Title: Principles and Responsibilities Regarding Conduct of Research	
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1.0 Policy Statement

To foster a research climate that promotes both scientific creativity and scientific integrity resulting in the generation of research of the highest quality and prevention of misconduct in research.

This document has been adapted from the University of Toronto, Faculty of Medicine "Principles and Responsibilities Regarding Conduct of Research" (October 2002) and should be reviewed in conjunction with Guidelines for Research at Baycrest.

2.0 Definitions

N/A

3.0 Background and Scope

N/A

4.0 Procedure

GUIDING ETHICAL PRINCIPLES

All Baycrest entities hold to the ethical principles, common standards, values and aspirations of the research community as expressed in national and international codes of research conduct. Baycrest staff members (includes physicians, students and trainees) who conduct research should be familiar with the *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans* (and subsequent revisions) and other relevant codes of ethics including those from funding agencies such as the National Institutes of Health (NIH). The *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans* lists the guiding ethical principles and staff members (including physicians, students and trainees) are advised to familiarize 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
- Minimizing Harm
- Maximizing Benefit.

Baycrest further holds to the principles and responsibilities as stated in the Tri-Council Policy Statement on Integrity in Research and Scholarship. Therefore, it is the responsibility of staff members (including physicians, students and trainees) conducting research to uphold the following principles:

1. Recognize the substantive contributions of collaborators and trainees including students and postdoctoral fellows;
2. Only use unpublished work of others with appropriate permission and with due acknowledgement;
3. Use archival material in accordance with the rules of the archival source;
4. 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;
5. Use scholarly and scientific rigor and integrity in obtaining, recording, analyzing, reporting and publishing results;
6. 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;
7. 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;
8. 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.

GUIDING ETHICAL PRINCIPLES – SPECIFIC

In addition to these principles, Baycrest expects staff members (including physicians, students and trainees) to:

1. Respect and support an environment of scientific integrity and scientific creativity by role-modeling high quality and honest scholarship;
2. Conduct research with the highest of ethical standards and comply with its policies and procedures and with the directions of the Research Ethics Board and funding agencies;
3. Reveal 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;
4. Ensure that those reporting alleged research misconduct who do so in good faith do not become subjected to retaliation of any kind;
5. Create a research climate that fosters self-regulation as a mechanism to protect research participants and the interests of Baycrest, other staff members and students by making good-faith efforts to assist Baycrest in identifying cases of research misconduct and in conducting an objective and thorough inquiry, and if appropriate, investigation into these matters;
6. Comply with Baycrest policies and procedures and with legislative and regulatory governance;
7. 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;
8. Do not enter into contracts and agreements with external parties or with collaborators without involving the appropriate individuals in Baycrest to review and/or approve the contracts and agreements;
9. Recognize 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.

GUIDELINES FOR ETHICAL STANDARDS IN RESEARCH

The following are general guiding principles that, although not exhaustive, highlight a number of important values in the context of specific situations.

1. Relationship with Collaborators

    a. Multi-investigator teams are important vehicles for conducting high quality research as they allow individuals from different disciplines or sub-fields to perform specialized 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.

    b. Baycrest expects staff members (including physicians, students and trainees) to abide by the rules of authorship that are commonly accepted standards or practices 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 principal 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.

2. Handling of Data

    a. 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.
    b. Team members should discuss rights of access in advance. 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 seven years.
    c. Trials conducted for regulatory approval have specific requirements as to how long such records need to be retained and staff members (including physicians, students and trainees) should ensure that they follow these legal requirements.

3. Authorship Guidelines

    a. The International Committee of Medical Journal Editors (ICMJE) has developed recommendations on what constitutes grounds for authorship and defines the roles of authorship and contributions to published work. The ICMJE defines four (4) criteria, including:

        i. Substantial contributions to the conception or design of the work; or the acquisition, analysis or interpretation of data for the work;
        ii. Drafting the work or revising it critically from the view point of important intellectual content;
        iii. Final approval of the version to be published; and,
        iv. Agreement to be accountable for all aspects of the work in ensuring that questions raised to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Specifically, those who do not meet all of the criteria cannot be acknowledged as an author. Most importantly, contributors who meet fewer than four of the criteria should not be listed as an author, but should be acknowledged. Examples of activities that merit acknowledgement, but not authorship, including the acquisition of funding; general supervision of a research group or general administrative support; writing and writing assistance of technical editing, language editing and proofreading; and access to an existing dataset.

It is important to note that violation of the policies for authorship on scientific and scholarly publications is considered research misconduct as defined by the Framework to Address and Investigate Allegations of Research Misconduct. (University of Toronto Faculty of Medicine Authorship Guidelines, https://www.deptmedicine.utoronto.ca/authorship-guidelines

4. Monitoring of the work of students[1]

   a. There is a graded and shared responsibility in any research team. The supervising staff member shares responsibility at all times for the work done under her/his mentorship. However, the degree of responsibility borne by a 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.
   b. Unusual results and results that seem too-perfect-to-be-true should be independently duplicated using blinded methods as appropriate.
   c. 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.
   d. Baycrest staff 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.
   e. The supervising staff fosters an environment that emphasizes the four principles of the Singapore Statement of Research Integrity, which are:
      - Honesty in all aspects of research.
      - Accountability in the conduct of research.
      - Professional courtesy and fairness in working with others.
      - Good stewardship of research on behalf of others.

[1] Includes undergraduate, graduate, and postgraduate students, including all students in degree-granting professional programs. Postdoctoral fellows are discussed separately, given the concept of graded responsibility and autonomy in research settings.

5. Monitoring the Work of Research Support Staff
    a. Supervising staff 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 when appropriate.

6. Multi-Investigator Teams
    a. In programs involving several staff members or collaborators who are considered principal investigators, attempts should be made to cross-check each other's raw data where appropriate.

7. Special Concerns in Clinical/Community 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 staff member (e.g. allied health staff member or physician) 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.

    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.

    a. 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* 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. Staff members involved in research should be vigilant about remaining updated about subsequent Tri-Council Policy Statements and other well-recognized ethical guidelines or policy statements within the scientific or academic community. The 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. Baycrest, as a University of Toronto-

affiliated institution, must 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.

Baycrest has ethical/legal obligations to protect human subjects. Although Baycrest's Research Ethics Board reviews research and approves research proposals, it is the responsibility of the staff member (including physicians, students and trainees) 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 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). 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 staff 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.

b. 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 are used for the purposes of the courts or other proceedings, or presented at a scientific conference, staff members (including physicians, students and trainees) are expected to disclose that the

results are early data and have not yet undergone a peer-review mechanism. Even when this rule is observed there are ethical considerations in the way that staff members (including physicians, students and trainees) present their work and themselves to the public media. Even when there are exciting preliminary results, staff members (including physicians, students and trainees) 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 creating false hope and of depriving colleagues of deserved credit. Therefore, it is incumbent on staff member(s) (including physicians, students and trainees) (i.e., authors of a Baycrest-led scientific paper) to work with Baycrest Public Affairs/Media Relations whenever they are engaging with the press. As a rule, journalists do not allow staff members (including physicians, students and trainees) to review a draft of their story before it goes to press – hence the importance of providing the most accurate reflection possible of the findings during the interview process.

c. Relationship between staff members (including physicians, students and trainees) and Industry:

While Baycrest does not have many industry-supported studies, the potential exists for this to increase. There is the ever-present danger of conflicts of interest in studies supported by manufacturers of pharmaceuticals and medical devices. Staff members (including physicians, students and trainees) should be vigilant about actual, apparent, perceived or potential conflict of interest situations and should report these situations to the appropriate individuals in Baycrest. Clinicians 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 Baycrest.

Staff members who are supervisors/ principal investigators have responsibilities as researchers, supervisors 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 supervisors, they are responsible for monitoring work performed by research support staff , student and trainees who may report to them as part of the research team; developing criteria for selection of these research staff members, students and trainees; 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. Staff members (including physicians, students and trainees)

must be fully knowledgeable about and able to interpret relevant codes, guidelines, and policies and procedures.

8. Issues Relating to Students

Baycrest, as a University of Toronto-affiliated institution, has a role in promoting an environment of scientific integrity because we supervise and train students and other young researchers.

By appropriate role modelling and mentoring, we can foster scientific integrity in future generations. Therefore, staff members must demonstrate integrity in how they collaborate with colleagues and in how they supervise and train our students 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; 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.

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.

a. 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 researchers will help establish the expectation of integrity from the start.

b. 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 scrutinize carefully the

students', postdoctoral fellows', research associates', or research support staff's work throughout their 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 their career.

c. Education

By analyzing 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.

9. Responsibilities of Students, Postdoctoral Fellows, 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 research (e.g. *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans).*

10. Research misconduct

To assure the credibility and integrity and to retain public trust, Baycrest has policies to deal with allegations of research misconduct and in founded cases, appropriate discipline and reporting duties. These policies are not to discourage creativity and innovation or penalize for honest errors and ambiguities of interpretation that are inherent in the scientific process. They 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 staff 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 staff member with respect to the possible research misconduct, then the matter will be pursued until the role of the staff member is clarified. More generally, Baycrest believes that the supervising staff shares responsibility at all times for the work done under their mentorship. However, the 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 Research Misconduct policy should be reviewed carefully by all staff members (including physicians, students and trainees) conducting research.

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. All staff members (including physicians, students and trainees) must be guided by the accepted tenets of scientific inquiry and the highest standards of ethical conduct.

5.0 Cross Reference Policies/Documents

Guidelines for Research at Baycrest
Framework to Address and Investigate Allegations of Research Misconduct

REFERENCES

1. *Guidelines to Address Allegations of Research Misconduct*, Faculty of Medicine, University of Toronto.
2. *Tri–Council Policy Statement: Ethical Conduct for Research Involving Humans (2018)*.
3. *Tri-Council Policy Statement: Integrity in Research and Scholarship*. Ottawa: Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada, August 2001.
4. Canadian Council on Animal Care (CCAC). All policies and guidelines from the CCAC including, but not limited to, the following: CCAC Guide to the Care and Use of Experimental Animals, Vol. 1, 2nd Ed., 1993; CCAC Guide to the Care and Use of Experimental Animals, Vol. 2, 1984; CCAC guidelines on: animal use protocol review, 1997; CCAC guidelines on: transgenic animals, 1997; CCAC guidelines on: choosing an appropriate endpoint, 1998; CCAC guidelines on: institutional animal user training and the Recommended Syllabus for an Institutional Animal User Training Program, 1999.
5. Animals for Research Act of Ontario, R.S.O. 1990, c. A-22. Amended by: 1994, c. 27, s.9; 1997, c. 41, s. 115; 1999, c. 12, Sched. A, s. 3.
6. *Guidelines: Relationship between Physician Trainees, Postgraduate Training Programs and Industry*, Faculty of Medicine, University of Toronto.
7. *Guidelines for Graduate Students Working in an Industry Supported Environment*, Faculty of Medicine, University of Toronto.
8. *Offer and Acceptance of Finders' Fees for the Recruitment of Research Subjects*, Faculty of Medicine, University of Toronto.

6.0 Appendices/Links

Approvals:
Research Management Committee
Baycrest Academy for Research and Education Executive Team