



McGill

Memorandum

Office of the Vice-Principal (Research and International Relations)

James Administration Building

Suite 419

Tel: 398-3991 Fax: 398-8257

| | |
|--------------------|---|
| TO: | Senate |
| FROM: | Professor Denis Thérien, Vice-Principal (Research and International Relations) |
| SUBJECT: | Revisions to the Policy on the Ethical Conduct of Research Involving Human Subjects |
| DATE: | April 25, 2008 |
| DOCUMENT #: | D07-55 |

FOR: **DECISION** **DISCUSSION** **INFORMATION**

ISSUE: Approval of revisions to Section 2.2 and Section 6.0 of the *Policy on the Ethical Conduct of Research Involving Human Subjects*

BACKGROUND: An application for designation of the Research Ethics Board-III by the Ministry of Health and Social Services for the purposes of review of research under the auspices of Article 21 of the Quebec Civil Code, was made by the Board of Governors in July 2007. Following review by the Ministry, conditional approval was granted pending several requirements for modifications including some revisions to Section 2.2 and Section 6.0 of the *Policy on the Ethical Conduct of Research Involving Human Subjects*. These required changes are shown below.

**MOTION OR
RESOLUTION
FOR APPROVAL**

Be it resolved that Senate approve, and recommend to the Board of Governors for approval, the following resolutions:

That Section 2.2 ,Research Ethics Boards, of the *Policy on the Ethical Conduct of Research Involving Human Subjects* be amended to read:
 - for biomedical research, and for all research reviewed by an REB designated by the Ministry of Health and Social Services~~all research under the auspices of Article 21 of the Quebec Civil Code~~, at least one member who is knowledgeable in the relevant law but is not the legal counsel of the University; this is advisable but not mandatory for other areas of research; and

That Section 6.0, Complaints, Concerns and Recommendations, of the *Policy on the Ethical Conduct of Research Involving Human Subjects* be amended to read:

Subjects who have specific complaints or concerns about any aspect of their participation in a research study should contact the Research Ethics Officer in the Office of the Vice-Principal (Research and International Relations). The Chair of the Advisory Council on Human Research Ethics~~relevant Research Ethics Board~~ will be notified immediately for investigation of the complaint. Once all the information is received, the Chair of the Advisory Council on Human Research Ethics~~REB~~ will determine if any further action is necessary. The subject and the Principal Investigator will be notified of any decision and the justification for any actions taken. If ~~noncompliance or~~ research misconduct is suspected, as defined under the University's Regulations Concerning Investigation of Research Misconduct, the Chair of the Advisory Council on Human Research Ethics~~REB~~ shall immediately initiate the reporting~~appropriate~~ process described in said Regulations~~under the University's regulations concerning the investigation of research misconduct~~. The REB involved must be notified of any investigation in progress to allow the REB to take any safety measures that may be necessary to protect the welfare of the research subjects. The subject and the Principal Investigator shall be so notified by the Chair of the REB. All complaints and actions taken, with confidentiality maintained, shall be reported in the ACHRE~~REB~~ annual report. All founded complaints or cases of research misconduct, including the researcher's nominative information, must be reported to the relevant authorities as required by the applicable regulations, policies, code or collective agreement to which the researcher is subject. This includes the Dean/Chair of the Faculty, School or Department, the Vice-Principal (Research and International Relations), the REB that approved the research, and where relevant, the Board of Governors and the Ministry of Health and Social Services, and to other persons who have a legitimate need to know. All REB records, including investigator proposals and nominative information, shall be made available to authorized individuals for the purposes of auditing, monitoring and investigation of complaints or research misconduct.

RATIONALE: These changes are required by the Ministry of Health and Social Services.

PRIOR CONSULTATION: Internal: Prof. M. Smith (Chair, Advisory Council on Human Research Ethics), REB-III, Office of the Vice-Principal (Research and International Relations), Line Thibault (General Counsel and Director, Legal Services), Prof. W. Foster, Associate Provost (Policies and Procedures)

External: Quebec Ministry of Health and Social Services Ethics Unit

NEXT STEPS: Approval by the Board of Governors

APPENDICES: The complete Policy with the tracked changes is posted on the Senate website at:
<http://www.mcgill.ca/senate/sectionforsenators/2007-2008senatemeetings/may72008/>
