

Overview:

The completion of the study is a change in activity and must be reported to the IRB.

Procedures – Completion or Permanent Closure

1. The Principal Investigator (PI) submits Form LL6713: *Human Subjects Research Protocol Closure* when one of the following criteria has been met:
 - a. The research was not conducted; **OR**
 - b. ALL the following has occurred:
 - i. Enrollment / accrual is permanently closed, AND
 - ii. Research related interventions, procedure and interactions with human subjects have ended; AND
 - iii. No individually identifiable private information (data) including follow-up data is being collected or used, unless the follow-up data are from procedures that subjects would undergo as part of clinical care

NOTE: data analysis, even with protected health information or protected individually identifiable data, may continue without IRB approval as long as the analysis is conducted with the protections that were approved in the IRB-approved protocol.
2. The IRB Chair and Program Manager will complete a prereview of the form and communicate with the PI if additional information is required.
3. The IRB Program Manager will email the PI of the approval for permanently closing the study.
4. The DOE IRB database will be updated as necessary.
5. The protocol and all application documentation will follow SOP #18: *Retention of IRB Records*.

Procedures – Administrative Closure

When the IRB approved protocol's expiration date has lapsed without the PI submitting the annual or continuing review documentation, all research must end. If the PI does not submit the necessary review documentation within 60 days of the expiration date of the IRB approved protocol, the IRB Office will close the study.

1. The IRB Program Manager will email the PI that the study has been permanently closed.
2. The DOE IRB database will be updated.
3. The protocol and all application documentation will follow SOP #18: *Retention of IRB Records*.

REFERENCES:

45 CFR 46
45 CFR 46.109 (f)(iii)
21 CFR 56.115

Document Review History

Revision Number	Date	Author	Summary of Changes
01	September 2017	Ann-Marie Dake	Complete Revision
02	November 2018	Dawn Whalen	Document control process added
03	November 2019	IRB Office	Complete Revision
04	October 2020	Ann-Marie Dake	Revisions and updates