Senate Research Ethics Board Terms of Reference

Approved by Senate
December 7, 2007
Last Revised
February 2008

Seven (7) days' notice shall be given for all meetings except that a meeting may be held at any time without due notice if all members of the Committee are able to be present and/or consent thereto.

Quorum: Unless otherwise stated in the approved terms of reference, quorum for Senate and all Senate committees is a simple majority of all filled positions. Committee members whose positions are listed as ** shall not typically be included in the total when quorum is counted.

Members of the Research Ethics Board must have respect for the diversity of research methodologies used by researchers engaged in human subject research.

Composition
Appointments to the REB, other than ad hoc appointments, are for a term of three years, renewable. Members of the Lakehead University REB, other than ad hoc members, are elected by Senate on the recommendation of the Senate Nominations Committee and will include:

1. Six faculty members with experience in or knowledge of human subject research. In order to accommodate the diversity of research methods applied in human subject research at Lakehead University, appointments will be made so as to maintain a balance in expertise between SSHRC, NSERC and CIHR-eligible areas of research.
2. Faculty members applying for service on the REB may be requested to provide Senate Nominations Committee with a brief description of their background and expertise in human subject research.
3. Two members without affiliation with the institution but recruited from the community served by the institution.
4. One faculty member with expertise in the area of ethics. TCPS guidelines require that there be one member who is "knowledgeable in ethics" (1.3c). This can be someone who has a teaching or research specialization in ethics, or someone who has had extensive experience in the area of research ethics.
5. One member from the Lakehead University Centre for Health Care Ethics.
6. One faculty member whose research is concerned with Aboriginal Peoples, selected by the Aboriginal Management Council.
7. One faculty member from the Northern Ontario School of Medicine (non-voting).**
8. Ad hoc members may be appointed by the REB whenever their expertise is requisite to the provision of fair and reasonable review of research.**
9. Manager, Office of Research (non-voting).**

Terms of Office
Other than ad hoc appointments, appointments are for three-year terms, renewable.

Absenteeism

As outlined in the Absenteeism on Standing Committees policy, "The chair and/or secretary of each Senate standing committee shall to the extent possible publish a meeting schedule for the year. Members of Senate committees are expected to attend committee meetings and are to inform the committee chair of their inability to attend. Members who exceed three (3) absences per academic year will have their membership automatically terminated unless determined otherwise by the Chair."

Organization

1. Chair: to be elected by the REB from among those members holding academic appointment
2. Secretary: Research Ethics and Administration Officer, Office of Research
3. Administrative Office: Office of Research

Annual Report

The REB shall provide an annual report to Senate by April 30 each year.

REB Meetings

1. The REB will hold meetings once monthly from September through April. Additional meetings will be held whenever necessary.
2. In making administrative decisions, the REB will follow University standards according to Robert's Rules of Order. Decisions shall be by consensus as declared by the Chair, subject to the right of any REB member to request a vote on any decision to override the Chair.
3. Observers will be admitted to REB meetings provided that they sign a confidentiality agreement form.
4. The quorum for REB meetings consists of any five voting members.

Reconsideration and Appeal of REB Decisions

Lakehead University's Research Ethics Appeal Board is Laurentian University's Research Ethics Board. Appeals may be granted only on procedural grounds or when there is a significant disagreement over an interpretation of the Tri-Council Policy. The decision of the Appeal Committee shall be final and binding within Lakehead University.

SEE ALSO "ETHICS PROCEDURES AND GUIDELINES FOR RESEARCH INVOLVING HUMANS" in the SENATE POLICIES

Lakehead
UNIVERSITY

Research: Ethics Procedures and Guidelines for Research Involving Humans

Effective Date: December 7, 2007

Approved by: Senate

Ethics Procedures and Guidelines for Research Involving Humans

A supplement to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

Research Ethics Board - Lakehead University

Last revised April 2004

View terms of reference and composition of Research Ethics Board here.

At Lakehead University, the primary purpose of ethics review of research involving human subjects is the protection of research subjects - their physical and psychological safety as well as their dignity and privacy - while maintaining Lakehead University's reputation as a research institution and the academic rights and freedoms of its faculty and students.

Defining research and research that requires REB review

All research involving human subjects, conducted by members of Lakehead University (faculty, support staff or graduate students) must receive ethics approval from Lakehead University's Research Ethics Board (REB). Undergraduate students involved in research with human subjects must receive approval from their departmental Research Ethics Board (see 3.2 below). For undergraduate or graduate student research, all applications for ethical approval must be submitted by the research supervisor as the Principal Investigator, with the student identified as the Student Investigator.

1.1a For the purposes of review by the REB, "research" is defined in the *Tri-Council Policy Statement B Ethical Conduct for Research Involving Humans* (TCPS) as a "systematic investigation to establish facts, principles, or generalizable knowledge".

1.1b Research involving human subjects occurs when:

- Primary data is obtained through intervention or interaction with a living individual(s) including interviews

and the use of such impersonal data-gathering instruments as questionnaires

- Research involves secondary data (e.g. medical or school records). "Secondary use of data refers to the use in research of data contained in records collected for a purpose other than the research itself" (TCPS, 3.4)

- Human remains, cadavers, human organs, tissues and biological fluids from individually identified subjects, embryos or fetuses are used. (Research involving human remains, cadaver, tissue, biological fluids, embryos or fetuses shall be also reviewed by Lakehead University's Biosafety Committee.)

1.1c Research off campus (including other institutions and projects conducted outside the country) requires REB approval. With respect to research conducted, wholly or in part, outside Lakehead University researchers are directed to Article 1.14 of the TCPS: "Research to be performed outside the jurisdiction or country of the institution that employs the researcher shall undergo ethics review both (a) by the REB within the researcher's institution and (b) by the appropriate REB, where such exists, which has authority in the country or jurisdiction where the research is to be done."

1.1d Research involving human subjects who are students, faculty or employees of the University or its affiliated institutions/centres by individuals who are not students, faculty or employees of the University will normally require an internal co-researcher who shall assume responsibility for the research being compliant with TCPS and University policies relevant to human subject research.

1.1e Outside researchers seeking access to Lakehead University academic or administrative records must have a Lakehead University affiliated researcher as part of their research team who is identified as a co-investigator.

1.2 Research that involves collection of the following types of data generally does not require ethics approval:

- Observation of behavior within a public gathering which cannot be associated with any particular individual or group of individuals, excluding audio or video recording

- Information which is already in the public domain (e.g. autobiographies, diaries or public archives)

- Student evaluation of teaching and classroom activities including testing within normal educational requirements are not subject to REB review unless they contain an element of research.

1.3 The TCPS defines "secondary data" as "data contained in records collected for a purpose other than the research itself" (3.4). Any project involving the extraction of secondary data from non-public records containing identifying information, such as school or medical records, requires REB approval. Research using secondary data which has already been made public through publication or data contained in an archive or database does not require REB approval. Researchers must exercise caution in the use of secondary data which can contain such identifying information as place of residence, postal code or ethnic origin which might be linked to individuals by process of inference or elimination. Special care is required in the use of secondary data gathered from small communities.

1.4 Any activity that involves an element of human subject research as defined by the TCPS is subject to REB review even where the primary aim of the activity is instructive or administrative.

1.5 Clinical trials must receive approval from a Research Ethics Board, and usually from Health Canada. According to Health Canada, "clinical trial" means "an investigation in respect of a drug or natural health product for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the drug, identify any adverse events in respect of the drug, study the absorption, distribution metabolism and excretion of the drug, or ascertain the safety or efficacy of

the drug." This may include the use of nutritional supplements. (The process for review of clinical trials is lengthy and complex. Consult with the Chair of the Research Ethics Board prior to submitting an application to the REB involving a clinical trial.)

Reconsideration and Appeal of REB Decisions

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3.0 Departmetal Undergraduate Ethics Committees

3.0a The REB delegates the ethical review of undergraduate research projects to Departmental Ethics Committees which are responsible for reviewing any undergraduate course-based research projects and honours theses that involve research on human subjects, and/or are a component of the pedagogical process.

3.0b Departmental Committees are responsible for referring to the REB any matter of ethical concern that the Departmental Committee is, by reason of disagreement or otherwise, unable to resolve, or is greater than minimal risk as defined by the TCPS.

3.0c Academic units regularly engaged in human subject research are to maintain an active research ethics committee charged with the review and monitoring of undergraduate research. This committee should consist of a minimum of three faculty members who have completed the *Introductory Tutorial for the Tri-Council Policy Statement*. The committee must be registered with the Office of Research, and keep formal records of their deliberations and decisions. A list of approved projects must be submitted to the REB twice annually, in January and July. Departments not regularly involved in human subject research are required to forward undergraduate research proposals involving human subjects to the REB for review.

3.0d Departmental level review cannot be used when a student's project is part of a faculty member's own research program. Such research must receive ethics approval from the Research Ethics Board.

4.0 Review Process

4.1 The review process followed by the REB varies according to the level of risk posed to research subjects.

Research which involves greater than minimal risk must be reviewed by the REB at a face-to-face meeting.

4.1a The determination of research as more than minimal risk can be made in two ways:
1) During the review process the Chair or any member of the REB may designate the proposal as more-than-minimal-risk.

2) In cases where status of degree of risk is in question, the REB may refer the proposal to an ad hoc committee of three suitably qualified reviewers in order to identify potential risks implicit in the research design.

4.1b When research proposals involve more than minimal risk, their scientific and scholarly merit will be subject to review. Evaluation of scholarly merit involves an assessment of the degree to which the research might further the understanding of the phenomenon being studied. The primary test for scholarly merit is the application of scientific and scholarly standards. A review of scholarly merit may be conducted as part of the ethical review process or may be delegated to an ad hoc committee of suitably qualified reviewers.

4.2 Outcomes of the Regular Review Process

4.2a Decisions shall be by consensus as declared by the Chair, subject to the right of any REB member to

request a vote on any decision to override the Chair.

4.2b Where the Chair is of the opinion that a consensus of the REB reveals ethical problems such that approval cannot be granted, the Chair will communicate the problems in writing to the applicant. If required, the Chair will then meet with the researcher(s) to determine if the protocol can be modified to satisfy the concerns of the REB.

4.2c Researchers have the right to meet with the REB to discuss the REB's application of TCPS guidelines to their proposals and to discuss ways in which ethical problems inherent in their research proposals might be resolved.

4.2d Where the Chair is of the opinion that a consensus exists against granting ethical approval, and attempts to address the ethical problems are unsuccessful, the Chair may disallow or suspend research on ethical grounds.

4.3 Delegated Review Process:

4.3a Lakehead University recognizes the concept of "delegated review", a streamlined review process by which approval can be granted on the basis of review by the Chair and any two members of the REB. Delegated review may be granted in cases where proposals:

- involve a replication of a previously approved protocol
- have been approved by an REB at another institution
- do not create risks greater than the minimum threshold; and/or
- do not include biomedical elements

4.3b If the proposal is a resubmission for review because of minor revisions to the protocol, the Chair may provide approval based solely on his or her review.

5.0 Review/Monitoring of On-Going Research and Reporting Requirements:

5.0a Protocols are approved for a period of one year. For approved projects that are ongoing, the principal investigator is required to submit an annual Request for Renewal form.

5.0b The REB shall be promptly notified when the project concludes with the completion of a Final report. The REB may request additional reports from time to time.

5.0c Changes to approved ethics protocols must be approved by the REB prior to being implemented. The REB must be notified in writing of any potential changes to recruitment procedures, or informed consent documents.

5.0d The REB must be promptly notified of any adverse events that occur during the course of the research.

5.0e All approved protocols are subject to monitoring by the Office of Research as part of a program of randomized spot checks of research activities. (See 7.1c below).

6.0 Standard Protocol for Course-Based Research Projects

6.1 Research which is carried out primarily for instructional purposes as part of course requirements requires REB approval if the research component of the coursework meets the TCPS definition of "research" (see 1.1a and 1.2 above) and will be required to meet the same ethical criteria as any other research on human subjects.

6.1a Research assignments that are repeated across sections and/or semesters can be approved as a

"standard protocol". Once a protocol has been approved for a particular course number, it can be applied to different sections, years or instructors. Reapproval will be necessary after five years or where course requirements are changed which substantially affect the methodology/research design of the research component of the course.

6.1b All graduate thesis work involving research on human subjects requires REB approval. Where research is carried out as part of graduate coursework, the research component of the course requires REB approval and may qualify for clearance as a standard protocol (see 6.1a above).

Researchers' Procedural Responsibilities

7.1 Submission of Proposals and Projects

7.1a It is the responsibility of the researcher(s) to obtain ethical approval for any active project, funded or not, involving human subjects and to submit that project with complete documentation as per the Researcher's Agreement Form to the Lakehead University REB.

7.1b Ethical review will normally take two to three weeks to complete. Cases involving biomedical elements, clinical trials, or those containing significant ethical problems may take substantially longer. It is the researchers" responsibility to ensure that there is adequate lead-time available for ethical review in relation to other deadlines.

7.1c It is the responsibility of the researcher to comply with requests made by the REB or the Office of Research with respect to ongoing monitoring of approved projects.

7.2 Funded Projects

7.2a Funds for research projects involving human subjects will not be released until ethics approval has been obtained. Research accounts will not be established until approval, either "in principle", or in full has been confirmed.

Researchers can apply for in principle ethics approval when their funded research will eventually require the use of human subjects, but the methodology is not sufficiently developed to submit a complete application to Research Ethics Board. Requests for in principle ethics approval can be made through the Office of Research.

Risks and Benefits – General Guidelines

- The researcher must assess and document all possible risks involved in and benefits expected from the research
- The researcher must demonstrate that there is no reasonable alternative methodology that would avoid or reduce possible risks
- Where appropriate in light of the risks involved, the researcher may be required to demonstrate successful prior first-hand experience with the methodology proposed and the absence of detriment to the subjects involved

Defining Risks

9.1a The TCPS discusses minimal risk as follows: "if potential subjects can reasonably be 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 can be regarded as within the range of minimal risk. Above the threshold of minimal risk, the

research warrants a higher degree of scrutiny and greater provision for the protection of the interests of prospective subjects." (1.4 C1)

9.1b The researcher must be concerned with risks to:

- the subjects involved
- clearly identifiable third parties
- the researcher and any staff involved; and
- broader cultural, ethnic and national interests

9.1c The researcher must be concerned with at least the following types of risk:

- physical harm
- psychological harm
- injury to reputation or privacy and
- breach of any relevant law

9.2 Defining Benefits

9.2a 'Benefits' include specific advantages or increases in knowledge both consciously sought by the researcher and likely to arise as byproducts of the research.

9.3 Balancing Risks and Benefits

9.3a It is always the responsibility of the researcher, and of the REB, to ensure that the projected benefits outweigh the possible risks.

9.3b The more incalculable the risks, or the less tangible the benefits, the more cautious must be the researcher and the REB.

9.3c The REB must ensure that the research design and proposed implementation procedures are consistent with sound research standards and, where appropriate, with sound standards of professional conduct and practice, in order to be satisfied that there is no unnecessary exposure to risk.

10.0 Informed Consent - Guidelines

10.1 Nature of informed consent: The objective of obtaining informed consent is to ensure adherence to the ethical principle of respect for persons. The elements of consent that must be considered are capacity, comprehension, and voluntariness. "Capacity" means that the individual providing the consent must have the capacity or ability to understand that to which he/she is giving consent, and the researcher has an obligation to ensure the capacity of the consenter. "Comprehension" indicates that the consent must be presented in such a way, and that the researcher has an obligation to ensure that, the person providing the consent understands that to which he/she is giving consent. "Voluntariness" implies that consent must be obtained without coercion or undue inducement, and the researcher has an obligation to structure the process in such a way that coercion and/or undue inducement are not perceived by the person giving consent.

10.1a The subject who is to give informed consent must be given sufficient time and opportunity to consider the information provided, including the opportunity to consult with an advocate or other knowledgeable person, depending on the discipline in question or the risks involved.

10.1b The researcher must provide any person who is to give informed consent with at least the following information:

- the individual is being invited to participate in a research project
- the identity of the researcher (and supervisor or Lakehead co-investigator in case of 1.1e)
- a description of the topic being researched
- a precise description of the subject's involvement
- a description of the research procedures
- a description of the possible benefits involved
- a description of the risks or discomforts involved
- a description of the extent to which privacy and confidentiality will be protected
- an assurance that prospective subjects are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements, and will be given continuing and meaningful opportunities for deciding whether or not to continue to participate
- that the participant may choose not to answer any question in survey or interview research
- contact information for the researcher, their supervisor, and the Research Ethics Board
- a description of how the data will be stored and/or when it will be destroyed
- an indication as to who shall have access to information collected on the identity of the subjects and descriptions of how confidentiality shall be protected, and anticipated uses of the data

Researcher's should consult the Informed Consent Checklist (see Researcher's Agreement Form) in the preparation of informed consent documentation.

10.1c Additional information that may be required, depending upon the research protocol includes:

- an assurance that exemplary care will be taken to safeguard the subject
- an assurance that any new information shall be provided to the subjects in a timely manner whenever such information is relevant to a subject=s decision to continue or withdraw participation
- the identity of the qualified designated representative who can explain scientific or scholarly aspects of the research
- information on the appropriate resources outside the research team to contact regarding possible ethical issues in the research
- an explanation of the responsibilities of the subject
- information on the circumstances under which the researcher may terminate the subject's participation in the research
- information on any costs, payments, reimbursements for expenses or compensation for injury
- in the case of randomized trials, the probability of assignment to each option

- the ways in which the research results shall be published, and how the subjects will be informed of the results of the research

10.1d Age of Consent to Participate in Research

Normally subjects must be at least 18 years of age in order to consent to participate in research. Parental consent is required for those under the age of 18 who wish to participate in research, except in the case of Lakehead University students age 16 and older who may provide their own consent to participate in research on-campus that is determined to involve no more than minimal risk by the REB. The requirement for parental consent may be waived under special circumstances and the REB will consider such requests on a case by case basis.

10.2 Format of Consent

10.2a Consent in any format must demonstrate that there has been compliance with the foregoing requirements:

10.2b Where written consent is culturally unacceptable or where there are good reasons for not recording consent in writing, researchers shall explain this, and shall document the alternate procedures used to seek and obtain free and informed consent.

10.2c Where appropriate to the risks involved, a neutral witness should be identified as being present when the consent is given.

10.2d The REB may waive the requirement for written consent if:

- the research involves no more than minimal risk to subjects
- the waiver is unlikely to adversely affect the rights and welfare of the subjects
- the research could not be practically carried out without the waiver

10. 3 Vulnerable Subject Populations

10.3a Vulnerable subject populations include the following:

- research involving children and mentally incompetent persons
- research involving prisoners and
- research involving 'captive groups' such as employees, students, legal wards and the therapeutically dependent

10.3b In all cases involving vulnerable subject populations, the researcher must consult with the REB to obtain details of any specific additional requirements for informed consent.

10.3c In cases involving children or mentally incompetent persons, written consent will normally be required of a person having legal authority to give that consent (See section 10.1d).

10.3d In cases involving 'captive groups', informed consent shall be obtained from each individual subject, save that the REB may grant a total or partial exemption from this requirement when it is satisfied:

- that it is impracticable to require that such individual consents be sought
- that the risks to the subjects involved are minimal and

- that informed consent is given by one or more proper persons with responsibility for the 'captive group' in the knowledge that informed consent is not being sought from some or all individual subjects within that group

10.3e Whenever possible, consultation with other, appropriate authorities will be carried out.

11.0 Deception - Guidelines

11.1a 'Deception' involves either the deliberate withholding of relevant information or the deliberate giving of false information as part of the methodology of research.

11.2a A REB may approve a deceptive consent procedure if the following conditions are satisfied:

- The research involves minimal risk to the participants, and minimal levels of risk are documented
- Participant rights and welfare are not adversely affected by the procedure
- The research could not be practically carried out without the deception.

In cases where deception is used, researchers must:

- justify their use of the procedure, identifying the manner(s) in which the benefits of the deception outweigh the potential costs
- the inappropriateness of alternative research methods has been explained
- precedents for using the proposed methodology in their application have been documented

11.3 Participants must be fully debriefed as soon as practicable following their involvement. This debriefing must include all pertinent information in which the exact nature of the deception and its necessity are clearly and fully articulated. A detailed written debriefing scenario that fully explains the manipulation and its need to the participant must be submitted as part of the application. Researchers must also provide an explanation of how potential negative effects will be handled.

11.4 Participants must be given the opportunity to have their data withdrawn from the study if, after debriefing, they feel they would not have participated had they known about the deception.

12. 0 Storage of Research Data

Data collected about human subjects shall be stored in a secure location at Lakehead University for a minimum period of five (5) years.

13.0 Non-compliance with this Policy

When an allegation of non-compliance is made, the Chair shall investigate the matter, and make a preliminary determination as to whether the allegation is valid.

The Chair shall inform the individual(s) involved in writing that an allegation has been made, and allow time to respond. The written response must be received prior to the emergency meeting.

If a problem is found, the Chair will inform the individual(s) involved in writing that an allegation has been made, and allow time to respond. In the meantime, an emergency meeting of the REB will be scheduled. The written response of the individual must be received prior to the emergency meeting.

In the event of an emergency where a meeting cannot be held within an appropriate amount of time, the Chair

and one (1) other designated individual from the REB can recommend immediate action to the appropriate Vice-President. The recommendation can include the immediate suspension of related activity.

The allegation and the response of the individual(s) involved will be communicated by the Chair to the REB. The REB must then make one of the following determinations:

- The response to the allegation is adequate. No further action is required.
- The response to the allegation is inadequate, and the allegation involves minimal risk (as determined by the REB). Recommendations must then be sent to the Principal Investigator/Supervisor, and a specified time period will be set for the issue to be resolved
- The response to the allegation is inadequate, and the allegation involves, or could potentially involve, significant risk. Recommendations to suspend activities will be sent immediately to the appropriate Vice-President by the REB.

The decisions of the REB shall be clearly documented in writing. All correspondence directed to the individual(s) involved in the allegation will be copied to both the Chair of the department and the appropriate Dean.

Recommendations to the Vice-President shall be made in a formal letter detailing the following:

- The issue
- The alleged infraction
- Steps taken to resolve the issue
- Recommendations of the committee/board
- Time period for response to be made to the committee

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