

Closure or Withdrawal

Purpose

The purpose is to outline the policies and procedures for closure or withdrawal of human research projects.

Definitions

Closure of a research project is an official action taken by the Institutional Review Board (IRB) or Exempt Review Committee (ERC) to finalize its IRBNet history and to set a date of destruction for all electronic and hard copy records maintained by the Office of Planning and Institutional Research (OPIE).

De-identification means the removal or separation of any and all data points that help establish or indicate an individual, or any other unique items of individually identifying information, from data or specimens.

Identifiable biospecimen is a biospecimen for which the identity of the subject is or may be readily ascertained by the investigator or associated with the information.

Identifiable private information occurs when the identity of the subject is or may readily be ascertained by the investigator or associated with the information:

- If subjects' identities are inseparable from data, then data are **directly identifiable**
- If subjects' identities are kept separate from data, with information connecting them maintained by a code or a master list, then data are **indirectly identifiable**
- Research data or records which retain indirect identifiers only are still considered identifiable.

Identifiers are data points that help establish or indicate an individual and may include items such as (1) name; (2) address; (3) elements of dates related to an individual (e.g., date of birth); (4) email address; (5) numbers, such as telephone/fax, social security, medical record, health plan/beneficiary, certificate/license, vehicle identifiers (e.g., license plate), accounts (e.g., bank/credit card), device ID/serial; (6) web URLs; (7) Internet Protocol (IP) addresses; (8) biometric identifiers (e.g., voice, fingerprints); (9) full face photographs or comparable images; (10) or any other unique identifying number, characteristic or code not assigned by the investigator for coding purposes (e.g., Global Positioning System readings).

- Some data points may not appear identifiable in and of themselves, but may be combined to create new data that may be identifiable (e.g., person over 85 in a singular zip code; combination of birth date and zip code, collection of many demographics with small sample size, etc.).

Withdrawal of a research project is a specific type of closure which is requested by a Principal Investigator (PI) or automatically made by the IRB or ERC under certain circumstances (i.e., project abandoned before approval, or approved but never implemented).

Policy

Because the IRB and ERC maintain oversight of human research projects throughout their entire life spans, principal investigators (PIs) are responsible for informing the IRB or ERC when their research has been completed or abandoned. A research protocol is considered to be open and active until the investigator has submitted a Closure Form through IRBNet (www.irbnet.org). Projects which remain open at the approach of their approval's one-year anniversary date, or projects for which the IRB has determined and documented an earlier date, must undergo an administrative or continuing review at least annually or as otherwise communicated by the IRB. See our Continuing Review policy for details.

Investigators must complete the Closure Form and submit it to the IRB or ERC via IRBNet within thirty (30) days of completion of the research. No closure

documentation is required for projects officially determined to be Not Research or Research Not Involving Human Subjects.

A research project must be closed when **ALL** of the following apply:

- If there were interactions or interventions, all subject recruitment and enrollment has ended (i.e., no advertising, consent process, or interaction/intervention remains)
- All subject data, records or specimens have been obtained (i.e., no further collection from or about living individuals)
- No further contact with enrolled subjects is necessary
- Analysis of subject identifiable data, records, or specimens has ended

If the only remaining activity is analysis of de-identified data, the research project may be closed. However, the investigator must explain exactly **how** the data are no longer identifiable so that closure may be considered.

Advisors of student investigators are responsible for ensuring that a Closure Form is filed with the IRB or ERC in a timely fashion.

Separation of PI

PIs who terminate employment or other association with Marywood University are responsible for submitting a Closure Form, unless another action is appropriate (see our Separation policy).

Administrative Closures

The IRB or ERC may administratively close a project under certain circumstances. Some examples are within three (3) months of the submission date if a package remains incomplete and idle, within three (3) months of a an official

determination letter's publication if a package remains idle without investigator action, after the conclusion of research courses when approved projects remain open without student response, or as otherwise appropriate.

Procedures

Closure

1. Upon conclusion of the research, the PI completes and submits a closure form to the appropriate board through IRBNet (www.irbnet.org), reporting the results and current state of the records.
2. If not closed at ninety (90) days prior to the one-year anniversary or expiration date, IRBNet sends an automated e-mail message to the PI and all who have been granted full project access. If no response is received, it repeats the messages at 60/30/10 days prior to the date, as well as one day after, to prompt the PI to submit the closure report. A staff member attempts contact to follow-up whenever possible.
3. A staff member reviews the submission. Unless there are questions, the project is marked as closed in the IRBNet system, and the expiration or report due date is deleted to halt automated reminders (Note: This date will still be indicated in the original and/or last approval letter).
4. Upon closure, a staff member marks the protocol's records as closed in the appropriate database. If a hard copy exists (full or federally funded studies), a staff member moves the protocol file from the active filing cabinet and stores it in the closed filing cabinet. Records are stored for the minimum time required by regulations and/or contracts, after which they are destroyed. IRBNet purges records every January 1 after the destruction date.
5. In scenarios described above under Administrative Closures, a staff member attempts contact within the mentioned time frames. If no response is received after a reasonable time and effort, the staff member administratively closes the project under steps 3 and 4.

Withdrawal

1. If a PI decides to abandon a project prior to final approval, or after approval but before implementation, the PI submits a closure report to the

appropriate board through IRBNet (www.irbnet.org), marking withdrawal and stating the reason.

2. A staff member reviews the submission and marks it as withdrawn/closed in the IRBNet system. If a hard copy exists (full or federally funded studies), a staff member destroys it.

Related Policies

- Approval of Research
- Continuing Review
- Mandatory Reporting
- Records Retention
- Separation of Principal Investigators
- Suspension or Termination

History

07/19/2013 - Created

10/24/2014 - Updated (De-identified Data)

12/05/2014 - Updated (Clarification on De-identified Data Reporting for Closure)

06/13/2017 - Corrected references to office name; updated formatting and related policies; updated procedures

07/05/2019 - Updated as a result of the Revised Common Rule

12/01/2021 - Updated idle period length and added clarifications