MCW Office of Research
Standard Operating Procedure

PROJECT CLOSURE

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

PURPOSE:
The MCW IRB requires Principal Investigators involved in human subject research to file a final report after termination or completion of a research project or the Investigator's part of the research project.

DEFINITIONS:
Final Report: The Principal Investigator (PI) upon either completion of a research project or determination that the research project cannot be completed must file a final Continuing Progress Report project report with the IRB. This is considered the project's final report and documentation the PI has decided to close the project.

"Completed" Status: An eBridge state designation for human subject project, when the IRB has received and accepted a final report.

"Approval Terminated" Status: An eBridge state designation for human subject projects, when the IRB has determined it is necessary to end a project for safety reasons, a determination of continued non-compliance or for the protection of the subjects enrolled.

POLICY:
A project may be considered completed when the following project activities are finished, or they are no longer occurring and have been halted:

- Screening and recruiting of new participants
- Enrolling participants into project
- Treatment of enrolled participants
- Follow up on enrolled participants
- Submitting of amendments
- Submitting Continuing Progress Reports
- Filing of SAE's
- Filing of Protocol Deviations

PROCEDURE:
Human Subject Research Approved by MCW IRB

For exempt research, contact the HRPP Office when closing a project.

For registered projects, please see *IRB SOP: Registration Projects*.

For all other research, follow the below steps:

1. The Principal Investigator (PI) must file a final Continuing Progress Report (CPR) to close a project when:
    a. all project activities are completed as designed; or

b. the PI determines the research will not be able to be completed as approved by the IRB
c. the project is terminated by the Sponsor or other party for any reason

A subset of projects may submit a “Final Report” to the IRB if the only activity occurring within the project is data analysis. To qualify the project must meet the following criteria:

a. Not federally funded
b. Is not regulated by FDA
c. Does not have an Inter-Institutional Agreement deferring IRB review from another institution to MCW.
d. Does not involve CW patients, staff or resources

2. Once the IRB reviews and approves the final report, this will move the eBridge SmartForm into a “Completed” state and closes the project to IRB oversight.

Human Subject Research Deferred to an External IRB

Investigators of research projects which have been deferred by the MCW IRB to an external IRB for oversight must notify MCW IRB Reliance when the project closes at this site. Reliance requests in eBridge should use the ‘Request to Close Project’ activity in the eBridge PRO workspace.

Retention of Research Records

- For federally funded projects Investigators should transmit and manage all research data in accordance with their IRB approved NIH data management and sharing plan.
- At a minimum, Investigators must maintain project records for at least ten (10) years from the date the project is closed with the MCW IRB, per *MCW Corporate Policy: Ownership, Access and Integrity of Research Data (RS.GN.070).*
- Requirements for record retention vary with the type of project conducted and provisions of the Investigator's funding source. It is the Investigator's responsibility to have a clear understanding of the retention requirements of a sponsor and/or the FDA as applicable.
- All project records must be accessible for inspection and copying by authorized
- representatives of the institution, the IRB, federal regulatory agency representatives, and the department or agency supporting the project.
- The inventory and location of the stored research records should be on file with the Investigator’s department in the event the Investigator is no longer with MCW.
- The Investigator must confer with the Sponsor of FDA regulated research projects before destroying the records.

REFERENCES:

N/A

SUPPORTING DOCUMENTS:
MCW Corporate Policy: Ownership, Access and Integrity of Research Data (RS.GN.070)
IRB SOP: Registration Projects

Effective Date:	04/28/2023
Version number:	6.0
Previous Version/date:	5.0, 06/15/2018
Responsible Office:	HRPP Office
Approval Date:	04/13/2023

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