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**LEGACY HEALTH IRB**

**FORM H: PROTOCOL DEVIATION/VIOLATION REPORT**

**Use this form for submitting all reportable deviations from or violations of the protocol. Reporting of a deviation or violation does not automatically mean non-compliance. The IRB will determine if non-compliance has occurred after reviewing the submitted information. Investigators are encouraged to submit deviation/violation reports and to assist the IRB is determining the most appropriate corrective actions.**

**See “Instructions Form H” for completing this form.**

**study information**

Study Title: Click or tap here to enter text.

Protocol Number: Click or tap here to enter text.

Principal Investigator name: Click or tap here to enter text.

Date of **Submission** of this form: Click or tap to enter a date.

Name of submitter for this report (name and contact information):Click or tap here to enter text.

**definitions**

**Protocol Deviation**: A protocol deviation occurs when provisions of the protocol were not followed due to a deviation by the subject or by the study staff. Examples include missing study visits by the subject or mistakes in dosing or administration of drugs. Deviations are mistakes.

**Protocol Violation:** A protocol violation occurs when the investigator or other staff violate the provisions or requirements of the approved protocol. Examples include failure to obtain informed consent, enrollment of subject who does not meet the inclusion/exclusion criteria, failure to perform a required lab test, medication dispensing error, failure to follow safety monitoring plan, implementation of unapproved recruitment procedures, or over-enrollment, failure to submit continuing review application prior to the IRB expiration date or conducting any study procedures not approved by the IRB.

**deviation/violation report information**

PATIENT INITIALS OR STUDY #: Click or tap here to enter text.

ON-SITE: [ ]  Yes [ ]  No

OFF-SITE: [ ]  Yes [ ]  No

DATE OF DEVIATION/VIOLATION: Click or tap here to enter text.

DATE DEVIATION/VIOLATION REPORTED TO PI:Click or tap here to enter text.

DATE OF THIS REPORT: Click or tap here to enter text.

DESCRIBE THE DEVIATION/VIOLATION IN DETAIL: Click or tap here to enter text.

DESCRIBE THE CORRECTIVE ACTION TAKEN BY THE SITE IN REGARD TO THE DEVIATION/VIOLATION:

Click or tap here to enter text.

**deviation/violation report ANALYSIS**

Did the event harm the research subject? [ ]  Yes [ ]  No

Did the event affect the safety or rights of the research subject? [ ]  Yes [ ]  No

Has the deviation/violation been reported to the sponsor and/or FDA? [ ]  Yes [ ]  No

Did the subject complain? [ ]  Yes [ ]  No

|  |  |
| --- | --- |
|  | Click or tap to enter a date. |
| Investigator Signature  | Date:  |

**end of application form**

**WHO TO CONTACT FOR FURTHER INFORMATION OR IF YOU HAVE QUESTIONS:**

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