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**Legacy Health IRB**

**Continuing Review form -- Version 7-19-2022**

**Form E Instructions**

Form E is to be used for reporting the status of previously approved and ongoing studies. The IRB is required by regulation to monitor and re-review and re-approve studies that are ongoing or not ready to close.

The IRB re-review and approval is required to be done prior to lapse of current IRB approval, and a lapse of IRB approval means that all study activity by the PI and site must stop, so the timely submission of information for IRB re-review and approval is a critical requirement to ensure research compliance and the ethical treatment of subjects in research. PI’s should answer the questions on Form E as soon as they receive the **“First Notice”** and submit the form back to the IRB. A **“Second Notice”** or **“Final Notice”** may mean that the study approval will lapse before the IRB can review the information.

Use the Continuing Review Form to provide important information regarding the status of the study, the number and status of subjects in the study, reportable information, compliance information, monitoring reports, amendments, and any preliminary results or publications resulting from this work. All questions must be answered.

Form E and any relevant documents for continuing review must be submitted to [irbsubmissions@lhs.org](mailto:irbsubmissions@lhs.org) for IRB review and approval before the study can be re-approved.

**Study Subjects**

Form E requires the PI provide data on the of status of subjects and on the numbers screened or failed screening, currently enrolled, actively participating, withdrawn or lost to follow-up, and the details of those numbers. Please answer all questions regarding study subject numbers and provide additional information if needed in the “Study Summary” section.

**Study Compliance**

This section requests information about whether there have been any compliance issues in the past year. The IRB also requires that sites confirm that they are using the correct protocol and consent form, and that all issues requiring IRB monitoring have been submitted in a timely manner. New conflicts of interest can be reported here if they have not been previously reported. This section also requests information about subject complaints and about PI problems related to licensing, medical board actions, etc.

**Study Monitoring**

This section request updates on interim data analysis, data safety monitoring board reports, publications, rate change of adverse events, and changes in the risks and benefits.

**Study Summary**

This section allows you to provide free text or additional information about any aspect of the research in the past year that needs additional explanation or elaboration.

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

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