

**STANDARD OPERATING PROCEDURES  
DIVISION OF CANCER PREVENTION (DCP)  
Phase I/II Consortia**

DCP SOP Number: 23

Title: Recording and Reporting Protocol Deviations (**Intended for CLO and PO**)

DCP Version Date: May 2, 2008

I. PURPOSE

This document describes the procedures to be followed by the Consortium Lead Organization (CLO) and their Participating Organizations (POs) for recording and reporting protocol deviations that occur on clinical trials.

II. SCOPE

This procedure applies to staff conducting cancer chemoprevention Phase I and II studies under contract with the National Cancer Institute/DCP.

III. RESPONSIBILITY

The Principal Investigator (PI) and the Site Coordinator are responsible for ensuring compliance with this procedure.

IV. REFERENCES

International Conference on Harmonisation (ICH) Guidelines: E6 Good Clinical Practice (GCP)

V. DEFINITIONS

*Refer to the glossary links on the DCP Website.*

VI. BACKGROUND

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 by the CLO Monitor 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 the 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 is also used as a quality assurance measure at the site.

The CLO and PO PIs are ultimately responsible for implementing and maintaining quality assurance/quality control as outlined in the site's data management plan (DMP) to ensure that studies are conducted according to the protocol (compliance). A deviation or noncompliance with the study protocol should be reported as soon as it is identified. This is consistent with GCPs. It is the CLO, PO PI and Site Coordinator's responsibility to report the deviation to the Medical Monitor at the time the deviation is noted.

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## VII. 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 with this SOP in Attachment #1.

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.

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](mailto: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).

## VIII. DOCUMENTATION

Sites participating in the DCP Prevention Consortia 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 at the end of this procedure (Attachment #1). 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/>). Completed copies of the form should be filed with study documentation. In addition, each CLO or PO will retain documentation of all relevant protocol deviation related correspondences.

## IX. REVIEW AND REVISION

This SOP will be reviewed on an annual basis. It may be reviewed and updated more frequently if indicated.

**ATTACHMENT 1  
DIVISION OF CANCER PREVENTION  
PROTOCOL DEVIATION NOTIFICATION**

*(REFER TO PAGE 2 FOR SPECIFIC COMPLETION INSTRUCTIONS)*

<b>1. Date Protocol Deviation Occurred:</b> <u>  /  /  </u> <small>(MM/DD/YYYY)</small>	<b>2. Reported to IRB:</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Required	<b>3. Date DCP Notified:</b> <u>  /  /  </u> <small>(MM/DD/YYYY)</small>
<b>4. Participant ID:</b>	<b>5. Local Protocol No.:</b>	<b>6. DCP Protocol #:</b>
<b>7. Agent(s) Name:</b>	<b>8. Site Name:</b>	<b>9. NCI Institution No.:</b> <small>(if applicable)</small>
<b>10. Protocol Deviation Description:</b>		
<b>11. Relevant Protocol Section No.:</b> <small>(describe below)</small>		
<b>12. Relevant Protocol Section Description:</b>		
<b>13. Action Taken:</b>		
<b>14. Completed By:</b> _____	<b>15. Email Address:</b>	
<b>16. Date:</b> <u>  /  /  </u> <small>(MM/DD/YYYY)</small>	<b>17. Phone No.:</b>	
<b>18. Principal Investigator:</b>	<b>19. Principal Investigator Email Address:</b>	
<b>20. By Checking this Box, I Confirm that the Principal Investigator has Reviewed this Form.</b> <input type="checkbox"/>	<b>21. Date Principal Investigator Reviewed Form:</b> <u>  /  /  </u> <small>(MM/DD/YYYY)</small>	
<b>For Medical Monitor Use Only</b>	<b>22. Protocol Deviation Grade*:</b>	
	<b>23. Medical Monitor (or designee) Review:</b>	
	<b>24. Medical Monitor (or designee) Name:</b> _____	
	<b>25. Date:</b> <u>  /  /  </u> <small>(MM/DD/YYYY)</small>	

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**\*Protocol Deviation Grade**

- 0 (Not a deviation) = Mistakenly reported as a deviation
- 1 (Minor) = No meaningful effect on data integrity and no meaningful risk to participant safety
- 2 (Moderate) = Potential to affect data integrity or jeopardize participant safety
- 3 (Major) = Will affect major endpoint data integrity or will have a major impact on participant safety or ethical concerns

**DIVISION OF CANCER PREVENTION  
 PROTOCOL DEVIATION NOTIFICATION INSTRUCTIONS FOR COMPLETION**

*NOTE: This must be completed by electronically typing into the fillable form. Once completed, save this to your desktop/files.*

**Question numbers 1-21 are to be completed by the clinical site reporting the deviation.**

1.	Date Protocol Deviation Occurred	Record the date the deviation occurred using the MM/DD/YYYY format.
2.	Reported to IRB	Indicate if the Local IRB was alerted of this protocol deviation by checking the Yes or No box. If notification to the IRB for protocol deviations is not a requirement at your institution, check 'Not Required.'
3.	Date DCP Notified	Record the date the Protocol Deviation Notification form was faxed to DCP using the MM/DD/YYYY format.
4.	Participant ID	Record the unique identification number assigned to the participant. This is the number that is used to report the participant's CRF data within the RDC database.
5.	Local Protocol No.	Record the institution-specific protocol number assigned by your institution to identify this protocol.
6.	DCP Protocol #	Record the protocol number assigned by DCP for this specific study. For example: UW103-1-01
7.	Agent(s) Name	Record the name of the study agent(s) for the specific protocol.
8.	Site Name	Record the name of the institution where the protocol deviation occurred.
9.	NCI Institution No. (if applicable)	Record the NCI institution code, if applicable, for the site at which the deviation occurred. If the NCI institution code is unknown, this field may be left blank.
10.	Protocol Deviation Description	Record a description of the deviation which includes reasons and contributing factors.
11.	Relevant Protocol Section No.	Record the specific section number from the protocol that is related to the deviation.
12.	Relevant Protocol Section Description	Describe the relevant protocol section (referenced in number 11) that has been deviated. This description can be copied verbatim from the protocol document or a brief description can be written that summarizes the appropriate section of the protocol.
13.	Action Taken	Describe the action taken to minimize harm to the participant, maintain data integrity and prevent reoccurrence.
14.	Completed By	Record the name of the staff member completing this form at the site.
15.	Email Address	Include a current email address.
16.	Date	Record the date the form was completed using the MM/DD/YYYY format.
17.	Phone No.	Include a current phone number.
18.	Principal Investigator	Record the name of the Principal Investigator at the clinical site where the deviation occurred.
19.	PI Email Address	Include the Principal Investigator's current email address.
20.	By Checking this Box, I Confirm that the Principal Investigator has Reviewed this Form.	Record confirmation that the Principal Investigator has reviewed the protocol deviation before it is provided to DCP.
21.	Date Principal Investigator Reviewed Form	Include the date of the Principal Investigator review using the MM/DD/YYYY format.

**Question numbers 22-25 are to be completed by the DCP Medical Monitor (or designee).**

22.	Protocol Deviation Grade	Assign a protocol deviation grade (0-3) using the following scale: 0 (Not a deviation) = Mistakenly reported as a deviation 1 (Minor) = No meaningful effect on data integrity and no meaningful risk to participant safety 2 (Moderate) = Potential to affect data integrity or jeopardize participant safety 3 (Major) = Will affect major endpoint data integrity or will have a major impact on participant safety or ethical concerns
23.	Medical Monitor (or designee) Review	Review the action plan to determine if appropriate action has been taken or has been planned to minimize participant harm, maintain data integrity and prevent reoccurrence. Record any additional comments, instructions or suggestions.
24.	Medical Monitor (or designee) Name	Record the name of the Medical Monitor (or designee).
25.	Date	Record the date using the MM/DD/YYYY format.