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**Legacy Health IRB**

**DEVIATION/VIOLATION REPORT FORM -- Version 6-1-2021**

**Form H Instructions**

Form H is to be used for any deviation or violation of the protocol that should be reported to the IRB for ongoing monitoring of risks of the research. The Common Rule specifies that investigators “promptly report…all unanticipated problems involving risk to human subjects”. Such reporting can vary greatly depending on the nature of the study.

The protocol approved by the IRB must be followed or amended. Inadvertent mistakes, deviations and violations by both study staff and subjects do occur. Adherence to the approved protocol is not always possible and in some cases, especially those involving patient safety, such incidences must be reported to the IRB to help determine whether appropriate safeguards are in effect and whether the consent form provides adequate information for a subject to provide informed consent. Reportable deviations/violations should be submitted to the IRB within five working days. That report should be in the form of a letter or use of Form H documenting the deviation/violation and providing a process by which to prevent further similar deviations/violations.

Use of Form H is also appropriate for documenting “exceptions”. An exception may be granted in advance through a waiver by the sponsor or may be the result of a physician’s decision that is in the best interest of the research subject. In those instances when adequate time exists, waivers must also be approved by the IRB via an amendment or modification of the research. This should be done using the IRB Revision/Amendment Form. In those instances where there is not adequate time to consult the IRB, waiver must be reported within five working days. This report should be in the form of a letter documenting the waiver. If the investigator can anticipate that a similar situation may arise in the future, then they must submit a protocol amendment to be reviewed by the IRB.

Form H and relevant documents for review must be submitted to Ms. Valerie Stallings at VStallin@LHS.ORG for IRB review and acknowledgment.

**Submission Requirements**

Use the form to determine the nature of the deviation/violation (or exception) and summarize in detail the date of the event, the date the event was reported to the principal investigator (PI), the date reported to the IRB, and whether the event was an on-site (Legacy subject) or off-site (non-Legacy subject). All on-site reports will receive review by the IRB and a formal response from the IRB e.g., acknowledgement, request for additional information, approval etc.

The PI should describe the event in detail and provide an analysis regarding the event and provide a corrective action plan to ensure that the deviation/violation does not recur.

The IRB will determine if the deviation/violation will warrant a finding of con-compliance, including serious non-compliance.

The IRB will determine if the PI’s corrective action plan is adequate for future purposes.

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

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