

UNIVERSITY OF PITTSBURGH
SCHOOL OF NURSING

ADMINISTRATIVE POLICIES AFFECTING THE
SCHOOL OF NURSING

TITLE OF POLICY: APPROVAL OF FACULTY AND STUDENT RESEARCH STUDIES/IRB

DATE EFFECTIVE: September 1, 1995

LAST REVIEWED/REVISED: April 2004

POLICY: Research studies proposed by faculty or students in the University of Pittsburgh School of Nursing (SON) must be reviewed and approved following appropriate scientific review and approved by the Director of the Center for Research and Evaluation (CRE) prior to Institutional Review Board (IRB) submission.

All research conducted by faculty, students, or employees of the University of Pittsburgh must be approved by the University of Pittsburgh IRB before data collection is begun.

The IRB is under federal and University mandate to review, require modification, approve or disapprove, and monitor all research involving human subjects.

The study must be reviewed and approved by the appropriate facilities where subjects may be recruited or research conducted. Verification of this approval must be submitted to the IRB.

The principal investigator (PI) must report immediately any adverse reaction or unexpected side effect to the University of Pittsburgh IRB.

PROCEDURE:

FACULTY RESEARCH

1. The PI obtains the Guidelines for the Use of Human Subjects in Research. These guidelines are available on the University of Pittsburgh IRB website at <http://www.irb.pitt.edu/regulate.htm>.
2. The PI follows the procedures for preparation of the required materials as indicated in the guidelines of the IRB.
3. The PI obtains review via a scientific review process and receives a notice of review from the CRE Director prior to submission to the IRB.
 - a. If a PI already has approval for a grant submission to a funding agency (refer to Policy No. 408, Research Proposal

Reviews) and their grant application has been scientifically reviewed and approved at the funding agency, the PI should obtain a Proposal Review Verification Form signed by the CRE Director to include with the IRB material.

- b. If a PI is requesting IRB approval for a proposal that has not been submitted to a funding agency or for a new aspect of a currently approved study, and therefore has not received scientific review, the PI submits the proposal (protocol section only) to the CRE administrator who will obtain scientific reviews from two members of the SON research faculty. Upon approval by the reviewers (no major revisions required), the CRE Director will complete a Review Verification Form for the PI to include with the IRB materials. If major revisions are indicated, a re-review of the proposal by the scientific reviewer will be required. The CRE Director has the authority to request reviews from research faculty outside SON, if necessary.
4. The PI submits the required number of copies to the University of Pittsburgh IRB and to the IRB of any other facility from which subjects will be accrued.
5. The PI provides the CRE with a copy of the IRB approval letter.
6. The PI submits a renewal application if data collection extends for more than one year. The protocols for renewal are included in the IRB Guidelines.
7. The PI submits to the IRB a request for modification at any time the study and/or procedures are modified.
8. The PI submits a report to the IRB upon completion of the research as requested in IRB Guidelines.

STUDENT RESEARCH

1. The student obtains the Guidelines for the Use of Human Subjects in Research from the University of Pittsburgh IRB website at <http://www.irb.pitt.edu/regulate.htm>.
2. The student follows the procedures for preparation of the required materials for IRB submission as indicated in the guidelines of the IRB.

3. The student obtains the scientific review forms from the CRE administrator.
4. If the research to be conducted by the student is a thesis or dissertation, the student obtains reviews of their IRB proposal from their research advisor and one other member from their thesis or dissertation committee. Otherwise, the student submits the IRB proposal through the IRB review process for faculty research.
 - a. Upon approval by the reviewers, the CRE Director will sign a Proposal Review Verification Form.
5. The student submits the required number of copies to the University IRB and to the IRB of any other facility from which subjects will be accrued.
6. The student provides their research advisor and the CRE with a copy of the IRB approval letter.
7. The student submits a renewal application if data collection extends for more than one year. Protocols for renewal are included in the IRB Guidelines.
8. The student submits to the IRB a request for modification at any time the study and/or procedures are modified.
9. The student submits a report upon completion of the research as requested in IRB Guidelines.

Approved by Graduate Council: 10/85

Approved by Administration: 10/85; 11/04

Revised by Administration: 9/89; 7/91; 5/93; 4/94; 4/95; 5/98; 10/99, 3/00; 4/04; 11/04