

Rules Governing the Participation of Medical Students as Experimental Subjects in Research Studies

The participation of medical students as experimental subjects in research studies raises important practical and philosophical problems. In discussing the situation, the Committee on Human Studies and the Faculty of Medicine have considered the principles that should govern the employment of human beings as research subjects, the motivation of the matter of financial remuneration, the protection of health, the conflict with scheduled studies, the moral and legal responsibilities of the investigator and of the Medical School, and the advisability of centralization of all pertinent records. After extensive study of these points, the Faculty of Medicine approved the following policies and procedures.

STATEMENT OF POLICY

1. The guiding principle in considering the participation of medical students as subjects in experiments is the belief that as far as their health and well-being are concerned, no student should be exposed to risk different from that considered generally acceptable for normal adult subjects by the Committee on Human Studies.
2. Inasmuch as motivation should stem from an opportunity to learn and to contribute, rather than from a financial inducement *per se*, payment should not ordinarily be made to the student for participation as a subject in an experiment. This does not preclude remuneration for collaborating in a research project nor for participation in programs in which a student may be employed during vacation period, or under special circumstances a other times during the academic year, or as a Student Research Fellow.
3. The contact between investigators and students is recognized as an excellent opportunity for investigators to demonstrate to the students both their personal responsibility for the student's health and safety and an active interest in furthering the student's education.
4. Student's time should not be invaded to the extent of creating conflicts with their scheduled work.

PROCEDURE

In order to simplify and to standardize the participation of medical students as experimental subjects, the following administrative procedure has been established for the mutual benefit of the student, the investigator and the Medical School.

1. Each project must be approved by the head of the department, of which the investigator is a member. This provision specifically shall include approval of the desirability of the proposed study, the details of the experimental protocol, and the use of medical students as subjects. It shall imply, in addition, the assumption of responsibility for any medical expenses that the student may incur as a consequence of participation.
2. Subsequent to such approval, the protocol must be submitted to the HMS/HSDM Committee on Human Studies for discussion and for approval/disapproval, including consideration of student participation. Prior to consideration by the Committee on Human Studies, the protocol must also be submitted to the Dean's Office and to the Director of the Medical Area Health Service for their information. In experiments involving the use of radioactive material, a copy of the protocol shall be submitted to the relevant Committee on isotopes.
3. If the protocol is approved, the investigator must explain the details of the project to the medical students in advance. Ordinarily, students on clinical rotations should not be asked by faculty from that rotation to participate as research subjects.
4. The investigator must report to the Health Service dosages of radioisotopes used on any student and the total body irradiation received. In addition and upon assent of the student involved, the investigator must report to the Health Service any significant medical observations that are made during the course of a given experiment.