Institutional Review Board

Closure of Institutional Review Board (IRB) Applications Procedure

Scope

Applies to Mayo Clinic Human Research Protection Program personnel when they are involved in research for which the Mayo Clinic is the IRB of Record.

Purpose

To provide instructions to investigators regarding criteria for closure of an IRB application and to describe the closure processes.

Equipment/Supplies

N/A

Procedure

Criteria for Closure

When all research-related interventions or interactions with human subjects have been completed, and all data collection and/or utilization/analysis of identifiable private information, for any purpose, have been concluded, then the research may be considered as completed and the application may be closed. The Principal Investigator (PI) should not close an IRB application as long as the investigator is using individually identifiable private information collected as part of the research.

The closure of an IRB application can be managed in one of the following ways:

- The PI may allow the IRB approval to expire.
- The PI may elect to submit a final report via the electronic system, such as when obligated under a specific regulatory (For example: Food and Drug Administration [FDA]) or sponsor requirement

Note: If after an IRB application is closed, the investigator seeks to engage in an activity such that the criteria for closure listed below would no longer be met, the Principal Investigator must submit a new application for IRB review and approval for the use of the previously collected data.

The PI may allow the IRB approval to expire or may submit a final report when:

- The research was not conducted or was canceled, or
- Each of the following conditions are met:
    - All human subjects have been accrued and IRB approved research-related activities, interventions or interactions with human subjects have been completed.

- All collection, use, and analysis of individually identifiable private information have been completed. No further collection of data/information from or about the individuals will be obtained;
- The study sponsor (Investigational New Drug [IND]/Investigational Device Exemption [IDE] -holder, funding entity, etc., as applicable) agrees to or recommends closure; and
- All publications and presentations derived from individually identifiable private information have been completed.

Investigator Responsibilities

The PI will:

- Continue to maintain confidentiality protections of the data.
- Destroy all subject identifiers connected with the research data, if the study was approved with a Health Insurance Portability and Accountability Act (HIPAA) Authorization Waiver and the investigator indicated in the IRB application that all subject identifiers would be destroyed upon completion of the research.
- Retain research records in accordance with Mayo Clinic's Research Retention of and Access to Research Data Policy (or the equivalent policy of a Relying Organization for which the Mayo Clinic IRB is the IRB of Record).
- Understand the specific regulatory and/or sponsor requirements which may obligate him/her to submit a final report to the IRB.
- Ensure that all research-related activities, interventions or interactions with human subjects have been completed at the site(s) approved under the Principal Investigator's IRB application at the time a final report is submitted to the IRB or at the time of approval expiration, whichever occurs first.
- If electing to submit a final report, submit the report through the IRB electronic (IRBe) system before the expiration of IRB approval.
- When a PI terminates employment or other associations with Mayo Clinic (or another organization[s] relying on the Mayo Clinic IRB), he or she is obligated to either:
  - Submit for IRB review and approval a modification requesting transfer of the study to another eligible Principal Investigator, or
  - Submit a final report to the IRB.

IRB Responsibilities

The IRB will:

- Review any new information provided in the final report and determine whether any additional action is required on the part of the IRB or the investigator.
- Upon receipt and review of a final report, ensure the status of the IRB application is changed to "Completed".

Troubleshooting

N/A

Procedural Notes

N/A

Related Documents

Final Report, IRBe Application Example (Form 10271)

Definitions

Final Report: A report the PI may elect to submit to the IRB to serve as a final record of any pertinent activity since the last continuing review report and to record research project completion.

Identifiable Private Information: Information or specimens are considered to be individually identifiable, as defined at 45 CFR 46.102 (f), when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

References

45 CFR 46

Owner

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Contact

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Revision History

Date	Synopsis of Change
01/14/2021	Scheduled review. Transferred to new template, updated Owner and Contact. Minor edits by Policy office.
08/24/2017	Minor revision. Updated the following definitions per Glossary review: Final report.
03/17/2017	Scheduled review. Minor edits for clarification; removal of final report process section since this is not a process document. Made Related Document, 45 CFR 46, a link.
06/23/2015	Scheduled review.
04/17/2014	Scheduled review.

07/01/2012	Approval for need to establish document: Office for Human Research Protection

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