National Cancer Institute (NCI), Division of Cancer Prevention (DCP) Requirements for Master Data Management Plan (DMP) For the Phase I and Phase II Clinical Trials of Cancer Chemopreventive Agents

I. Purpose:

- Data Management is the administration and supervision of "tasks associated with the entry, transfer and/or preparation of source data and derived items for entry into a clinical trial database." (CDISC Glossary, 2008; http://www.cdisc.org/glossary/CDISC_Glossary_V6.0.pdf). It is an essential activity for those data collected during the conduct of a clinical trial funded by DCP to ensure quality and accuracy of data; and compliance with Federal regulations, such as Good Clinical Practice (GCP) guidelines and Health Insurance Portability and Accountability Act (HIPAA) requirements. The purpose of the DMP is to assure that sites have procedures and controls in place to ensure protection of human subjects participating in a study and the authenticity, integrity, and confidentiality of study data.
- A Data Management Plan (DMP) is a document prepared by the Consortium Principal Investigator (or designee) to address data management practices and processes at the Consortium Lead Organization (CLO). This plan is submitted to DCP for review and approval. All DCP Chemoprevention Consortia should use the DCP DMP template as the foundation for developing a consortium specific data management plan.

II. General Requirements:

- DCP requires that data management practices comply with Federal regulations including but not limited to 21 CFR Part 11, GCP and HIPAA requirements and that organizations conducting clinical trials under DCP funding demonstrate their compliance with these regulations.
- The Consortium Principal Investigator has the ultimate responsibility for ensuring that Consortium protocols are conducted in compliance with the NCI/DCP Data Management Requirements as documented in the NCI/DCP-approved DMP.
- Each DCP Chemoprevention Consortium will have an approved Master DMP on file that will be applied as the default to all protocols that originate through that Consortium. This Master DMP will describe the procedures and controls for data management for the Lead Organization and all Participating Organizations that enroll participants on consortia studies. For unique circumstances, such as an Interconsortia Study, a study specific plan will supersede the consortium specific DMP for each participating consortium.
- Lead and Participating Organizations will use the NCI/DCP-hosted electronic remote data capture (RDC) systems to manage and report clinical data with exemptions approved by NCI/DCP.
- NCI/DCP requires that site staff that perform any aspect of data management, or use NCI/DCP-hosted RDC have the education, training, and experience required to perform their assigned tasks. The Monitoring Contractor will contact the site for a list of the key personnel assigned to each role in the NCI/DCP-hosted RDC who have