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**Legacy Health IRB**

**FORM K: STUDY CLOSURE FORM -- Version 7-19-22**

**Form K Instructions**

Form K is to be used for closing a study when the study is complete and no longer needs IRB oversight. The key elements that should be satisfied for closure purposes is that the study is permanently closed to enrollment, that there is no longer any subjects in the study that are being monitored or having data collected from them, there is no long-term follow-up of subjects being conducted, no additional risks have been identified that might need to be conveyed to subjects, and where data analysis for ongoing study activity are concluded. Studies that involve long-term follow-up of subjects must remain open, even if enrollment of new subjects has ended. And some studies still in data analysis might be required to remain open, depending upon the type of study.

The study should not be closed where there are pending issues with study suspensions, non-compliance issues, new risk assessments, subject complaints, adverse events, etc. The IRB may require that the study stay open at Legacy where pending matters must be resolved before closure.

The IRB also may require more information regarding how study closure might affect subjects e.g., sponsor bankruptcy, loss of treatment benefit to subjects were investigational drug or device is being withdrawn due to efficacy or futility, etc.

A reason must be given for closure, which may include any of the following:

* All research activities involve human subjects, including data analysis and reporting, are complete.
* The investigational product is found to be futile or efficacious and no further study data is needed.
* The Data Safety Monitoring Board or Committee is requiring/requesting the study be closed.
* Human subject involvement is complete e.g. there is no follow-up planned with subjects, data no longer contain identifiers, and there are no identifying codes to the de-identified data that can link the data to individuals).
* The Sponsor is requesting closure.
* The research is no longer funded and cannot continue.
* The PI never initiated the study.
* The research project has been open for a lengthy period time and the PI has enrolled no subjects in the study, collected no data from records, nor collected/received specimens during this interval.
* The PI is leaving the institution.

Form K requires that you provide some information about your publication/presentation plan, however rudimentary. The IRB does appreciate receiving research results and articles regarding the approved research.

Provide information about the plan for retention of the study records and data obtained from the study.

**Submission Requirements**

Form K and relevant documents for review must be submitted to irbsubmissions@lhs.org for IRB review and approval before the study can be closed.

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

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