7. PROTOCOL DEVIATION REPORTING

7.1 Purpose

The purpose of this section is to provide a definition of a protocol deviation and the process for reporting these deviations to DCP.

A deviation is any noncompliance with the DCP and Institutional Review Board (IRB) approved protocol and may result from actions by the study participant, the investigators, or the clinical staff conducting the study. A deviation may not always be construed as a deficiency although it may be discovered and reported during an on-site monitoring visit. Deviations from the protocol may be inadvertent, and cannot always be used as a measure of site performance. Proper documentation and reporting of protocol deviations as they occur is helpful for investigators and study sponsors, as these data can be used to determine the need for amendments to the protocol and/or the related documents. The monitoring of the frequency and nature of protocol deviations can also be used as a quality assurance measure for the site.

A deviation or noncompliance with the study protocol should be reported as soon as it is identified. This is consistent with Good Clinical Practices (GCPs). It is the PI and Site Coordinator's responsibility to report the deviation to the Medical Monitor at the time the deviation is noted.

7.2 Procedure

Site staff should record a single deviation from the protocol on the DCP Protocol Deviation Notification form (version 5/2/08). Instructions for completing each field of this form are included in the form (See Appendix D). The DCP Protocol Deviation Notification form is available on the DCP website at http://dcp.cancer.gov/files/clinical-trials/ProtocolDeviationNotification.doc.

The Site Coordinator must determine which site staff are authorized to complete this form. Using the Instructions for Completion as a guide, fields one through twenty-one should be completed by site staff.

The PI must review the completed DCP Protocol Deviation Notification form before the form is submitted to DCP for review. The designated staff member who completes the form should check box twenty to acknowledge that the PI has reviewed the completed form. The designated staff member should email the completed DCP Protocol Deviation Notification form to the appropriate DCP Medical Monitor (See Appendix A for the email addresses of the DCP Medical Monitors by Research Group).

The DCP Medical Monitor or designee will review the DCP Protocol Deviation Notification form. Once any queries have been resolved, the Medical Monitor or designee will complete fields twenty-two through twenty-five. This form is then submitted via email to the DCP Monitoring Contractor via the DCP Help Desk (nci-dcpmonitoring@westat.com).

Site staff should expect to receive the completed form, with comments from the DCP Medical Monitor (or designee), via email from the DCP Monitoring Contractor, within seven calendar days of receipt from DCP. Site staff should file the completed form in the specific study participant's record and/or protocol specific record, and should follow recommendations, as directed, by the DCP Medical Monitor (or designee).

7.3 Documentation

Site staff will use the DCP Protocol Deviation Notification form (version 5/2/08) to document protocol deviations. An example of the DCP Protocol Deviation Notification form can be found in Appendix D. The Protocol Deviation Notification form must be completed by electronically typing into the fillable form. Site staff may access the form from the DCP website (http://prevention.cancer.gov/) specifically at http://dcp.cancer.gov/files/clinical-trials/ProtocolDeviationNotification.doc. Completed copies of the form should be filed with study documentation.