Protocol Deviation[1] / Non-Compliance[2] Form

TriHealth Institutional Review Board

Major Deviations[3] must be reported within 10 business days

Minor deviations[4] should be reported on the Protocol Deviation Reporting Log and submitted with your Continuing Review

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:

3. Current Study Status: (check all that apply)

Enrollment: ☐ **Open** ☐ **Closed** ☐ **On Hold** ☐ **Suspended**

Subjects: ☐ **Active** ☐ **Not Active** ☐ **Follow-up Only** ☐ **Data Analysis Only**

☐ **Chart Review** ☐ **Database Search** ☐ **Survey**

4. Deviation information

Subject(s) ID and Subject(s) Initials:

Is/are the subject(s) still participating in the study? ☐ **Yes** ☐ **No** ☐ **N/A**

If No, please explain:

Date of Protocol Deviation/Non-compliance (event):

Has the sponsor be notified of the Protocol Deviation/Non-compliance (event)?

☐ **Yes** ☐ **No** ☐ **N/A** **If No, date sponsor will be notified:**

5. Deviation/Non-Compliance Type (check all that apply):

☐ **Informed Consent / HIPAA** ☐ **Protocol** ☐ **Documentation**

☐ **Recruitment Procedure** ☐ **Withdrawal Criteria** ☐ **Concomitant Medications**

☐ **IRB reporting** ☐ **Missing lab results** ☐ **Drug Accountability**

☐ **Other (please specify):**

6. Deviation Description

Provide a detailed description of Deviation/Non-compliance including the outcome of the event, impact to subjects and/or integrity of the study and how it was resolved:

Describe corrective measures that have been put in place to avoid re-occurrence:

[1]**Protocol Deviations:** Any alteration or modification in the conduct of the research that has not been approved by the Board.
[2]**Non-compliance:** "Failure to comply with federal regulations, determinations and/ or requirements of the Board"
[3]**Major deviation:** A deviation that may impact the subject's rights, safety and welfare of the subjects; the integrity of the data; or substantially alter the risks to the subjects.
[4]**Minor deviation**: A deviation that does not affect the right, safety or welfare of the subjects; the integrity of the data; nor substantially alter the risks to the subjects.

7. Deviation submitted by:

Signature of Principal Investigator

Date

Submit this form and supporting documents to irb_hrpp@trihealth.com

Please note if your submission is incomplete, processing will be delayed.