**YALE UNIVERSITY**

**SCHOOL OF MEDICINE POLICY**

ACCESS TO MEDICAL STUDENTS AS RESEARCH SUBJECTS

# Background

Due to the increasing number of research projects utilizing medical students as subjects, a committee has been established to review and approve these requests for student participation. The purpose of this review is to ensure that the issues of power are addressed. Power issues may arise, for example, when the investigator requesting student participation is in an evaluative role in relationship to the student(s) such as a clerkship or elective director. The 2015-16 members of The Committee to Review Student Participation (the Committee) in Research are Nancy Angoff, Associate Dean for Student Affairs; Michael Schwartz, Associate Dean for Curriculum; Janet Hafler, Associate Dean for Educational Scholarship; and Belinda Nhundu, student representative.

**Policy**

Yale Medical School faculty, residents and students proposing research intended to utilize Yale medical students as subjects must obtain written approval from the Committee to Review Student Participation in Research and approval or exemption from review from the Institutional Review Board (IRB).

The use of class time for surveys or other types of research participation will not be approved except in exceptional circumstances.

Program evaluation and curricular assessment conducted for curricular oversight and improvement are not reviewed by The Committee unless they are being carried out for the purpose of publication

**Procedure**

Applicants must email the materials listed below to the chair of the Committee to Review Student Participation in Research. Once approval is obtained the researcher then submits the study documents and approval letter from the Committee to Review Student Participation in Research to the IRB.

1. The Committee will review the proposal and send an email to the PI if revisions requested, or rejection. If approved the PI will receive a formal approval letter.
2. The PI will submit the Committee’s approval letter with their study documents to the IRB.
3. The IRB will review and either 1) request revisions to be addressed before approval or exemption are granted, 2) grant approval or 3) grant an exemption from review.
4. The IRB will communicate their decision to the PI.

**The following materials must be submitted to the Committee to Review Student Participation for review:**

1. A written description of the research proposal (IRB application or exemption request), which includes all data collection instruments and the Informed Consent Document or Verbal/Online Script
2. An explanation of how issues of power dynamics that may exert undue influence on students’ participation will be handled.
3. A copy of the invitation to the students to participate as well as advertisements, postings, etc.