***This form is for IRB use only. Please follow all Colquitt Regional Medical Center 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

Colquitt Regional Medical Center?

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 Laboratory specimen not obtained

Medication error by healthcare provider Medication missing from site

Participant did not use HIPAA form Participant lost to follow up

Participant signed older version of consent form Participant was seen outside of window Participant did not date the consent form or used the wrong date

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:**

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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 If Yes, how & when:

No

Not a Sponsored Study

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Principal Investigator Acknowledgement** | | | | | |
| ***I attest that the information contained herein is a true and accurate representation of my ongoing study.*** | | | | | |
| P.l.’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.***

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| --- | --- | --- |
| **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: | | |