

Dalhousie University
Policy on the Ethical Conduct of
Research Involving Humans

Approved by Senate
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List of Acronyms

CDHA	Capital District Health Authority
CIHR	Canadian Institutes of Health Research
DHSS	United States Department of Health and Social Services
FOIPOP	Freedom of Information Protection of Privacy Act (NS)
HRERS	Human Research Ethics Review System
IWK	Izaak Walton Killam Health Centre
MOU	Memorandum of Understanding on the Roles and Responsibilities in the Management of Federal Grants and Awards
NIH	National Institutes of Health (US)
OHRP	US Department of Health and Human Services Office of Human Research Protections
PIIDPA	Personal Information International Disclosure Protection Act (NS)
PIPEDA	Personal Information Protection and Electronic Documents Act (CAN)
REB	Research Ethics Board
TCPS	Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

1. PREAMBLE

1.1 Intent

In order to maintain public trust, Dalhousie University must have, and follow, policies and procedures that enable University researchers to attain the highest ethical standards in the conduct of human participant research.

This policy is intended to ensure that all human participant research conducted by University faculty, students and staff, or conducted under the auspices of the University is carried out according to the relevant ethical and legal standards by

- promoting awareness and understanding of research ethics within the University
- establishing independent ethics review and monitoring procedures, and
- providing adequate administrative and educational resources.

This policy sets out the guiding ethical principles that govern the responsible conduct of research involving humans and describes the various components of the University's Human Research Ethics Review System – a complex of individuals, infrastructure and activities that supports the implementation of these principles. It also describes the mandate, authority and responsibilities of each component of this system. In addition, the jurisdiction of this policy is described, as are the requirements for institutional compliance with national standards that provide the rationale for its adoption and implementation by the University.

In September of 1999, the University Senate adopted a preliminary set of administrative guidelines – *Administration of the Policy on the Ethical Conduct for Research Involving Humans at Dalhousie University* – with the intent of reviewing and revising them after an initial period of implementation. This policy replaces that document.

1.2 Guiding Ethical Principles

Research ethics is founded on the principles of respect for persons, concern for welfare (beneficence) and justice. These principles were first clearly articulated in the Belmont report (1978), a document that emanated from a series of meetings organized by the U.S. National Commission for the Protection of Human Subjects whose goal it was to clarify the ethical guidelines applying to research involving humans in any setting. These principles provide the foundation for, and are reiterated in, the Canadian Tri-Council Policy Statement *Ethical Conduct for Research Involving Humans* (TCPS). As such, they provide the underlying framework that guides the process of ethics review in Canadian Universities.

1.2.1 Principle 1: Respect for Persons

The most important ethical principle that must be applied in the conduct of research involving humans is that of *respect for persons*. Researchers have an obligation to treat individuals as autonomous beings who have the right to make a voluntary and informed choice about their participation in research.

Researchers also have an obligation to provide special protections for those individuals who have diminished autonomy, or diminished capacity to make a decision about research participation. Children, who cannot reasonably be expected to have the capacity to appreciate the ramifications of being research participants; incarcerated offenders who have diminished autonomy because of their circumstances; adults whose health, or whose temporary situation, diminishes their decisional capacity (e.g. under the influence of narcotic medications) are examples of what are considered *vulnerable populations* in need of special protections.

Similarly, those who do not have the educational background to appreciate the implications of research participation cannot be reasonably expected to make an informed choice with respect to this participation.

Researchers must be prepared to take special precautions to ensure that such individuals are not subject to exploitation, however inadvertent it might be. However, determining when a person, by virtue of their condition or situation, is lacking in decisional capacity is sometimes difficult and researchers also must be careful not to improperly prevent an individual from exercising their right to make a decision to participate in research on their own behalf.

Participation in research must also be free and voluntary. Researchers must ensure that recruitment strategies are free from coercion or undue influence. Factors that can compromise the voluntariness of research participation include power dynamics of relationship (e.g. a faculty researcher recruiting students) and high levels of compensation (monetary or other).

A fundamental concept for the ethical conduct of research involving humans is that of informed consent. The informed consent process is an ongoing dialogue between the researcher and the research participant, using various means, that ensures that participants are provided with adequate relevant information to enable them to make an active, informed choice about participating in a research study.

Finally, demonstrating respect for persons involves the protection of privacy and confidentiality of research participants. There are two basic objectives that a researcher must consider when planning and executing his/her research. The first is that of enabling anonymity of research participation *where possible*. Harms can come to research participants merely by their being associated with some kinds of research. Therefore, researchers should endeavour to safeguard the identities of their research participants as much as possible. Only a few methodologies truly allow for anonymous participation

(e.g. mail-in surveys, some internet surveys); more frequently, the identity of participants will be known at least to the researchers. However, by controlling the visibility of research participation, limiting access to data and reporting results carefully, researchers can limit the potential for an individual's identity to be linked to a study. Such precautions are most important when the research involves highly sensitive or personal information or even illegal activities.

Confidentiality refers more broadly to the potential for an individual's contribution to a research study to be linked to his or her identity. A breach of confidentiality necessarily results in a breach of anonymity. However it is possible for someone to be identified as a participant in a study i.e. not participate anonymously (through being observed by others in the research setting), while their individual data remains confidential (i.e. unlinkable to them, or known only to the Principal Investigator).

At the other end of the spectrum, it may be desirable to offer participants the opportunity to waive anonymity or confidentiality, especially where participants feel that having their voices heard is an important reason for their participation. In either case, researchers must be clear and explicit in the measures they plan to take to address issues of anonymity and confidentiality.

1.2.2 Principle 2: Concern for Welfare

This principle dictates that researchers have a responsibility to maximize the benefits and minimize the potential for harm or risk that the research poses to participants. Because the benefits of research almost always reside in the value of the new knowledge created by the research, researchers must design and conduct their protocols in such a way as to ensure that the outcome of the research will yield useful and valid results. In other words, the research methodology should be appropriately chosen to achieve the stated objectives.

Concurrently, researchers must ensure that the methodology is chosen in such a way as to pose the least possible risk to participants, while simultaneously being consistent with good scholarly practices.

1.2.3 Principle 3: Justice

Implementing the principle of justice relates primarily to how participants are selected for research, and to the responsibility of researchers to spread both the benefits and burdens (i.e., risks) of research equitably. The selection of research participants should be guided by the objectives of the research, and should not be driven solely by convenience or the ability to take advantage of a given population because of their particular situation. While it may be logistically attractive to draw upon certain readily available groups of participants (students in classrooms, prisoners in correctional facilities, friends and family), researchers should target their recruitment in such a way as to support the intent of their research. For example, studies that intend to generalize results to the general population should involve adequate representation of gender, ethnicity, age and other

relevant demographic characteristics. A much narrower recruitment strategy can be employed when the focus of the research, and the ultimate application of results, is limited to a particular group (e.g. geographic community, disease sufferers).

By the same token, when drawing upon vulnerable populations, researchers must justify why this is necessary (i.e. how the research questions dictates that these individuals must be sought as participants). Children are a special case of this.

2. COMPLIANCE

2.1 External

As a signatory to the *Memorandum of Understanding on the Roles and Responsibilities in the Management of Federal Grants and Awards (MOU)*, the University must demonstrate compliance with the relevant policies which fall under this agreement with the three federal Granting Councils. With respect to research involving humans, the primary policy document is the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)*. The TCPS requires that all institutions who wish to be eligible to receive research funding from the Granting Councils, must develop and implement internal policies and procedures that articulate how the standards of the TCPS will be applied to all research involving humans. University researchers must also comply with *CIHR Guidelines for Human Pluripotent Stem Cell Research* (June 2010).

In addition, compliance with relevant Federal and Provincial laws must be demonstrated. The relevant laws are those that deal with the responsible handling of personal information (i.e., *Personal Information Protection and Electronic Document Act (PIPEDA)*, *the Nova Scotia Freedom of Information and Protection of Privacy Act (FOIPOP)*, *the Nova Scotia Personal Information International Disclosure Protection Act (PIIDPA)* and *The Nova Scotia Hospital Act*) and those that stipulate the legal duty to report certain kinds of information (i.e. *The Nova Scotia Adult Protection Act* and *The Nova Scotia Children and Family Services Act*) that may be disclosed during the conduct of research. University policies and procedures that guide the ethical conduct of human participant research must be consistent with these laws.

2.2 Internal

Other University policies that affect the conduct of research involving humans are the *Policy on Conflict of Interest and Integrity in Scholarly Activity*. The procedural guidelines that have been developed to implement this policy are intended to reflect the relevant requirements of these documents within the scope of the ethics review process.

3. SCOPE OF THE POLICY

3.1 Application

This policy applies to all **research involving humans** that meets any of the following criteria:

- 3.1.1 is research carried out by members of the University, or those employed by members of the University acting in their university capacity. Members of the University include:
 - faculty (full-time, part-time or emeritus)
 - staff (administrative or research)
 - students (undergraduate, graduate)
 - postdoctoral fellows
 - research associates
 - visiting or adjunct scholars
- 3.1.2 is research carried out using University facilities
- 3.1.3 is research carried out using data that is in the custody of the University or members of the University
- 3.1.4 is research carried out using research funding held or granted by the University

3.2 Exclusions

Excluded from this policy are those activities carried out internally within the University solely for the purpose of educational performance review (e.g., tests and exams of students), or quality assurance (e.g., teaching and/or course evaluations). Research conducted by the University administration, if intended solely for use internally for the improvement or operation of University programs, is also excluded from this policy. Research and other activities exempt from REB review include those described in the TCPS articles 2.2 – 2.6.

4. DEFINITIONS

4.1 Research

The definition of **research** that is referred to in this policy is that stated in the Tri-Council Policy Statement Article 2.1 (Application), namely “...an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.”

Research involving human participants includes research involving living human

participants and human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals (TCPS 2.1).

4.2 Minimal Risk

The definition of **minimal risk** referred to in this policy is that stated in the Tri-Council Policy Statement, p. 23, namely: "...“minimal risk” research is defined as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research”.”

4.3 Vulnerable Population

The concept of ‘**vulnerability**’ as it applies to research participants refers to those factors that may compromise the ability of the individual to make a free and informed choice regarding participation. Factors that affect decisional capacity such as extreme youth or age, or mental incapacity (permanent or temporarily induced by medication or illness), and circumstances that may impair or limit freedom of a participant’s choice (e.g. incarceration, influential relationships) are the two main sources of vulnerability. Children, adults with mental disability and prisoners are typical examples of vulnerable populations. Others may, however, be vulnerable with respect to the particular circumstances dictated by a given research project (e.g., students may be considered vulnerable with respect to participation in faculty research).

5. DALHOUSIE’S HUMAN RESEARCH ETHICS REVIEW SYSTEM (HRERS)

5.1 Structure and Functions

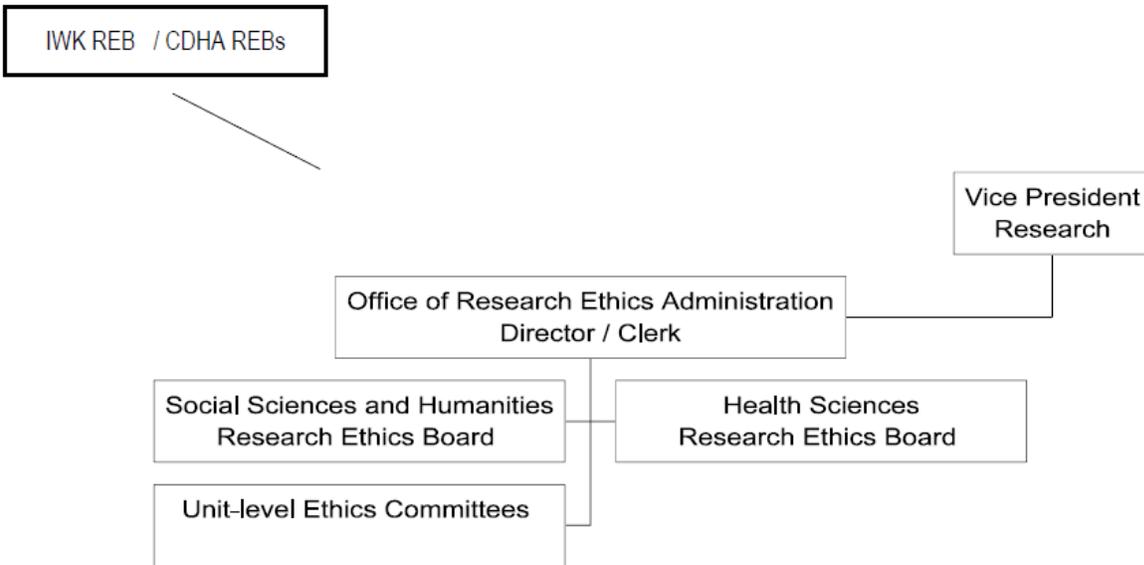
The University’s HRERS consists of the following structural elements

- Vice President Research
- Research Ethics office
- two University Research Ethics Boards
- Departmental Research Ethics Committees
- arrangements with affiliated Health Science Centres (in particular the CDHA and IWK)

Its main functions include:

- development and maintenance of policies and procedures
- administration / documentation of the ethics review process
- management of access to research funding
- education / training of REB members

- education of researchers



DALHOUSIE'S HUMAN RESEARCH ETHICS REVIEW SYSTEM

5.2 Responsibility

5.2.1 Responsibility of the Administration

The Vice President Research has senior administrative responsibility for oversight of the HRERS. This includes the allocation of resources to support the ethics review process, and ensuring that policies and procedures are in place to guide the process.

Responsibility for the development and maintenance of appropriate arrangements with Dalhousie's affiliated Health Science Centres also falls to the Vice President Research.

Academic administrators, such as Deans, Directors and Department Chairs or Heads, have a responsibility for the ethical conduct of research carried out within their jurisdiction. Additionally, they have a duty to create a climate for ethical practice of such research by promoting awareness of this policy and the requirement for ethics review to researchers. Where students are engaged in research, this responsibility should extend to ensuring that students are adequately instructed in the principles and implementation of research ethics, and that the appropriate review mechanisms are in place at the local level (see Section 5.2.4 Unit-level Research Ethics Committees).

Academic administrators are also responsible for ensuring that appropriate individuals are identified to serve as Research Ethics Board members where there is designated

representation from their Department or Faculty. The process of recruitment of REB members is conducted in consultation with the Director, Research Ethics to ensure the necessary representation of disciplinary expertise and research experience on the Board. In selecting individuals to serve on the University REBs, academic administrators should be mindful of the significant workload that participation on the REBs entails and ensure that this is appropriately acknowledged.

5.2.2 Responsibility of Research Ethics

Research Ethics is responsible for the overall administration and documentation of the ethics review process and for management of the two University Research Ethics Boards. The office is also responsible for the development of procedures to guide the review process in consultation with the two Research Ethics Boards. The major activities of the office include:

- recruitment and orientation of Board members
- management and documentation of Board meetings and the review process
- development and promulgation of ethics review guidelines and forms
- provision of guidance to researchers in the preparation of ethics submissions
- conducting educational events for researchers and Board members
- liaising with other administrative units in relation to the release of research funding
- liaising with Departmental Research Ethics Committees
- liaising with affiliated Research Ethics Offices (CDHA / IWK)
- liaising with external agencies in relation to ethics review
- acting as initial contact point for complaints from research participants

The Director, Research Ethics also sits as an ex-officio member of both University Research Ethics Boards.

5.2.3 Responsibility of the University Research Ethics Boards

Dalhousie has two University REBs: the Health Sciences REB and the Social Sciences and Humanities REB that operate according to Terms of Reference established by the Vice President (Research), in consultation with the Director (Research Ethics). As stipulated by the TCPS these Boards have the authority to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants that is conducted within, or by members of, the institution. Furthermore, the University must respect the authority delegated to the REB and decisions of the REB cannot be overridden except by the University Research Ethics Appeal Board, in accordance with the process set out in Section 14.

The two University REBs are responsible for the review of:

- faculty, staff and postdoctoral research

- student research (with the exception of course-based research that poses no greater than minimal risk to participants and does not involve a vulnerable population); this includes graduate and undergraduate thesis research.

when it is conducted within the jurisdiction, or under the auspices, of the University. This includes both initial review and ongoing review or monitoring as necessary. In addition, they have general oversight responsibility for research that receives ethics review by a Unit-level Ethics Committee.

Members of the Board are appointed by the Vice President Research, acting upon recommendations by the relevant Deans, Directors, Heads or Chairs.

5.2.4 Unit-level Research Ethics Committees

Academic units (i.e. Departments or Schools within Faculties) may review some research that is carried out by students as part of academic course research, as described below (ref. TCPS Article 6.12). It is expected that Departments or Schools whose students undertake human participant research as part of their education will

- establish a standing ethics review committee that will function throughout the academic year
- require that members of this committee are familiar with, and apply, the TCPS and this policy
- ensure that students undertaking human participant research activities receive the appropriate instruction in research ethics
- ensure that all human participant research activity being undertaken by students receives the appropriate review
- ensure that no faculty member reviews his/her own students' work
- submit a timely report to Research Ethics (per TCPS, p. 79) for distribution to the University REB on all student research projects reviewed by the Unit-level Ethics Committee
- report any complaints or difficulties raised by research participants involved in student research projects to Research Ethics immediately.

Since any student research that is considered to pose greater than minimal risk to participants or involves a vulnerable participant population must be reviewed by a University REB, Unit-level Research Ethics Committees should refer those projects to Research Ethics for allocation to a University REB.

Unit-level ethics review cannot be used when a student is carrying out a faculty member's research project. Such projects must be reviewed by a University REB.

Undergraduate student research

All research that is carried out by undergraduate students, including undergraduate thesis research, must receive ethics review. Course-based research may be reviewed by a Unit-level Research Ethics Committee where the research poses no greater than minimal risk to participants and where participants are not characterized as a vulnerable population. All other undergraduate student research must be reviewed by a University REB.

Graduate student non-thesis research

Graduate student research that is conducted as part of academic course-work must be reviewed. This review may be carried out by a unit-level Research Ethics Committee where the research poses no greater than minimal risk to participants and where participants are not characterized as a vulnerable population.

All graduate student research that is conducted as part of academic course-work and that exceeds minimal risk or involves a vulnerable population must be reviewed by a University REB.

All graduate thesis research, regardless of risk level, must be reviewed by a University REB.

5.2.5 Responsibility of Researchers

Researchers undertaking human participant research have the primary responsibility to ensure that their research is carried out in an ethical manner. They are responsible for the protection of both the rights and the welfare of those who participate in their research.

Researchers must be familiar both with this policy and with the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans. In addition, it is the responsibility of researchers to obtain ethical approval prior to conducting human participant research, as stipulated in this policy and described in the guidance documents produced by Research Ethics that relate to the ethical review process.

All members of a research team who conduct research under the supervision of others are also responsible for the ethical conduct of the research undertaken by them. The Principal Investigator should ensure that members of a team under his/her supervision are aware of this responsibility, and of the relevant policies that relate to it. The Principal Investigator must also ensure that those involved in the research under his/her supervision have adequate training and competence to carry out their duties.

5.2.6 Responsibility of Supervisors of Graduate Student Researchers

While graduate students are considered to be Principal Investigators with respect to their own research, all graduate student research must be supervised by a faculty member who is responsible for the ethical conduct of that research. Supervisors must ensure that their students have adequate training both in the methodology of their research and in the ethical principles and policies that must be observed in carrying it out. Familiarity with University policies and guidelines is considered a minimum in this respect.

The Supervisor must also ensure that a student is aware of his/her responsibilities as a researcher and that prior to conducting the research he/she submits it for ethics review. Where this research is a thesis project this review is conducted by one of the two

University REBs. Supervisors are required to review the ethics application to ensure it is of appropriate quality and completeness prior to signing the “Confirmation of Supervisor’s Review” form that must be submitted with the student’s application. Because theses are published documents, the plan for management and retention of thesis data must be consistent with the University Policy on Scholarly Integrity (or successor policies).

Where graduate students are conducting research within the context of academic course work, supervisory responsibility rests with course instructors who must ensure that appropriate ethics review is sought, initially consulting with the standing Unit-level Research Ethics Committee in this regard.

5.2.7 Responsibility of Supervisors of Undergraduate Student Researchers

Supervisors of undergraduate students engaged in undergraduate thesis, or independent research projects must ensure that their students conduct the research in an ethical manner and also have sufficient training and competency to do so. The Supervisor must also ensure that the research is reviewed at the appropriate level, initially consulting with the standing Unit-level Ethics Committee in this regard, prior to its being initiated.

Where undergraduates are engaged in non-thesis research, supervisory responsibility rests with course instructors. Instructors must also ensure that an appropriate review is carried out, initially consulting with the standing Unit-level Ethics Committee in this regard.

5.2.8 CDHA and IWK Research Ethics Committees

In order to minimize duplication of ethics reviews, a *Research Ethics Review Cooperation Agreement* was created between the University, the IWK Health Centre and the Capital District Health Authority, which became effective as of June 1, 2006. The Agreement describes the jurisdictional criteria that determine which institutional Research Ethics Board or Committee will review research projects carried out by faculty, staff and students. This is especially important for those individuals who may hold appointments in more than one institution or members of the University community who may wish to conduct research involving health center patients, facilities or data.

Those projects that are reviewed by either the CDHA or the IWK, under the terms of the Cooperation Agreement, do not additionally require review by a University REB. However, for projects where ethics review is conducted by a CDHA or IWK Research Ethics Board (or Committee), but where research funding is held at the University, written proof of the ethics approval must be provided either to Research Services or to Research Ethics in order for access to this funding to be given.

The Cooperation Agreement extends only to the three named institutions; human participant health research conducted by University faculty, students or staff, at any other health facility or hospital, must be reviewed by a University REB.

6. CRITERIA FOR ALLOCATION TO A UNIVERSITY BOARD

Article 6.4 of the second edition TCPS stipulates that members should have broad expertise in the areas of research that are covered by the REB. As such, it is necessary to provide criteria to guide the allocation of research projects to the appropriate Board (i.e. where the necessary expertise resides to review the research). The following approach has been adopted by the University REBs.

The determination of which Board will review a particular project is done according to the subject matter and population of the study (not the Faculty or Departmental affiliation of the researcher). The Health Sciences REB deals with medical, dental or physical/mental health-related topics, while the Social Sciences and Humanities REB deals with social, behavioural and cultural research in non-medical contexts. Because of the differing make-up of the Board membership, projects where the review requires clinical expertise, or that involve a population of participants who are characterized by a clinical condition, should be submitted to the Health Sciences REB.

7. MULTI-CENTRE/MULTI-SITE RESEARCH

Some research is carried out collaboratively by teams of researchers holding appointments at different institutions. Where University researchers are involved in such projects, Research Ethics will direct researchers as to what kind of an ethics submission should be made.

8. REB OPERATIONAL POLICIES AND PROCEDURES

Research Ethics is responsible for documenting and promulgating the detailed practices and procedures that guide the operation of both University REBs, and the ethics review process, in the form of guidance documents and forms for researchers. These are updated from time to time and are made available both in hard-copy and on-line through the Research Ethics webpage.

9. CONFIDENTIALITY

The desirability of transparency and accountability with respect to the operation of the REBs must be balanced by considerations regarding confidentiality of proprietary information contained in research proposals, and the need to encourage free discussion at REB meetings. Normally, regular REB review meetings and other Board meetings are only open for attendance by REB members and support staff. However, researchers may be invited to meetings from time-to-time to expedite discussions of particular protocols. Meetings with the REB may be requested by researchers; however, these will only be arranged where circumstances warrant a face-to-face

meeting.

Minutes of the meetings are only accessible to Board members and staff; or other representatives of the University authorized by the Vice President Research.

Documentation submitted by researchers to the Research Ethics and REB for ethics review shall be considered confidential.

10. EDUCATION

10.1 Education of REB members

The complexity of conducting an ethical review demands that University REB members gain an adequate familiarity with the relevant policies and procedures. This is accomplished in a number of ways:

- required completion of the online TCPS 2 Tutorial (Course on Research Ethics) by all REB members. Certificates of completion are filed with Research Ethics.
- provision to REB members of a binder containing copies of the TCPS, University Guidelines, other relevant policy documents (e.g. *Psychology Department Policy on the Student Subject Pool*, *Nova Scotia Child and Family Services Act*, *Nova Scotia Adult Protection Act*)
- provision to REB members of *The Handbook for REB Members*
- attendance of new Board members at initial Board meetings as an observer
- notification of other local educational opportunities (e.g. NCEHR workshops, Health Law Institute Seminars)

In addition, other educational opportunities may be provided through Research Ethics, independently or in collaboration with the CDHA and IWK as resources permit.

10.2 Education of Researchers

Education of researchers in the principles, policies and procedures relating to research ethics and research ethics review is the responsibility of Research Ethics. This objective is achieved in a number of ways: through presentations and workshops, provision of guidance documents, and individual consultation with the Director and staff of Research Ethics.

Research Ethics maintains a website where current copies of relevant documents and forms are made available to researchers.

11. NON-COMPLIANCE WITH THE POLICY

Instances of non-compliance with policies or procedures regarding human participant research

should be brought to the attention of the Director, Research Ethics, who will notify the Chair of the appropriate REB. Where such an instance is deemed to be of relatively minor significance, the Director and Chair will work with the researcher to resolve and remediate (as necessary) the situation. Where no resolution is attained, or where circumstances warrant, the REB will refer the matter to the Vice President Research.

12. US DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF HUMAN RESEARCH PROTECTIONS (OHRP) FEDERAL WIDE ASSURANCE STATUS FOR DALHOUSIE UNIVERSITY

To be eligible to hold funding from the United States Department of Health and Social Services (DHSS), such as National Institutes of Health (NIH) grants for human participant research, the University must obtain a Federal Wide Assurance number. This is the responsibility of Research Ethics, and is renewed on an annual basis.

13. REGISTRATION OF CLINICAL TRIALS

Registration of clinical trials is the responsibility of the trial sponsor. For those trials that are investigator initiated, or where the University is the legal entity that has responsibility for the conduct of the trial, the University is the sponsor. In such circumstances, researchers are responsible for contacting Research Ethics, who will carry out the registration process on behalf of the University.

14. RESEARCH ETHICS PROTOCOL APPEAL PROCESS

Mandate

In accordance with the requirements of the Tri-Council Policy Statement *Ethical Conduct for Research Involving Humans*, the University must establish an official appeal mechanism for research protocols that have been reviewed and rejected by either of the two University REBs. To meet this objective, it is the responsibility of the Vice President Research to establish the Dalhousie University Research Ethics Appeal Board (the Appeal Board) as a standing committee.

The Appeal Board Chair is appointed by the President of the University or his delegate. Appeal Board members are similarly appointed by the President in consultation with the Vice President Research, and the Appeal Board Chair.

Membership

The Appeal Board will include at least five members, including both men and women, of whom

- at least two members have broad expertise in human participant research
- at least one member is knowledgeable in ethics

- at least one member is knowledgeable in law
- at least one member has no affiliation with the institution but is recruited from the community served by the institution

In addition:

- Appeal Board members shall not be selected from among the current Chairs or members of the University REBs to avoid potential conflict of interest
- Quorum is 5 members, and must include the ethics specialist, the community member and the legal specialist
- Terms of membership are 3 years. Members may be reappointed with due consideration to the evolving requirements of the Appeal Board. Terms of members may be staggered to allow for continuity within the Appeal Board over time
- Administrative support to the Board is provided through Research Services, but should not include members Research Ethics.

Grounds for an Appeal

If a researcher has requested and received a reconsideration of a REB decision and is not satisfied with the decision of a University REB to reject his/her protocol, the researcher has the right to appeal a University REB's decision. The Appeal Board will review negative REB decisions launched for procedural or substantive reasons (breaches of the review process or any elements of the REB decision that are not supported by the TCPS) (per Article 6.20).

Appeal Procedures

1. A Researcher requesting an appeal of a protocol rejection (the appellant) will do so in writing to the Chair of the University Research Ethics Appeal Board.
2. The appellant will be provided with a copy of all the documentation upon which the REB based its original decision to reject the protocol, including any external reviews that may have been solicited by the REB in the evaluation of the project, along with a copy of the main Research Ethics file.
3. The Appellant will then provide a written submission to the Chair describing the basis for the appeal.
4. The Chair will determine whether the allegation raises an appropriate ground for an appeal. The decision of the Chair regarding the eligibility for appeal is final.
5. If, in the opinion of the Chair, the allegation raises an appropriate ground for an appeal, the Chair will forward a copy of the appellant's written submission to the Director, Research Ethics for response, and will convene the Appeal Board.
6. Copies of all documentation considered by the REB relating to the review process

will be provided to members of the Appeal Board including, but not limited to, any external reviews that might have been solicited in the evaluation of the project, along with a copy of the main Research Ethics file associated with the project. In addition a copy of the written submission of the Appellant and the Director, Research Ethics' response to this submission will be provided to the Appeal Board members.

7. The Appeal Board will meet with the appellant, the Director, Research Ethics and other persons deemed relevant to the discussion. Following the meeting, the Appeal Board will deliberate in camera. If external opinions are sought and received by the Appeal Board a copy will be provided to the Appellant and the Director, Research Ethics for comment. If necessary, more than one such meeting may be held, prior to the Appeal Board rendering a decision.
8. The Appeal Board has the authority to make the following determinations:
 - 1) was a substantive error made by the REB in applying the ethical principles supported by the TCPS made with respect to the original review and rejection of the protocol?
 - or
 - 2) was there a substantial failure in the REB review process?

If not, the original finding of the REB is upheld.

If so, the Appeal Board must make a further determination, namely, does the protocol meet the requisite ethical standards of the TCPS and the Institution such that it may receive ethics approval?

If so, the Appeal Board may grant ethics approval of the protocol.

If not, the Appeal Board must reject the protocol.

9. The Appeal Board will undertake its deliberations in a timely fashion and communicate its decision in writing to the REB that originally rejected the project, the Principal Investigator of the project that was rejected, and Research Ethics. In doing so it must provide reasons for either overturning or upholding the REB's original decision.
10. After reaching a decision, the Appeal Board will submit a written report to the Vice President Research, copied to the Chair of the REB and the Principal Investigator. This report will address the Appeal Boards' findings both with respect to the REB's conduct of the original review and with respect to final ethical approval of the protocol.

Authority

Decisions of the Appeal Board are final.