

TITLE: PRINCIPLES AND RESPONSIBILITIES REGARDING ACCESS TO PROFESSIONAL PROGRAM STUDENTS AND RESIDENTS AS RESEARCH SUBJECTS

DATE: September 2004

CLASSIFICATION: Faculty of Medicine, University of Toronto

Summary: This statement ensures that there is ethical review and oversight of any studies involving professional students and residents. It provides the Faculty of Medicine's principles for preventing unduly frequent surveys and repeated requests for participation in research studies, of past and current students, protecting student rights, ensuring access to students is appropriate and protecting Faculty integrity.

Purpose: The purpose of this statement is to articulate guiding principles with respect to access to students and postgraduate trainees (or to data about them); reinforcing the need for review of selected projects by a Research Ethics Board; and implementing a process for requesting permission for access to students and postgraduates trainees (or data about them).

Deans, Directors and Chairs receive requests for access to institutional student/resident databases and email listservs for research purposes. When requests are accepted information is disseminated directly to students/residents from the relevant University officers. Under no circumstance is direct access to University databases and email listservs given to those requesting access.

Those requesting access are required to submit a copy of their approved study protocol and letter of approval from the Research Ethics Board (for research involving human subjects). Ethics approval does not guarantee that the study will be undertaken. The study protocol, with the ethics approval, is circulated to the offices of the relevant Education Deans, who maintain a record of the number of approaches made to students/residents to ensure that their rights are protected and they are shielded from unduly frequent surveys and repeated requests for participation in research studies. Based on the frequency of surveying within a specific educational program, the Education Dean will make the final decision about the feasibility of the survey within a specific timeframe.

All applications for access to student and postgraduate trainees (or data about them) should be accompanied by a copy of the approved study protocol and the approval letter from the Research Ethics Board. Study protocols should include the following information:

- Study title; Title and names of authors; Background, purpose and objectives; Research methodology; Participants; Recruitment; Risks and benefits; Privacy and confidentiality; Compensation; Conflict of interest; Informed consent process; Scholarly review; Ethics review; and References.
- University of Toronto Graduate students performing research in a hospital setting should apply to both the hospital's Research Ethics Board for ethics review and to the appropriate University of Toronto Research Ethics Board according to the current policy of the University of Toronto and the School of Graduate Studies. Documentation of approval from both the hospital and university ethics review boards is necessary to proceed to review by the Education Deans. For a proposal that will be located only on-campus, not within the hospital setting, ethics approval by the University of Toronto Research Ethics Board should be obtained.
- University of Toronto Postgraduate students performing research in a hospital setting should apply to the hospital's Research Ethics Board for ethics review. When more than one hospital is involved in a study, approval must be sought from each participating institution individually. The Toronto Academic Health Sciences Network Core Application Form is a common form recognized by the fully affiliated institutions, as well as the University of Toronto, when accompanied by a UofT Ethics Application Cover Sheet. Please contact the UofT ethics office linked below for more information. The Hospital University Ethics

Committee hopes to further streamline this process in the future. Documentation of approval from the relevant Research Ethics Board(s) is necessary to proceed to review by the Education Deans.

- Students, Graduate or Health Professional students or postgraduate trainees from outside the University of Toronto performing research in a hospital setting should apply to the hospital's Research Ethics Board for ethics review and to their home university-based ethics board. Documentation of approval from both the hospital and university ethics review boards is necessary to proceed to review by the Education Deans. If the proposal applies only to an on-campus study, ethics approval must be obtained from both the home-university ethics board and the University of Toronto Research Ethics Board.
- OISE/UT students should submit a Statement of Intent and ethical review protocol to the appropriate OISE/UT Ethical Review Departmental Coordinator who will conduct a pre-review prior to submission to the Education Research Ethics Board.

The Associate Deans of Undergraduate Medical Education, Postgraduate Medical Education, Graduate and Inter-Faculty Affairs and Continuing Education consider requests received by the Faculty of Medicine and approval is based on the following considerations:

- The administrative requirements stated above have been met;
- The objectives of the study are realistic and achievable;
- A description of how privacy and confidentiality will be protected has been included (including a description of data maintenance, storage, release of information, access to information, use of names or codes, destruction of data at the conclusion of the research; include information of the use of audio or video tapes)
- The potential for conflict of interest has been considered and disclosed;
- Students do not receive unduly frequent surveys and repeated requests for participation in research studies;
- At all times, student's rights are considered and protected;
- The research is timely and appropriate given any unusual events or special contexts (e.g. infectious disease outbreaks, service disruptions for other reasons and other occurrences).
- Issues are relevant to the professional health services;
- The level of funding estimated and received to support the study is appropriate.

Ethics Approval Process: The *Research Involving Human Subjects: Student Guide on Ethical Conduct* website located at http://www.library.utoronto.ca/rir/ethics_hshome.html provides application instructions, forms, procedures and deadlines as well as the following helpful information:

- What to include in your application; Sample consent forms; Where to drop off or send your application; What expedited review is and what applications qualify; Reference documents; Answers to frequently asked questions; and Who to contact for assistance.