Protocol Deviation Reporting Log

TriHealth Institutional Review Board

1. Protocol Information

Study/IRB Number: **PI Name:**

Protocol Number: ☐ **check if N/A**

Protocol Version/Date:

Title:

Sponsor:

2. Contact Information for this submission:

Name:

Phone:

Email:

Please utilize this form to report minor protocol deviations and simple logistical conflicts at the time of continuing review. None of the items on this list should include any violations from currently approved protocol procedures that adversely affect the rights, safety, health or welfare of subjects, nor significantly impact the integrity of research data. Those should be reported as an **Unanticipated Problem**.

Study teams are responsible for updating this log in a timely manner and for maintaining this log in the Regulatory Binder.

4 or more **Minor** deviations of the same type require you to submit this form to the IRB as soon as the fourth deviation is recognized. The IRB Chair will decide if the multiple deviations constitute a **Major** violation.

Protocol Deviation Codes:

1=Recruitment Procedure

2=Documentation

3=Withdrawal Criteria

4=Concomitant Medications

5=Event Outside Time Frame

6=Study Conduct

7=Informed Consent

8=IRB Reporting

9=Administrative Issues

10=Drug Accountability

11=Missing Lab Results

12=Other

3. Event:

Event Date				
Subject ID/Site/ Initials				

Deviation Code (1-12)				
Description of Deviation (including assessment of the net effect on Risk/Benefit)				
Reason for Deviation and Date of Sponsor Approval				
Corrective Action Taken to Avoid Recurrence				

I certify the above as being an accurate and complete accounting of the minor deviations that occurred during the reporting period.

Signature of Principal Investigator:

Date:

Submit this protocol deviation form and supporting documents to irb_hrpp@trihealth.com
Please note if your submission is incomplete, processing will be delayed.