** **

**Legacy Health IRB**

**ADVERSE EVENT/SERIOUS ADVERSE EVENT FORM I -- Version 7-19-22**

**Form I Instructions**

Form I is to be used for any adverse event (AE) or serious adverse event (SAE) 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. For treatment studies an adverse event could be a treatment related side effect or any of a number of physical injuries related or unrelated to the drug or device. For studies that do not involve treatment, an adverse event could be a breach of confidentiality. Some studies define the range of adverse events that must be reported while others refer to FDA definitions as to what constitutes an adverse event that must be reported to the IRB.

Form I and relevant documents for review must be submitted to [irbsubmissions@lhs.org](mailto:irbsubmissions@lhs.org) for IRB review and acknowledgment.

**Submission Requirements**

Use the form to determine the nature of the event and summarize in detail the date of the subject’s AE/SAE, the date the AE/SAE was reported to the principal investigator (PI), the date reported to the IRB, and whether the AE/SAE 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.

Off -site reports will be reviewed by the Legacy IRB office and may or may not be formally reviewed by the IRB, depending upon the nature of the report. Some off-site reports have been reviewed by Legacy IRB and those reviews have resulted in sponsor changes to research, so the information needs to be initially reported so that it can be assessed.

The PI should describe the event in detail and provide an analysis regarding whether the AE/SAE is related to the research or any research procedure.

The PI should note whether the current consent form (if any) or protocol is anticipated by the research and whether the study needs modifications and/or new risk information needs to be provided to subjects, and when those actions may occur.

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

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