



Canadian Society for Medical Laboratory Science
Société canadienne de science de laboratoire médical

GUIDELINES FOR RESEARCH INVOLVING HUMAN SUBJECTS

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CSMLS POLICY STATEMENT ON ETHICAL CONDUCT IN RESEARCH

1. In recognition of the need for research conduct that respects human dignity and well-being, The Canadian Society for Medical Laboratory Science endorses the principles put forth in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects (TCPS).¹
2. The CSMLS encourages the individuals involved in its institutional research activities (who include executive and administrative staff, consultants and research associates or assistants) to maintain the highest standards of ethical conduct in every aspect of research including applications, proposals, the research itself, reports and publications.
3. The CSMLS includes the following attributes among its expectations for demonstration of the highest ethical standards in research. They originate in the TCPS documentation and are consistent with the high standards expressed in the Code of Professional Conduct for the Medical Laboratory Science profession.^{2,3}
 - respect for the dignity of research subjects and participants;
 - accurate representation of data and information;
 - due acknowledgement of the work of others;
 - maintenance of confidentiality and appropriate use of confidential information;
 - appropriate and responsible use of resources intended for research purposes;
 - dissemination of research findings and implications;
 - commitment to research for the benefit of the medical laboratory profession, for the advancement of Canadian health care, and for the creation and translation of knowledge.
4. The CSMLS has created a set of guidelines to encourage increasing awareness of ethical issues and to outline its supportive administrative measures for an ethics review process that embodies the principles expressed in the TCPS document. The object of the CSMLS guidelines is to foster ethical conduct without interfering with freedom of inquiry and without causing unnecessary administrative burdens.
5. Because it is not possible or advisable to anticipate or prescribe ethical issues under all circumstances, this policy statement and the guidelines leave many specific matters untouched. The CSMLS expects its policy and guidelines on ethical conduct in research to evolve as the organization's research mandate and program develop.
6. Allegations of inappropriate research activity will be taken seriously by the CSMLS following the established practices and procedures of the applicable professional jurisdictions and codes of ethics.

Affirmed March 2009 (Reference Updated 2015)

¹ Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. December 2014. Note: For the most recent information on amendments, please consult the official online version of the TCPS[Online]. Available: <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>
Accessed June 5 2015

² CSMLS. (2011). *Code of professional conduct*. Hamilton: CSMLS. [Online]. Available http://www.csmls.org/csmls/media/documents/Governance/Code_of_Professional_Conduct-en.pdf
Assessed June 5 2015.

CHAPTER 1: INTRODUCTION

Purpose of This Document

This document has been created to communicate research ethics policies, practices, and guidelines to CSMLS researchers, Research Ethics Board (REB) members, and interested observers. It is intended to ensure that research carried out by the CSMLS meets high ethical standards, and has been developed in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects (TCPS).

As expressed in the TCPS document, the ethic of research involving human subjects includes “(1) the selection and achievement of morally acceptable ends and (2) the morally acceptable means to those ends” (p. 1.4). The CSMLS guidelines embody the general guiding ethical principles expressed in the TCPS:

- respect for human dignity;
- respect for free and informed consent;
- respect for vulnerable persons;
- respect for privacy and confidentiality;
- respect for justice and inclusiveness;
- balancing harms and benefits;
- minimizing harm;
- maximizing benefit.

The CSMLS guidelines are not exhaustive and are not expected to anticipate all possible ethical considerations. The ethics review process outlined here relies on the individuals involved to create a balance of experience, practicality, and ethical principles. It is intended to exhibit a certain level of fluidity in its responsiveness to changing research needs and to unanticipated demands. For situations not addressed directly in this document, the reader is referred to the TCPS.

The CSMLS Research Mandate

The CSMLS has traditionally conducted membership-based research to support the operations of the society. Many of these projects have involved institutional document and data analysis and have not required ethical review. Requests from external researchers for assistance contacting CSMLS members have always been subject to approval by the CSMLS Board of Directors and have hinged on prior approval of the project by the Research Ethics Boards of the principal investigators' primary institutions.

More recently, the occasional CSMLS projects involving clear researcher/subject relationships with human participants have made use of *ad hoc* ethics review processes. However, the CSMLS is experiencing a dramatic increase in the number and complexity of its research undertakings. Current pressing issues within the health care system, including health human resources discussions, have highlighted large gaps in profession-specific data and research on medical laboratory science in Canada that are not being addressed within traditional academic research communities. These gaps hinder understanding and decision-making about the profession and result in delays to creating and implementing policy that adequately meets Canada's changing health care needs.

To address these information gaps and to thereby contribute to high quality health care in Canada, the CSMLS established a research mandate in 2006 to conduct and facilitate research on the medical laboratory profession in Canada.⁴ With the adoption of this specific research mandate, the CSMLS acknowledges the need for formal ethics review policies and protocols to demonstrate its commitment to research ethics and integrity. The CSMLS seeks to conduct and facilitate research in accordance with accepted Canadian practices as laid out in the Tri-Council Policy Statement. This document is an expression of that goal and will evolve as the CSMLS research program develops.

⁴ CSMLS. (2007). Research. [Online]. Hamilton: CSMLS. <http://www.csmls.org/About-Us/What-We-Do/Research.aspx> Accessed August 26 2015

CHAPTER 2: THE CSMLS RESEARCH ETHICS REVIEW PROCESS

The REB policies and processes outlined in this document permit the CSMLS to meet anticipated research needs while allowing flexibility to address unexpected circumstances and ensuring that review processes are sufficiently rigorous to meet nationally-accepted standards for research involving humans. They have been designed to meet the specific research focus of the CSMLS, which differs in several respects from the breadth of research anticipated in the procedures outlined in the TCPS. These differences include the following points:

- CSMLS-based research may be best understood as social sciences research, or more specifically, as health services and policy research; it consists of non-experimental, non-biomedical social sciences research; however, it could be interpreted as falling within the definition of 'clinical research' of the Canadian Institutes of Health Research. (See the glossary, Appendix A, for definitions of the underlined terms);
- Most, if not all, of CSMLS-based research qualifies for the category of 'minimal risk' (See the "Key Concepts in the Ethical Review Process" section, pp. 10-11, for a discussion of 'minimal risk');
- The CSMLS anticipates a fairly small volume of research ethics applications (five to ten per year);
- Individuals who can be expected to have the necessary qualifications and expertise for participation in a CSMLS Research Ethics Board are few and geographically dispersed.

For these reasons, and in light of the acknowledged limitations of TCPS policies for social sciences research,⁵ this document outlines the procedures that will best meet the CSMLS's current needs for ethics review and ethical conduct of research while ensuring that high standards for research ethics, integrity, and value are met.

The CSMLS ethics review policy departs from the TCPS recommendations in that board meetings have been planned as teleconferences rather than the recommended face-to-face sessions. The TCPS allows for such adaptations; in the CSMLS's case, they are justified by the specific needs of the organization as outlined above. The CSMLS procedures and policies will evolve as the CSMLS research program matures and its needs are more fully understood.

⁵ Social Sciences and Humanities Research Ethics Special Working Committee. (2004). Report of the Social Sciences and Humanities Research Ethics Special Working Committee to the Interagency Advisory Panel on Research Ethics. Ottawa: Interagency Advisory Panel and Secretariat on Research Ethics.

Mandate of the Research Ethics Board (REB)

In acknowledgement of the concept that the foundation of ethical research is good research,⁶ the CSMLS REB has both instructive and ethics review roles. It reviews all CSMLS research projects in which human subjects are involved for their ethical soundness and for their potential to contribute to the body of knowledge about the health professions. The REB has the authority to approve, disapprove, propose modifications to, or terminate any proposed or ongoing research involving human subjects conducted within, or by members of, the CSMLS. The CSMLS may choose to authorize its REB to accept the review decision of other REBs constituted under the TCPS.

It is also possible that the CSMLS REB may be called upon to review outside requests for ethics review if the submission involves a project for which CSMLS has a partnership or stakeholder role.

REB approval is not required for access to publicly available information or materials, nor for CSMLS document analysis and non-research activities. The REB reports directly to the CSMLS Chief Executive Officer.

REB Membership

The following terms guide the composition of the CSMLS REB:

- The CSMLS will identify a board membership of approximately 10 REB individuals with relevant expertise; of these, the REB chair will convene the members for any application requiring a full review process (i.e., any application posing more than minimal risk);
- For all applications identified as qualifying for 'expedited review' (discussed in the 'Key Concepts' section), the REB chair will identify a subcommittee of two members (3 in total including the chair) on the basis of their expertise and availability for the review;
- Each review subcommittee as a whole is expected to represent expertise in relevant methods or areas of research, in legal issues relevant to research, and in research ethics. One member is to be a non-medical laboratory health professional and is to be recruited from the community served by the CSMLS; at least one member should have experience working on research ethics boards;
- The term of office is two years, renewable;
- The chair will be appointed by and from among the REB members on an annual basis;
- The REB may nominate *ad hoc* members for reviews that require particular expertise or subject representation.

These requirements are intended to ensure the expertise, multidisciplinary and independence essential for a competent review by the REB. The eventual goal is to stagger

⁶ University of Toronto Committee on Human Subjects in Research. (2007). *Guidelines and practices manual for research involving human subjects*. Toronto: University of Toronto. [Online] Available: http://www.research.utoronto.ca/wp-content/uploads/documents/2012/12/ERO_Guidelines_Manual-2007.pdf Accessed Sept 3, 2015.

the REB membership to ensure a balance/diversity of expertise, to maintain continuity, to allow for sharing of knowledge and experience gained from participation in the REB, and to avoid undue burden on any one member.

Responsibilities of REB Members

REB members are expected to:

- be present and adequately prepared for all assigned scheduled review sessions;
- review and evaluate submitted protocols and annual progress reports following guidelines laid out by the CSMLS and the TCPS;
- maintain an appropriate level of confidentiality with respect to reviews, decisions, and related information;
- abide by the CSMLS guidelines for conflict of interest, be alert to the potential for conflicts of interest and notify fellow REB members where this occurs;
- express differences of opinion and alternative viewpoints within a respectful and collegial framework;
- maintain appropriate documentation;
- make efforts to become informed and to remain current about best practices in ethical research and related policies.

Meetings, Attendance, Communication Processes and Record Keeping

Meetings and all communication and record-keeping processes will be coordinated by a CSMLS staff member designated as the REB administrative assistant (REBAA), who will serve as the liaison between the REB and CSMLS staff or researchers.

- Meetings of the standing REB subcommittee will take place by teleconference on an as-needed basis. The CSMLS acknowledges that, according to the TCPS, face-to-face meetings are ideal for full board review; given the small volume of review submissions anticipated, and the geographical dispersion of REB members, teleconferences are considered to be the decision-making environment of choice for the CSMLS REB. This policy will be reviewed on an annual basis;
- The REBAA will circulate submission materials to the Chair upon receipt of an application. The Chair will appoint two members to serve on a subcommittee that will meet by teleconference; the chair will notify the REBAA to circulate the relevant materials to the two appointed members;
- The Chair will assess the eligibility of the application for full or expedited review, identify any special resources needed prior to the meeting, and notify the REBAA of their conclusions. If the application is deemed to be expedited, a summary of the expedited review will be sent by e-mail to the full REB.
- The Chair will complete the REB decision form (Appendix B); S/he will circulate it to the rest of the Board members and submit it and all other meeting materials to the REBAA at the completion of the decision-making process for a given application in a timely manner (ideally, within one week of the meeting);
- Reviewers will destroy any printouts of the application materials after the review has been completed;
- Email will be used for circulation of REB materials; Submission materials will be circulated as password-protected PDF files using an agreed-upon password that is circulated separately.

- In addition to proposal submission materials, agenda items for the review meetings may also include discussions of the operations of the REB itself. REB members will be encouraged to submit any relevant agenda items;
- The REBAA maintains minutes of its meetings, including clear documentation of decisions, any dissents, and the reasons for them. The minutes should be accessible to authorized representatives of the CSMLS, researchers, and funding agencies upon request.
- An annual meeting of the Research Ethics Board will take place at the CSMLS offices in Hamilton.

The Application Procedure (please refer to Figure 1)

1. The submission of an application is made by the researcher to the CSMLS using the approved application form. The application will initially be reviewed briefly by the REBAA for completeness to ensure that the application includes a complete application, protocol or project summary, budget or explanation of funding and a consent form where applicable.
2. The REBAA forwards this application to the chair via email in the form of a password-protected PDF file
3. The chair reviews the application and if s/he expects that an expedited review is appropriate, s/he selects a sub-committee of 2 individuals. If the chair and subcommittee may determine the application is incomplete for review. If additional resources are required, the REBAA will be informed and the missing information will be requested of the researcher.
4. If the subcommittee confirms an expedited review, the REBAA organizes a teleconference for the subcommittee (Chair and 2 selected REB members) within 2 weeks of application distribution to subcommittee.
5. If the has application does not qualify for expedited review, it is reviewed first by the established subcommittee and then in a teleconference with the full board. In the full board meeting, the subcommittee presents their initial impressions of the application and then the remainder of the board is invited to present any additional comments. The information is then be summarized by the chair.
6. In either an expedited review or a full board meeting, comments and requests of the subcommittee and board plus the decision (approval, provisional approval or rejection) should be summarized by the chair and issued to the REBAA, who forwards the information to the researcher. In the case of an expedited review, the summary must also be distributed to the full REB. If the full REB have any additional comments, they may also submit these comments to the chair for follow-up notification to the researcher.
7. * Throughout this process, if additional resources are required in order for the board to make their final decision, it is reasonable for the board to grant 'provisional approval' with the stipulation that 'full approval' may be granted upon submission of satisfactory information from the researcher.

This additional information submitted should be reviewed by either the chair or SC to grant the final approval.

Decision-Making

REB members are asked to keep the following points in mind:

- The review of an application should be based upon fully detailed research proposals (or progress reports in the case of an annual review). Reviewers are asked to consider the ethical (harms and benefits) and scholarly merit of each application (see the 'Key Concepts' section). The reviewer's checklist (Appendix C) may prove useful in these assessments;
- The depth of the evaluation is to be consistent with the 'proportionate approach' advocated by the TCPS (see p. 11 of the 'Key Concepts section');
- Researchers may be called upon to provide information to discussions but may not be present when decisions are made;
- Consensus is the decision-making approach of choice;
- Negative decisions should be fully documented with reasons and should provide researchers with an opportunity to reply or to provide further information;
- The CSMLS encourages a dialogic approach to the review process. Accordingly, decisions may be deferred to allow time for the researcher to provide further information or to modify the proposal;
- Decisions and supporting notes or documentation should be forwarded to the REBAA, who then forwards the materials to the researcher as well as informing the CSMLS Chief Executive Officer of the outcome; the REBAA also forwards any materials identified by the REB subcommittee as requiring the researcher's attention;
- REB decisions are circulated to all members of the REB;
- Researchers may request reconsideration of decisions affecting their research project, including the submission of up to two rounds of amendments, to be reviewed by the same individuals who initially reviewed the application;
- If the REB subcommittee is not satisfied with the amendments after the second round of submissions, the researcher may be requested (at the discretion of the REB) to discuss the issue with a member of the REB. Researchers and board members are encouraged to resolve differences at this stage;
- Once approval has been granted, the researcher commences the study;
- In the case of a pending negative decision, the researcher must be given the opportunity to reply before the final decision is made;
- Exceptions to this or other processes in the guidelines must be justified;
- Figure 1 offers a diagrammatic representation of the REB processes.

As mentioned previously, the processes outlined for ethics review of CSMLS research projects differ slightly from those recommended in the TCPS. Research undertaken by the CSMLS can be expected to meet one or more of the criteria for expedited review (see the "Key Concepts" section, p. 11). Research involving physical interventions (whether therapeutic or diagnostic) is not anticipated. Most methodologies will involve written or e-mail surveys, telephone or face-to-face interviews, focus groups, and expert panels. Nonetheless, particular methodologies do not automatically qualify a study as eligible for expedited review, and expeditable status will not be assumed. For this reason, and in order to allow the CSMLS REB members an opportunity to accustom themselves to the processes and research areas of the organization's research program, the CSMLS REB subcommittee is constituted to offer a fuller review process than traditionally occurs with expedited reviews.

The board may grant one of three decisions as listed below. If final approval is not granted, the board should provide the researcher with clear, well-defined reasons for the REB's decision and recommendations should be given.

Final Approval	All requirements have been met for this application. The REB is satisfied that this application meets the ethical standards imposed by this board. If there are any major changes to the information or conduct of this project or study the researcher must inform the board.
Provisional Approval	Approval has been granted by the board with stipulations. The project may move forward but enrolment of any kind must not be initiated until the stipulations imposed by the board are met by the researcher.
Rejection	The application has been denied. The information within this application does not meet the ethical standards that are required by this board. In order to proceed with this project or study, the application must be re-formulated and re-submitted to the board.

Appeals

The REB and researchers are encouraged to resolve differences without resorting to an appeal board. However, where the REB and the researcher(s) have not reached a satisfactory decision about the application after two rounds of amendments, the proposal may be taken to an appeal board. The appeal board's membership and procedures must meet the requirements of the TCPS. An *ad hoc* appeal board is not permitted. The CSMLS appeal process is not fully developed at this time.

Training and Support

The CSMLS will endeavor to respond to REB members' requests and suggestions for support and training in topics and activities related to research ethics. All reviewers will receive summaries of REB decisions so that they may gain familiarity with decisions made by subcommittees other than their own. Reviewers may consult the list of online resources in Appendix E of this document. Other resources will be added as they become available.

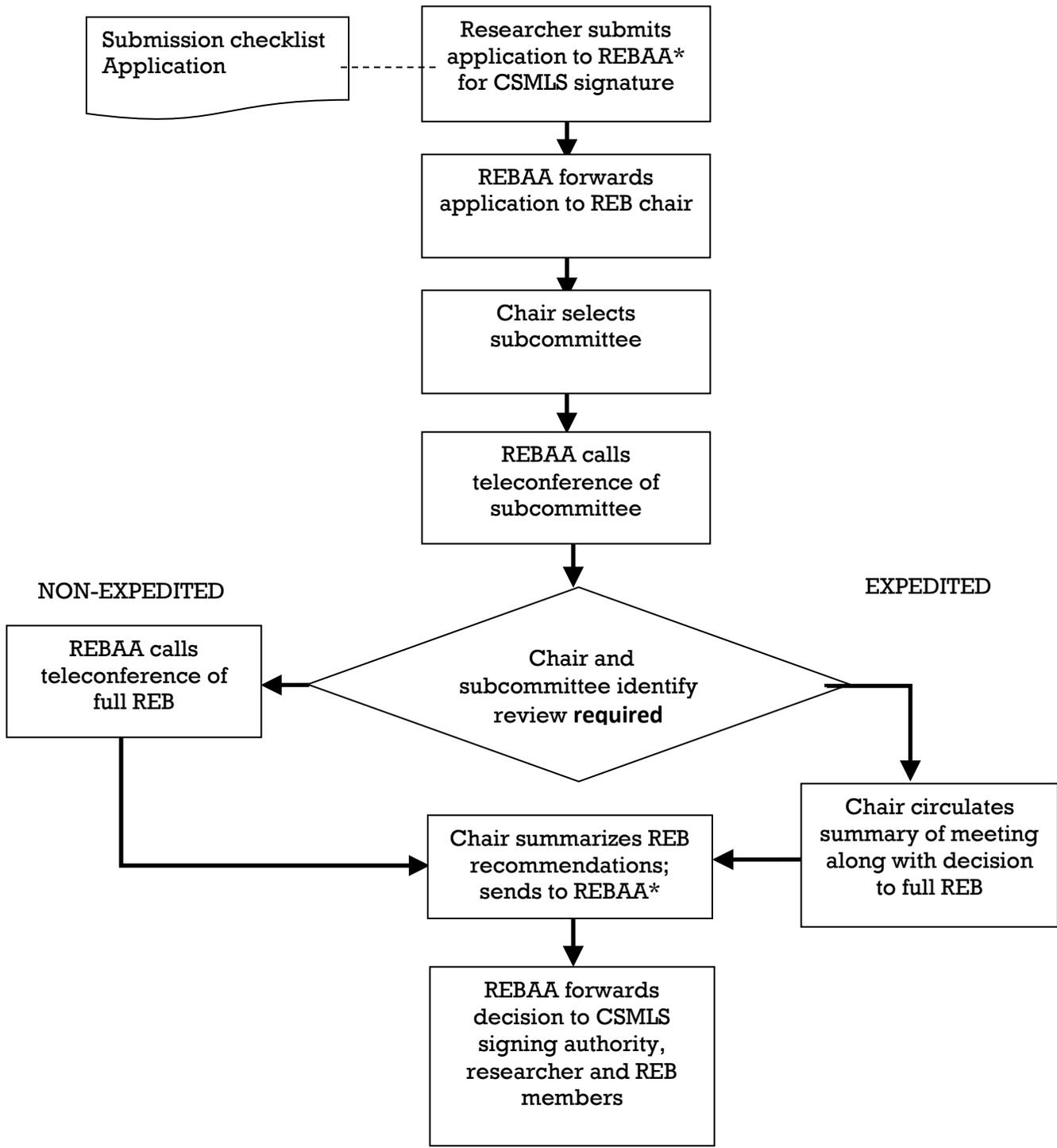
Ongoing Review

Ongoing review is considered to be a collective responsibility essential to maintaining ethical standards. The ongoing review practices outlined here are consistent with practices for minimal risk studies as outlined by the TCPS. Ongoing review should consist of at least the submission of a succinct annual status report to the REB by the project's principal investigator. This report is subject to the principle of proportionate review (see the discussion in the 'Key Concepts' section) and will include: any changes to protocol, forms or personnel; an indication of the number of participants currently in the study, and the

numbers who have completed the study or withdrawn; and a discussion of any ethical concerns arising in the project. This report is due yearly from the start date of the project.

The principal investigator will notify the REB when the project concludes. Principal Investigators of projects of less than one year's duration will submit a report upon completion of the study. Where a study exceeds five years in length, the researcher is required to submit a new ethical review application for consideration by the REB. The CSMLS Chief Executive Officer will utilize documentation of ongoing review as part of the annual report to the CSMLS Board of Directors and an annual summary report to the REB.

FIGURE 1: FLOW CHART FOR
CSMLS RESEARCH ETHICS BOARD (REB) PROCESSES



* Notes:
REBAA = Research Ethics Board Administrative Assistant
If additional resources are needed, the REBAA will contact the researcher for the required information

FIGURE 2: CSMLS REB REVIEW PROCESS CHART

TASK	WHO'S RESPONSIBLE	TIMELINES
Researcher submits application	PI	
REBAA forwards application to REB chair	REBAA	
Chair reviews application	REB Chair	
Chair selects subcommittee	REB Chair	
Subcommittee confirms type of review required	Subcommittee	
REBAA calls teleconference of appropriate REB members	REBAA	
Reviewers discuss application & make recommendations	Review committee	Expedited? Non-expedited?
Chair summarizes recommendations & sends to REBAA	REB Chair	
REBAA forwards recommendations to researcher and informs CSMLS ED	REBAA	

Jurisdictional Issues

The CSMLS is responsible for the ethical conduct of research undertaken by its staff and representatives, regardless of the location where the research is conducted. All applicable national and provincial laws will be taken into consideration for the REB review process. The CSMLS will ensure that research performed outside of the CSMLS's jurisdiction or outside Canada will undergo ethics review both by the CSMLS REB and by the REB that holds responsibility for legal and ethical safeguards in the host institution, jurisdiction or country where the prospective research is to be carried out.

Key Concepts in the Ethical Review Process

REB members may find the following discussions helpful.

Harms and risks

A REB must be prepared to assess whether the potential risks of research-related activities are incurred only for the needs of the research; to minimize any harms; and to ensure that the harms are proportionate to the benefits that could be expected to arise from the research. The TCPS requires that:

- foreseeable harms should not outweigh anticipated benefits
- research subjects must not be subjected to unnecessary risks of harm
- the socially beneficial aims of the research cannot be achieved without the participation of humans
- the benefits associated with the research are made as great as possible and the risks are minimized.⁷

The TCPS defines minimal risk in the following way: “the probability and magnitude of possible harms implied by participation in the research can reasonably be expected by participants to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research, or during the performance of routine physical or psychological examinations or tests” (p. 1.5).

Similarly, there is also a threshold for undue or excessive offers of benefit: for example, offers of payment for research participation may constitute an undue incentive. The level of risk posed by a project can be evaluated on the basis of methodology, subject population or the implications of the research.

It is recognized that some research may be deliberately and legitimately opposed to the interests of the subjects, particularly in the humanities and social sciences. Such research should not be blocked through use of harms-benefits analysis.

⁷ Inter-Agency Advisory Panel on Research Ethics. (2004). *Introductory tutorial for the Tri-Council Policy Statement: Ethical conduct for Research involving humans (TCPS)*. [Online]. Available: http://www.pre.ethics.gc.ca/english/tutorial/01_process.cfm Accessed August 26 2015.

The proportionate approach

The general principle underlying the proportionate approach to ethics review is that the most intensive scrutiny, and hence the greatest level of protection, is reserved for the most ethically challenging research. This foundational concept for REBs is summarized in the TCPS in this way: “the more invasive the research, the greater should be the care in assessing the research” (p. 1.7). Applying the concept of minimum risk, the REB assesses the nature, magnitude and likelihood of potential harms from the subjects’ perspective.

Expedited review

The TCPS proposes three levels of review:

1. full REB review;
2. expedited REB review by an individual or subgroup of the REB; and
3. department-level review (i.e., of undergraduate projects).

According to the TCPS, categories of research that are expected to involve minimal risk may be approved by the chair or a designated member or subcommittee of the REB (the expedited process). Examples of such categories are:

- research protocols that involve no more than minimal risk;
- annual renewals of approved projects in which there has been little or no change in the ongoing research;
- research involving review of patient records by hospital personnel;
- affirmations that conditions laid down by the REB as a condition of approval have been met;
- annual renewals of studies that originally qualified for expedited review and which have not encountered adverse incidents or ethical problems;
- studies approved by the REB of another institution;
- minor amendments to previously approved research where changes do not increase risk to participants;
- research to collect materials that will not be used for research purposes;
- research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies.

In the case of the CSMLS, a ‘quality assurance methodology’ includes projects conducted to assess the impact of organizational processes and policies. For example, a survey of CSMLS members to inquire about the effectiveness of a continuing education marketing campaign could be considered a quality assurance methodology.

The full REB must be notified of all research projects ultimately approved using the expedited review process.

Expedited forms of review are not appropriate in studies where participation in the research and subsequent identification would result in a risk of criminal or civil liability or would disadvantage subjects’ financial standing, employability, insurability, or reputation. REBs may not expedite disapproval of a project.

A full review is required for any project that does not meet the criteria of an expedited review. See Appendix D for a checklist for expedited review.

Scholarly merit

Traditions for evaluating scholarly and ethical merit differ. It is advisable that the CSMLS REB be constituted so that the individuals are sufficiently well-versed in academic research and the literature of medical laboratory science that they can provide a peer-based assessment of the scholarly merit of the application under consideration. Duplication of review processes (i.e., an ethics review *and* a review of scholarly merit) should be avoided. With respect to scholarly merit, the TCPS provides the following observation:

In evaluating the merit and the scholarly standards of a research proposal, the REB should be concerned with a global assessment of the degree to which the research might further the understanding of a phenomenon, and not be driven by factors such as personal biases or preferences. REBs should not reject research proposals because they are controversial, challenge mainstream thought or offend powerful or vocal interest groups. The primary tests to be used by REBs should be ethical probity and high scientific and scholarly standards. (p. 1.6)

In addition, the REB is asked to consider the extent to which the research meets CSMLS goals for knowledge translation as part of its evaluation of a project's scholarly merit.

Informed consent

The CSMLS will conduct research only among participants who have given and who continue to give free and informed consent. Evidence of free and informed consent by research subjects consists of a statement signed by the subject. In the case of anonymous written surveys, submission of the survey shall be considered consent to participate. Where research subjects express concern about the use of their data in the research, the researcher may give the subject the option of removing his or her data from the project. This approach is suitable only when the elimination of the subject's data will not compromise the validity of the research design. The researcher will report those concerns of the subject to the REB.

Participants must voluntarily give free and informed consent; the researcher will provide full and frank disclosure of all relevant information to prospective subjects. This includes:

- the statement of invitation to participate in a research project;
- a statement of the research purpose, the identity of the researcher, the expected duration and nature of participation, and a description of research procedures;
- a description of reasonably foreseeable harms and benefits that may arise from research participation;
- assurance that prospective subjects are free not to participate and have the right to withdraw;
- the possibility of commercialization of research findings or of any potential conflict of interest on the part of the researchers, research institution, or research sponsors;
- information on who will have access to information collected, descriptions of how confidentiality will be protected, and anticipated uses of the data.

Privacy and confidentiality

The CSMLS acknowledges that the best protection of the confidentiality of personal information and records is achieved through anonymity. Approval for obtaining identifiable personal information about subjects will include:

- the type of data to be collected;
- the purpose for which the data will be used;
- limits on the use, disclosure and retention of the data;
- appropriate safeguards for security and confidentiality;
- modes of observation that may permit identification of particular subjects;
- anticipated secondary use of identifiable data (REB approval must be sought for this use; see TCPS Articles 3.3 and 3.4 for further information);
- anticipated linkage of the collected data with other data; (see TCPS article 3.6);
- provision for confidentiality of the project data.

Conflicts of Interest

Both researchers and REB members will disclose potential conflicts of interest, whether actual or perceived, to the REB. An REB member who has a personal interest in the research under review may not be present when the REB is discussing or making its decision although the member may disclose and explain the conflict.

The REB will review details on each research project including budgets, commercial interests, consultative relationship and other relevant information to ascertain the presence and potential impact of researcher conflict of interest (see TCPS Section 4 for further information). The REB will require the researcher to disclose any real or apparent conflict of interest to prospective subjects during the process of free and informed consent. The REB may provide a plan or other guidance to the researcher on how to resolve the conflict. A failure to disclose a conflict of interest constitutes either non-compliance with the CSMLS ethics review guidelines, or research misconduct. In these cases, the CSMLS will follow the established practices and procedures of applicable professional jurisdictions and codes of ethics for the medical laboratory profession.

The REB maintains an arm's length relationship with the CSMLS. The CSMLS will respect the autonomy of the REB and ensure that the REB has the appropriate financial and administrative independence to fulfill its primary duties.

Inclusion

The fair distribution of benefits and burdens demand attention to inclusion and exclusion. Researchers will not exclude prospective subjects on the basis of such attributes as culture, religion, race, mental or physical disability, sexual orientation, ethnicity, sex or age, unless there is a valid reason for doing so (for example, research focused on a group of individuals who share a specific characteristic that is relevant to the study). Research involving special interest groups will conform to TCPS requirements as outlined in Sections 5 and 6.

Timelines for the Ethical Review Process

Application Due Date

The REB will be expected to convene, by teleconference the last week of every second month; therefore, applications will be due by Friday of the second week of the month corresponding to the REB meeting in order to make it into the meeting agenda. Suitable applications will be forwarded by the REBAA by email to the chair using a password-protected PDF file. The chair will assess the application with 2-3 days of receipt, and select the subcommittee (SC). The REBAA will forward copies of the application to the SC.

General Review

In general, the REB will be expected to convene, by teleconference the last week of every second month, unless there are no applications to review. REBAA will organize this teleconference on a day of this week that is most convenient for all members. (For example, Jan, Mar, May, July, September)

Expedited Review

In an expedited review, the REB SC will be established and review the application within 2 weeks of receipt of the application. Once the REBAA contacts the chair with the information, the chair will contact the SC and ensure the process can be completed by this group within this time-period. If this is NOT possible, the chair and/or REBAA will contact the application investigator to determine a suitable solution.

CHAPTER 3 – THE ROLES OF RESEARCHERS

Researchers associated with the CSMLS have the responsibility to ensure that their research is carried out in an ethical manner and that the dignity, rights and welfare of all research subjects are safeguarded. Ethical research is founded in the integrity of researchers and the research process. This ensures that the CSMLS research program maintains the trust and respect of society in general and of the health care and medical laboratory communities in particular.

Guidelines for Researchers

CSMLS researchers will demonstrate integrity, ethical standards, and good research practice by:

- ensuring their own familiarity with CSMLS policies and with the requirements laid out by the TCPS;
- obtaining ethical approval prior to commencement of the study;
- communicating with the REB as required for approval, review, and conflict of interest processes;
- ensuring that the appropriate approvals are obtained from the host site (whether REB or other form of administrative consent) in cases where the research is to be conducted in another institution or jurisdiction;
- demonstrating ethical conduct throughout the study;
- obtaining ongoing approval through the submission of an annual report where projects last longer than one year;
- submitting a report upon closure of the project
- notifying the REB of completion of the study;
- notifying the REB of significant changes to the research protocol;
- refraining from data falsification, fabrication or omission and from using data in a misleading way;
- reporting any adverse events, conflicts of interest or non-compliance with ethical guidelines to the REB.

The Principal Investigator has the responsibility of ensuring that researchers on the project are aware of CSMLS research ethics guidelines and adhere to the expectations listed above.

Submission of Applications

The Primary Investigator for a project submits an application for REB review including the items/elements listed in the submissions checklist (Appendix F) and should be accompanied by the submission cover sheet (Appendix G).

CHAPTER 4: THE ROLE OF THE CSMLS

The CSMLS maintains an arm's-length relationship with the REB. It provides administrative support in the form of relevant documentation and guidelines, recruitment of members, and the services of an administrative assistant to facilitate communication processes, record-keeping and archiving. The CSMLS will provide resources to allow for the financial and administrative independence of the REB. The CSMLS will allocate time for the REBAA to carry out her/his responsibilities. It will respect decisions made by the REB. The CSMLS cannot overturn a negative REB decision but may choose not to carry out previously-approved projects if the organization's priorities change.

The CSMLS Chief Executive Officer or designate must sign research protocols prior to their submission to the REB to document their awareness of the project under review. The signing authority should not have an interest in the project.

The CSMLS Chief Executive Officer has a responsibility to be aware of, and to ensure the ethical conduct of, research projects within the institution. The responsibilities of the Chief Executive Officer include:

- assisting with REB recruitment, scheduling, and orientation;
- implementing the recommendations of the REB;
- developing ethics review policies and relevant documentation;
- providing guidance on ethics review protocols to other researchers and individuals associated with research projects;
- guiding the REB administrative assistant with REB support activities;
- preparing an annual report for the CSMLS Board of Directors on REB activities;
- providing annual feedback and summaries to the REB on its activities;
- monitoring the ethics review process and identifying areas for improvement.

Given the likelihood of the Research Director's participation in CSMLS projects as a researcher in some capacity, this individual will not be involved in REB decision-making.

The REB administrative assistant (REBAA) will maintain records for the REB's activities, coordinate communication and scheduling, and serve as the liaison for the REB with CSMLS. The REBAA will respect the special confidentiality needs for the communications between researchers and the REB.

The CSMLS Board of Directors will:

- provide approval in principle for research projects to be undertaken by the CSMLS;
- review/evaluate the annual report of the Chief Executive Officer on ongoing and completed projects to consider:
 - their congruence with CSMLS values/vision/mission/strategic plan;
 - their effectiveness;
 - the appropriateness of the ethics review process;
 - emerging areas of research and ethical implications evidenced by each project;
 - unexpected findings or adverse events;
- provide feedback and direction to the Chief Executive Officer.

APPENDICES

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A: Glossary of terms

The following terms have been used in this document. A common understanding of their meanings will be helpful to researchers and the REB.

Adverse event: any unfavourable or unintended occurrence or a change in current health status (including mental, emotional or psychological) in a subject participating in a research study.⁸

Biomedical research: “Research with the goal of understanding normal and abnormal human functioning, at the molecular, cellular, organ system and whole body levels, including development of tools and techniques to be applied for this purpose; developing new therapies or devices that [sic] improve health or the quality of life of individuals, up to the point where they are tested on human subjects. Studies on human subjects that do not have a diagnostic or therapeutic orientation.”⁹

Clinical research: Research with the goal of improving the diagnosis, and treatment (including rehabilitation and palliation), of disease and injury; improving the health and quality of life of individuals as they pass through normal life stages. Research on, or for the treatment of, patients.⁸

Confidentiality: the expectation that information communicated in the context of a special relationship will be held in confidence or kept secret.¹⁰

Expedited review: ethics review of research proposals within the range of minimal risk by an individual or subgroup of the REB. Expedited review may also be used for some annual renewals of approved projects, some research involving health record review, and for affirmation that the modifications requested by the REB as a condition for approval have been met.¹⁰

Experimental research: research is considered to follow an experimental design when the researchers control the allocation of a treatment to the research subjects. Contrast this with an observational design, where the researchers do not have this control.¹¹

⁸ University of Toronto Committee on Human Subjects in Research. (2007). Guidelines and practices manual for research involving human subjects. Toronto: University of Toronto. [Online] Available: http://www.research.utoronto.ca/wp-content/uploads/documents/2012/12/ERO_Guidelines_Manual-2007.pdf Accessed Sept 3, 2015

⁹ Canadian Institutes for Health Research. (2005). Developing a CIHR framework to measure the impact of health research. [Online]. <http://publications.gc.ca/collections/Collection/MR21-65-2005E.pdf> Accessed Sept 3, 2015

¹⁰ Inter-Agency Advisory Panel on Research Ethics. (2014). TCPS 2 (2014)— the latest edition of *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. [Online]. Available: <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/> Accessed Sept 3, 2015.

¹¹ Simon, S. (2006). Stats: Steve’s attempt to teach statistics. [Online]. Children’s Mercy Hospitals & Clinics. Available: <http://www.childrens-mercy.org/stats/definitions.asp> Accessed August 26, 2015.

Free and informed consent: the dialogue, information sharing, and general processes through which prospective subjects choose to participate in research.⁹

Harms and benefits: the physical, psychological, social, economic or legal impact of research on a research subject and/or on society. Harms and benefits vary according to the research discipline and the methodology used. They may be difficult to predict.⁹

Health services and policy research: Research with the goal of improving the efficiency and effectiveness of health professionals and the health care system, through changes to practice and policy. Health services research is a multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviours affect access to health care, the quality and cost of health care, and, ultimately, Canadians' [sic] health and well-being.⁸

Human subject: a living individual about whom an investigator conducting any kind of research interaction or intervention (including physical procedures, or interpersonal contact) obtains data or individually identifiable private information.

Identifiable personal information: information relating to a reasonably identifiable person who has a reasonable expectation of privacy. This can include information about personal characteristics such as culture, age, religion and social status, as well as their life experience and educational, medical or employment histories.⁹

Knowledge translation: The exchange, synthesis, and ethically-sound application of knowledge – within a complex set of interactions among researchers and users – to accelerate the capture of the benefits of research for Canadians through improved health, more effective services and products, and a strengthened health care system. This broad definition can include for example, the translation of health research results into forms that will influence decision-making in the health policy or medical practice sectors, or the development of commercial products from health research.⁸

Minimal risk: The probability and magnitude of possible harms implied by participation in the research can reasonably be expected by participants to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research, or during the performance of routine physical or psychological examinations or tests.¹¹

Research: a systematic investigation to develop or contribute to facts, principles, or generalizable knowledge (which is expressed, for example, in theories, principles, and statements of relationships). Intent to disseminate the results of the investigation in the form of a report, thesis, book, journal article or conference presentation may also signal a scholarly intent.^{9,12} More recently, this definition has been expanded to include:

- “traditional or emergent methodologies and techniques that are accepted as characteristic of the specific discipline; and

¹² Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. 2010 [Online]. Available: http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf Accessed Sept 3, 2015.

- contribution or addition to a body of knowledge, or obtaining or confirming knowledge, which includes the expectation that the knowledge will be disseminated.”¹³

Researcher: any person who conducts or advances research in association with the CSMLS or conducts researching using CSMLS resources, including space, materials, equipment or human resources (adapted from University of Toronto guidelines).⁷

¹³ ProGroup. (2008). Refinements to the proportionate approach to research ethics review in the TCPS: A discussion paper. Ottawa: Subgroup of Procedural Issues for the TCPS (ProGroup): A working committee of the Interagency Advisory Panel on Research Ethics (PRE). Available: <http://www.pre.ethics.gc.ca/eng/archives/policy-politique/reports-rapports/rcrer-pcsecpr/> Accessed Sept 3, 2015.

B: REB decision form

Name of project _____

Principal researcher: _____

Date of REB meeting: _____

Decision:

- This application has been granted final approval.
- This application has provisional approval; final approval will be forthcoming upon the completion of the items listed below.
- This application is awaiting approval of the full REB.
- This application does not require REB approval.
- This application is not approved for the reasons outlined below. Please re-submit this application.

Attach additional materials if necessary.

Please indicate any additional materials/comments unrelated to the decision itself that are to be forwarded to the applicant. This may include requests or suggestions for additional materials in the case where a decision is deferred or amendments are necessary.

This approval is for protocols as submitted. If there are any changes, the Principal Investigator is expected to submitted a letter to the REB describing the changes. If there is a change to the informed consent form, then the revised form should be submitted for REB approval. The Principal Investigator is expected to submit an annual report to the REB on ongoing projects, as well as a report upon project closure.

Chair Date

C: REB checklist for completeness of application

REB members may wish to use this checklist to verify the completeness of the application and to prompt consideration of key principles for the review. This checklist is not meant to be an exhaustive list of the topics that reviewers consider.

CONTENTS

- cover sheet
- project protocol or summary with introduction, methods
- Budget or explanation of funding
- Informed Consent Form (ICF) – where applicable
- Conflict of Interest Statement – where applicable

INITIAL RISK ASSESSMENT

- | | | | |
|----------------------------|------------------------------------|---------------------------------|--|
| Level of risk | <input type="checkbox"/> low | <input type="checkbox"/> medium | <input type="checkbox"/> high |
| Recommended review process | <input type="checkbox"/> expedited | <input type="checkbox"/> full | <input type="checkbox"/> review not required |

CONGRUENCE WITH GUIDING ETHICAL PRINCIPLES

- respect for human dignity;
- respect for free and informed consent;
- respect for vulnerable persons;
- respect for privacy and confidentiality;
- respect for justice and inclusiveness;
- balancing harms and benefits;
- minimizing harm;
- maximizing benefit.

COMMENTS:

ASSESSMENT OF SCHOLARLY MERIT

- demonstrates sound research design
- makes use of recognized and validated methods
- evidences potential to contribute to the body of knowledge about the health professions
- demonstrates potential for practical application in health care(knowledge translation)

COMMENTS:

D. Criteria checklist for expedited review¹⁴

The project falls within one of the two following general categories:

- The research activities present no more than minimal risk.¹⁵
- The application concerns minor changes in a previously approved project.

In addition, the project should meet the following criteria:

- The proposed procedures are consistent with sound research design.
- Where possible, researchers are gathering data using procedures already being performed on subjects.
- The risks of the research are reasonable in relationship to the anticipated benefits, if any, to the subjects and the important of the knowledge that may be gained.
- Subject selection is equitable
- Researchers will seek and document informed consent.
- Where appropriate, there is a plan to collect and monitor data to ensure subject safety.
- The privacy of subjects and maintenance of confidentiality of data are protected.
- Where necessary, additional safeguards have been included to protect vulnerable subjects.

¹⁴ Adapted from Oki, G. S. & Zaia, J. A. (2006). Expedited institutional review board review. In E. A. Bankert & R. J. Amdur, Institutional review board: Management and function, 2nd ed., pp. 97-100. Toronto: Jones and Bartlett Publishers.

¹⁵ Where 'minimal risk' is defined as "the probability and magnitude of harm or discomfort anticipated in the research are not great in and of themselves than those ordinarily encountered in the daily life or during performance of routine physical or psychological examinations or tests." (Oki & Zaia, 2006, p. 97).

E: Reviewers' resources

Bankert, E. A. & Amdur, R. J. (2006). Institutional review board: Management and function, 2nd. ed. Toronto: Jones and Bartlett Publishers.

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, **Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans**. December 2014. Last retrieved Aug 17 2015 from <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>

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W. Maurice Young Center for Applied Ethics. (no date). Applied ethics resources on WWW: Research Ethics. [Online]. Available: <http://www.ethicsweb.ca/resources/research/> Accessed August 26 2015

F: Submission checklist for researchers

The application must contain the following elements in the order listed:

- Completed cover sheet

Project outline with the following information:

INTRODUCTION

- rationale for proposed research (provide just enough information to give the reviewers an understanding of why the research is being proposed, and of the research has been done in this area)
- explanation of relevance and potential practical application of research to health care

METHODS

- including data collection/analysis methods
- types of data to be sought
- copies of data gathering instruments (i.e., survey instruments or interview question scripts/guidelines) when applicable; these may be placed in an appendix;
- description of the researcher's experience with methods if they involve greater than minimal risk, collection of sensitive data or a vulnerable population

PARTICIPANTS/INFORMANTS/SUBJECTS

- who they are; how they are selected
- how subjects are to be recruited
- whether compensation is being offered
- possible risks: physical, psychological/emotional, social, legal; risk level (low/medium/high) and rationale
- possible benefits
- copies of cover letters and other correspondence
- the consent process: (where signed statements are to be used, include a copy)
- participant access to study findings
- protocol for participant withdrawal

CONFIDENTIALITY AND PRIVACY

- confidentiality of data: use of labels/pseudonyms, access to data,
- data storage and backup
- data retention period;
- long-term custodian upon project completion

CONTINUING REVIEW

- anticipated format

PROJECT BUDGET

- source(s) of funding
- breakdown by category: wages & related personnel costs, capital expenditures, overhead costs, in kind contributions
- yearly breakdown in the case of projects over 12 months in length

rsf005e April 2010

PROJECT TITLE

BRIEF ABSTRACT (2 – 3 sentences)

RESEARCHERS

Name	Institutional Affiliation
(PI)	

Anticipated Type of Review: <input type="checkbox"/> Expedited <input type="checkbox"/> Full Rationale

EXTERNAL APPROVAL NECESSARY? Yes No

DATA GATHERING STRATEGIES(check all that apply):

- Document analysis
- Electronic communication
- Observation/participation in online collaborative environments
- Written survey
- Telephone interview
- F2F Interview
- Site visit/observation

DESCRIPTION OF SUBJECTS

SOURCE OF FUNDING

PROJECT TIMING CONSTRAINTS (if any)

	YEAR	MONTH	DAY
ANTICIPATED PROJECT START DATE			
ANTICIPATED PROJECT END DATE			

By signing and submitting this application, the principal investigator agrees that CSMLS may place the project abstract, title, and PI name on the CSMLS website once the project has received REB approval.

Principal Investigator

Date

CSMLS Chief Executive Officer (or designate)

Date

CREB #

H: Annual report to the REB on ongoing projects

Name of Project	
Project Start Date	
Project End Date	
Principal Investigator	
Project Status	Has anything changed that might affect the project's ethical approval status?
	Have there been any unexpected events in conducting the project, particularly with respect to the informed consent process?
	Have there been any complaints about the project?
Other comments	

Principal Investigator's Signature

Date

CREB #

I: Report to the REB on completed projects

Name of Project	
Project Start Date	
Project End Date	
Principal Investigator	
Project Status	Were there any changes or unexpected events in conducting the project that could have affected the project's ethical review?
	Were there any complaints about the project?
Project Outcomes & Dissemination	Brief Description
Data archiving	How/how long will data be archived and who will be custodian?
Other comments	

Principal Investigator's Signature

Date

J. Decision form for project amendments

Proposal Title:

Amendment #:

REB #:

Please respond by date:

Hello REB Sub-committee member,

Thank you for taking the time out of your busy schedules to review this amendment.

I have reviewed this amendment and found the changes to be acceptable. As an original reviewer of this application, please review this amendment and decide if you want to:

Please check only one:

Accept the changes, no further comments

Ask the investigator for more information before approval, Please explain:

Reject the amendment, Reason:

Call a conference call with the sub-committee or full REB to discuss amendment
If Yes, please indicate: **Sub Committee** **OR** **Full REB**

Please email or fax your response to the chair by:

Julie Carruthers
CSMLS REB Chair
carrutj@mcmaster.ca
Fax: 905-524-2983

Sub-committee Member Name: _____

Sub-committee Member Signature: _____

Date: _____

K. Bibliography

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