

Separation of Principal Investigators

Purpose

The purpose is to outline the policy and procedures for separation of faculty, staff or students who serve as the Principal Investigator (PI) for research involving human subjects.

Definitions

Employees or agents are individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. They may include staff, students, contractors, and volunteers.

Engaged in research activities is when an institution's employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.

A **human subject** is a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. Information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
2. Obtains, uses, studies, analyzes, or generates identifiable, private information or identifiable biospecimens.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Principal Investigator (PI) is the individual with primary responsibility for the oversight of a research study, including (1) design, development and implementation of the study plan, (2) affirmation that all members of the research team are appropriately qualified, trained and supervised, and (3) maintenance of all administrative and compliance aspects of the study.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Policy

Research falls within the Institutional Review Board's or Exempt Review Committee's (ERC) jurisdiction whenever it engages Marywood University (MU) in human research or is conducted under the auspices of another institution on the premises of Marywood University, even if approved by another IRB. Upon the decision of a Principal Investigator (PI) to separate from the institution, the PI must notify the IRB or ERC so that a decision may be reached regarding the future management of the project. This decision may include:

- Complete closure of the project
- Closure and transfer of authority to another institution
- Change in PI to an employee or agent of MU
- Addition of a MU advisor or co-investigator who is an employee or agent of MU

Where complete closure is desired, no research activities may continue at another location unless they involve only data analysis of de-identified information.

Where transfer of authority to another institution is desired, the project file must still be closed with MU's IRB or ERC as of the date of the employee or agent's separation. For IRB studies, the PI must supply the IRB with the new institution's Federalwide Assurance number at time of closure.

Where identification of a new PI who is an employee or agent of MU is desired, the existing PI must submit a revision to the IRB or ERC and receive approval. The new PI must meet all training requirements.

Where the original PI will continue in his/her role as lead researcher, but there is a need to retain MU's authority, a new employee or agent of MU must be named as advisor or co-investigator if one is not already involved with the project. This individual must meet all training requirements. If there's a new institution involved, the PI must review the institution's policies to see if it requires the addition of MU's IRB to its Federalwide Assurance, and an authorization agreement between both institutions must be created.

Timing

The PI must notify the IRB or ERC within five (5) business days of the decision to separate from Marywood University. The PI then has three (3) business days to submit the appropriate documentation to the IRB or ERC.

Procedures

The PI consults with IRB staff within the time frame noted above in order to decide the best method of action.

Complete Closure

1. With the exception of data analysis of de-identified information, all research activities cease.
2. The PI submits closure form to the IRB or ERC via IRBNet.
3. A staff member closes the file.

Transfer of Institutional Authority

1. The PI submits a closure form to the IRB or ERC via IRBNet.
2. The PI includes on the form the Federalwide Assurance (FWA) number of the new institution, if applicable. FWA numbers may be found at the Office of Human Research Protections' website at <http://ohrp.cit.nih.gov/search/> by clicking on the FWA tab and entering the institution's name.
3. A staff member closes the file.
4. The PI applies for review at the new institution.

Identification of a New PI (employee or agent of MU)

1. The PI submits a revision application form to the IRB or ERC via IRBNet, requesting a change in PI.
2. The new PI must be an employee or agent of MU and meet all training requirements.
3. The project remains open until the new PI closes it.

Retention of Institutional Authority Where PI Remains as Lead

1. The PI submits a revision application form to the IRB or ERC via IRBNet, requesting the addition of the new team member (advisor or co-investigator) who is an employee or agent of MU.
2. The new team member must meet all training requirements.
3. If the PI is at another institution, he/she reviews the new institution's policies to see if it must add MU's IRB to its Federalwide Assurance, and an authorization agreement between both institutions is created to retain MU as the IRB of record.

Related Policies

- Approval of Research
- Closure or Withdrawal of Research
- Mandatory Training
- Responsibilities of Investigators and Sponsors

History

5/19/2014 - Created

07/08/2019 – Updated as a result of the Revised Common Rule