

# **McMaster Research Ethics Board Guidelines and Researcher's Handbook**

## **A. THE ROLE AND RESPONSIBILITIES OF THE RESEARCHER AND THE RESEARCH ETHICS BOARD**

### **1.0 McMASTER'S POLICY and MANDATE**

Research involving human participants is premised on a fundamental moral commitment to advancing human welfare, knowledge and understanding. As a research intensive institution, McMaster University shares this commitment in its promotion of responsible research.

The fundamental imperative of research involving human participation is respect for human dignity and well-being. To this end, the University endorses the ethical principles cited in the [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans](#).

McMaster University has mandated its Research Ethics Boards to ensure that all research investigations involving human participants are in compliance with the Tri-Council Policy Statement. The University is committed, through its Research Ethics Boards, to assisting the research community in identifying and addressing ethical issues inherent in research, recognizing that all members of the University share a commitment to maintaining the highest possible standards in research involving humans.

### **2.0 McMASTER UNIVERSITY RESEARCH ETHICS BOARD (MREB)**

The McMaster Research Ethics Board was created by the President's Council in 1974. It was charged with the responsibility for reviewing all non-medical research proposals involving human subjects, and with the responsibility of educating the University community and setting University policies with respect to research involving human subjects.

Medical Research involving human subjects is carried out under the guidance of two research ethics boards; the joint Hamilton Health Sciences/Faculty of Health Sciences Research Ethics Board, and the St. Joseph's Healthcare Ethics Research Board. McMaster University and its affiliated hospitals have adopted virtually identical policies for research involving humans.

[McMaster University Policy Statement for Research Involving Human Participants](#).

### **3.0 RESPONSIBILITIES FOR PROTECTING HUMAN SUBJECTS**

#### **3.1 The Principal Investigator**

As the individual responsible for the implementation of research, the principal investigator bears direct responsibility for ensuring the protection of every research subject. The responsibility starts with protocol design, which must minimize risks to subjects while maximizing research benefits. The Principal Investigator must ensure that all members of the research team comply with the requirements of the research ethics board, and that consent of participants is informed and freely given.

#### **3.2 The McMaster Research Ethics Board (MREB)**

The McMaster Ethics Review Board is formally constituted to review and monitor all non-medical research involving human subjects conducted under the auspices of the University.

The Board is an autonomous entity whose primary responsibility is ensuring the safety and well-being of all human subjects involved in research programs carried out by McMaster researchers.

[McMaster Research Ethics Board Terms of Reference](#)

### **3.3 The University Administration**

McMaster University administration, under the direction of the Vice-President for Research, is ultimately responsible for overseeing the protection of human subjects involved in research programs conducted by the University. The Administration is responsible for ensuring that sufficient resources are allocated to the McMaster University Research Ethics Board to allow it to perform its review, record-keeping and monitoring functions.

## **4.0 TYPES OF RESEARCH THAT REQUIRE REVIEW**

All research involving human subjects requires review and approval by the Research Ethics Board, prior to commencement of the research.

Research is defined as a systematic investigation to establish facts, principles or generalizable knowledge. [\[TCPS, Article 1.1a\]](#)

Human subject has been defined as “a living individual about whom an investigator conducting research obtains data either through intervention or interaction with the individual or through identifiable private information.

Research involving human remains, cadavers, tissues, biological fluids, embryos or fetuses are also subject to review by the Research Ethics Board. [\(TCPS, Article 1.1b \)](#)

Research requiring review includes any research that:

- Is conducted by University faculty, staff or students;
- Is performed on the premises of the University;
- Is performed with or involves the use of facilities or equipment belonging to the University;
- Involves University students, staff or faculty;
- Satisfies a requirement imposed by the University for a degree program or for completion of course of study;
- Is certified by a dean or department head to satisfy an obligation of a faculty appointment at the University, or
- Is conducted by or under the direction of any employee or agent of the University in connection with his or her institutional responsibilities.

**The opinion of the Research Ethics Board should be sought whenever there is any doubt about the whether the research requires review.**

## **5.0 EXEMPTIONS TO THE REVIEW PROCESS**

The following areas are identified by the Tri-Council Policy statement as being exempt from review and approval by a Research Ethics Board

Quality assurance studies, performance reviews or testing related to assessing performance of employees or students within normal educational or employment requirements provided that the study contains no element of research. [\(TCPS Section 1, Article 1.1\)](#)

Research about a living individual involved in the public arena, or an artist, when the research is based exclusively on publicly available information, documents, records, works, performances, archival materials or third party interviews. If the individual(s) are approached directly for interviewing or for access to private papers, ethics review is required to ensure that the request for the interview or access to the private papers is made in accordance with ethical and professional standards. [\(TCPS, Section 1, Article 1.1\)](#)

Naturalistic observation of participants where it can be expected that the participants are seeking public visibility, such as political rallies, demonstrations or public meetings. [\(TCPS Section 2, Article 2.3\)](#)

## **6.0 CRITERIA USED BY THE BOARD FOR REVIEW**

The following criteria will be considered by the Board when reviewing an application to involve human participants in research:

1. The overall level of risk to human subjects
2. Whether the risks to participants are minimized by using procedures /methods which are consistent with sound research design but which do not expose participants to unnecessary harm
3. Whether the risks are reasonable (balanced) in relation to the anticipated benefits to the subjects.
4. Whether the protocol provides for informed and freely volunteered consent, including providing for withdrawal from the research
5. Whether there is adequate protection of the privacy of the subjects and the confidentiality of the information/data being obtained
6. Whether the selection and recruitment of the participants is inclusive and appropriate in relation to the human subjects and to the research
7. Whether appropriate provisions are made for the on-going monitoring of the participant's welfare
8. Whether the purpose of the study is fully outlined, or if deception is necessary, there is appropriate debriefing of the participants
9. Whether there is any conflict of interest which should be considered, and if so, whether appropriate mechanisms for handling the conflict have been put into place

### **6.1 Additional criteria for review**

The Research Ethics Board may consider additional criteria where it is appropriate and in keeping with their mandate.

## **7.0 LEVELS OF REVIEW**

### **7.1 The Principle of Proportionate Review**

The Research Ethics Board has adopted a proportionate approach to ethics assessment, based upon the general principle that the more invasive the research, the greater should be the care in assessing the research. [\[TCPS Section 1, D, Article 1.6\]](#)

Based upon the principle of proportionate review, the McMaster University Research Ethics Board reviews applications for research involving human subjects at the following three different levels:

- 1) Full Board Review
- 2) Expedited Review

3) Review by a Student Research Ethics Committee (SREC)

4) Executive Review

## **7.2 Full Board Review**

Review by the fully convened McMaster Research Ethics Board is the default requirement for all research involving human participants, unless the proposed research meets the criteria for Expedited Review or Review by a Student Research Ethics Committee.

Research that requires full committee review includes:

- Research that involves children or other vulnerable populations;
- Research that involves experimental drugs or devices;
- Research that involves invasive procedures;
- Research that involves deception
- Research that involves sensitive questions or information about AIDS

All research which involves greater than minimal risk will be reviewed by the full board at a regularly constituted meeting.

## **7.3 More Than Minimal Risk**

The standard of minimal risk is defined as follows:

If potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that related to the research then the research can be regarded as within the range of minimal risk.

Minimal risk in research proposals is assessed through one of three methods:

- 1) The Chair of the MREB reviews the proposal and assesses whether subjects will incur greater than minimal risk.
- 2) The Secretariat (ethics administrative personnel) sends the proposal to two reviewers of the MREB for an initial assessment of the level of risk. If either of these two reviewers identify factors within the research proposal which indicate the potential of greater than minimal risk, the proposal will be reviewed by the full board at a regularly constituted meeting.
- 3) A Student Review Ethics Committee reviews the proposal and the committee identifies factors within the research proposal which indicate the potential of greater than minimal risk.

## **7.4 Expedited Review**

Research proposals meet the criteria for expedited review where:

- a) The proposal involves no more than minimal risk;
- b) The proposal is a replication of a previously approved protocol with significant revisions.

Protocols which are conducted by expedited review are assessed by the following method:

Where the proposal involves no more than minimal risk, or involves significant revisions it will be sent to two MREB members for review and the reviewers will provide a written assessment of the level of risk and any other ethical issues arising from their review.

### **7.5 Review by a Student Research Ethics Committee**

McMaster University has established a number of Student Research Ethics Committees for the review of course, individual and honours thesis research by undergraduate students. The Student Research Ethics Committees review research conducted by undergraduate students when the research meets all of the following criteria:

1. The research is conducted as part of an undergraduate course, offered by the University
2. The research involves no more than minimal risk
3. The research is not part of a faculty members' research program already subject to review by any other research ethics board.

### **7.6 Course-Based Research**

Undergraduate courses which include class projects and activities designed to develop research skills require the filing of a separate "Request for Approval of Course-Based Research Projects" form which is reviewed by the Student Research Ethics Committee where applicable. Separate Guidelines for Course-Based Projects may be found at:

[http://www.mcmaster.ca/ors/ethics/faculty\\_guidelines\\_courses.htm](http://www.mcmaster.ca/ors/ethics/faculty_guidelines_courses.htm)

### **7.7 Executive Review**

Research proposals meet the criteria for Executive review, by the Chair of the MREB only, where:

1. The protocol has previously been approved by another Research Ethics Board; the Chair of the MREB may issue a clearance certificate based upon the Chair's review of the information included in the application to the other institution, including all supporting documentation.
2. The protocol is an application for approval "in principle" to allow for activities not involving human participants, in accordance with the Memorandum of Understanding.
3. The protocol is a replication of a previously approved protocol without significant changes.

## **8.0 DECISION MAKING BY THE MREB**

Applications for review of non-medical research involving human subjects may be:

1. Approved without questions or request for modification
2. Approved subject to clarification and/or modifications;
3. Deferred, pending receipt of additional information or major revisions; or
4. Disapproved

The MREB encourages ongoing discussion with researchers prior to the submission of applications for review and during the review process. The MREB will strive to reach consensus of all members in respect to its decisions concerning applications for review. In the event that consensus cannot be reached, the decision of the majority of the Board shall prevail.

## **9.0 APPEALS**

When a researcher and the MREB cannot reach agreement, the decision of the MREB may be appealed by the researcher to the McMaster University Research Ethics Appeal Board.

### [McMaster University Policy for Appeals of Research Ethics Board Decisions](#)

Appeals will be heard by a panel of four members of the Appeal Board, selected by the Chair or Vice-Chair of the Appeal Board. The Chair of MREB may not serve on an appeal panel reviewing an MREB decision.

### [Terms of Reference for the McMaster University Appeals of Research Ethics Board](#)

The Appeal Panel will conduct a full review of the application and associated documentation, which may include the original ethics application, the original research ethics board decision, all subsequent written communications, documents and records, including REB minutes pertaining to the submission, a copy of a research proposal for funding of the proposed research, if applicable, relevant references or copies of pertinent guidelines, internal and external policies and legislation.

The Appeal Panel will render a final and binding decision by majority vote, which may either

- 1) Uphold the original decision;
- 2) Modify the original decision or
- 3) Impose specific conditions for approval of the project.

In the event a majority vote is not rendered, the Chair or the Vice-Chair shall cast the deciding vote.

The Appeal Panel will communicate its decision in writing, with reasons, to the researcher, the Chair of the McMaster Research Ethics Board, and to all members of the Appeal Board.

The Appeal Panel will provide advice to the Research Ethics Board in the event of the modification of the original decision of the Board, or in the event of the imposition of specific conditions for approval of the project.

### [Guidelines for the Appeal of Research Ethics Boards' Decisions](#)

#### **9.1 Appeals from Student Research Ethics Committee decisions**

Appeals from a decision of a Student Research Ethics Committee shall be made to the McMaster University Research Ethics Board, and the decision of the MREB when rendered, shall be final.

## **10.0 MULTI-CENTRED and INTER-INSTITUTIONAL REVIEW**

### **10.1 Research that requires review**

All research as defined in article 4.0 in these guidelines, is subject to ethics review by the McMaster University Ethics Review Board.

### **10.2 Research in other jurisdictions or off of university premises**

All research conducted by or involving McMaster faculty, students or employees or agents, conducted in other jurisdictions or off of University premises must comply with the research ethics policy at McMaster, and at the ethics board or through the equivalent board, committee or process at the additional location or institution, provided that there is such a process reasonably available.

### **10.3 Approval by other research boards**

Research protocols which have been reviewed and approved by research ethics boards other than those of McMaster University, may be subject to Executive Review, by the Chair of the MREB, provided that the MREB is provided with the particulars of the approval of the other institution, including but not limited to:

- The application for ethics approval
- The consent form and letter of information if applicable
- The advertising / recruitment material
- The debriefing information sheet

### **10.4 Multi-institutional research**

Multi-centre research may include:

- a research project conducted at more than one institution or organization either by the same or different researchers;
- a research project conducted jointly by researchers affiliated with different institutions or organizations; and
- a research project being conducted by a researcher who changes affiliation from one institution or organization to another.

Where research involves a number of different institutions and researchers, McMaster retains accountability for the research within its institution.

In order to minimize unnecessary duplication of review, the research ethics board needs to be advised as to whether the same protocol has been reviewed by another research ethics board, including reviews conducted outside of Canada.

In order to facilitate coordination of the ethics review of a multi-centred study, the researcher shall where appropriate, distinguish between core elements of the research which cannot be altered without invalidating the pooling of data from the participating institutions – and those elements that can be altered to comply with McMaster's local requirements. The MREB will communicate any concerns that they may have with other research ethics board's reviewing the same project.

## **11.0 MONITORING AND COMPLETION**

Research at McMaster is subject to ongoing review, proportionate to the risk involved in the research. Researchers are expected to propose to the Research Ethics Board the continuing review process which they feel is appropriate for their research. McMaster expects that all researchers will conduct their own monitoring of their research studies.

Researchers are expected to advise the Research Ethics Board annually, concerning the status of their research, and to advise the Research Ethics Board as soon as the research has been completed.

[\[TCPS Article Section 1 F, Article 1.13\]](#)

## **12.0 ADVERSE EVENTS**

Faculty investigators and supervisors must immediately report any adverse effects (undesirable and unintended, although not necessarily unexpected events) arising out of the research. Reports should be directed to the Chair of the Research Ethics Board and to the Secretariat, and they should be effected as soon as practically possible subsequent to their occurrence, but in no event later than 3 days of their occurrence.

## **13.0 NON-COMPLIANCE**

Researchers should view protection of research participants and compliance with research ethics policies and guidelines as a matter of professional ethics, not as a matter of "compliance" with policy. Researchers should be aware that failure to comply with these guidelines and policies constitutes misconduct in research and that allegations of non-compliance shall be treated in accordance with the McMaster University Policy on Research Ethics. Data collected prior to research ethics approval may be required to be destroyed, and may not be utilized in the context of any publication.

## **B. THE PRINCIPLES OF REVIEW**

### **14.0 RISKS AND BENEFITS**

The Research Ethics Board will determine whether the risks of the research are reasonable in relation to the anticipated benefits (if any) to the human subjects and the importance of the knowledge that may reasonably be expected to result. Foreseeable harms should not outweigh anticipated benefits. [\[TCPS Section C\]](#)

#### **14.1 Risks**

Research participants must not be subject to unnecessary risks of harm, and their participation in research must be essential to achieving scientific and societally important aims. The Research Ethics Board is concerned about risks of:

1. Physical harm
2. Psychological or emotional harm
3. Injury to reputation or privacy; and
4. Breach of any relevant law

The Research Ethics Board is concerned about risks to:

1. The subjects involved
2. Clearly identifiable third parties
3. The researcher personally and any staff involved
4. Broader cultural, ethnic and national interests

#### **14. 2 Benefits**

In all research involving human participants, there is a duty not only to benefit others, but to maximize the net benefits of the research. Benefits include:

1. Specific advantages to participants to third parties or to society or a segment thereof
2. Any general increase in human knowledge
3. Increased knowledge of the researcher

### **14.3 Risk Assessment**

The Research Ethics Board must determine that risks to participants in all research are minimized by the use of procedures that are consistent with sound research design and which will not expose the subjects to unnecessary risks. In keeping with this principle, the Research Ethics Board will examine the research plan, including the research design and methodology, and including the risk that the research is so poorly designed or is so lacking in statistical power that meaningful results cannot be obtained.

The Research Ethics Board will also consider the professional qualifications and resources of the research team in its assessment of risk.

### **14.4 Guidelines for the use of high risk test instruments**

Guidelines for Confidentiality and Follow-up for Research Anticipated to Reveal Information about Risk of Serious Harm to Self or Others

These guidelines apply to test instruments that can provide a valid indication that an individual is at very high risk of seriously harming himself/herself or others, and when the likely occurrence of such an event can be anticipated in advance. They also apply to qualitative projects where the revelation of such information can be anticipated. These guidelines should be adjusted to take account of the particular research context.

1. Review the data immediately.
2. When possible and appropriate, the review should keep the identification of worrisome cases at arm's length from the participant/researcher relationship and any participant/teacher relationship. This could involve review by a third party who is not part of the research team, or consultation of the identifying key only by the third party.
3. Establish procedures in advance for follow-up with highly worrisome cases, including the identification of a qualified individual who is available immediately when needed.
4. Keep the data confidential, but not anonymous.
5. When obtaining informed consent, clearly state the limits to confidentiality and the procedures that will be followed in the event that a person's data indicate that he or she is at very high risk of seriously harming himself/herself or others.
6. When stating the limits to confidentiality, be clear that the only information to be shared is that which concerns the risk of harm to self or others.
7. When applicable to a specific protocol, provide all participants with information about where and how to access help about problems that can be anticipated.
8. In the event a participant withdraws from a study, follow these guidelines if sufficient information has been gathered to identify risk and describe this intended practice in any letter of information and consent form.

## **15.0 INFORMED CONSENT**

### **15.1 Elements of informed consent**

Informed consent is a process whereby a choice is made:

- By a competent person
- On the basis of adequate information concerning the nature and foreseeable consequences of the research and all available alternatives; and
- Without controlling influences such as “force, fraud, deceit, duress, over-reaching or other ulterior form of constraint or coercion” ([Nuremberg Code](#))

The informed consent process is different from the consent form. It involves meeting with a potential subject, finding out whether he or she is capable of giving consent, and discussing the purpose, risks, and benefits of participation. Obtaining informed consent is not just giving a prospective subject a consent form and getting it signed. Researchers should strive to convey information to subjects, not merely disclose it to them.

## **15.2 Competence**

Competence means that a person is capable of making a morally and legally valid choice to participate in research. At the core, competence is the measure of the “fitness” of an individual to act or behave in certain situations. In the context of research, it means the mental ability to understand the nature and consequences of one’s acts, so as to be fit to make informed choices concerning participation in research protocols. Competence is determined by both the situation and the person’s understanding of it. A prospective research participant may be incompetent in certain situations but competent in others.

To be considered competent to make a valid choice, prospective research participants should be able to understand and appreciate:

- the nature and purpose of the research in question;
- why they, as opposed to others, are being selected and asked to participate;
- the fact that the suggested intervention is for research purposes;
- the relevant elements of uncertainty about the protocol;
- what participation in the particular research protocol means for the participant;
- whether or not the intervention may provide any direct personal benefit to them;
- how the consequences of a decision to participate or not to participate will affect their own current and future lives;
- that they will be free to withdraw from participation at any time during the course of the protocol;
- that a decision not to participate or to withdraw from participation will not adversely affect their care,
- any conflict of interest on the part of the person recruiting the participants or conducting the study.
- the confidentiality of any records that identify the subject;
- for research that involves physical contact or physical activity, whether compensation or medical treatment will be viable if the subject is injured and where to get further information about this;
- who can answer questions about the research, including the principal investigator and a neutral third party who can explain the rights of research subjects

## **15.3 Disclosure of Information**

Informed choice means a choice based upon all relevant information concerning the proposed research. The researcher must provide information concerning the purpose and nature of the research, the potential harms and benefits, and the process of research participation, however, the prospective research participant should not be overwhelmed with minutiae. Research participants must be provided with specific information concerning confidentiality, reimbursement, the right not to participate, and the right to withdraw.

Information must be provided both verbally and subject to the limited exceptions noted below, in writing. The relevant information must be provided:

1. in the prospective research participant's preferred language.
2. in lay terms that avoid the overuse of technical terms
3. preferably in the first or second person (e.g., "you" or "your child")
4. at an appropriate level for the person's age and educational level
- 5 with descriptive accounts of relevant information

#### **15.4 Voluntariness**

For consent to be voluntary, free and genuine; an individual must have the opportunity to choose between consent and refusal, without undue interference, fear, constraint, compulsion or undue inducement. Undue influence includes physical duress; fraudulent misrepresentation, or promises of companionship, love or affection; economic incentives; emphasis on benefits over risks or burdens; or appeals to emotional weaknesses, loyalty to professional caregivers, or family solidarity.

Particular care must be taken in cases where the prospective research participants are students, or employees, or are dependent upon family or other caregivers, or where the prospective participants are in long-term care facilities.

Payments or incentives to participate must be reasonable and must not place undue pressure on research participants either to join or remain within a research project. Generally, participants may be reimbursed for out-of-pocket expenses, and lost wages and inconvenience, provided that these are at an appropriate (not inducing) rate.

#### **15.5 When to discuss participation**

Potential research participants should not be presented information all at once or only at the last minute. They should not feel rushed or coerced, and they should have the time to consult with others such as family, friends, religious advisors, about their participation. Participants need time, especially if the information is disturbing or particularly complex, to digest the information and come to terms with it.

#### **15.6 Consent in writing**

Evidence of free and informed consent by the subject should ordinarily be in writing. Where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek consent must be documented. In most cases, a written statement of the information conveyed in the consent process, signed or not, should be left with the subject. [\[TCPS Section 2 A. b\]](#)

#### **15.7 Alternatives to individual written consent**

Where individual written consent is inappropriate, either because of the nature of the research or the characteristics or culture of the proposed research participants, an alternative process for consent should be developed by the researcher and details of the alternative process should be submitted to the REB for review and approval or amendment.

#### **15.8 Exceptions and alterations to the normal requirements for informed consent**

The Research Ethics Board may approve a consent procedure which does not include, or which alters some or all of the elements of the normal requirements for informed consent, or waive the requirement to obtain informed consent, provided that the REB documents that:

1. the research involves no more than minimal risk to the participants;
2. the waiver or alteration is unlikely to adversely affect the rights and welfare of the subjects;

3. the research could not be practicably carried out without the waiver alteration;
4. whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation; and
5. the waiver or altered consent does not involve a therapeutic intervention

[TCPS, Section 2.1.(c)]

Consent is not required from organizations such as corporations or governments for research about their institutions. However, individuals who are approached to participate in a research project about their organization have the right to give free and informed consent. In particular, they should be fully informed about the views of the organization's authorities, if these are known, and of the possible consequences of participation.

When in doubt about an issue involving free and informed consent, researchers should consult the Research Ethics Board.

### **15.9 Feedback to participants**

As a general principle, participants in human research must be involved in a debriefing session at the end of their participation in the research. [TCPS Article 2.1(c)(iv)] Often, the debriefing can be quite simple and straightforward. In sensitive cases, researchers should provide a full explanation as to why participants were misled or given less than full disclosure, if that has occurred. In cases where the research may have impacted upon the psychological health or well-being of the participant, it may be appropriate to provide additional follow-up or to offer counseling or other types of assistance.

Immediate full debriefing may not be feasible in all cases, for example where data has been collected over an extended period of time, debriefing may have to be deferred until the end of the project. In some cases, it may be more appropriate to debrief the parents, guardians or authorized third parties, or an entire family or community.

## **16.0 SPECIAL RESEARCH CIRCUMSTANCES AND VULNERABLE POPULATIONS**

In the context of non-medical research, special research circumstances include the following:

- research involving children
- research involving those who are not legally competent to consent
- research involving mentally incompetent persons
- research involving "captive" groups such as employees, students, legal wards and the therapeutically dependent

### **16.1 Individuals who are not legally competent to consent**

Individuals who are not legally competent to consent to research or who are included in the definition of special research circumstances, shall only be asked to become research participants when:

- 1) the research question can only be addressed using individuals within the identified groups;
- 2) the research does not involve more than minimal risk without the potential for direct benefits for them;
- 3) the written consent of the personal having legal authority to give that consent is obtained, and
- 4) if a legally incompetent individual is capable of understanding the nature and consequences of the research, the researcher shall seek to ascertain the wishes

of the individual concerning participation, and the potential participant's dissent will preclude his or her participation, regardless of the authorization of the person having legal authority.

### **16.2 Research involving children and young people**

Research involving children and young people should only be conducted where:

- 1) the research question posed is important to the health and well-being of the children
- 2) the participation of children is indispensable to the purpose of the research
- 3) the study method is appropriate for children and young people; and
- 4) the circumstances in which the research is conducted provide for the physical, emotional and psychological safety of the child or young person

### **16.3 Research involving persons who are mentally incompetent**

Researchers should consider that those who are not competent to consent for themselves should not be automatically excluded from research which could potentially benefit them as individuals or the group that they represent. [\[TCPS Article 5.3\]](#)

An incompetent participant's withdrawal of consent must be respected, whether or not the participant was competent at the time of the withdrawal.

### **16.4 Authorized Legal Representative and Legal Age of Consent**

An authorized legal representative cannot consent to research that is not in the best interests of the person they represent.

In general, a potential research participant's next-of-kin cannot give a legally valid consent, unless they have been specifically authorized to take that role.

There are no clear legal guidelines about children's abilities to consent to, or refuse, participation in a research project. A child's consent can be given whenever that person or child has sufficient competence to make a decision about participating in the research. Similarly, a child or young person can withdraw consent or refuse to participate.

Researchers may obtain some direction and assistance relating to consent by children and young adults by consulting a summary of age-based legal milestones for youth in Ontario, which is can be found at: [Justice for Children and Youth](http://www.jfcy.org/agebased.html) < http://www.jfcy.org/agebased.html >

### **16.5 Research involving "captive" groups**

In cases involving "captive groups" informed consent shall be obtained from each individual subject. The research ethics board may grant a total or partial exemption from this requirement, provided that:

- 1) it is impracticable to require that such individual consents be sought;
- 2) the risks to the subjects involved are minimal; and
- 3) informed consent is given by one or more proper persons with responsibility for 'the captive group' in the knowledge that informed consent is not being sought from some or all individual subjects within that group; and
- 4) the research does not involve a therapeutic intervention.

### **16.6 Research involving Aboriginal Peoples**

Researchers proposing research involving aboriginal peoples should consult and be familiar with the provisions of a number of relevant documents relating to special considerations for research involving aboriginals. These documents include but are not restricted to the following:

1. [\*Ethical Principles for the Conduct of Research in the North\*](#), Association of Canadian Universities for Northern Studies, Ottawa, ACUNS, 1982; 1988

2. [\*Ethical Guidelines for Research, Royal Commission on Aboriginal Peoples Appendix B; RCAP, 1993\*](#)

Researchers involved with aboriginal communities should consider and implement the good practices outlined in the [TCPS, Section 6 B.](#)

## **17.0 PARTICIPANT RECRUITMENT**

Research benefits and burdens should be distributed fairly. Studies with the potential to address issues relevant to both sexes must recruit both genders, and minority populations should be included in a study population wherever feasible. Researchers must justify the exclusion of women or minorities, and exceptions should be made only when there is adequate scientific justification for exclusion.

Women shall not automatically be excluded from research solely on the basis of sex or reproductive capacity. [\[TCPS Article 5.2\]](#)

### **17.1 Recruitment of students, employees, colleagues and subordinates**

Researchers should avoid using their own students or employees, colleagues or subordinates as research subjects, as subtle coercion can occur in these cases.

If there is good scientific reason for including students, researchers should:

- 1) make sure students are confident that their participation will not influence class standing, grades, or other benefits under the control of the researcher;
- 2) limit the use of extra credit points as a reward for participating; they should be used only when the research is closely tied to the courses subject matter, and they should not raise a student's grade inordinately
- 3) keep financial rewards commensurate with the risks of participation;
- 4) not use class time to recruit subjects or complete study instruments;
- 5) inform students who might participate about the review process, the rationale for the study, the process of data collection and the researcher's interest;
- 6) post recruiting advertisements throughout the university to recruit from a broad base of students;
- 7) avoid any personal solicitations of students by faculty, graduate assistants or fellows students;
- 8) offer a number of research project options if student participation in research is to be used as a course requirement; and
- 9) provide alternative and equal methods for meeting course credits (or extra credits) requirements, such as attending a series of research presentations by faculty, writing a brief paper, conducting one's own research.

Researchers who include colleagues or subordinates as research subjects, must be able to provide a rationale other than convenience for selecting them and must how that the recruitment method does not lead colleagues to think they will be compromised by not participating.

## **18.0 PRIVACY AND CONFIDENTIALITY**

Confidentiality refers to the legal and ethical obligation that arises from a relationship in which a person receives information from or about another. The recipient has an obligation not to use that information for any purpose other than that for which it was given.

Privacy is the right to decide the extent to which personal data that is not already in the public domain, may be disseminated.

Research participants have a right to privacy and researchers have a corresponding duty to treat private information in a respectful and confidential manner. When reviewing applications for approval, the research ethics board must balance the need for research against infringements of privacy and invasions of privacy must be minimized as much as possible. The value of privacy of research participants is not absolute, some public interests such as protection of health, life and safety may require infringement of the right to privacy, as may the type of research being conducted; without access to personal information, it would be difficult if not impossible to conduct important societal research in such fields as epidemiology, history, genetics and politics.

Different cultures will value privacy in different ways and these values must be respected. The issue of privacy must be looked at from the cultural perspective of the subject, not the researcher.

As a general guide, the best protection of the confidentiality of personal information and records will be achieved through anonymity.

Researchers are responsible for ensuring the confidentiality of data on human subjects by maintaining such data in secure storage and by limiting access to data to authorized individuals.

The research design must include procedure appropriate to securing the degree of confidentiality guaranteed to the research participant by the researcher, as outlined in the informed consent process.

## **19.0 CONFLICT OF INTEREST**

Researchers and Research Ethics Board members must disclose actual, perceived or potential conflicts of interest. [\[TCPS Article 4.1\]](#)

At the commencement of the free and informed consent process, researchers shall provide prospective participants with information pertaining to the possibility of commercialization of the research findings, and the presence of any actual or potential conflict of interest on the part of the researchers, their institutions or sponsors. [\[TCPS Article 2.4\(e\)\]](#)

McMaster University's policy on Research Ethics defines research misconduct as including:

- failure to reveal any material conflict of interest to the sponsors to those who commission work or when asked to undertake reviews of research grant applications or manuscripts for publication, or to test products for sale or distribution to the public; and
- failure to reveal to the University any material financial interest in a company that contracts with the University to undertake research, particularly research involving the company's products. Material financial interest includes ownership, substantial stock holding, a directorship, significant honoraria or consulting fees but does not include routine stock holding in a large, publicly traded company.

### **19.1 Conflicts of interest involving researchers**

The expression "conflicts of interest" used in an ethical sense, refers to conflicting obligations or influences confronting an individual in the course of a relationship or activity that has some moral content. Conflicts of interest may or may not involve financial or monetary interests. The central issue is that individuals engaging in conduct that has ethical dimensions are drawn in two directions at once in such a manner that their judgment may be affected, or their motives may be open to question.

To identify and address conflicts properly, researchers must advise the research ethics board on budgets, commercial interests, consultative relationships and any other relevant information. When a significant real or apparent conflict of interest is apparent, the research ethics board will require the researcher to disclose this conflict to the prospective participants during the informed consent process.

In order to assess the likelihood of a real or an apparent conflict of interest which must be disclosed, researchers should consider:

- whether an outside observer would question the ability of the individual to make a proper decision despite possible considerations of private or personal interests; and
- whether the public would believe that the trust relationship between the relevant parties could reasonably be maintained if they had accurate information on the potential sources of conflict of interest.

Conflicts of interest are not usually the result of malign motivations of particular individuals, but most often arise out of the structural features of relationships or practices. In many situations it is impossible to eliminate conflicts of interest, however, they must be identified so that steps can be taken to disclose them openly and to control their impact.

### **19.2 Criteria for assessing likelihood of a conflict of interest**

In order to assess the likelihood of a real or an apparent conflict of interest which must be disclosed, researchers should consider:

- whether an outside observer would question the ability of the individual to make a proper decision despite possible considerations of private or personal interests; and
- whether the public would believe that the trust relationship between the relevant parties could reasonably be maintained if they had accurate information on the potential sources of conflict of interest.

Conflicts of interest are not usually the result of malign motivations of particular individuals, but most often arise out of the structural features of relationships or practices. In many situations it is impossible to eliminate conflicts of interest; however, they must be identified so that steps can be taken to disclose them openly and to control their impact.

### **19.3 Conflicts of interest by REB members**

If the research ethics board is reviewing research in which a member of the board has a personal interest (e.g. as a researcher or as an entrepreneur), conflict of interest principles require that the member not be present when the REB is discussing or making its decision. [\[TCPS Article 1.12\]](#)

No member of an ethics committee should adjudicate on research in which he or she has any conflict of interest, including any personal involvement or participation in the research,

financial interest in the outcome, involvement in competing research, or an interest as an academic supervisor of a student researcher.

#### **19.4 Institutional conflict of interest**

The research ethics board maintains an arms-length relationship with the University, and is an autonomous board, with a mandate to ensure that all research investigations involving human participants are in compliance with the Tri-Council Policy Statement, including avoiding and managing real and apparent conflicts of interest between the institution and human research participants.

#### **20.0 DECEPTION**

Free and Informed Consent requires that subjects be fully informed about the purpose of the study before being asked to agree to participate. In some fields of research, in particular in social / behavioural research, studies cannot be conducted without deception, concealment or covert observation. Such research may be approved by the Ethics Review Board, provided that at a minimum:

- 1) The research involves no more than minimal risk
- 2) The use of deception is unlikely to adversely affect the rights and welfare of the subjects;
- 3) The research could not be carried out without the use of deception, concealment or covert observation;
- 4) Wherever possible, the subjects are provided with full debriefing subsequent to their participation
- 5) The research does not involve a therapeutic intervention

#### [TCPS Article 2.1 (c)]

In addition, the researcher should provide the research ethics board with information specifically detailing the precise extent of the deception, concealment or covert observation. In cases where deception is utilized, researchers should be especially careful to ensure that participants are informed that they have the right to withdraw data obtained from them during the research without their knowledge or consent.

#### **21. NATURALISTIC OBSERVATION**

Ethics review is normally required for research involving naturalistic observation. Naturalistic observation which does not allow for the identification of the subjects and that is not staged should normally be regarded as of minimal risk and eligible for expedited review.

Protocols involving the use of naturalistic observation where it is clear that the participants are seeking public visibility (for example at political rallies, demonstrations or public meetings) and where participant confidentiality and anonymity are ensured do not require ethics review.

#### **22. SECONDARY USE OF DATA**

Secondary use of data is the use in research of data contained in records collected for a purpose other than the research itself, such as patient or school records, or records from previously conducted research.

If the data to be used allows for the possible identification of the individual who provided the information, ethics review is required.

## C. SUBMITTING RESEARCH FOR REVIEW: THE APPLICATION PROCESS

### 23.0 WHAT TO SUBMIT

All forms that researchers must file with the research ethics board to apply for review are available, with specific instructions on the [Research Involving Humans website](#), or from the Research Ethics Secretariat which is located at Gilmour Hall, Room 305/H. The Research Ethics Secretariat can assist researchers with the completion of the application and with any questions which they might have relating to the ethics review process. The secretariat can be e-mailed at [ethicsoffice@mcmaster.ca](mailto:ethicsoffice@mcmaster.ca), or phoned at extension 23142.

The forms are found on the [Forms webpage](#):

- Faculty and graduate application form
- Change Request form
- Completed / Renewal Status Report form
- Request for approval of a course-based research project form
- Undergraduate student application form

#### 23.1 Faculty and Graduates

Faculty and Graduate students complete the MREB form "Faculty and Graduate Application to Involve Human Participants in Research". Where the applicant is a faculty member, faculty must sign the "faculty investigator assurance", located on the final page of the form. Where the applicant is a graduate student, the faculty member who is supervising the student and the graduate student must sign the "faculty supervisor assurance", located on the final page of the form. Original signatures are required.

#### 23.2 Undergraduates

Undergraduate students complete the MREB form "Undergraduate Student Application to Involve Human Participants in Research". The student researcher and the faculty supervisor must sign on the final page of the form. Original signatures are required.

#### 23.3 Course Applications

Instructors who wish to oversee the conduct of class project student research should complete and submit a "Request for Approval of Course-Based Research Projects" form for the class. Course-based projects are subject to specific guidelines which can be found [here](#):

#### 23.4 Documents to be submitted with the application form

The application form and all accompanying material should be submitted in quadruplicate if being submitted in hard copy, or by e-mailing a single copy, and sending the original, signed signature page to the Ethics Secretariat, Room 305/H, Gilmour Hall.

Applications should be accompanied by: (where applicable)

- a copy of any and all questionnaires or test instruments;
- a copy of any recruitment notices, e-mails, advertisements or any other material to be used to solicit participants;

- a description of the verbal explanation to be given to participants before they are asked to consent to participate in the study;
- a transcript of any telephone script to be used;
- a copy of any consent form(s) to be completed;
- a copy of any debriefing script or materials to be provided to the participants;
- any other material which the researcher feels may be relevant to the MREB decision;
- a change request form if the application is a request to change a previously approved protocol.

## **24.0 WHERE TO SUBMIT THE APPLICATION FORMS**

All applications, whether for faculty, undergraduate or course-based research projects, should be submitted to the McMaster Research Ethics Board Secretariat, located at the Office of Research Services, Room 305/H Gilmour Hall. E-mailed applications should be sent to [ethicsoffice@mcmaster.ca](mailto:ethicsoffice@mcmaster.ca). Four copies of the application and all accompanying materials are required if the application is being submitted as a paper copy. If the application is being sent by e-mail, a single copy including the attachments should be e-mailed to the Secretariat and the original signed signature page should be delivered or mailed.

## **25.0 COMPLETION OF THE APPLICATION FORM**

### **25.1 Title of the Project**

The title of the project should succinctly describe the area/focus of the project for which ethics clearance is sought. If the project is funded, the title of the project should be identical to that on the corresponding grant application. If the project is affiliated with a larger multi-institutional study, please indicate the project to which the application is affiliated.

### **25.2 Other Research Ethics Board Approval**

If the protocol has been reviewed and approved by another institutional research ethics board, the protocol may be eligible for expedited review. If the research has been approved by another research ethics board and the researcher can provide the required information, then the balance of the MREB application does not need to be completed, unless the researcher is advised by the Ethics Secretariat that a complete application is required. The information required is:

- The title of the project approved elsewhere
- The name of the other institution
- The name of the other board
- The date of the decision
- A contact name and phone number for the other board
- A copy of the application to the other institution together with all accompanying materials and correspondence.

### **25.3 Conflict of Interest**

Researchers are required to disclose any conflict of interest that might exist in relation to the project or its results. (See Item 19). Examples of conflict of interest include financial benefits

such as remuneration, intellectual property rights, rights of employment, consultancies, board memberships, share ownership, or stock options received by the researcher, members of the research team, and / or their partners or immediate family members.

If a conflict of interest is deemed by the research ethics board to be material, the board will make recommendations to the researcher(s) concerning how the conflict should be managed. These recommendations may include, but are not restricted to:

- Requiring that the researcher publicly disclose the conflict of interest, possibly in the context of the informed consent document;
- Monitoring the research by independent reviewers;
- Modifying the research proposal or plan;
- Disqualifying the investigator from a portion of all of the research;
- Requiring that the researcher divest him or herself of the financial interest;
- Requiring the researcher sever the relationship with the sponsor.

#### **25. 4 Experience**

Researchers are required to cite their experience and training in the type of research being conducted so that research ethics board may be ensured that the researcher is adequately trained to conduct the research. Experience is also a factor considered in assessment of risk.

#### **25.5 Number and characteristics of participants**

The number of proposed participants should be cited as accurately as possible. If it is difficult to predict how many participants there will be, an optimum number should be specified. If exclusion of participants based upon any criteria such as age, gender, ethnicity, culture, religion or similar criteria is being proposed, the researcher must provide the scientific justification for proposing such an exclusion. (See Item 17)

#### **25.6 Compensation of participants**

If participants are to be compensated, the details of the compensation must be provided. The compensation must be commensurate with the risks of participation and must not be so significant that they could be perceived to be an inducement to participate. Details must be provided concerning what the impact of withdrawal from the study will have on the compensation. (See item 17.1)

#### **25.7 Risks and Benefits**

The risks to participants should be described and an explanation should be provided as to how those risks will be minimized and how they will be managed by the researchers throughout the conduct of the study. (See Item 14)

The proposed benefits should be realistically described, in relation to the participants, the researcher, and in relation to the scientific community and society as a whole. Types of answers that might be appropriate include:

- Student researcher: increase understanding of research methods and cognition;
- Participants: participants may learn about research methods; may have some questions answered about their situation; may benefit from knowing that their experience and knowledge is being valued and recorded; no direct benefit;
- Scientific community: this study may provide insights into how, when, etc. ....; or none, I will be replicating a well-known phenomenon;

- Society: better understanding of ... may lead to effective techniques for enhancing/ training, treating etc.

### **25.8 Informed Consent**

Instructions for preparation of an Information Letter/Informed Consent may be found [here](#).

### **25.9 Additional Information**

Researchers should attach any additional information which they think may assist the research ethics board in making its determination. Samples of additional attachments have included research articles, grant applications, a more in-depth or technical description of the study; listings of standard instruments that are proposed to be used, references to earlier research projects, and other similar information and documentation.