Ethics Review for Research Involving Humans: Guidelines &Process

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OVERVIEW

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

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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. CIHR stem cell research; 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

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SCOPE OF REVIEW REQUIREMENTS

Research requiring ethics review must receive review and approval by a McGill Research Ethics Board **BEFORE** the research begins.

- conducted by students, faculty or staff whether conducted at McGill or elsewhere
- funded and non-funded research including course assignments, theses, independent study projects, pilot studies
- research or recruitment conducted by non-McGill members using University premises/data
- if student activities covered by supervisor's approval then further ethics approval isn't needed

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

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SCOPE OF REVIEW REQUIREMENTS

What is research involving humans that needs REB review?
(TCPS,ch.2)

- *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)

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SCOPE OF REVIEW REQUIREMENTS

Research involving humans that does not need REB review

- research that relies exclusively on publically available information when:

  a) the information is legally accessible to the public and appropriately protected by law; or

  b) the information is publically accessible and there is no reasonable expectation of privacy

- observational research in public (natural or virtual) spaces (not necessarily the same as publically 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

- 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 (collected for a purpose other than the current research purpose) of **anonymous** information or **anonymous** biological materials

  Anonymous - the information never had identifiers

  Anonymized - information has been permanently stripped of direct identifiers and no code is kept

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

REVIEW PROCESS & ISSUES

PROCESS

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 apply directly to the REB of that institution (see website for detailed guidance).
- Consult the website of the relevant REB for all forms and submission requirements.
- 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., review and signed approval by supervisor), corrections to be made and 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

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REVIEW PROCESS & ISSUES

ISSUES

Guiding ethical 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 people fairly; equitable distribution of burdens and benefits

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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 medium must be provided e.g. ads, emails, information letters, radio scripts, videos etc.

REVIEW PROCESS & ISSUES

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.

REVIEW PROCESS & ISSUES

ISSUES

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

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

  Comprehension - the information presented must be understandable; consider target population, literacy, timing, ongoing consent.

  Documentation – The norm is written consent; sometimes is a legal requirement (Art.21 CCQ; Health Canada); oral consent may be more appropriate for literacy or cultural reasons or where it poses a risk of harm; always document.

REVIEW PROCESS & ISSUES

ISSUES

- **Informed Consent Process**

Voluntariness - consent must be given voluntarily, free from coercion or undue influence. Consent may always be withdrawn at any time.

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 it 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.

REVIEW PROCESS & ISSUES

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 raw data- anonymous, coded, linked files, computer passwords; security of transmitted data; limits to confidentiality; security of data in conflict settings; use of translators or community members; uses of video or audio-taping; location of interviews

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.

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

RESPONSIBILITIES

- Approvals are only valid for a maximum of one year. Continuing review and approval is required for ongoing projects.
- Modifications to the project such as changes in research design, recruitment or consent procedures or any changes that may increase the risk level, must be approved by the REB **before** they can be initiated except where necessary to reduce harm to a participant.
- Unanticipated issues must be reported in a timely manner.
- 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- http://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 without an appointment- every Wednesday, 2-4 p.m. James Admin Bldg. rm 429

- McGill Policy on the Ethical Conduct of Research Involving Human Participants – http://www.mcgill.ca/secretariat/policies/research/

- Research that is carried out in one of the McGill affiliated hospitals is normally reviewed by that hospital's REB. Contact the hospital REBs for further information.

  MUHC Research Ethics Office- http://ww.muhc.ca/research/ethics/

  Jewish General Hospital Research Ethics Office- http://ww.jgh.ca

  Centre de Recherche Interdisciplinaire en Réadaptation- http://ww.crir.ca

  St. Mary's Hospital Centre- http://www.smhc.qc.ca/en/research/research-review/research-review-committee

  Douglas Hospital – http://ww.douglas.qc.ca/hospital/ethics.asp

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RESOURCES

- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/
- Research in Nunavut http://www.nri.nu.ca/apps/authoring/dspPage.aspx?page=home
- Research in the Yukon http://www.tc.gov.yk.ca/scientists_explorers.html
- Research in the Northwest Territories http://www.nwtresearch.com/

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QUESTIONS?

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