Subject: **Research Studies**	Page **1 of 2**	Policy # **Version: 1.0**
Title: **Enrollment of Students and Trainees in Research Studies**	Revision of:	Effective Date: September 21, 2017
		Removal Date:

I. PURPOSE

The purpose of this policy is to balance the wishes of students and postdoctoral trainees who want to participate as research subjects in studies approved by an Institutional Review Board (IRB) against the responsibility of the Feinberg School of Medicine (FSM) to recognize special circumstances and prioritize risk of well-being.

Background: This issue is not unique to FSM; many peer institutions have concerns about enrolling their students and trainees as research subjects. General concerns include the following:

1) The risk of coercion. Students and postdoctoral trainees do not come to FSM as new learners expecting to be research subjects. They may feel or perceive unwanted pressure to participate in research studies conducted by faculty or their agents or their supervisors who are involved in grading, evaluating, or recommending them for future advancement or jobs.
2) The risk of loss of confidentiality. Students or postdoctoral trainees do not expect others in their program to have access to private information about them. FSM students and postdoctoral trainees are at a higher risk for breeches in confidentiality than other research participants because peer students or postdoctoral trainees, staff, or faculty who know them may have access to protected personal data.
3) The risk of being studied. Students and postdoctoral trainees, because they want to excel in their studies, are a captive subject pool and may be less willing or able to evaluate personal risk by wanting to please. Moreover, some research studies provide financial inducements that may invite decisions against self-interest.

II. PERSONS AFFECTED:

Investigators wishing to enroll FSM students or postdoctoral trainees in research studies.

III. POLICY STATEMENT

The Vice Dean for Education must pre-approve all studies seeking students or postdoctoral trainees as research subjects before IRB review.

Failure to comply with these policies will lead to sanctions, up to and including administrative suspension of activities, loss of faculty appointment, department or unit financial penalties, or dismissal from the university.

IV. PROCEDURE STATEMENT

Provided below is additional guidance for preparing such studies at FSM.

A. Research studies unrelated to medical education

Investigators wishing to enroll FSM students or postdoctoral trainees in research studies unrelated to medical education must be aware of the following issues in preparing IRB protocols:

1) Participation. Participation of students or postdoctoral trainees in research studies by investigators or their agents who teach, grade, or academically mentor or supervise the student or trainee is not allowed. If the study becomes IRB-approved, students or trainees not subject to the above restrictions may be recruited, but only through general notifications such as posting of IRB-approved advertisements. Investigators may not directly email or contact students or trainees.

2) Pre-review. The Vice Dean for Education will pre-review and determine which research studies involving students or postdoctoral trainees are acceptable or unacceptable. Examples of acceptable studies might include such things as blood draws, urinalyses, non-invasive fetal monitoring, cheek swabs, or gait assessments. If personal information is required for these studies, each question must have an answer choice that says "prefer not to answer". Research studies that involve the keeping of diaries or detailed medical or behavioral records, taking of investigative drugs, or procedures such as body imaging, electrocardiograms, genetic sequencing, or invasive procedures such as endoscopy or a biopsy or other complex procedures are generally considered unacceptable.

3) Additional Protections. Investigators including students or postdoctoral fellows as research subjects in acceptable studies must provide specific plans in their IRB protocols describing ways to ensure that the privacy of students and postdoctoral trainees will be protected due to their special status as a known study participant. The investigator must also provide the IRB with invitation language designed to ensure student participation is voluntary.

B. Research studies involving medical education

Research aimed at improving the educational process may be allowed under the following circumstances:

Approval is obtained through the appropriate course or clerkship director at FSM and the project is designated as acceptable by the Vice Dean for Education.

V. **POLICY UPDATE SCHEDULE**:

Policy review to occur one year after initial implementation and every three years thereafter.