

REPORT OF PROTOCOL DEVIATION/UNANTICIPATED PROBLEM/SERIOUS ADVERSE EVENT				HSR #
				SUBMISSION DATE
PRINCIPAL INVESTIGATOR		CODE	PHONE	E-MAIL
PROJECT TITLE				
PROJECT DESCRIPTION AND METHODOLOGY SUMMARY <i>(Use continuation sheet if necessary)</i>				
Work unit number: _____		Area of Research Pre-approval attached		
CURRENT RISK LEVEL/REVIEW TYPE				
Minimal Risk Exempt Category _____ Expedited Category _____ Convened Board Greater than Minimal Risk				
ORIGINAL APPROVAL DATE		LATEST APPROVAL DATE		APPROVAL EXPIRATION DATE
SUBJECT ID <i>(If applicable)</i>		DATE OF EVENT/PROBLEM		DATE IDENTIFIED
SUBMISSION TYPE <i>(Check all that apply)</i>			IS THE POSSIBILITY OF THIS EVENT NOTED IN THE CURRENT IRB APPROVED CONSENT DOCUMENT?	
Protocol Deviation Unanticipated Problem Serious Adverse Event			Yes No N/A	
DESCRIPTION OF EVENTS/PROBLEMS/CORRECTIVE ACTIONS				
<i>(Use a continuation sheet if necessary to provide a complete answer)</i>				
DESCRIBE THE PROTOCOL DEVIATION/UNANTICIPATED PROBLEM/SERIOUS ADVERSE EVENT <i>(Include dates and details)</i>				
DESCRIBE HOW THIS EVENT/PROBLEM WAS MANAGED				

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DESCRIBE THE CORRECTIVE ACTIONS TAKEN TO ENSURE THAT THIS TYPE OF EVENT/PROBLEM DOES NOT OCCUR IN THE FUTURE

PI ASSESSMENT

THE DEVIATION/UNANTICIPATED PROBLEM/ADVERSE EVENT:

Did affect the rights of the study subject.	AND	Did not affect the rights of the study subject.
Did affect the safety of the study subject.	AND	Did not affect the safety of the study subject.
Did have an effect on the scientific integrity of the study.	AND	Did not have an effect on the scientific integrity of the study.

IMPACT THE EVENT WILL HAVE ON SUBJECT RIGHTS, SUBJECT SAFETY, OR SCIENTIFIC INTEGRITY

Principal Investigator: I certify that the information provided in this report is complete and correct.

PRINCIPAL INVESTIGATOR	SIGNATURE	DATE
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		SUBMISSION DATE
IRB REVIEW		
THE DEVIATION/UNANTICIPATED PROBLEM/ADVERSE EVENT:		
Did affect the rights of the study subject.	AND	Did not affect the rights of the study subject.
Did affect the safety of the study subject.	AND	Did not affect the safety of the study subject.
Did have an effect on the scientific integrity of the study.	AND	Did not have an effect on the scientific integrity of the study.
IRB RECOMMENDATIONS		
BASED ON EXPEDITED REVIEW, THE IRB RECOMMENDS THAT THE:		
Study continue as planned; no modifications required.		
Study continue pending the following modification(s):		
Study be suspended pending further investigation.		
Convened IRB to review this deviation/event.		
BASED ON THE CONVENED IRB REVIEW, THE IRB RECOMMENDS THAT THE:		
Study continue as planned; no modifications required.		
Study continue pending the following modification(s):		
Modifications may be reviewed and verified by the IRB chair via the expedited process.		
Study continue pending the following modification(s):		
Modifications must be reviewed by the convened IRB prior to being forwarded to the Commander for approval.		
Study be suspended pending further investigation.		
IRB CHAIR/VICE CHAIR	SIGNATURE	DATE
INSTITUTIONAL OFFICIAL		
Acceptable		Unacceptable, additional information required.
SIGNATURE (<i>Institutional Official</i>)		DATE