IRB2 PROTOCOL DEVIATION REPORT

While conducting research, investigators are required to document and report any deviations to the original research protocol that was approved by IRB2. Please complete and submit the following information to the IRB2 Administrator. If you have questions, please contact the IRB2 Administrator at: IRB2@hhs.texas.gov.

Principal Investigator:	Phone Number:
IRB2 Tracking Number:	Date of Event:
Protocol Title:	
1. Briefly describe the purpose of the study.	
2. Date of *discovery* of the event:	
3. Category of deviation:	

☐ Recruitment was over number of currently approved subjects.

☐ Procedures were performed that were not described in currently approved protocol.

☐ Procedures were not preformed as described in currently approved protocol.

☐ Conducted research activities without IRB approval.

☐ Other (specify): _____

4. Describe the specific deviation.

5. Has this protocol deviation (or similar deviations) previously occurred in this study? If yes, describe the event(s) and when the event(s) occurred.	☐ Yes ☐ No
6. In the opinion of the PI, does this deviation affect the safety of the subjects?	☐ Yes ☐ No
7. In the opinion of the PI, does this deviation affect the integrity (i.e., validity and ethics) of the research?	☐ Yes ☐ No
8. Describe your preventive/corrective action plan to avoid this occurrence in the future.	
9. Is the research federally funded? If yes, give the name of the agency:	☐ Yes ☐ No

If your computer allows email submission, after completing the form click the "Submit" button located below, otherwise submit the form and applicable documentation.
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