Ethics Review for Research Involving Humans: Guidelines and Process

OVERVIEW

- Regulatory Framework
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REGULATORY FRAMEWORK

- Agency guidelines – e.g. CIHR stem cell research; school board guidelines
- McGill Policy on the Ethical Conduct of Research Involving Human Subjects – 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.

- 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.

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

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 -

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

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; distribution of harms and benefits

REVIEW PROCESS & ISSUES

ISSUES

- Recruitment (TCPS ch.3, 9, 11, 13)

  Privacy is a person's right to control access to themselves. How, where, and when will participants be approached? Where are you getting their information from? Do you have permission to access it (ex. class list, database, listserv)? Consider: vulnerability of participants (cognitive/emotional; physical; social/legal; captive), potential for undue influence/coercion(control may be physical, psychological, financial, professional, dual role relationships), cultural norms, community approvals/collaboration, inclusion/exclusion criteria.

  Attach all medium e.g. ads, emails, information letters, radio scripts, videos etc.

REVIEW PROCESS & ISSUES

ISSUES

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

Risk is a function of the magnitude and the probability of possible harms. The magnitude of potential harms ranges from minimal (e.g. test anxiety) to substantial (e.g. serious physical injury). The nature of potential harms can be physical, psychological, emotional, economic or social; group or individual harms. Consider sensitivity of the data; invasiveness of procedures; vulnerability of the participants; location of the research. The probability is the likelihood of a participant actually experiencing a harm. A thoughtful consideration of risks is needed; 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.

  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; consider incentives, conflicts of interest such amkg1(nt)3(

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; explain what degree of confidentiality will be offered; who will have access to the confidential data; maintenance and storage of raw data- anonymous, coded, linked files, computer passwords;

how are results disseminated - pseudonyms, identifying quotes, identification of communities, aggregate results;

when will confidentiality be broken ex. disclosure of illegal activities, child abuse, harm to oneself or others

security of data in conflict settings; use of translators or community members; uses of video or audio-taping; location of interviews; focus group limitations; potential secondary use

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), Ethics Officer- 398-6831
  - For FAES REB only-Lynn Murphy (lynn.murphy1@mcgill.ca) – 398-8716

- McGill Policy on the Ethical Conduct of Research Involving Human Subjects – 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 www.muhc.ca/research/ethics/

  Jewish General Hospital Research Ethics Office www.jgh.ca

  Centre de Recherche Interdisciplinaire en Réadaptation- www.crir.ca

  St. Mary's Hospital Centre- www.smhc.qc.ca/epidemiology/

  Douglas Hospital – www.douglas.qc.ca/hospital/ethics.asp

RESOURCES

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