# Ethics Info Sheet 5

## Senate Policy Policy
## for the Ethics Review Process
## for Research Involving Human Participants

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**Notes:** Approved by Senate on 24 June 1993; Amendments approved by the Senate Committee on Research on 11 April 2001; Concurrence of the Academic Policy and Planning Committee received on 14 June 2001; Amendments approved by Senate on 28 June 2001; Amendments approved by Senate on May 23, 2002; Revised and Replaced by Senate on June 19, 2003.

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**Approval Authority:** Senate

**Signature:** "Harriet Lewis"

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**I. Context for an Ethical Framework**

York University has formulated a policy for the conduct of research[1] involving human participants[2], human remains, cadavers, tissues, biological fluids, embryos or foetuses. **This policy applies to all Faculties and the Libraries of the University.** It is intended to protect the Researcher[3] and/or Principal Investigator, the Subject and the University jointly, and protect various rights and responsibilities of the respective parties to the research endeavour. Information provided by the Principal Investigator (PI) in these documents is confidential and will be retained in the files of the *Office of Research Administration.*

The Senate of York University affirms that researchers must respect the safety, welfare, and dignity of human participants in their research and treat them equally, fairly, and not as a means to an end. The University values the academic freedom of its researchers, and the ethics review process shall not unfairly censor researchers who support unorthodox views. However, academic freedom is complemented by the requirement to respect the rights of human participants.

This policy acknowledges the need for continuing interpretation and refinement of applicable policies to account for changes in research methods, contexts and cultures. It is imperative that researchers strive for ethical conduct. Ethical guidelines need to be respected and revised as necessary. Thus, continued awareness and debate of the topic in the research community is essential. The University's principal reference for ethics review is the *Tri-Council Policy Statement* (TCPS), with which the University has agreed to comply pursuant to the *Memorandum of Understanding* (September 2002) between the University and the three agencies that make up the Tri-Council[4].

**II. Ethics in the Design of Research Projects Which Involve Human Participants**

**1. General Principles**

A research investigation that involves human participants should be designed to take account of the well-being of prospective participants. Human participants should be clearly, fairly, and fully informed of the research objectives, procedures, foreseeable risks, and potential benefits. Their decision to participate should be fully voluntary. The risks (if any) should never be excessively harmful and the risk-to-benefit ratio should be taken into consideration when

proposing the research. Participants' anonymity and confidentiality shall be fully protected, unless this right is expressly waived (or unless disclosure is authorized or required by law).

Research design should be especially sensitive to ethical issues when the research involves not legally competent individuals and vulnerable populations (such as indigenous peoples, children, the elderly, ward clients, students in the researcher's courses, medical patients, and prisoners), as well as when it involves risky procedures, deception, or withholding of information.

Concerns regarding the ethical propriety of the research or the interpretation and application of the Senate policy should be addressed to the Manager, Research Ethics, Office of Research Administration.

**2. Informed Consent**

*(a) Principles of Informed Consent*

Ethical research involving humans requires free and informed consent. To that end, all potential human participants (e.g., interviewees, research subjects, community members, etc) have the right to be informed of:

- the nature of the research (hypotheses, goals and objectives, etc.);
- the research methodology to be used (e.g., medical procedures, questionnaires, participant observation, etc.);
- any risks or benefits;
- their right not to participate, not to answer questions, and/or to terminate participation during data collection or at anytime without prejudice (e.g., without academic penalty, withdrawal of remuneration, etc.);
- their right to anonymity and confidentiality; and
- any other issues of which the participants should be aware that are relevant to specific protocols and research projects.

Free and informed consent from participants should be in writing, unless shown to be inappropriate. The manner in which a Principal Investigator obtains informed consent may be restricted as a result of the nature of the research, status of the participants, and culturally-specific norms. The principles of informed consent must be met; however, the reviewing bodies shall be flexible in how that consent is obtained where circumstances warrant. The following three methods of informed consent are acceptable:

**Informed Consent Form:**

The traditional informed consent form is the standard for research involving human participants and it is the one required to be used routinely. This details the principles outlined above, and require the participants' or their representative'(s) signature(s).

**Letter:**

Where the traditional informed consent form is not appropriate (e.g., interviews with artists or government officials, mass mailed questionnaires, etc.), the researcher may seek permission by means of a communication signed by the Principal Investigator inviting participation. This letter ***must*** incorporate the principles of informed consent outlined above.

**Verbal statement:**

***Only in extenuating circumstances,*** where written communication is not feasible (children, illiterate adults, certain communities), may researchers relay the principles outlined above verbally, the script of which must be provided to the review Committee.

*(b) Informed Consent and Research Involving Individuals Not Legally Competent*

Generally, research involving not legally competent subjects[5] should be restricted to questions that can not be addressed with competent subjects. Subject to applicable legal requirements, individuals who are not legally competent shall only be asked to become research subjects when:

(i) the research question can only be addressed using individuals within the identified group(s);
(ii) free and informed consent is obtained from their authorized representative(s); and
(iii) the research does not expose them to more than minimal risks without the potential for direct and significant benefits for them.

**3. Conflict of Interest**

Any conflict of interest that exists or may appear to exist as it relates to any of the researchers must be described, even though this need not preclude the continuance of the research. A conflict of interest may exist if there is potential benefit to the researcher(s) beyond the professional benefit from academic publication or presentation of the results (and consequent honoraria, royalties, etc.).

**III. Research that is Subject to Ethics Review**

All University-based research involving human participants, whether funded or non-funded, faculty or student, scholarly, commercial, or consultative, is subject to the ethics review process. Research subject to review includes, but is not limited to, surveys, questionnaires, interviews, and participant observation.

1. For clarity, the following specific situations are subject to review:

(a) Research involving human remains, cadavers, tissues, biological fluids, embryos or foetuses shall be reviewed by the *Advisory Committee on Biological Safety*[6] and if the research involves human participants who are requested to contribute biological fluids and/or tissues to the research, it shall also be subject to ethics review.

(b) Where the research involves interaction with an individual in public life or an artist as a research subject by way of a request for an interview or for access to private papers, the ethics review shall focus only on whether these requests will be made in accordance with appropriate ethical and professional standards.

(c) Research involving participant or naturalistic observation is subject to ethics review except for those instances in which the observation involves participants in political rallies, public demonstrations, etc.

(d) Generally, research that has been approved by another institution (or multi-centred research) is, notwithstanding that
approval, subject to ethics review and approval at York University. If, however, all the research data has been collected pursuant to a research protocol that has been approved by another institution that subscribes to the TCPS, then the research is not subject to ethics review.

(e) Pilot or preliminary research.

2. For further clarity, the following specific types of research are **not** subject to review, or are subject to a limited ethics review:

(a) Research about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews, is not required to undergo ethics review. Such research only requires ethics review if the subject is approached directly for interviews or for access to private papers, and then only to ensure that such approaches are conducted according to professional protocols.

(b) Research about a living individual, particularly one in public life, or criticism of a living artist based exclusively on published or publicly available works, performances, archival materials, or information derived from third-party interviews, does not require ethics review because such research involves no interaction with the person who is the subject of the public records. Interviews with third parties shall be conducted according to a professional interview protocol and potential interviewees shall be fully informed about publication of the interview and their identity. Third-party interviews shall not be controlled in any way by the primary focus of the research.

(c) Quality assurance studies, performance reviews or testing within normal educational requirements are not subject to ethics review. This means that studies related directly to assessing the performance of an organization or its employees or students, within the mandate of the organization or according to the terms and conditions of employment or training, is not subject to ethics review. However, performance reviews or studies that contain an element of research in addition to assessment may need ethics review. Whenever there is any doubt about the applicability of this Policy to a particular research project, the Principal Investigator may contact the Manager, Research Ethics in the *Office of Research Administration.*

(d) Practica are generally not subject to ethics review because they do not involve research. If a practicum placement requires that a student conduct research on human participants as part of the course requirement, then it is subject to ethics review.

## IV. The Ethics Review Process

### 1. Overview of the Ethics Review Process

All research that is subject to ethics review must be approved by the appropriate ethics review body before the research may begin. Course-related (undergraduate and graduate), non-funded, minimal-risk[7] research (including Major Research Papers and Comprehensive Examinations) is reviewed by a Faculty, Department, School or Graduate Program review committee. All other research is reviewed by the University-wide ethics review committee, *the Human Participants Review Committee* (HPRC). The HPRC shall conduct either a full or expedited review, depending on the level of risk, the status of the research, and the urgency of the review[8].

All researchers must complete and submit the relevant Protocol Form[9] for ethics approval to the appropriate ethics review body. The review shall be conducted according to the principles and procedures set out in this document. If an ethics review body refuses to approve the research or if the body requires amendment to the research as a condition of approval and the Principal Investigator disagrees with the proposed amendments, the Principal Investigator may appeal the ethics review body's decision to the York Ethics Appeal Committee[10] which shall conduct an ethics review of the research Protocol and the procedures followed by the body that conducted the first review. Research that is subject to ethics review and that is not approved may not be undertaken.

### 2. Governing Principles of the Ethics Review Process

(a) Review procedures should ensure that there is accountability by way of a paper trail from the researcher to HPRC to the Senate Committee on Research (SCOR).

(b) Ethics review should be an integral part of a research proposal, but should not become so cumbersome that researchers see it as a "nuisance."

(c) Reviews should be conducted in an efficient and timely manner.

(d) If there is an actual or perceived conflict of interest between the Principal Investigator and a member of the ethics review body, the member of the ethics review body shall declare the conflict and withdraw from the consideration of the proposal.

### 3. The Human Participants Review Committee (HPRC)

The University-wide Human Participants Review Committee serves the York research community in three ways; it:

- contributes to the education of research ethics;
- conducts independent, multi-disciplinary review of research proposals; and
- oversees the ethics review conducted by the Faculty, Department, School and Graduate Program review bodies.

HPRC is a sub-committee of the Senate Committee on Research (SCOR). It is responsible for ensuring that researchers respect the safety, welfare and dignity of human participants in their research and treat them equally and fairly and not as a means to an end. Through both financial and in-kind support from the *Office of Research Administration* and the Associate Vice-President Research the HPRC shall have the requisite financial and administrative support to ensure that it has both the autonomy and resources to fulfill its responsibilities[11].

*(a) Terms of Reference*

The HPRC shall:

(i) Conduct ethics reviews within the context of the University's responsibility to ensure that the research meets high scientific and scholarly standards;
(ii) Delegate course-related, non-funded, minimal risk (including MRP's and Comprehensive Examinations) research to the relevant Faculty, Department, School or Graduate Program ethics review body for review and approval; and oversee that review process;
(iii) Terminate any research that it considers to be threatening or causing distress to the participants, deviates from the approved Protocol, or has not been approved by the appropriate body;
(iv) Ensure that Faculties and Libraries are familiar with, and adhere to this Senate Policy.
(v) Act as an advisory body for the University, educating the community on ethics in research and providing guidance on the ethics review process;
(vi) Report at least once a year to SCOR on its activities, including a list of Protocols reviewed and approved;
(viii) Ensure that Faculties advise research assistants and students about the relevant aspects of ethics in research and that they treat participants ethically and respectfully.

*(b) Composition*

The HPRC is composed of the following:

*Voting Members*

- at least 5 faculty members (appointed in accordance with the Guidelines and Procedures for Senate Nominations, The Senate and Committee Rules, Procedures and Membership);
- a community representative who has no affiliation with the University; and
- the Associate Deans of the Faculty of Graduate Studies (for purposes of graduate research review);
- additional members may be appointed as required to ensure that all of the following subject areas are represented:

(a) social sciences or humanities
(b) ethnographic research methodology
(c) ethics
(d) law
(e) psychology
(f) biomedical sciences

*Ex-officio Non-Voting Member*

- the Director of the Office of Research Administration

The composition of the HPRC shall reflect the University's commitment to gender equity. The term of service for members on HPRC is three years, with one-third of the membership appointed each year, thereby ensuring continuity and consistency of membership. Members of the HPRC shall be appointed by the Vice-President Research and Innovation in consultation with the Associate Vice-President Research and the Chair of SCOR. The Chair and Vice-Chair of HPRC shall be chosen by the members of the Committee.

*(c) Meetings*

The HPRC shall meet at least bi-monthly to review completed Protocol Forms. All members are expected to attend the meetings; however, quorum for meetings shall be a majority of the voting members. The HPRC shall keep minutes of its meetings.

**4. Faculty, Department, School or Graduate Program Ethics Review Committees**

All Faculties shall establish, under the authority of the HPRC, an ethics review committee(s). The committee may be a subcommittee of the Faculty research committee. Departments, Schools or Graduate Programs within Faculties may establish an ethics review committee if the level of research activity within the unit warrants. The HPRC encourages Faculties to establish joint review committees with other Faculties, Departments, Schools or Graduate Programs[12].

The Faculty, or where it exists, the Department, School or Graduate Program Committee shall be responsible for conducting the ethical review of all course-related, non-funded, minimal risk research proposed by students in Departments, Schools or Graduate Programs, with the exception of theses and dissertations which are to be reviewed by an Associate Dean of the Faculty of Graduate Studies and the Chair or Vice-Chair of HPRC.

The Faculty, Department, School or Graduate Program ethics review committees shall:

(a) Establish review procedures according to the guidelines set out above and approved by the HPRC[13];

(b) Review all course-related, non-funded, minimal risk research proposals (including MRP's and Comprehensive Examinations) that are subject to ethics review according to the policies and review criteria set out in this document;

(c) Report to the HPRC by July 30th[14] of each year on the research proposals (name of Principal Investigator and topic or research title) reviewed and the decisions made for the 12 month period ending June 30th; and

(d) Obtain a written statement from the instructor or supervisor confirming that the Principal Investigator has been advised that all human participants in the research **must** have either signed a written consent form or have provided oral consent for their participation in the research. The Principal Investigator must also be advised that consent forms shall be retained by the Principal Investigator for two years following the completion of the research.

**5. Types of Review**

Ethics review shall be by way of an *expedited review, a Faculty, Department, School or Graduate Program review or a full review* of the proposed research depending on the status of the research and the level of risk involved in the research.

*(a) Expedited review*
An expedited review is conducted upon request by the Principal Investigator and when a Protocol meets certain criteria. The HPRC shall adopt an expedited review process for:

(i) research protocols that involve no more than minimal risk *and the review is urgent*;[15]
(ii) annual renewals of approved projects in which there has been little or no change in the ongoing research; and
(iii) Graduate theses and dissertations that involve minimal risk research to human participants.

Protocols under expedited review shall be reviewed by the Chair (or Vice-Chair) of HPRC, and one other committee member. Graduate theses and dissertations shall be reviewed by an Associate Dean, FGS and the Chair or Vice-Chair of the HPRC.

*(b) Faculty, Department, School or Graduate Program Review*
Course-related, non-funded, minimal risk research (including MRP's and Comprehensive Examinations) shall be reviewed by a Faculty, Department, School or Graduate Program ethics review committee.

*(c) Full review*
All other research that is subject to review by the HPRC shall be reviewed by the full HPRC.

**6. Review Procedure**

*(a) General Considerations*

The Principal Investigator must complete and file the Protocol Form with the relevant ethics review body. Any procedural change that is contemplated after the research has begun must be communicated to the applicable ethics review body. Any appearance of risks in the course of the research that were not foreseen in the original application must also be communicated to the ethics review body. Such changes, if not minor, may require re-approval by the reviewing body before the project can continue.

*(b) General Procedures*

The Principal Investigator is responsible for determining whether the proposed research is subject to ethics review and the particular review body that is responsible for reviewing the research. Questions about whether the proposed research is subject to review or the appropriate ethics review body should be directed to the Manager, Ethics Review or the person responsible for research in the Faculty (normally the Chair of the Research Committee). For research that is subject to ethics review, the Principal Investigator shall:

(i) Complete and file the Protocol Form with the appropriate ethics review body.
(ii) Not proceed with the research until advised by the ethics review body that the research has been reviewed and approved.
(iii) Advise the ethics review body in writing of any change in the research or any increased anticipated risks to human participants. If the changes or risks are not minor, the Principal Investigator may be required to apply for a further ethics review of the research.
(iv) Advise the ethics review body in writing when the research is completed.
(v) Retain for 2 years following the completion of the research, approved Protocol Forms, including a sample of the consent form used, or the text of oral consent.

*(c) Procedures for the Review of Research Involving Individuals Not Legally Competent*

For research involving not legally competent individuals, the ethics review body shall ensure that, as a minimum, the following conditions are met:

(i) The Principal Investigator shows how the free and informed consent will be sought from the authorized third party, and how the subjects' best interests will be protected;
(ii) The authorized third party shall not be the Principal Investigator or any other member of the research team;
(iii) The continued free and informed consent of an authorized third party shall be required to continue the participation of a not legally competent subject in research so long as the subject remains not legally competent;

(iv) When a subject who was entered into a research project through third-party authorization becomes competent during the project, his or her informed consent shall be sought as a condition of continuing participation; and
(v) The script of a verbal communication is provided to the ethics review committee when a Verbal Statement is the method of informed consent used in the research project.

Where free and informed consent has been obtained from an authorized third party, and in those circumstances where the not legally competent individual understands the nature and consequences or the research, the Principal Investigator shall seek to ascertain the wishes of the individual concerning participation. The potential subject's dissent will preclude his or her participation.

**7. Decisions**

Following a review of the Protocol, the ethics review body may:

(a) approve the Protocol or approve the Protocol subject to terms, conditions or modifications;
(b) request additional information from the Principal Investigator;
(c) defer approval pending a review of the Protocol by the full HPRC; or
(d) not approve the Protocol. Prior to issuing a "research is not approved" decision, the ethics review body shall provide the Principal Investigator with an opportunity to appear before the before the body and address any issues raised by the body.

All decisions require unanimous consent of those members of the ethics review body who review the Protocol.

The ethics review body shall not approve research in which the research is conditional upon the subject or subjects having the right to veto the research project or the public dissemination of the research findings after the completion of the data collection; however, research subjects may refuse to co-operate with the researcher(s)/Principal Investigator(s) or withdraw from the research at any time prior to the completion of the data collection phase of the project. Principal Investigators who are conducting "participatory action research" should be especially sensitive to the need to keep research subjects fully involved in both the design of the research as well as the research findings.

The Secretary/Chair will convey the decision of the ethics review body in writing to the applicant.

Approval is for a 12 month period or for the duration of the MRP, Thesis or dissertation research, unless there are changes in the research design. A Protocol may receive up to three subsequent annual renewals by the Manager, Research Ethics, upon confirmation in writing (via an annual status report) from the Principal Investigator that the risks, if any, are as anticipated in the approved Protocol (and that there are no new or unanticipated risks and there are no material change(s) to the research). If there are new risks or there are material changes to the research, the Principal Investigator shall not continue with the research until a new Protocol has been submitted, reviewed and approved by the ethics review body.

**8. Appeals of Decisions: York Ethics Appeal Committee (YEAC)**

Applicants whose research proposal is not approved by the HPRC or by the relevant Faculty, Department or Graduate Program ethics review body, may appeal that decision to the York Ethics Appeal Committee (YEAC). The decision of YEAC is final and binding on the Principal Investigator.

*(a) Terms of Reference*

The York Ethics Appeal Committee (YEAC) is a subcommittee of SCOR. YEAC shall:

(i) Hear appeals from Principal Investigators whose research Protocol has not been approved by the ethics review body or who object to the terms and conditions imposed by the ethics review body; and

(ii) Report annually to SCOR on appeals heard and the disposition of those appeals, including a summary of the reasons given for its decision.

*(b) Composition*

The Committee is composed of the following:

- at least 5 faculty members (appointed in accordance with the *Guidelines and Procedures for Senate Nominations*, The Senate and Committee Rules, Procedures and Membership)
- a community representative who has no affiliation with the University;
- additional members may be appointed as required to ensure that all of the following subject areas are represented:

(a) life sciences
(b) ethnographic research methodology
(c) ethics
(d) law
(e) psychology
(f) biomedical research

The term of service for members of YEAC is three years. Members of the YEAC shall be appointed by the Vice-President Research and Innovation following consultation with the Associate Vice-President Research and the Chair of SCOR. Ideally former members of the HPRC will serve on YEAC.

*(c) Grounds of appeal*

The grounds for an appeal are that the ethics review body failed to follow the procedures set out in this document and/or failed to comply with the policy and principles set out in this document.

*(d) Procedures for an Appeal*

(i) An applicant may file an appeal of a decision of the ethics review body within 15 days of receipt of the ethics review body's decision.
(ii) Appeal applications must contain the text of the ethics review body's decision, the specific ground on which the appeal is made and evidence in support of these grounds.
(iii) Applicants may appear in person before the YEAC to present their appeal, and must inform the committee of their intent to appear at a meeting.
(iv) YEAC has the right to all documents that were considered by the ethics review body. Responsibility for the provision of these documents rests with the applicant.

*(e) Decisions*

Following a review of an appeal, YEAC may:

(i) Accept the appeal and approve the research, subject to terms and conditions;
(ii) Refer the matter back to the ethics review body for reconsideration, with instructions for the re-consideration; or
(iv) Reject the appeal and affirm the decision of the ethics review body.

The Secretary to the YEAC will convey the decision of the Committee in writing to the applicant.

**V. Education and Dissemination**

York University is committed to the provision of an education process and outreach service on ethics in research generally and the Senate Policy on the ethics review. To that end, the University is committed to the dissemination of information on the guiding ethical principles and the requirements of its ethics review process to faculty, students, staff and the community. They are:

(a) meetings and presentations to relevant faculty members - specifically:

- the members of the various ethics review committees (including HPRC);
- the Associate Deans whose responsibilities include research; and
- Department Chairs.

(b) open sessions in the Faculties - designed to address a broader audience, including all faculty, staff and students. These sessions are regular features, typically offered prior to granting council submission deadlines.

(c) a web site[16] - to provide policy and process information to the University community, including:

- guidelines and a summary of the presentations made in the open sessions;
- the Tri-Council Policy Statement; FAQs and responses;
- ongoing information about and links to developments in research ethics;
- York's ethics review policies and process;
- information about the HPRC, Animal Care Committee, and Biological Safety Committee;
- the *Senate Policy for the Ethics Review Process for Research Involving Human Participants*; and
- the Protocol Form.
- appropriate language for consent forms

The *Centre for Practical Ethics* is a partner of the HPRC in the educative role. It assists in the co-ordination of and participates in the presentations at the information sessions.

Questions on any of the above information can be addressed to the Manager, Research Ethics in the *Office of Research Administration.*

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Footnotes

[1]Research, for the purpose of this Policy, involves a systematic investigation to establish facts, principles or generalizable knowledge, and it includes pilot or preliminary research.
[2]Human Participants are persons who provide data or information to the researcher, which are typically, not part of their professional capacity, or in the public domain.
[3]The term "researcher" and/or "Principal Investigator" when used in this policy includes:
a. any member who conducts or advances research in that capacity or who accesses University students or staff as human research participants;
b. any other person who conducts or advances research as connected with the University; and

c. any person who conducts research using University resources (whether research space, materials, equipment or human resources).

The term "member" when used in this Policy includes faculty, emeritus faculty, contract faculty, staff, administrators, students, visiting or adjunct scholars, fellows and chairs, paid and unpaid research associates and assistants and any person in a like position.

[4]The TCPS and the *Memorandum of Understanding* is on file with the Manager, Research Ethics.

[5]Consistent with the TCPS, competence refers to the ability of prospective subjects to give informed consent in accord with their own fundamental values. It involves the ability to understand the information presented, to appreciate the potential consequences of a decision, and to provide free and informed consent.

[6]The ACBS is a separate sub-committee of the Senate Committee on Research.

7Minimal risk means: "If potential subjects can be reasonably expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research then the research is minimal risk research".

[8]The types of review are described in Section IV, 5.

[9]A copy of the HPRC Form is attached as Appendix A. Faculties may create their own protocol forms providing that the form(s) are consistent with the Senate Protocol Form and it is approved by the HPRC.

[10]The Appeals Committee is described in Section IV. 8.

[11]The HPRC is provided web and administrative support through the *Office of Research Administration* (ORA) and the new position of Manager, Research Ethics. In addition, the University has created the positions of Research Officer, partially funded by the A-VPs office. The purposes of the officers are to help liaise with ORA, and be a "local contact" for research issues. In addition to the resources provided to the HPRC in its role as a sub-committee of SCOR, the HPRC is also supported financially through the provision release time for the Chair of the HPRC as the review process is brought in line with the Tri-Council Policy Statement.

[12]For example, a joint committee of the corresponding Department and Graduate Program, or between Departments of similar/related disciplines such as DLLL and French in the Faculty of Arts.

[13]A copy of the Faculty procedures is attached as Appendix B.

[14]A flow chart of the Review and Reporting Structures is attached as Appendix C.

[15]An urgent review is a review, which through no delay of the P.I., must be reviewed in 7 days or less.

[16]The web-site is housed and maintained by the Office for Research Administration

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Appendix A - Protocol Form

Appendix B - *Pending*

Appendix C - Flow Chart of the Review and Reporting Structure

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