical research studies.

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 merged into a comprehensive Clinical Trials Resource (MAH portal in development), which will be on the DCP website and will be updated regularly.

The manual provides general information about DCP's mission and organization. Study staff roles and responsibilities are described. Participant enrollment and study record maintenance are outlined. Serious Adverse Events (SAEs), protocol deviations, and participant status changes are reviewed. The content of the various types of monitoring visits are delineated as well as the process for conducting the visits. A list of staff, key to the management of clinical trials, is provided as well as a Glossary of Terms.

### 1.2.1 Manual Feedback

Feedback about the manual content and organization can be directed to Detra Robinson at detrarobinson@Westat.com.