Streamlining and Harmonization of Research Ethics Review Processes

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redefine THE POSSIBLE.

Overview of Ethics Review Requirements

- All research involving human participants requires ethics review and approval *prior to* the commencement of said research activities
- Research ethics compliance requires:
  - Ethics protocols must be reviewed and approved by the relevant and applicable review body;
  - Continuing review and approval required for all research that extends beyond one year;
  - Additional review and approval for any amendment to an approved protocol;
  - Adverse/unanticipated events must be reported to the HPRC and follow up action as required.

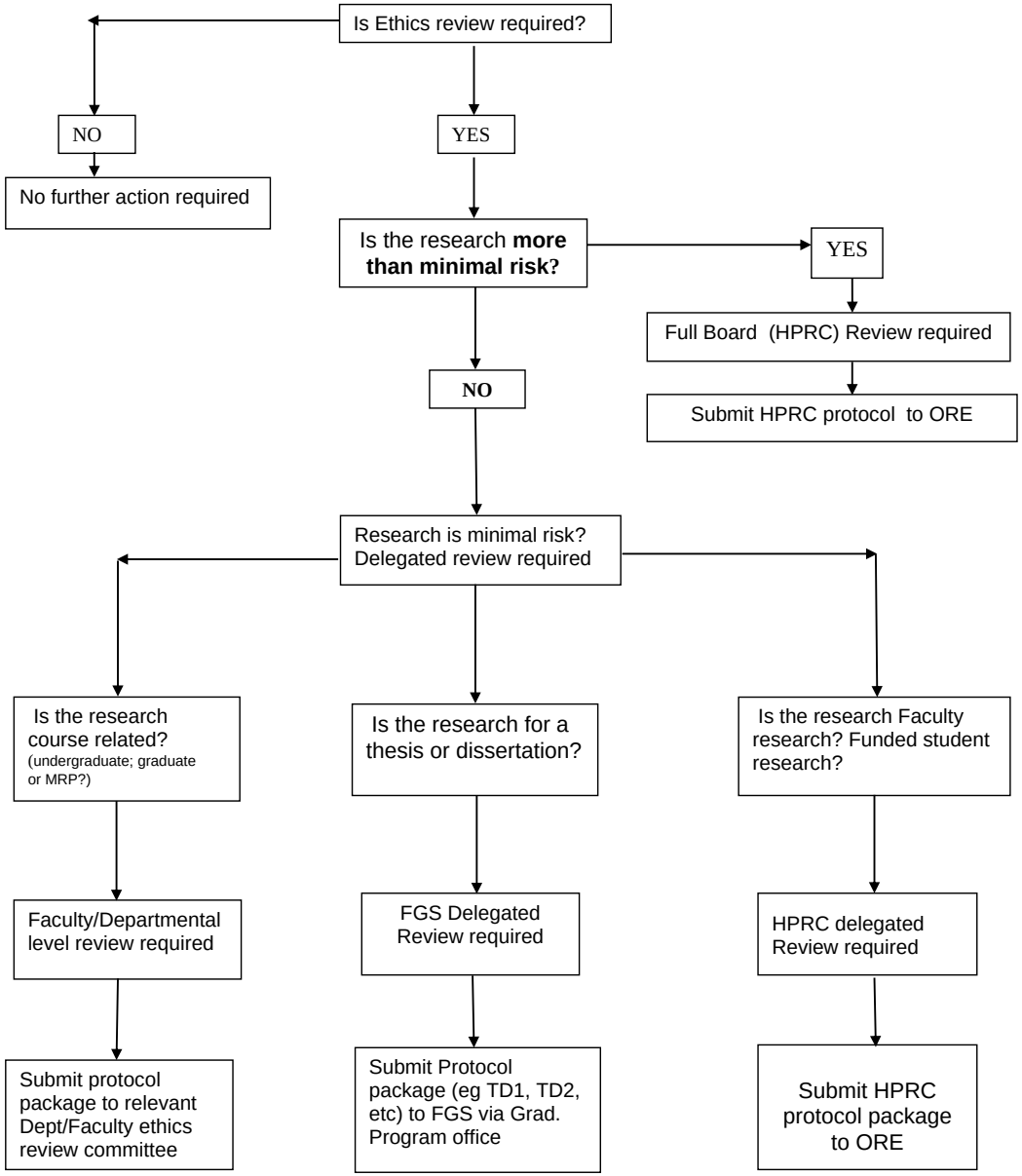
Ethics Review Committees: Roles

- **HPRC:** Reviews all Faculty led research as well as all non-minimal risk and/or clinical trial and/or Aboriginal research.

- **FGS Ethics Review Committee**: Reviews research in support of theses and dissertations.

- **Faculty/Departmental Ethics Review Committees** (or Delegated Review Committees): Reviews graduate and undergraduate course-related research including undergraduate theses and graduate MRPs.

Decision Chart: Full Board & Delegated Ethics Review Processes



** please contact your department/program office for further information regarding relevant forms/protocols

Current Ethics Review Processes/ Protocols: Issues

- Multiple different protocol forms across Faculties and/or departments;
- Multiple different informed consent documents across Faculties and/or departments;
- Outdated forms in circulation which do not reflect current guidelines and Senate policy;
- Senate Annual Reporting of ethics review processes and protocols inconsistent across Faculties;

External Drivers that Mandate Change

- Changes mandated by TCPS 2 (2014)
  - Enhanced reporting requirements for delegated review
  - Enhanced review requirements for all levels of review
- Changes due to emerging issues in research ethics:
  - Secondary data analysis and the challenges of “Big data”
  - Aboriginal research ethics requirements
  - Research versus program evaluation – When is ethics review required?
- Changes in response to compliance gaps
  - Clarity required re student responsibilities in conduct and oversight of research involving human participants

Streamlined Ethics Review Protocols/ Processes

Streamlining ethics review protocols and processes serves to:

- Standardize research ethics protocol; one protocol to be used by all researchers – student and faculty
- Harmonize communication of ethics review policy and processes
- Enhance ethics review and reporting through use of standardized forms and/or resources

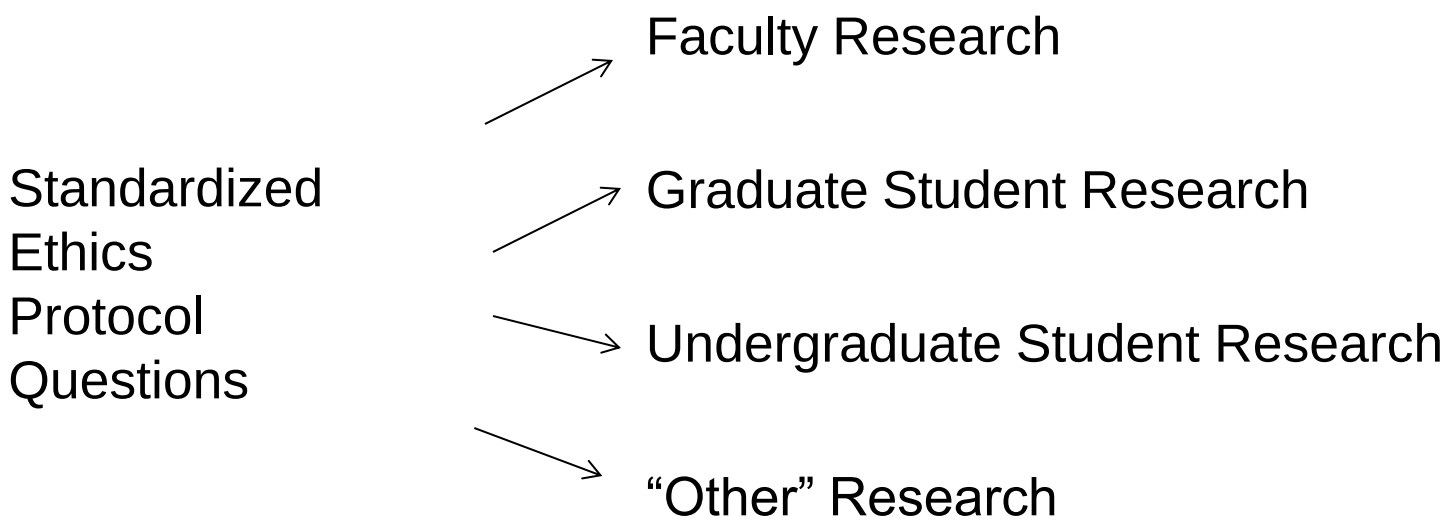
Impacts of Harmonized Ethics Protocols and Processes

- Increased effectiveness of review process and reporting
- Enhanced compliance with current guidelines
- Reduced ethics review time through improved efficiency

What's changed?

- Updated protocol form(s)
- Streamlined reporting templates
- Increased training
- New ethics resources

Standardized Ethics Protocol



Enhanced Ethics Protocol

- Document Checklist – new!
- New questions:
  - Aboriginal Research
  - Clinical trial Research
  - Secondary data analysis
  - External approvals/permissions
- Improved/better defined questions
  - Data security and management
  - Risks
  - Informed consent
  - Methodology

Enhanced Question - Example

Does your research involve Aboriginal/Indigenous Peoples?
[ ] N
[ ] Y

Should your answer require clarification, please describe in the space below why your research may or may not involve Aboriginal/Indigenous peoples:

The following questions may assist in determining whether your research involves Aboriginal/Indigenous peoples:

a.) Will the research be conducted on Aboriginal land (Canada; international) for which permission and/or approval from an authority (such as a band council, First Nations Research Ethics Board etc.) may be required?	N	Y
b) Will recruitment criteria include Aboriginal identity as either a factor for the entire study or for a subgroup of the study?	N	Y
c) Will the research seek input from participants regarding an Aboriginal peoples' cultural heritage, artefacts, or traditional knowledge?	N	Y
d) Will research in which Aboriginal identity or membership in an Aboriginal community be used as a variable for the purpose of analysis of the research data?	N	Y
e) Will interpretation of research** results refer to Aboriginal communities, peoples, language, history or culture?	N	Y

New Question: Example

O. Does this research involve another institution? Research involving another institution (such as a school, university, business, government agency) may require additional ethics review and approval or permissions if using institutional resources (such as internal listservs, or conducting interviews on the premises of the institution).

__ N (if "No" please go to the next question)

__ Y

a)	Does the research involve another institution or site? *If Yes:* Specify the institution(s)/site(s):	N	Y
a)	Do any of the institution(s)/site(s) require administrative permission?	N	Y
a)	Has any other REB cleared this project? *If **Yes**, please submit the original application and provide a copy of the clearance letter.*	N	Y

NOTE: If the research is to be conducted at a site requiring ethics approval or administrative permission, please include all draft informed consent forms/administrative permission requests. It is the responsibility of the researcher to determine what other means of clearance are required, and to obtain clearance prior to starting the project.

Streamlined reporting

Standardized ethics review reporting forms and/or templates to enable easier tracking and reporting of ethics submissions, reviews and approvals:

- For Course Directors
- For Program Administrators
- For Delegated Ethics Review Committees
- For Associate Deans Research

Enhanced training

For Delegated Ethics Review Committees:

- Individual and/or group training

For Course Directors:

- Class room presentations

For the Research Community:

- One-on-one consultations
- Ethics “101”
- Monthly “Brown Bag” presentations

New Ethics Resources

- Revised/Enhanced Responsibility documents
  - Administrators
  - Course directors
  - Researchers
- Revised Guidelines
  - Research Conducted in a Hospital Setting
  - External Researchers
- New guidelines
  - Data security standard
  - Secondary Data Analysis
- New Forms
  - Pre-release document
  - Research Team Member confidentiality
- CAREB SOPs

Next Steps

- Refine Draft Delegated Review Documents:
  - Protocols – Course Related Research:
    - Generic and Individual
    - MRPS
  - Responsibility document(s)
  - Annual report template
- Communication, consultation and outreach sessions:
  - Monthly Brown Bag Ethics series:
    - First Brown Bag presentation: January 18th, 11:30-12:30, 626 Kaneff Tower
- Implementation of streamlined ethics protocol and processes:
  - HPRC and FGS - January 2017
  - Delegated Ethics Review (Course Related)
    - January through May 2017 – Consultation and communication
    - Fall 2017 – Implementation of streamlined ethics protocol and processes for delegated reviews

Office of Research Ethics

Should you have any questions about matters relating to research ethics, please contact:

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