Appendix D

Protocol Deviation Notification

ATTACHMENT 1
DIVISION OF CANCER PREVENTION
PROTOCOL DEVIATION NOTIFICATION

(REFER TO PAGE 2 FOR SPECIFIC COMPLETION INSTRUCTIONS)

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

Revised May 2, 2008

***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: UWI03-1-01
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. 15. 16. 17.	Completed By Email Address Date Phone No.	Record the name of the staff member completing this form at the site. Include a current email address. Record the date the form was completed using the MM/DD/YYYY format. Include a current phone number.
18. 19. 20.	Principal Investigator PI Email Address By Checking this Box, I Confirm that the Principal Investigator has Reviewed this Form.	Record the name of the Principal Investigator at the clinical site where the deviation occurred. Include the Principal Investigator's current email address. 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. 25.	Medical Monitor (or designee) Name Date	Record the name of the Medical Monitor (or designee). Record the date using the MM/DD/YYYY format.