

	Reference No.: BatStateU-FO-BERC-013	Effectivity Date:	Revision No.: 00
PROTOCOL DEVIATION/VIOLATION REPORT FORM			

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the documents that you checked in Section 3 Checklist of Documents.

1. General Information			
Title of the Study			
BERC Code (To be Provided by BERC)		Study Site	
Name of Researcher		Contact Information	Tel No:
			Mobile Number
			Fax No:
Co-Researcher (if any)			Email:
Institution			
Address of Institution			
Ethical clearance effectivity period			
Progress Report			
1. Start of Study		2. Expected end of study	
3. Number of enrolled participants		4. Number of required participants	
5. Number of participants who withdrew			
6. Deviations from the approved protocol		7. Explanation for deviation/violation	
8. Impact of deviation/violation on participants' risks/harms and integrity of data		9. Actions taken to prevent future deviation/violation	