Study Protocol Deviation/Violation Report

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: *Obtain an electronic copy of this form and encode all information required in the space provided. Information submitted under this form is subject to full board review by the UPCHE REC. Print the report then date and sign this form before submission.*

UPCHE REC CODE:		
Study Protocol Title:		
Approval Date:		
Principal Investigator/Research Proponent:		
Email:	**Telephone:**	**Mobile:**
Study Site:		
Study Site Address:		
Sponsor/Funding Agency:		
Report Submission Date: (to be filled out by UPCHE REC)		

1. NATURE OF REPORT

1.1. ☐ **MINOR PROTOCOL DEVIATION** (nonsystematic protocol deviations/violations with minor consequences, in terms of its effect on the participant's/subject's rights, safety or welfare, or the integrity of study data; includes deviations that are administrative in nature)

1.2. ☐ **MAJOR PROTOCOL DEVIATION OR PROTOCOL VIOLATION** (persistent protocol deviations/violations with potentially serious consequences that could critically affect data analysis or put participants' safety at risk)

Person involved:

☐ Researcher ☐ Staff ☐ Participant ☐ Others:

2. DESCRIPTION OF REPORTED DEVIATION/VIOLATION:

3. DESCRIPTION OF INVESTIGATOR CORRECTIVE ACTION:

4. DESCRIPTION OF INVESTIGATOR PREVENTIVE ACTION:

5. ASSESSMENT OF IMPACT ON SAFETY OF PARTICIPANT AND CREDIBILITY OF DATA
6. SPONSOR ASSESSMENT OF SEVERITY: **6.1.** ☐ MAJOR **6.2.** ☐ MINOR
7. DESCRIPTION OF SPONSOR CORRECTIVE ACTION:
Date of Deviation/Violation:
Reported by:
Date of Report:
P.I./RP Signature:
For students, name and signature of thesis adviser:

For UPCHE REC use only:	
TYPE OF REVIEW:	
☐ Expedited Review	☐ Full Review
ASSESSMENT OF NONCOMPLIANCE: ☐ MAJOR ☐ MINOR	
REVIEWER'S COMMENTS (i.e., whether noncompliance have potentially serious consequences that could critically affect data integrity or put patients' safety at risk. **Reviewers should provide comment(s) on the overall risk-benefit assessment.**)	
RECOMMENDATION(S)	
RECOMMENDED ACTION:	

☐ No further action ☐ Request information: (specify the information needed from PI/RP) ☐ Recommend further action: (specify the required action from PI/RP)	
REVIEWER (Scientist or Non-scientist) Date:	Signature Name Position