APPENDIX D. PROTOCOL DEVIATION NOTIFICATION

DIVISION OF CANCER PREVENTION

PROTOCOL DEVIATION NOTIFICATION

Patient No.:	Drug Under Investigation:	Study (Indication):
Sponsor: NCI, DCP	IRB Protocol No.:	NCI Contract No:
Investigator:	Site:	
Phone No.:	FAX No.:	
NCI is being notified of the following protocol deviation (describe and include specific criteria and		
protocol section):		
Reason for deviation:		
Action to be taken to prevent this from recurrence:		
Form completed by PI (print name):		
PI Signature:	Date:	month/day/year
Review of protocol deviation by the NCI Monitor and any required action to be taken:		
NCI Monitor signature:	Date:	
cc: Protocol File at Westat; Contract File at CCSA; AND Case Report Form Binder at Site		

Revised August 2002