

TITLE: PRINCIPLES AND RESPONSIBILITIES REGARDING CONDUCT OF RESEARCH

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CLASSIFICATION: Faculty of Medicine, U of Toronto.

Summary. This statement provides the Faculty of Medicine's principles for preventing research misconduct and outlines the responsibilities of Faculty members in conducting their research.

Purposes. The purpose of this statement is to foster a research climate that will promote both scientific creativity and scientific integrity.

1.0 PREFACE

After the Governing Council of the University of Toronto approved the University Policy on Ethical Conduct in Research (March 1991), the various divisions were expected to formulate their own guidelines. The Faculty of Medicine's statement "Framework for Ethical Conduct of Research and Guidelines to Address Research Misconduct" was subsequently approved by the Faculty Research Committee, the Hospital University Research Co-ordinating Committee, Departmental Chairs and the Faculty Council.

Two new statements --- (a) Principles and Responsibilities Regarding Conduct of Research (this document); and (b) Guidelines to Address Allegations of Research Misconduct¹ have replaced that Faculty statement. These new statements should not be interpreted as supplementary to that earlier guideline.

2.0 INTRODUCTION

Faculty members in the Faculty of Medicine are engaged in investigations that, directly or indirectly, can have a profound effect on the health of the public. The generally accepted tenets of scientific inquiry and the highest standards of ethical conduct in dealing with human subjects, animals or hazardous materials must guide our faculty members. The research community, funding agencies, and the public at large, must be confident that research results and the process leading to them are honest and reliable.

3.0 GUIDING ETHICAL PRINCIPLES

3.1 Guiding Ethics Principles - General

The Faculty embraces the ethical principles, common standards, values and aspirations of the research community as expressed in national and international codes of research conduct. Our faculty members should be familiar with the *Tri-Council Policy Statement on*

*Ethical Conduct for Research Involving Humans*² (and subsequent revisions) and other relevant codes of ethics including those from funding agencies such as NIH. The *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans*² lists the guiding ethical principles and our faculty members are advised to familiarise themselves with these and to understand their importance. These are:

- Respect for Human Dignity
- Respect for Free and Informed Consent
- Respect for Vulnerable Persons
- Respect for Privacy and Confidentiality
- Respect for Justice and Inclusiveness
- Balancing Harms and Benefits
- Minimising Harm
- Maximising Benefit

The Faculty further embraces the principles and responsibilities as stated in the Tri-Council Policy Statement on Integrity in Research and Scholarship³. Therefore, it is the responsibility of our faculty members to uphold the following principles:

- a. recognise the substantive contributions of collaborators and trainees including students and postdoctoral fellows;
- b. only use unpublished work of others with appropriate permission and with due acknowledgement;
- c. use archival material in accordance with the rules of the archival source;
- d. obtain appropriate permission before using new information, concepts, or data originally obtained through access to confidential documents as a result of being a peer reviewer or a referee;
- e. use scholarly and scientific rigor and integrity in obtaining, recording, analysing, reporting and publishing results;
- f. ensure that authorship of published work includes all those who have materially contributed to, and share responsibility for, the contents of the publication, and only those people;
- g. reveal to sponsors, universities, journals or funding agencies, any material conflict of interest, financial or other, that might influence their decisions on whether the individual should be asked to review manuscripts or applications,

test products or be permitted to undertake work sponsored from outside sources;

- h. reveal to sponsors, universities, journals or funding agencies, any material conflict of interest, financial or other that might influence or be perceived to influence their interpretation of research findings when such findings are submitted for publication or presentation or otherwise made public.

3.2 Guiding Ethical Principles - Specific

In addition to these principles, the Faculty emphasises that it expects faculty members to:

- a. respect and support an environment of scientific integrity and scientific creativity by role-modelling high quality and honest scholarship;
- b. conduct research with the highest of ethical standards and comply with the policies, procedures and directions of the Research Ethics Board, Use of Animals and Biohazards Committee, and funding agencies;
- c. reveal to the university any conflict of interest they might have when making an allegation of research misconduct or when asked to comment or review a case concerning research misconduct;
- d. ensure that those reporting alleged research misconduct who do so in good faith do not become subjected to retaliation of any kind;
- e. create a research climate that fosters self-regulation as a mechanism to protect the public and the interests of faculty, staff and students by making good-faith efforts to assist the Faculty in identifying cases of research misconduct and in conducting an objective and thorough inquiry, and if appropriate investigation, into these matters;
- f. comply with university policies and procedures and with legislative and regulatory governance;
- g. comply with contracts and agreements with external parties and with collaborators which are in concordance with these principles and responsibilities regarding the conduct of research;
- h. do not enter into contracts and agreements with external parties or with collaborators when the terms and conditions are not in keeping with these principles and responsibilities;
- i. recognise the importance of publishing work in a timely fashion and ensure that they do not contribute to long and unjustifiable delays in preparing, submitting, or revising a manuscript for publication.

4.0 GUIDELINES FOR ETHICAL STANDARDS IN RESEARCH

4.1 Introduction

The goal of the Faculty of Medicine is to create and maintain an environment in which high ethical standards are pervasive. The primary objective of these guidelines is to foster a research climate that will promote both scientific creativity and scientific integrity resulting in the generation of research of the highest quality and prevention of misconduct in research.

4.2 Responsibilities of Faculty Members

Faculty members are expected to adhere to the highest standards of scholarly integrity. Guidance can be found in the general guiding principles (Section 3.0) and in the following guidelines that, although not exhaustive, highlight a number of important values in the context of specific situations.

4.2a Relationship with Collaborators

Multi-investigator teams are important vehicles for conducting high quality research as they allow individuals from different disciplines or sub-fields to perform specialised functions or to contribute in novel ways. However, they also provide challenges for the allocation of credit and responsibility. Matters of authorship, attribution and acknowledgement are more complex in collaborative research. The international academic community are hearing increasing numbers of complainants between collaborators and their trainees (including graduate students and postdoctoral fellows) over credit for work to which many have contributed. We expect faculty members to abide by the rules of authorship that are commonly accepted standards or practises of the relevant research community including those from peer-reviewed journals. In the latter respect, journals are increasingly demanding that there be clear delineation of the nature of the contributions of different members of the research team so that any associated rights and responsibilities are transparent for reviewers, editors, and readers.

Misunderstandings or differences of opinion ideally are discussed openly by members of research teams. These can often be resolved by frank discussion. Allegations of research misconduct can often be averted when open discussion within research teams is the norm. Parties should work out issues of principle investigator, authorship, ownership of data and other important issues at the time a collaborative project is being considered or as soon as the team starts to solidify. It is at this time that individuals are best able to articulate their interests and arrive at creative solutions that are tailored to their individual teams or fields. Creative solutions may involve the co-writing of a research agreement where rules are clearly stated and agreed to prior to the commencement of the work. There will be a dimension of uncertainty with respect to issues that may arise and collaborators need to be willing to discuss these as the collaboration unfolds or the research is underway in the hopes of reaching an agreement among the individuals.

4.2b Handling of Data

As a general rule, all the key scientific members of the research team should have access to raw data unless there is some exceptional circumstance that warrants controlled access. Rights of access should be discussed in advance by team members. Rapid sharing of new data is essential among members of the team given their collective responsibilities. In general, raw data should be recorded in permanent media; data books or computer discs and should be kept for at least five years. Trials conducted for regulatory approval have specific requirements as to how long such records need to be retained and all faculty members should ensure that they follow these legal requirements.

4.2c Monitoring of the work of students¹ and Postdoctoral Fellows

There is a graded and shared responsibility in any research team. The supervising faculty member shares responsibility at all times for the work done under her/his mentorship, however, the degree of responsibility borne by the trainee increases steadily from the limited burden of a new graduate student to a very high degree of onus for full compliance that must be borne by a senior postdoctoral fellow. Unusual results and results that seem too-perfect-to-be-true should be independently duplicated using blinded methods as appropriate. Students' and postdoctoral fellows' data should be presented frequently for discussion at laboratory meetings and drafts of papers should be circulated for critical review to knowledgeable members of the department prior to publication. Faculty members should be sensitive to the circumstances of individual trainees, including students and postdoctoral fellows and give guidance, encouragement and critical evaluation of their work as appropriate.

4.2d Monitoring the Work of Research Support Staff

Supervising faculty members should monitor the research procedures and results of research support staff. This includes, but is not limited to, establishing a system as outlined in 4.2c when appropriate.

4.2e Multi-Investigator Teams

In programs involving several faculty members who are considered principal investigators, attempts should be made to cross-check each other's raw data where appropriate.

4.2f Special Concerns for Faculty Members in Non-laboratory Settings

The problem of preventing fraud and maintaining high ethical standards in clinical or community research is for the most part not different from basic science settings, especially when the research is largely laboratory-based. The responsibilities of the faculty member in the clinical/community setting in the supervision of students, post doctoral fellows, research associates, and research support staff with regard to data gathering and storage, authorship and publication do not differ from those of basic science colleagues.

¹ Includes undergraduate, graduate, and postgraduate students, including all students in degree-granting professional programs. We discuss postdoctoral fellows separately, given the concept of graded responsibility and autonomy in research settings.

The major difference is that errors (both inadvertent and fraudulent) can more directly and more immediately harm patients when faulty results are applied to the diagnostic and therapeutic processes or used to inform the public, health care practitioners and policy-makers. The following points are three areas of particular challenge for those conducting clinical and community research. However, in appropriate circumstances, they are also of concern in biomedical research.

i) Human Experimentation: Analysis of unethical research involving human beings has resulted in the establishment of clear international and national guidelines. The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*² should be known to all members of clinical/community research teams and must be adhered to irrespective of how (or whether) the research is funded. Faculty members should be vigilant about remaining updated about subsequent Tri-Council Policy Statements and other well-recognised ethical guidelines or policy statements within the scientific or academic community. The University has guidelines entitled “Guidelines on the use of Human Subjects” (University of Toronto, 1979 written by Bernard Dickens) which should be used in conjunction with the Tri-Council Guidelines. All affiliated institutions adhere to the Tri-Council Policy Statement, other internationally accepted ethical guidelines, and other guidelines that are consistent with the spirit and direction of these guidelines. The University is similarly adherent and expects faculty members to conduct themselves according to these widely accepted ethical tenets. The University and the affiliated institutions each have ethical/legal obligations to protect human subjects.

Although University and hospital research ethics committees review clinical/community research proposals before they are approved, it is the responsibility of faculty members to ensure that ethical guidelines are respected during the actual conduct of the investigation.

Absolute prerequisites for the continuation as well as the initiation of clinical/community research projects are: informed voluntary consent by competent subjects (or legally valid substitute decision makers when subjects are not competent to consent); oversight as appropriate by a study safety and monitoring committee that is charged with reviewing the benefit: harm ratio in the study at intervals; assurance of privacy and confidentiality for subjects including confidentiality of research records; and procedures to treat and compensate for research-induced injury. In addition, special consideration is due when research subjects are particularly vulnerable (e.g., children, incompetent adults, involuntary hospitalised patients or prisoners). If deception is part of the experimental procedure, this must be scrupulously justified and approved.

Although informed consent from a patient is normally obtained, in certain instances it is impossible to do so. Examples of this are studies using data collected for another purpose (e.g., registries) where it may not be possible to obtain informed consent from those whose data or information is contained in that database. Providing that the use of that data for the purposes of the research does not contravene the original or current legal protections for the health information, the data can be used as long as the faculty members abide by the special rules issued when the data was released to them. Although such studies do not involve the use of informed consent from a

subject, they should, nonetheless, be brought to the attention of the research ethics committee/board and given either approval to proceed or acknowledgement that the particular study does not need to be reviewed before proceeding with the research at the institution.

ii) Media Contacts: The traditional rule in presenting scientific results is to expose them first to appropriate scientific and professional peer groups for review and criticism before they are revealed to the public at large. If this is not possible because the data is used for the purposes of the courts or other proceedings, faculty members are expected to disclose that the results have not yet undergone a peer-review mechanism. Even when this rule is observed there are ethical considerations in the way that faculty members present their work and themselves to the public media. Dangerously false hopes may be raised by premature and unproven claims. Further, even when there are exciting preliminary results, faculty members must be extremely cautious in interpreting their findings and their own roles to the press and must constantly be aware of the very real risks of misleading patients and of depriving colleagues of deserved credit. This problem is compounded by interviewers and reporters not allowing faculty members to review material before it is published or goes on the air.

iii) Relationship between Faculty members and Industry: There is the ever-present danger of conflicts of interest in studies supported by manufacturers of pharmaceuticals and medical devices. Faculty members should be vigilant about actual, apparent, perceived or potential conflict of interest situations and should report these situations to the Faculty and/or to the affiliated institution as appropriate. Clinical faculty members must not permit their clinical practices to be swayed by such support and they must be free to think independently, to conduct research freely and to publish negative as well as positive results promptly. When such freedom is not assured, accepting financial support from interested commercial parties threatens the ethical standards of the Faculty and of the University-affiliated institutions where faculty members conduct research. Faculty members who are supervisors/ principal investigators have responsibilities as researchers, employers, and teachers. As researchers they must ensure that research performed is of the highest quality. Important foci for attention are collection and storage of data, cross-checking work of collaborators, and conducting in-depth internal peer review. As employers they are responsible for monitoring work performed by paid staff (e.g., research support staff) who may report to them as part of the research team; developing criteria for selection of these research staff; and transmitting relevant expectations, obligations and responsibilities to all persons under their supervision. As teachers they have a responsibility to act as ethical role models and mentors and to instruct students in the ethical conduct of research. Faculty members must be fully knowledgeable about and able to interpret relevant codes, guidelines, policies and procedures and must be familiar with relevant Faculty guidelines (*Guidelines: Relationship Between Physician Trainees, Postgraduate Training Programs and Industry*⁶; *Guidelines for Graduate Students Working in an Industry Supported Environment*⁷; and *Offer and Acceptance of Finders' Fees for the Recruitment of Research Subjects*⁸).

4.3 Issues Relating to Students and Postdoctoral Fellows

Universities have a unique and distinctive role in promoting an environment of scientific integrity because we supervise and train students, postdoctoral fellows, and other young researchers. By appropriate role modelling and mentoring, we can foster scientific integrity in future generations. Therefore, our faculty members must demonstrate integrity in how they collaborate with colleagues and in how they supervise and train our students, postdoctoral fellows and other young researchers. An environment of honesty and integrity must be fostered through the training of junior members of the research community and by reinforcing the responsibilities of senior members through guidelines developed for these purposes.

Research integrity must always take into consideration the potential for real or perceived exploitation, which may occur between individuals who possess unequal levels of authority or power. Authority dimensions of research integrity may be reflected, for example, in the supervision of graduate and undergraduate students, research associates, and postdoctoral fellows; activities with pre-tenure faculty; service on peer-review committees for grants selection, publication or promotion and tenure; activities with staff; allocation of resources in support of research: or recognition of contributions to research and publication, among others. Sensitivity to the potential for abuse, real or perceived, of "power relationships" is a prerequisite to good practices. Care should be taken to ensure that institutional practice reflects a high degree of integrity with respect to the management of authority. A number of institutional mechanisms exist to handle abuses of power relationships as well as to prevent such abuses from happening. These include mentoring and advising programs, the equity office, educational activities and the ombudsperson, among others.

Emphasis on high ethical standards is important at the beginning of a research career in learning the methods and techniques of science. These can be fostered in several ways.

4.3a. Selection of Students, Postdoctoral Fellows, Research Associates, and Research Support Staff

When students, postdoctoral fellows, research associates, and research support staff are interviewed attention should be paid not only to their potential for becoming good scientists but also to their attitudes regarding truth, honesty and fairness. A focus on the responsibilities and virtues required of scientists will help establish the expectation of integrity from the start.

4.3b. Supervision

Close supervision by the supervisor (usually the principal investigator) is essential. Since role modelling is most important, the supervisor must set an example of high quality and honest scholarship. It is the supervisor's responsibility to scrutinise carefully the student's, postdoctoral fellow's, research associate's, or research support staff's work throughout his/her term in the research setting. In many cases, errors are made unintentionally due to inexperience or impatience and good supervision will not only correct these but also will give the student or research fellow a sound model for the conduct of science throughout his/her career.

4.3c Education

By analysing ethical and unethical research, including previous examples of fraud in science and problems inherent in the use of human and animal research subjects, students, postdoctoral fellows, research associates, and research support staff will develop greater sensitivity to these issues. Moreover, by becoming familiar with relevant codes of conduct and understanding the need for ethical principles, they will be better equipped to deal with new and challenging problems they may encounter. Students should also be encouraged to take a course on ethical problems in research. For example, the Institute of Medical Science (MSC 1051H; MSC 3004Y) offers relevant courses and The Collaborative Program in Bioethics has a listing of a number of relevant courses. The Joint Centre for Bioethics has information about bioethicists who are available for advice relating to research proposals. It is hoped that successful completion of a research ethics course will be required for all our graduate students.

4.4 Responsibilities of Students, Postdoctoral Fellows, Research Associates, and Research Support Staff

Students, postdoctoral fellows, research associates, and research support staff, have a responsibility for the ethical conduct of research by becoming knowledgeable about the norms of good science and by acting in accordance with them. These norms should be understood as applied to research in the basic, clinical sciences, and community health. In addition, the ethical considerations of research involving human and animal subjects are areas that need to be addressed. In particular, students, postdoctoral fellows, research associates, and research support staff must be familiar with relevant ethical codes and guidelines governing medical research (e.g. University guidelines, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*² and the *Canadian Council on Animal Care Guidelines*⁴ and the *Animals for Research Act of Ontario*⁵).

5.0 RESPONSIBILITIES OF DEPARTMENTAL CHAIRS AND DIRECTORS OF EXTRADEPARTMENTAL UNITS

It is the primary responsibility of the Departmental Chair and/or the Director of an Extradepartmental Unit (EDU), where appropriate, to create a climate in which the Department's faculty members accept high ethical standards as the norm and are strongly discouraged from dishonest behaviour of any kind. They should carefully recruit their students, postdoctoral fellows, research associates and research support staff. They also have a responsibility to the public to promptly notify the appropriate officer of the university or of the affiliated institution regarding possible cases of research misconduct as set out in applicable Faculty or in affiliated institutional policies and procedures.

6.0 RESPONSIBILITIES OF THE DEAN

The Dean (or by delegation the Vice-Dean Research) has responsibility for fostering a climate for ethical standards in research within the Faculty. This is done, in part, through consultation with relevant Faculty officers/members and by promulgating and enforcing relevant guidelines and policies that encourage ethical conduct.

7.0 RESEARCH MISCONDUCT

To assure the credibility and integrity of our research community and retain public trust, the Faculty of Medicine must have in place policies to deal with allegations of research misconduct and in founded cases, appropriate discipline and reporting duties. These policies must not discourage creativity and innovation or penalise for honest errors and ambiguities of interpretation that are inherent in the scientific process. They should instead identify and deal responsibly with intentional fabrication, falsification, or plagiarism as well as other practices that deviate seriously from the commonly accepted standards or practices of the relevant research community. While faculty members should carefully supervise the work of their students, postdoctoral fellows, research associates, and research support staff, they will not necessarily be the subject of investigation simply because of their supervisory role. That said, if there is some question as to the involvement or responsibility of the faculty member with respect to the possible research misconduct, then the matter will be pursued until the role of the faculty member is clarified. More generally, the Faculty believes that the supervising faculty member shares responsibility at all times for the work done under her/his mentorship. However, this degree of responsibility borne by the trainee increases steadily from the limited burden of a new graduate student to the major onus for full compliance borne by a senior postdoctoral fellow. The Faculty's *Policy and Procedures Concerning Allegations of Research Misconduct*⁴ is consistent with this current statement on *Policies and Principles in Research* and should be carefully reviewed by all faculty members and staff conducting research on campus.

8.0 CONCLUSION

The successful conduct of science rests upon a reverence for truth and the pursuit of enhanced understanding of human and non-human nature by use of the scientific method. Faculty members in the Faculty of Medicine must be guided by the accepted tenets of scientific inquiry and the highest standards of ethical conduct.

9.0 REFERENCES

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