INSTITUTIONAL REVIEW BOARD
Protocol Deviation Report

This form is for IRB use only. Please follow all PPMH Policies and Procedures in reporting possible patient care issues.

Principal Investigator:

Study Title:

PI Address:

PI Telephone / Email:

Date of Submission:

Protocol Deviation

Date of Event:

Patient ID#: Patient Age:

Gender: ☐ Male ☐ Female

Did the violation occur at a Phoebe Putney Health facility? ☐ Yes ☐ No

If No, list facility:

Protocol Deviation Identified by:

☐ PI ☐ Coordinator ☐ Monitor ☐ Other:

Did the deviation have a major effect on patient care? Example: subject given wrong dose of study medication.

☐ Yes

☐ No

If yes, explain:

Does the deviation affect the integrity of the study data? Example: enrollment of an ineligible subject.

☐ Yes

☐ No

If yes, explain:

Did the deviation impact the rights of research participants? Example: subject enrolled without proper documentation of informed consent.

☐ Yes

☐ No

If yes, explain:

Nature of Protocol Deviation

☐ Dosing error by participant

☐ Medication error by healthcare provider

☐ Participant did not use HIPAA form

☐ Participant signed older version of consent form

☐ Participant did not date the consent form or used the wrong date

☐ Laboratory specimen not obtained

☐ Medication missing from site

☐ Participant lost to follow up

☐ Participant was seen outside of window

☐ Other (specify):

Describe the Protocol Deviation in the space below:

Explain why the Protocol Deviation occurred:

Explain what is being done to prevent a future occurrence:

Was the patient informed of the Protocol Deviation?

☐ Yes

☐ No

Explain:

Will the patient remain on the protocol?

☐ Yes

☐ No

Was the sponsor notified?

☐ Yes

☐ No

☐ Not a Sponsored Study

If Yes, how & when:

Principal Investigator Acknowledgement	
I attest that the information contained herein is a true and accurate representation of my ongoing study.	
P.I.'s Name:	Date:
Electronic Signature:	

Submit Form

Please save a copy of the form for your records and submit the final form electronically by clicking the "Submit Form" to the left or at top of page.

IRB Review of Protocol Deviation (Completed by IRB Office Only)
Date of Receipt: _____
The Protocol Deviation: ☐ Does not represent risks to participants or others ☐ Does represent risks to participants or others
Full Board Review Date: