Ethics Review for Research Involving Humans: Guidelines &Process

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FAES Research Ethics and Conduct Seminar
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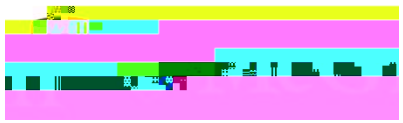
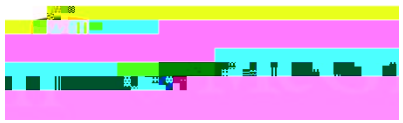


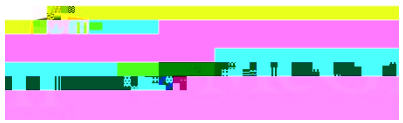
OVERVIEW

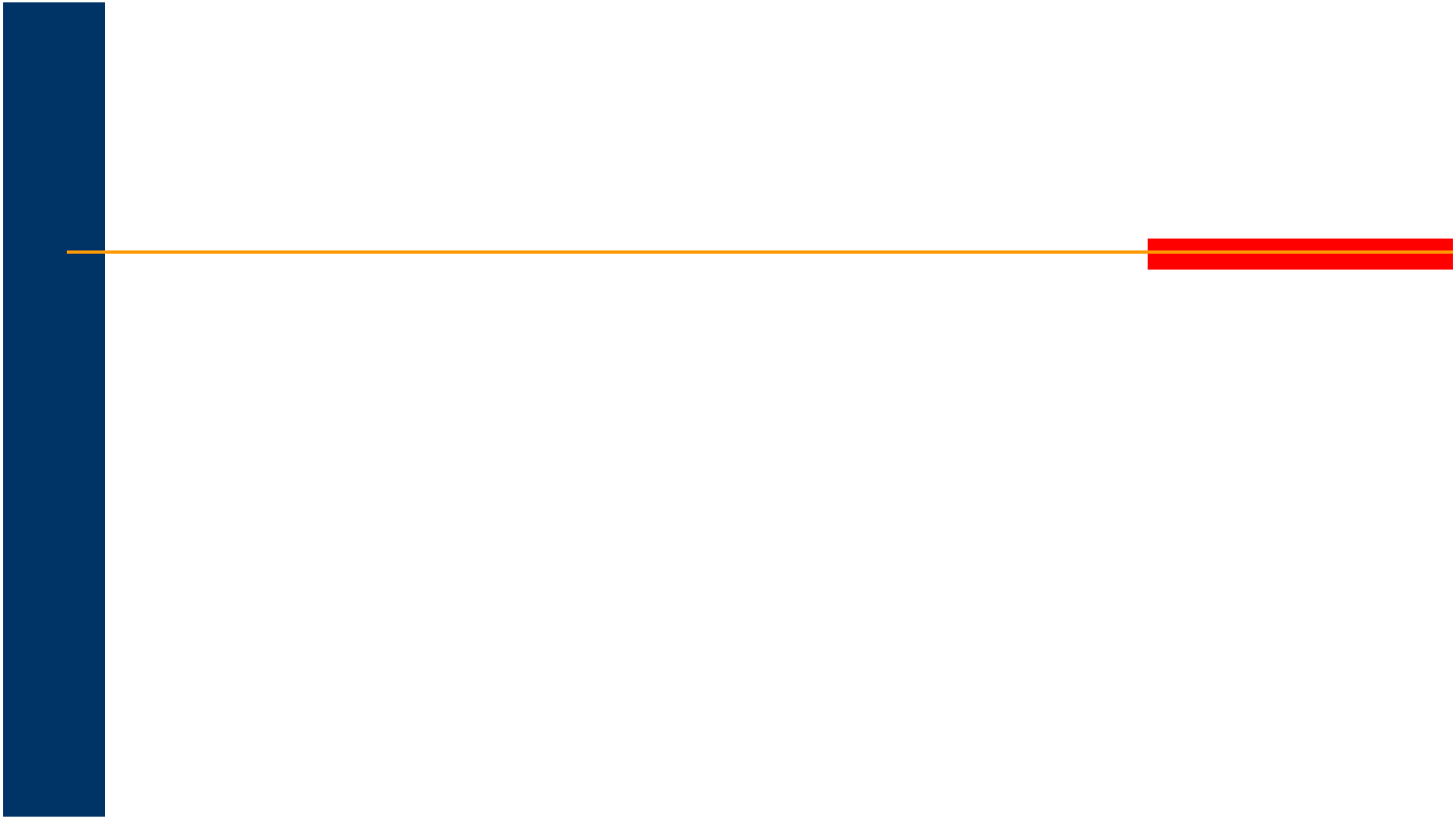
- Regulatory Framework
- Scope of Review Requirements
- Review Process and Issues
- Responsibilities
- Resources



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





SCOPE OF REVIEW REQUIREMENTS

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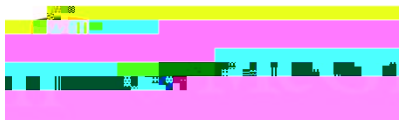
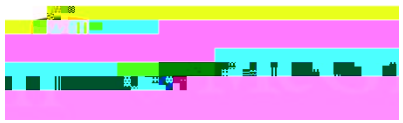


SCOPE OF REVIEW REQUIREMENTS

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

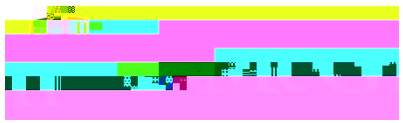
- *Human participant* - a) living human participant whose data, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question
  - b) human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells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



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



REVIEW PROCESS & ISSUES

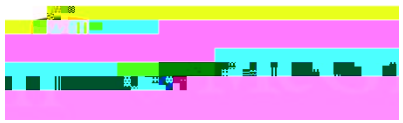
PROCESS

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
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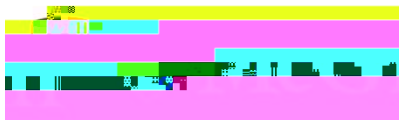
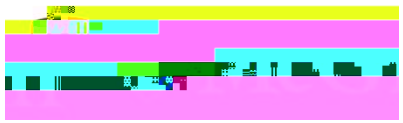


REVIEW PROCESS & ISSUES

PROCESS

Types of review

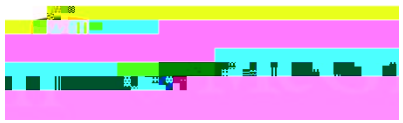


REVIEW PROCESS & ISSUES

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



REVIEW PROCESS & ISSUES

ISSUES

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

  Privacy - a person's right to control access to themselves.

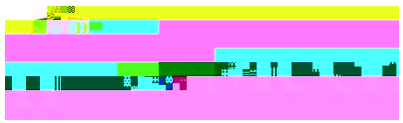
  Where - are you getting their information from (e.g. class list, listserv)

  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.

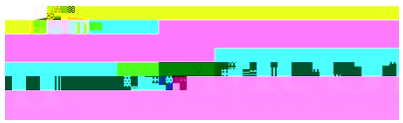


REVIEW PROCESS & ISSUES

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 anxi



REVIEW PROCESS & ISSUES

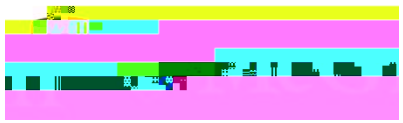
ISSUES

- **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.



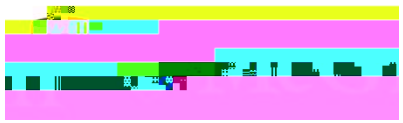
REVIEW PROCESS & ISSUES

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).



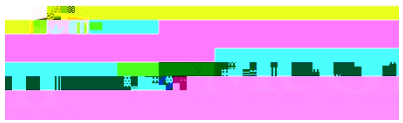
REVIEW PROCESS & ISSUES

ISSUES

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

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

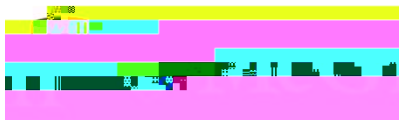
Consider - degree of confidentiality offered; access to the confidential data; maintenance and storage of raw data- anonymous, coded, linked files, computer passwords; security of transmitted data; limits to confidentiality; security of data in conflict settings; use of translators or community members; uses of video or audio-taping; location of interviews

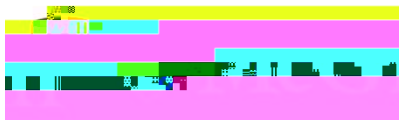


RESPONSIBILITIES

- 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.

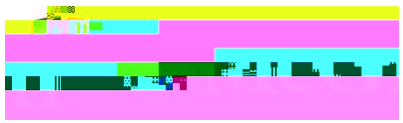
- Researchers are responsible for ensuring their research receives the necessary





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/



QUESTIONS?