University of Pittsburgh School of Medicine

Research Studies Involving School of Medicine Medical Students as Subjects

I. PURPOSE

The UPSOM aims to support investigative efforts, and to balance the interests of investigators with those of research subjects, with particular attention to involvement of medical students as research subjects.

II. SCOPE

This policy applies to:

- Medical students
- Faculty

III. POLICY

All research studies that include University of Pittsburgh School of Medicine (UPSOM) medical students as subjects must be approved by the Research on Medical Students Review Committee (ROMS). This includes studies that do not require Institutional Review Board (IRB) approval.

Medical students are defined as individuals who are pursuing the Doctor of Medicine (MD) degree, including those enrolled in programs such as the Medical Science Training Program (MSTP) while they are pursuing additional educational experiences.

Research is defined as a systematic investigation designed to develop or contribute to generalizable knowledge. Course surveys that are exclusively focused on determining if the presentation of material is optimal, and aimed at improving the course, are not research and do not require ROMS or IRB approval. Similarly, anonymous surveys for quality improvement of an educational program are not considered to be research, and do not require approval. However, any survey or intervention that collects identifiable private information about an individual (which can be linked to that individual) does require a submission to the IRB and ROMS.

ROMS approval of a study does not replace the judgment of the University of Pittsburgh IRB (or another IRB with a reliance agreement with the Pitt IRB), and consent to proceed will be contingent on obtaining the appropriate IRB approval.

IRB approval of a study does not remove the requirement for ROMS review of a study that involves UPSOM medical students as subjects, including surveys arising from other institutions. The Pitt IRB will not approve a study involving medical students until ROMS approval is obtained.

The primary criterion used by ROMS to determine appropriateness of studies involving medical students is risk to the trainees. There must be no real or perceived coercion, educational disadvantage, or interference with other curricular activities. The confidentiality of students and their records must be preserved when sensitive information is being obtained. In addition, study design must be compliant with the Federal Family Education Rights and Privacy Act of 1974 (FERPA), regulations promulgated by the U.S. Department of Education, and University of Pittsburgh Policy AC-04, "Access to and Release of Education Records."

This policy is not applicable to a study that is open to a broad population, and is not targeted to medicals students.

IV. POLICY AUTHOR(S)

- Office of Medical Education

V. RELATED POLICIES AND PROCEDURES

University of Pittsburgh Policy AC-04, "Access to and Release of Education Records"

VI. REFERENCES

- University of Pittsburgh Human Research Subjects Protection Office Policies and Procedures, Chapter 14, Considerations for Special Populations, Students as Research Subjects
- University of Pittsburgh Policy AC-04, "Access to and Release of Education Records"
- Federal Family Education Rights and Privacy Act of 1974 (FERPA)

VII. APPROVALS

Dean, School of Medicine, originally approved February 28, 2018.

Education Policy Council, revision approved June 2, 2023.
Executive Committee, revision approved July 10, 2023.
Dean, School of Medicine, revision approved July 28, 2023.

VIII. PROCEDURES

ROMS membership consists of all individuals who serve on the Curriculum Committee Executive Subcommittee; its leader will be appointed by the Curriculum Committee Chair. ROMS may utilize consultant faculty who have specific expertise, to help determine appropriateness of proposed studies. In addition, ROMS may consult with the IRB leadership and/or the Provost's Office in determining whether a proposed project is compliant with applicable laws and regulations.

Although ROMS may comment on the scientific design of a project and/or its scientific value, approval is not contingent on this evaluation. Instead, the following questions will be considered when approving a study:

- Might the study lead to either disadvantages or advantages to students who participate in the study (e.g., participants receive an advantage such as course materials not provided to all learners)?
- If the study is designed as anonymous (de-identified), might information be collected that allows some participants to be identified?
- If the study requires subject consent, is this included in the study design?
- Might the study interfere with the academic progress of some participants?
- Might the study lead to release of confidential information regarding students?
- Is the study compliant with FERPA and other relevant regulations?
- Are timelines proposed for the study reasonable and accurate?
- Might the findings of the study lead to reputational damage to the University or UPMC?

All proposals to ROMS must include a faculty mentor or investigator. The information provided to the committee must allow for an understanding of the student experience from beginning to end, and should include:

- All the components of an IRB protocol in draft form (a PDF version of the protocol drafted in the Pitt-Pro system prior to submission)
- Recruitment documents, procedures, and scripts
- Outcome data/measures
- Follow-up expectations (if any)
- Data security/use

Proposals should be sent directly to the chair of ROMS, who will lead the review with the full committee. Investigators are encouraged to contact the ROMS chair in advance of the submission to discuss their proposed project.

The Pitt IRB will automatically refer any protocol with medical students as participants to ROMS. However, failure to consult with ROMS in advance could lead to approval delays if ROMS requires a modification in study design.

Projects that are best described as quality improvement do not need ROMS or IRB approval. For instance, faculty can use student satisfaction data regularly collected by the school to evaluate the efficacy of an educational intervention without any further review.

Generally, the Office of Medical Education circulates opportunities to participate in research studies to medical students. At most, three solicitation emails will be circulated.

To preserve the capability of students to participate in studies proposed by Pitt members, typically surveys originating from other institutions will not be circulated unless a Pitt faculty member is actively involved in designing the study or interpreting the findings. Under no circumstances can Pitt medical students be solicited to participate in a research study without ROMS approval.

ROMS will conduct its review and general provide investigators with a response within three weeks of submission. Changes may be requested by ROMS prior to approval. The IRB may also require two weeks or longer to approve a study. Thus, submission of a proposal well ahead of the anticipated start date is recommended.