

**UNIVERSITY OF PITTSBURGH  
SCHOOL OF NURSING**

**ADMINISTRATIVE POLICIES AFFECTING THE  
SCHOOL OF NURSING**

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**TITLE OF POLICY:**                   **APPROVAL OF FACULTY, POST-DOCTORAL FELLOW AND STUDENT RESEARCH STUDIES/IRB**

**DATE EFFECTIVE:**                   **SEPTEMBER 1995**

**LAST REVIEWED/REVISED:**       **AUGUST 2016**

**POLICY:**                   Research studies proposed by faculty, post-doctoral fellows or students in the University of Pittsburgh School of Nursing (SON) must be reviewed and approved following appropriate scientific review and approved by the department Vice Chair for Research (VCR) prior to submission to the Human Research Protection Office (HRPO) for review by the Institutional Review Board (IRB).

All research conducted by faculty, post-doctoral fellows, students, or employees of the University of Pittsburgh must be approved by the 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 HRPO Policies and Procedures which are available on the University of Pittsburgh HRPO website at <http://hrpo.pitt.edu/content/policies-and-procedures>
2. The PI follows the procedures for preparation of the required materials as indicated in the guidelines of the HRPO.
3. The PI obtains review via a scientific review process and receives a notice of review from the department VCR prior to submission to the HRPO.
  - a. If a PI already has approval for a grant submission to a funding agency (refer to Policy No. 408A on 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 their department VCR to include with the IRB submission.
  - b. If a PI is requesting IRB approval for a protocol 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 protocol through the online IRB submission system to the CRE staff administrator who will obtain scientific reviews from two members of the SON research faculty. Upon approval by the reviewers (i.e., no major revisions required), the department VCR will approve the submission to the IRB via online IRB submission system. If major revisions are indicated, a re-review of the protocol by the scientific reviewer will be required. The department VCR has the authority to request reviews from research faculty outside SON, if necessary.

4. The PI maintains a copy of the IRB approval for their records and provides the Department Grant Analyst with a copy of the IRB approval letter for funded research to share with the Office of Research.
5. The PI submits a renewal application if data collection extends for more than one year. The protocols for renewal are included in the HRPO Policies and Procedures.
6. The PI submits to the HRPO a request for modification at any time the study and/or the procedures are modified.
7. The PI submits a final report to the HRPO upon completion of the research as requested in HRPO Policies and Procedures.

#### POST-DOCTORAL FELLOW AND STUDENT RESEARCH

1. The student or post-doctoral fellow obtains the HRPO Policies and Procedures which are available from the University of Pittsburgh HRPO website at <http://hrpo.pitt.edu/content/policies-and-procedures>.
2. The student or post-doctoral fellow follows the procedures for preparation of the required materials for HRPO submission as indicated in the policies of the HRPO.
3. The student or post-doctoral fellow obtains the scientific review forms from the CRE staff administrator.
4. Research proposals developed by students or post-doctoral fellows that have been reviewed and approved by funding agencies or by the student's thesis, DNP project or dissertation committee may serve as the scientific review prior to IRB submission. However, if the research to be conducted by a student is prior to the approval of the student's thesis, DNP project or dissertation proposal, the student obtains reviews of their IRB protocol from their research advisor and one other member from their thesis, DNP Project or dissertation committee. If the research to be conducted is by a post-doctoral fellow, the post-doctoral fellow obtains reviews of their IRB protocol from their research mentor and one other member from their mentoring or research team.
5. Upon approval by the reviewers or thesis, DNP project or dissertation committee and the department VCR, the CRE staff administrator will indicate the approval of the submission via online IRB submission system.
6. The student or post-doctoral fellow maintains the IRB approval letter for their records and provides copy of the letter to their research advisor or mentor. If research is funded, the PI also provides their departmental grants analyst with a copy of the IRB approval letter to share with the Office of Research.
7. The student or post-doctoral fellow submits a renewal application if data collection extends for more than one year. Protocols for renewal are included in the HRPO policies.
8. The student or post-doctoral fellow submits to the HRPO a request for modification at any time the study and/or the procedures are modified.
9. The student or post-doctoral fellow submits a final report upon completion of the research as requested in HRPO policies.

Approved by Graduate Council: 10/85

Approved by Administration: 10/85; 11/04, 08/16, 02/19

Revised by Administration: 9/89; 7/91; 5/93; 4/94; 4/95; 5/98; 10/99, 3/00; 4/04; 11/04, 08/16, 02/19