University of Pittsburgh School of Medicine

# Research Studies Involving School of Medicine Medical Students as Subjects

## I. PURPOSE

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 but not limited to those enrolled in programs such as the Physician Scientist Training Program, (PSTP), Medical Science Training Program (MSTP), Clinical Scientist Training Program (CSTP), or other special programs 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 University of Pittsburgh 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 University of Pittsburgh 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

Educational Policy Council approved September 11, 2025

## VIII. PROCEDURES

ROMS membership consists of the following individuals:

- Curriculum Committee Chair
- Curriculum Committee Vice Chair
- Associate Dean for Clinical Education
- Associate Dean for Student Affairs
- Assistant Dean for Medical Education
- Assistant Dean for Foundations
- At least two members of the Curriculum Committee
- At least one member of the Office of Accreditation and Continuous Quality Improvement

The leader of ROMS 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 University of Pittsburgh IRB leadership 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?
- For clinical studies, what steps will be taken to ensure medical students will not be coerced?

Investigators are strongly encouraged to consult with the ROMS Chair prior to submitting protocols to the IRB, in order to confirm that the proposed study design is appropriate. Failure to consult with ROMS in advance could lead to approval delays if ROMS requires a modification in study design.

When a protocol involving the participation of medical students is submitted to the IRB, the ROMS Chair will automatically receive notification through the Pitt-PRO system. The ROMS Chair is responsible for completing an ancillary review in Pitt-PRO, which reflects the determination of the ROMS Committee. To initiate the review process, the ROMS Chair will download the PDF versions of the protocol and related documents from Pitt-PRO and distribute them via email to members of the Committee. Following the Committee's deliberation, the decision must be entered into the Pitt-PRO system. If revisions to the protocol are required, the ROMS Chair will be notified by email once the investigator has submitted the changes. The Chair must then review the revisions to ensure they satisfy the Committee's requirements. Once all necessary modifications have been addressed, the ROMS Chair must record final approval of the ancillary review within Pitt-PRO.

Projects that are best described as quality improvement (such as surveys to determine the success of a teaching methodology) 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.

The Office of Accreditation and Continuous Quality Improvement circulates opportunities to participate in research studies to medical students. At most, three solicitation emails will be circulated. Investigators should not directly solicit the participation of medical students in a study.

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

ROMS will conduct its review and general provide investigators with a response within two 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.