Ethics Review for Research Involving Humans: Summary of Guidelines & Process

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OVERVIEW

- Regulatory Framework
- Scope of Review Requirements
- Review Process and Issues
- Responsibilities
- Resources
REGULATORY FRAMEWORK

- Tri-Agency Framework: Responsible Conduct of Research- institutions are bound to uphold the TCPS

- Tri-Council Policy Statement: Ethical Conduct For Research Involving Humans (TCPS)- principles and articles guiding the ethics review process

- Relevant federal, provincial, international regulations – e.g. Quebec Civil Code; Quebec Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information; Health Canada; US Code of Federal Regulations
REGULATORY FRAMEWORK

- Organization specific guidelines e.g. school board guidelines
- McGill Policy on the Ethical Conduct of Research Involving Human Participants- articulates the administrative structures, responsibilities and procedures for the review and conduct of research involving humans under the auspices of McGill
- Research Ethics Board guidelines
SCOPE OF REVIEW REQUIREMENTS

Research requiring ethics review must receive review and approval by a McGill Research Ethics Board **BEFORE** the research begins. (McGill Policy on the Ethical Conduct of Research Involving Human Participants)

- all members of McGill – any person acting in connection with their institutional role including students, faculty, staff
- all research conducted at or under the auspices of McGill
- funded and non-funded research including course assignments, theses, independent study projects, pilot studies
- research or recruitment conducted by non-McGill members using University resources/premises/non-public personal information

There is **NO** retroactive approval. Ethics certificates must be submitted with thesis submission; required by many journals.
SCOPE OF REVIEW REQUIREMENTS

What is research involving humans that needs REB review?

(TCPS, ch. 2)

- **Research** - an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation. A determination that research is the intended purpose of the undertaking is key for differentiating activities that require ethics review by an REB and those that do not.

- **Human participant** - a) living human participant whose data, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question
  - b) human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells (from living or deceased individuals)
SCOPE OF REVIEW REQUIREMENTS

Research involving humans that does not need REB review (TCPS, ch.2)

- research that relies exclusively on publicly available information when:
  a) the information is legally accessible to the public and appropriately protected by law; or
  b) the information is publicly accessible and there is no reasonable expectation of privacy

- observational research in public (natural or virtual) spaces (not necessarily the same as publicly accessible) where it is evident there is no reasonable expectation of privacy; no staged intervention or direct interaction with those being observed; no identification of specific individuals in dissemination of results
SCOPE OF REVIEW REQUIREMENTS

Research involving humans that does not need REB review (TCPS, ch.2)

- research involving individuals who are not themselves the focus of the research but can provide information on organizational policies, statistical reports, practices etc. e.g. public relations officers or public officials

- research that relies exclusively on secondary use (data collected for a purpose other than the current research purpose) of anonymous data (data never had identifiers) or anonymous biological materials. This does not apply to secondary use of coded or anonymized data.
REVIEW PROCESS & ISSUES

PROCESS

Research Ethics Boards (REBs) (TCPS ch.6)

- The TCPS requires that research involving humans undergo review and approval by an independent body – the REB; governance and structure of the REB ensures independent decision making.

- The mandate of the REB is to review the ethical acceptability of research with the primary objective of protecting the rights and welfare of participants.

- The REB can approve, reject, require modifications to or terminate any proposed or ongoing research.
How to apply at McGill *(Ethics website)*

- McGill has 5 REBs. The relevant REB to apply to primarily depends on departmental or faculty affiliation. Researchers located in, or who wish to recruit from or conduct research in, a McGill affiliated hospital, must normally apply directly to the REB of that institution (see website for detailed guidance).
- Consult the website of the relevant REB for submission requirements and all current forms to be used.
- Minimum initial review time is 3-4 weeks; final approval could take longer. Turnaround depends on many factors including the complexity of the project, the completeness of the application (answer every question, attach all required instruments including consent forms, interview guides, surveys, questionnaires recruitment ads etc., signed by applicant and supervisor), corrections to be made, response time of researcher.
- Contact the REB office for guidance. They are there to help.
REVIEW PROCESS & ISSUES

PROCESS

Types of review
- Full REB review - review by the full REB at a convened meeting is the default
- Delegated review - review by one or more REB members may be done for research considered to be of minimal risk

Minimal risk – 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.

Outcomes of a review
- approved
- endorsed with conditions that must be met before final approval is given
- a decision cannot be made based on the information provided and a decision is deferred pending additional information/major revisions
- disapproved
ISSUES

Guiding core principles for the conduct of research regardless of discipline or level of risk *(TCPS ch.1)*

- Respect for Persons – respect for autonomy and the requirement to seek free, informed consent; protect those with developing, impaired or diminished autonomy

- Concern for Welfare – impact on physical, mental, emotional, economic well-being; privacy or control of information

- Justice – obligation to treat all people with equal respect and concern; equitable distribution of burdens and benefits
REVIEW PROCESS & ISSUES

ISSUES

- **Recruitment** *(TCPS ch. 3, 9, 11, 13)*
  Privacy - a person’s right to control access to themselves.

  *Where* - are you getting their information from (e.g. class list, listserv)

  *How* - will participants be approached?

  *When* - will they be approached?

  Consider - vulnerability of participants (cognitive/emotional; physical; social/legal; captive); potential for undue influence/coercion (e.g. dual role relationships); cultural norms; community approvals.

  All recruitment information must be provided e.g. ads, emails, information letters, radio scripts, videos etc.
ISSUES

- **Balancing Risks and Benefits** *(TCPS ch.2, ch.4)*

  *Risk* - a function of the magnitude and the probability of possible harms.

  *Magnitude* - ranges from minimal (e.g. test anxiety) to substantial (e.g. serious physical injury).

  *Probability* - the likelihood of a participant actually experiencing a harm.

  *Harms* - can be physical, psychological, emotional, economic or social; group or individual harms.

  A thoughtful consideration of risks is needed. Consider sensitivity of the data; invasiveness of procedures; vulnerability of the participants; location of the research; how are risks avoided, reduced and managed?

  *Benefits* - can be to the individual, to a group or to the expansion of knowledge. It must be demonstrated that potential benefits merit any risks.
ISSUES

- **Informed Consent Process** *(TCPS ch.3, ch.10; REB guidelines)*

  *Information* - adequate information must be given to make an informed decision about participation; explanation of purpose, potential harms and benefits, dissemination of data, confidentiality, compensation, procedures, time commitment, anticipated uses of data by others.

  *Comprehension* - the information presented must be understandable; consider target population age and literacy; allow adequate time to consider.

  *Documentation* – The norm is written consent and may sometimes be mandatory (e.g. Health Canada regulations); oral consent may be more appropriate in some circumstances considering literacy levels, cultural norms or where written consent poses a risk of harm; always document.
ISSUES

- **Informed Consent Process**

  *Voluntariness* - consent must be given voluntarily, free from coercion or undue influence. Consent may always be withdrawn at any time, which means that the data is destroyed unless otherwise specified.

  Consider - incentives (should not be so large or attractive as to encourage reckless disregard of risks); conflicts of interest (must be declared and explained how they will be managed); deception (needs debriefing and opportunity to reconsider).

  *Capacity* - the ability to understand information presented about the research and to appreciate the potential consequences of their decision to participate or not; consent from a legally authorized third party needed for participants who lack capacity to consent on their own; individuals who cannot consent on their own may still be able to express their assent or dissent to participation.
ISSUES

- **Privacy&Confidentiality (TCPS ch.5)**

  Is a consideration through recruitment, initial data collection, analysis, dissemination of results, storage and retention/destruction of data.

  Consider - degree of confidentiality offered; access to the confidential data; maintenance and storage of data (anonymous, anonymized, coded, locked cabinet, password protection, encryption); security of any transmitted data; limits to confidentiality; location of data collection; use of translators; use of video or audio-taping.
RESPONSIBILITIES

- Researchers have the primary responsibility to ensure their research is carried out in an ethical manner and are responsible for the protection of the rights and welfare of the participants.

- Researchers are responsible for ensuring their research receives the necessary ethics review and should always consult with the REB to clarify what types of research must be reviewed and what exceptions may exist.

- Researchers are responsible for ensuring their research is conducted in accordance with the University policies and procedures governing the ethical conduct of research involving human participants.

- Ethics approval must be obtained before recruitment or the collection of data begins.
RESPONSIBILITIES

- Approvals are valid for a maximum of one year. Continuing review and approval is required for ongoing projects. Notify the REB when the study ends.

- Modifications to the project such as changes in research design, recruitment, location of study, survey instruments, consent procedures investigators, etc. or any changes that may increase the level of risk for participants or have other ethical implications that may affect a participant’s rights or welfare or decision to participate, must be approved by the REB before they can be initiated except where immediately necessary to reduce harm to a participant.

- Unanticipated issues that may increase the level of risk to participants, or has other ethical implications that may affect participants’ welfare must be reported without delay.

- As of January 15, 2016, completion of the TCPS on-line tutorial will be mandatory by all applicants before the application is submitted to the REB.

- There is NO retroactive approval. Noncompliance can have serious consequences such as inability to use data, non-acceptance of thesis, loss of funding, suspension of research.
RESOURCES

- Links to all McGill Research Ethics Boards; general information; guidance documents - www.mcgill.ca/research/researchers/compliance/human/
  Contact - Deanna Collin (deanna.collin@mcgill.ca), Ethics Review Administrator-398-6193
  - Lynda McNeil (lynda.mcneil@mcgill.ca), Manager, Research Ethics- 398-6831
  Drop-in consultations (for REB-I,II,III,FAES) without an appointment - every Wednesday, 2-4 p.m. James Administration Bldg. rm 429
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans
- TCPS online tutorial http://tcps2core.ca/welcome
- McGill Policy on the Ethical Conduct of Research Involving Human Participants –
  http://www.mcgill.ca/secretariat/policies/research/
- Research in the Yukon http://www.tc.gov.yk.ca/scientists_explorers.html
- Research in the Northwest Territories http://www.nwtresearch.com/
QUESTIONS?