

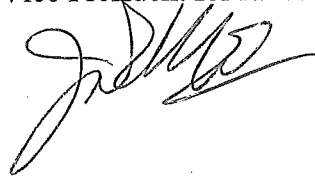
EDINBORO UNIVERSITY OF PENNSYLVANIA
Protection of Human Subjects

Policy No. C026

Supersedes Policy C026, Dated 7/13/93

Recommended for Approval by: Philip Ginnetti, Provost and Vice President for Academic Affairs

Approved by: James Moran, Interim President on 5/21/12



Review Date: As Required

INTENT

This policy establishes the Institutional Review Board (formerly called the Human Subjects Review Board) of Edinboro University of Pennsylvania (the University) for the purpose of protecting the rights and welfare of human subjects involved in research.

The Institutional Review Board shall operate under the administration of the Dean for Graduate Studies and Research. Additionally, the Office of Grants and Sponsored Programs (GSP) shall inform the University community of basic procedures for operation and guidelines for reviewing human subject research based upon accepted codes of ethical principles. These basic procedures and guidelines shall be available to assist all researchers within the University in order to provide for the well-being of human subjects.

POLICY

The Institutional Review Board (IRB) shall review all proposals for human subjects research to be conducted under the auspices of the University.

PROCEDURES

Proposals for human subjects research must be submitted for review *prior to* the initiation of data collection. Each proposal will be evaluated to determine that:

1. Rights and welfare of the human subjects are adequately protected;
2. Potential benefits and the importance of the knowledge to be gained from the research outweigh risks to the human subject;
3. The human subjects are informed and their consent is obtained before participation in the research, and that the research utilizes methods that are adequate and appropriate;
4. Confidentiality procedures are sufficient for protecting the human subject; and
5. The researcher possesses the qualifications required for conducting the research.

Both the administration and the principal investigators shall be advised concerning the acceptability of the proposed project relative to the welfare of the human subjects based on the accepted codes of ethical principles (DHHS regulations) and federal regulations (on the protection of human subjects as codified in Title 21 Parts 50 and 56 of the Code of Federal Regulations), as applicable.

An approval by the IRB signifies only that the proposal adequately satisfies requirements for the protection of human subjects. The University reserves the right to disapprove any research project, but may not approve a project previously disapproved by the IRB.

INSTITUTIONAL REVIEW BOARD

Membership and Voting

1. The IRB will consist of seven (7) members, with varying backgrounds sufficiently qualified through experience and expertise, including one member who has no relationship with the University and one member currently serving on the Senate Research Committee.
2. All members except the representative from the Senate Research Committee shall serve for a term of three years and may be re-appointed by the President upon recommendation by the Dean of Graduate Studies and Research and Provost. The representative from the Senate Research Committee will serve only for the time period during which he/she is also a member of the Senate Research Committee.
3. The chairperson of the IRB will regularly apprise the Dean of Graduate Studies and Research of the membership of the Board. When a member's term expires, the chairperson will inform the Dean of the expiration, including whether or not the member wishes to be considered for an additional term. When an opening occurs on the Board, a call for applications will take place. The IRB will review the applications and make recommendations to the Dean of Graduate Studies and Research. The President, based upon recommendations from the Dean of Graduate Studies and Research and Provost, will appoint members to the Board.
4. Members of the IRB may not be involved in review of any activity in which they have conflicting interests.
5. The IRB shall meet as often as necessary to provide review and advisement, but at least twice per semester and in the summer if necessary. Four members of the Board shall constitute a voting quorum. Acceptance of a proposal shall require a minimum of four supporting votes.

Levels of Review

All research involving human subjects will be submitted to the chairperson of the IRB through the Office of Grants and Sponsored Programs. The chairperson shall determine the level of review. The level of review determines whether the research is exempt from review or whether a review is required.

Only the Director of Grants and Sponsored Programs or the IRB Chair may make the determination of exempt as investigators do not have the authority to independently make that decision. Exemptions do not apply to research involving: prisoners, pregnant women, fetuses and human in vitro fertilization. Research involving the following situations may be exempted from review:

1. Research in common educational settings involving normal educational practices where students are not identified;
2. Research using educational tests with no identifiers of human subjects;

3. Research using surveys or interviews of adults where respondents are not identified and the content is benign;
4. Research involving observations of public behavior; and
5. Research involving collection, study, use of existing data, documents, records or specimens where subjects are not identified.

Projects requiring review may be reviewed under two levels: Expedited or Full Review. The IRB Chair will determine the level of the protocol.

1. Expedited Review: Research projects that are judged to present only a minimal risk may receive an Expedited Review.
 - a) "Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research is not greater in and of themselves from that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
 - b) An expedited review can be made by the chairperson or by one or more reviewers designated by the chairperson from among members of the IRB.
 - c) A collaborative research proposal that has been reviewed and approved by a duly-constituted IRB from the co-investigator's institution may be handled as an Expedited Review.
 - d) Previously approved projects may receive an expedited review:
 - i) Continuing reviews
 - ii) Minor changes to procedures
2. All other projects will require Full Review.

Application Process

1. All personnel (including students) involved in research must complete required training prior to protocol review. Training information is available at <http://gradschool.edinboro.edu/graduate-home/research/human-subjects.dot>
2. The Principal Investigator of record must be a non-student University employee.
 - a) Student research involving human subjects must be conducted under the direct supervision of a principal investigator (faculty research advisor).
 - b) Investigators not affiliated with EUP must identify a non-student University employee at this institution who is willing to serve as the local contact person.
3. The Principal Investigator will submit to the Office of Grants and Sponsored Programs one copy of the Human Subjects Review Application.
4. Upon receipt of the complete application material and confirmation that all personnel involved completed the required training; the materials will be reviewed for level determination.
5. After level determination, the Office of Grants and Sponsored Programs will
 - a) Distribute one copy of the submitted materials to each of the members of the IRB or
 - b) Inform the Principal Investigator that the protocol is exempt from review
6. The Principal Investigator must be available to discuss the research project at the discretion of the IRB.
7. The Principal Investigator will be notified of the IRB's decision by the Office of Grants and Sponsored Programs.

IRB Actions

The IRB may take one of the following four actions in regard to the proposed research project:

1. Exempt
2. Approved
3. Approved Subject to Modifications or
4. Disapproved.

Determination Notification

The Office of Grants and Sponsored Programs will prepare a letter providing the IRB's determination and distribute copies of it to:

1. Principal Investigator
2. Members of the IRB
3. The appropriate files.

Complaints

The IRB may be requested to serve in an advisory capacity if complaints involving threats to the welfare of human subjects should be submitted to the President's Office. In order to serve in this advisory capacity, the Board shall be informed of all complaints involving matters related to human subjects research.

RELATED POLICIES

C037 – Surveys and Related Research

CONTACT INFORMATION

Contact	Office	Address	Telephone
Director	Grants and Sponsored Programs	148 Biggers House	814-732-1052