

Responsibilities of Investigators and Sponsors

Purpose

The purpose is to outline the responsibilities of investigators and sponsors (or advisors) of research involving human subjects.

Policy

By electronically signing and submitting an application to the Institutional Review Board (IRB) or Exempt Review Committee (ERC), investigators and sponsors (or advisors) affirm that:

1. They are familiar with the policies and procedures of Marywood University regarding human participants, as presented on the IRB or ERC website. They subscribe to the standards described and will adhere to the policies and procedures explained therein.
2. They are familiar with the published regulations and guidelines for the ethical treatment of participants (e.g., Code of Federal Regulations, Title 45 Part 46, Title 21 Part 50 and Title 21 Part 56, the Family Educational Rights and Privacy Act, the Health Insurance Portability and Accountability Act, etc.), including those associated with their particular field of inquiry (as published by the American Psychological Association, American Sociological Association, NASW Code of Ethics, etc.).
3. They are familiar with and will adhere to official policies in their school or department concerning research activity (e.g., Psychology Department, School of Social Work, etc.).
4. They have completed mandatory training through the CITI Program or will do so prior to receiving final approval for their research.

5. They will take proper measures to ensure confidentiality and security of all information obtained from or about participants.
6. They understand that all applications and reports must be made via an online submission and management system (IRBNet).
7. They understand that upon consideration of the nature of their project, the IRB or ERC administrator may change the category of review or may request a full application for review of the research at his/her discretion and convenience.
8. They understand that no part of the proposed research, including participant recruitment and collection of data, may be carried out until they have received complete and final approval from the IRB or ERC.
9. They understand that Marywood University's IRB or ERC has the authority to suspend or terminate approval of research that is not being conducted in accordance with IRB requirements, or that has been associated with unexpected harm to participants.
10. They understand that research records must be kept for the longest applicable period (minimum of 3 years or longer) according to regulations and/or professional organizations.
11. They understand that a status report is due six months from the date of approval (IRB only), or a final status/closure report is due if the study is completed prior to six months (IRB and ERC), even if the research was part of a class assignment.
12. They understand that a final status/closure report is due prior to the expiration date, unless a researcher applies for continuing review (see #13). They also understand that research is considered to be complete only after data collection and analysis have ended.
13. They understand that once approved, the approval is only valid for one year. If research will continue beyond one year, they must reapply to the IRB or ERC prior to the expiration date by submitting a continuing review (renewal) application and all required materials.
14. They understand that if approval expires, all research activities must cease as of the expiration date until they apply for continuing review (renewal) and that renewal has been reviewed and approved by the IRB or ERC.
15. They understand that if they make any revisions to approved research, however minor, they must notify the IRB or ERC and receive final approval for the revisions prior to implementation.

16. They will notify the IRB or ERC of any deviations or violations which occurred from the version of the protocol which was approved.
17. They will notify the IRB or ERC, Assistant Vice-President for Research, and the Dean or Departmental Chairperson of any physical, psychological, or social injury suffered by a research participant due to his or her participation in a research activity.
18. They will notify Research and Sponsored Programs, and then the IRB or ERC, upon separation from the institution.
19. They understand that members of the research team (principal investigators, co-investigators, sponsors, research assistants, etc.) may not enroll in their own projects as subjects.
20. They understand that student researchers who plan to graduate in a given semester must apply by the end of the semester prior to the one in which they plan to graduate, so as to allow adequate time for review, possible changes, implementation, data analysis and writing or presentation.

By electronically signing an application to the IRB or ERC, sponsors/advisors affirm that they agree to the above, AND:

21. They agree to sponsor the study.
22. They will collaborate with the student PI during the preparation of the IRB application, including proofreading for errors.
23. They will make adequate time to consult with the student PI on a regular basis to monitor research progress.
24. They have THOROUGHLY read the application and attest to its completeness.
25. They affirm that no data have been collected by the investigator.

Related Policies

- Approval of Research
- Closure or Withdrawal
- Continuing Review

- Mandatory Reporting
 - Mandatory Training
 - Records Retention
 - Revisions to Approved Research
 - Separation of Principal Investigators
 - Suspension or Termination
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History

5/19/2014 - Updated to include separation information

5/28/2014 - Updated to include FERPA, HIPAA, additional sponsor responsibilities and a list of related policies

5/29/2014 - Updated to include IRBNet and graduating student information