Research Ethics Board Standard Operating Procedures

Thunder Bay Regional Health Sciences Centre June 2012

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Terms of Reference for the Research Ethics Board: Review of Research Involving Human Subjects

Prepared by:

Research Ethics Office

Approval Granted by the by the TBRHSC Board of Directors
Original Terms of Reference: approved May 2009
Version # 2: updated and approved September, 2011

our Vision

Healthy Together

our Mission

To advance world-class Patient and Family Centred Care in an academic, research-based, acute care environment.

Values

Patients ARE First

- Patients First
- Accountability
- Respect
- Excellence

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A: Preface

i. Abbreviations Used within this Document

Board	Board of Directors, Thunder Bay Regional Health Sciences Centre
GCP	Good Clinical Practice Guidelines
ICH	International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use
REB	Research Ethics Board, Thunder Bay Regional Health Sciences Centre
REO	Research Ethics Office, Thunder Bay Regional Health Sciences Centre
SOP	Standard Operating Procedures for the Research Ethics Board
TCPS 2	Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans
TBRHSC	Thunder Bay Regional Health Sciences Centre

ii: Website References for Research Ethics Review

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, **TCPS 2** *Tri-Council Policy Statement: Ethical conduct for Research Involving Humans*, December 2010:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

International Conference of Harmonization of Good Clinical Practice Guidelines (ICH:GCP), General Guidelines for Clinical Trials as adopted by Health Canada:
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php

Health Canada: Food and Drug Regulations: Part C: DRUGS (Division 5):
http://laws.justice.gc.ca/en/showdoc/cr/C.R.C.-c.870/bo-ga:l_C-gb:l_5//en#anchorbo-ga:l_C-gb:l_5

Personal Health Information Protection Act, 2004:
http://www.health.gov.on.ca/english/public/pub/ministry_reports/phipa/bill_159.pdf

Quality of Care Information Protection Act, 2004:
http://www.health.gov.on.ca/english/providers/legislation/priv_legislation/quality_info.html

US Food and Drug Act:
http://www.fda.gov

1. Terms of Reference

1.1 Introduction:

The Research Ethics Board (REB) of Thunder Bay Regional Health Sciences Centre (TBRHSC) functions to ensure that all research involving humans at the Health Sciences Centre meets the highest ethical standards prior to study initiation in accordance with the TCPS 2: Tri-Council Policy Statement Guidelines on Research Involving Humans.

The REB will ensure that all research reviewed demonstrates respect for the Values, Mission and Vision statements articulated by Thunder Bay Regional Health Sciences Centre.

The REB will endeavour to safeguard the rights, safety and well-being of patients, clients, staff, TBRHSC programs and members of the community who serve as research participants by upholding the principles outlined in the TCPS 2:

- Respect for Persons
- Concern for Welfare
- Justice

1.2 Responsibilities of the REB:

The primary responsibility of the REB is to conduct the ethical assessment of all research proposed to the Health Sciences Centre, researchers having an association with TBRHSC, and any research involving patients, clients, health records, human biological materials of living or deceased individuals, staff or programs of TBRHSC.

1.3 Duties of the REB:

The duties of the REB are:

- to approve, reject, propose modifications to, monitor, suspend or terminate any proposed or ongoing research activities within the TBRHSC using the criteria described in the following documents as the minimum standards:
    - TCPS 2: Tri-Council Policy Statement for Research Involving Humans,
    - International Conference on Harmonized Good Clinical Practice (ICH:GCP) Guidelines as adopted by Health Canada,
    - Health Canada: Food and Drug Regulations: Part C: DRUGS (Division 5),
    - US Food and Drug Act,
    - Accreditation Canada,
    - Personal Health Information Protection Act (PHIPA), 2004,
    - Quality of Care Information Protection Act (QCIPA), 2004.
- to review its membership regularly to ensure composition and function according to the TCPS, and ensure the necessary expertise is available to carry out its responsibilities,
- to provide continuing ethics review of approved research studies,

- to establish standard operating procedures for consistent and transparent review of all protocols, continuing ethics review and closure of all research projects conducted within the organization or by staff of the organization, including delegated review processes. All decisions reached through delegated processes will be reported to the full REB,
- to engage in ongoing education on research ethics issues and to share their knowledge with the research community at the TBRHSC, and
- to schedule a minimum of 8 meetings per year to facilitate timely review of research protocols.

1.4 Accountability:

In order for the REB to perform its duties properly and maintain high ethical standards, it is an administratively independent body within Thunder Bay Regional Health Sciences Centre which operates at arm's length from administrative, governance, programmatic and research structures within TBRHSC. While autonomous in its decision making role, the REB must be responsible and accountable to the Board.

All REB decisions will be reported to the Board for information. The reporting process will be defined by the Board.

Thunder Bay Regional Health Sciences Centre retains the authority to deny the initiation of REB-approved research protocols for reasons other than research ethics, in the assurance that all projects and protocols are in accordance with the vision and mission of TBRHSC. Research protocols reviewed and approved by the REB may be subject to further feasibility reviews by the Senior Management Team and/or the Board.

1.5 Appointment to the REB:

Membership to the REB will be approved by the Board. REB members may serve three three-year terms (consecutive) for a total of 9 years. The Chair of the REB will be nominated by the REB membership, and approved by the Board. The Chair of the REB should have a minimum of one year of experience as a REB member.

1.6 REB Membership:

Ensuring compliance as outlined in the TCPS 2, the composition of the REB will consist of a minimum of seven voting members, both men and women, including:

- at least two members with broad expertise in the methodology,
- at least one member knowledgeable in ethics,
- at least one member knowledgeable in health law,
- at least one member knowledgeable in privacy issues, and
- at least one community representative having no affiliation with the TBRHSC*, and
- a staff member from the Research Ethics Office (permanent non-voting member.

* Due to the diversity of services provided by TBRHSC, the REB membership would be strengthened by the inclusion of a second community representative.

1.7 Responsibilities of the Chair of the REB:

The responsibilities of the Chair of the REB are:

- to Chair the REB meetings in compliance with TBHRSC policies and relevant guidelines;
- to be available for delegated reviews and processes, and consultation regarding REB issues;
- to monitor the REB's decisions for consistency, to oversee the proper documentation of all decisions, and to ensure that researchers are given written communication of the REB's decisions in a timely fashion.
- to recruit a REB member in good standing with one year experience to be appointment as Acting Chair. The role of the Acting Chair is to fulfill the duties of the Chair when the Chair is not available, or must declare conflict of interest in reviewing a specific application.

1.8 Responsibilities of the Research Ethics Office Staff:

The role of the Research Ethics Office is to provide administrative resources to the REB Chair and the members. The responsibilities of the Research Ethics Office are:

- to attend all REB meetings as a non-voting member;
- to examine all protocols submitted by researchers for completeness and request additional information as appropriate, before protocols are evaluated by the REB;
- to advise the REB Chair of required policies and procedures which meet national standards for efficient review of research involving humans;
- to maintain records of all REB activities in accordance with the TCPS 2, including minutes and all relevant correspondence with investigators and researchers;
- to coordinate all administrative reviews and delegated approvals for the REB Chair, as outlined in the standard operating procedures for the REB;
- to prepare new or revised standard operating procedures for review and approval by the REB;
- to investigate ethical standards specific to emerging methodologies;
- to monitor approved research protocols for researchers submitting to the REB;
- to coordinate educational events for REB members; and
- to facilitate the application process for researchers submitting to the REB.

1.9 Quorum:

Quorum for the REB is defined by fulfilling the minimum requirements of expertise as stipulated by TCPS 2 [Article 6.9] and having a minimum of fifty percent (50%) plus one of voting REB members in attendance.

1.10 Voting:

There shall be a requirement of a minimum of fifty percent (50%) plus one favourable votes of REB members in attendance to resolve or approve any issue requiring a vote.

2. REB Review Process

2.1 Overview

All research activities involving humans and/or their health records require REB review and approval before initiation of the project. Chart reviews, program evaluation or multi-centered quality improvement/assurance projects involving an external investigator may require REB approval. Internal quality assurance, quality improvement and program evaluation audits including those within normal educational requirements are not, as a general rule subject to REB review and approval. Questions regarding the requirement of REB approval should be directed to the Chair of the REB through the Research Ethics Office.

There are two types of reviews:

A. Full REB review:
   All new research studies will undergo full REB review. Exceptions may be granted by the Chair of the REB, if the proposal is both low risk and does not involve a vulnerable population as outlined in the TCPS 2.

B. Delegated review:
   Items which may be considered for delegated review:
   - B.1 Protocols which have minimal risk and do not involve vulnerable populations,
   - B.2 Eligible annual re-approvals of approved project with little or no change,
   - B.3 Amendments with administrative changes only.

   All approvals granted by the REB Chair through the delegated process will be reported at the next REB meeting.

2.2 Decisions of the REB:

The REB will make one of the following decisions regarding each new protocol, re-approval or amendment submitted:

1. approval, no revisions required.
2. minor clarifications/revisions requested by the REB, to be submitted to and reviewed by the Chair, REB. Final REB approval is delegated to the Chair of the REB pending acceptable revisions.
3. clarifications/revisions required for submission and approval as per directive in the motion of the REB [e.g., review by identified REB member; sub-committee of REB; electronic distribution of revisions to entire REB with timeline for comments]. After revisions are submitted and reviewed according to the REB motion, final REB approval is delegated to the Chair of the REB.
4. major clarifications/revisions are requested. Principal Investigator is requested to resubmit a revised application for full REB review. Principal Investigator may or may not be asked to attend the second REB meeting.
5. not recommended for approval. Principal Investigator may request reconsideration.
6. decision deferred.

All decisions will be communicated to the Principal Investigator promptly following the REB meeting. If required, requested revisions/clarifications will be communicated outlining a process for submission. All actions taken will be reported and recorded in the subsequent REB meeting minutes.

All REB decisions will be reported for information to the Board.

DISCLAIMER: The Research Ethics Webpage version of this document is considered the most current. Please ensure that you have reviewed all linked documents and other referenced material within this guideline.

SOP Title:	Principles, Guidelines and Regulation References
Issued By:	Research Ethics Office
Approved By:	SJCG Research Ethics Board ~ June 2012 TBRHSC Research Ethics Board ~ May 2012

1.0 PURPOSE

The purpose of this reference document is to list the principles, guidelines and regulations utilized in the standard operating policy and procedure (SOP) established by the St. Joseph's Care Group and Thunder Bay Regional Health Sciences Centre Research Ethics Boards. The documents reference the national standards used in the ethical review and oversight of research involving human subjects and human biological materials.

2.0 POLICY STATEMENT

The Board of Directors acknowledges the importance of facilitating the pursuit of new knowledge and understanding in health care, the social sciences and technology and the value of investigative research in the continuing effort to improve the quality of health care.

The Board of Directors authorizes the Research Ethics Board to review the ethical acceptability of research involving humans and/or human biological materials, including approving, rejecting, proposing modifications to, or terminating any proposed or ongoing research involving humans. The institution recognizes the autonomy of the Research Ethics Board in their decision making authority in regards to the ethical review of research involving humans.

3.0 PRINCIPLES, GUIDELINES AND REGULATION REFERENCES

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 2010: (short name: TCPS 2)
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

The Tri-Council Policy Statement for Research Involving Human Subjects, 1998 (short name: TCPS)
http://www.pre.ethics.gc.ca/eng/archives/tcps-eptc/Default/

Guidelines for Researchers - REB submission for SJCG/TBRHSC (September 2011)
http://www.tbrhsc.net/about_TBRHSC/research_ethics/forms.asp or
http://www.sjcg.net/departments/research-services-ethics/reb.aspx

Good Clinical Practice: Consolidated Guideline (GCP) for Pharmaceutical Guidelines (ICH Harmonized Tripartite Guidelines: General Guidelines for Clinical Trials: (short name: GCP Guidelines)
http://www.fda.gov/cder/guidance/959fnl.pdf

Health Canada: Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials: Part C: DRUGS (Division 5)
http://laws.justice.gc.ca/en/showdoc/cr/C.R.C.-c.870/bo-ga:l_C-gb:l_5//en#anchorbo-ga:l_C-gb:l_5

Personal Health Information Protection Act, 2004:
http://www.health.gov.on.ca/english/public/pub/ministry_reports/phipa/bill_159.pdf

Quality of Care Information Protection Act, 2004:
http://www.health.gov.on.ca/english/providers/legislation/priv_legislation/quality_info.html

US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21, Parts 56.108, 56.115 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56

U.S. Department of Health and Human Services (HHS): Code of Federal Regulations (CFR), Title 45 Part 46.103, Part 46.108 http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

U.S. Department of Health and Human Services (HHS): Office for Human Research Protections (OHRP) Policy & Guidance Library http://www.hhs.gov/ohrp/policy/index.html

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SOP Title:	Definitions
Issued By:	Research Ethics Office
Approved By:	SJCG Research Ethics Board ~ June 2012 TBRHSC Research Ethics Board ~ May 2012

1.0 PURPOSE

The purpose of this reference document is to outline the terms, definitions and acronyms utilized in the standard operating policies and procedures (SOPs) established by St. Joseph's Care Group Research Ethics Board (SJCG REB) and Thunder Bay Regional Health Sciences Centre Research Ethics Board (TBRHSC REB). The terms used are to facilitate compliance with the principles, guidelines and regulations applicable to the ethical review and oversight of research involving humans, their information and/or biological materials.

2.0 POLICY STATEMENT

The Research Ethics Office (REO) is a shared service between St. Joseph's Care Group and Thunder Bay Regional Health Sciences Centre. The REO administratively supports the duties outlined in the Terms of Reference for St. Josephs' Care Group and Thunder Bay Regional Health Sciences Research Ethics Boards respectively.

Written SOPs provide the framework to promote ethical standards in the review, oversight and conduct of research involving humans and/or human biological materials. SOPs describe the procedures to be followed and documented to assure that the rights and welfare of the human participants involved in research are overseen and protected in a uniform manner.

3.0 DEFINITIONS (including acronyms, in alphabetical order)

Access Log: a document that records the names and signatures of those accessing the identifying information of the research participant, and the date at which this occurred.

Acting Chair: fulfills the duties of the Chair when the Chair is either not available, or must declare conflict of interest in reviewing a specific application. The Acting Chair is recruited by the REB Chair and is an REB member in good standing with one year experience on an REB.

Amendment: a written description of modification(s) or formal clarification(s) of the previously approved research.

Approval Period: the standard approval period is calculated as the one-year anniversary from the REB meeting date when the study was last considered which resulted in approval, or for delegated review, the date the delegated approval was granted. When the REB determines that a more frequent review is required, the approval period will be determined by the REB (i.e., six months from the date of the REB meeting date).

REB-SOP-I-03.01 Definitions

Authorized Signatory: individual(s) authorized to sign documents on behalf of the REB. Also referred to as "signing authority".

Board: Board refers to the Board of Directors for either St. Joseph's Care Group or Thunder Bay Regional Health Sciences Centre. Board shall always be prefaced with the appropriate corporation; e.g., SJCG Board or TBRHSC Board. The use of the term "Boards" within the Standard Operating Procedures shall imply both corporations.

Chair, REB: Chair of the Research Ethics Board (REB) will be nominated by the REB membership, and approved by the appropriate Board as outlined in the REB Terms of Reference for each institution.

Confidentiality: refers to the agreement between the investigator and the participant as to how personal data will be managed and used.

De-identification: means to remove any information that identifies the individual or for which it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify the individual.

Delegated Review: under a delegated review procedure, the review may be performed by the Research Ethics Board (REB) Chair or delegated to one or more experienced reviewers from among the REB members. Delegated review procedures may be used for certain kinds of research involving minimal risk, and for minor changes in approved research (see REB-SOP-V-02.01: Delegated Review).

External Safety Report: a Report of a serious unexpected adverse drug reaction that occurs at any other centre involved in a study using the same investigational agent.

Ex-Officio members: membership on the REB by virtue of a particular office or position held. The Manager and Officers of the Research Ethics Office are ex-officio members.

GCP Good Clinical Practice

ICH: GCP International Conference of Harmonisation: Good Clinical Practice Guidelines

Identifiable information: means information that identifies an individual or for which it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify an individual. TCPS 2: Chapter 5 offers the following guidance for assessing information which may be identifying:

- Directly identifying information – the information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).
- Indirectly identifying information – the information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic).
- Coded information – direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the principal investigator retains a list that links the participants' code names with their actual name so data can be re-linked if necessary).

- Anonymized information – the information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.
- Anonymous information – the information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.

Institutional Official: senior official who signs an institution's human subjects assurance, making a commitment on behalf of the institution to comply with 45 CFR Part 46, the US Code of Federal Regulations covering protection of human subjects.

Key File: a document that links the unique study identifier with the identifying information of the research participant.

Legally Acceptable Representative:
an individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective participant, to the participant's participation in a research study.

Manager: refers to the Manager, Research Ethics Office who oversees the operations of the Research Ethics Office.

Minimal risk: if potential participants 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 participant 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.

Minor amendment/change: any change that would not materially affect an assessment of the risks and benefits of the study or does not substantially change the specific aims or design of the study.

Multi-centre: in the context of OCREB means that the research is reasonably expected to be conducted at more than one centre in Ontario.

Personal health information (PHI):
means identifying information about an individual in either an oral or in a recorded form, if the information:

- relates to the *individual's* physical or mental health, including family health history
- relates to the provision of health care, including the identification of *persons* providing care
- is a plan of service for an *individual* requiring long-term care
- relates to payment or eligibility for health care
- relates to the donation of body parts or bodily substances or is derived from the testing, or examination of such parts or substances
- is the *individual's Provincial health number*; or
- identifies an individual's *substitute decision-maker*.

Any other information about an individual that is included in a record containing personal health information is also included in this definition. This definition does not include information about an individual if the information could not reasonably be used to identify the individual.

Principal Investigator (PI): the individual who is responsible for the overall study at the institution. The PI may be either a local Principal Investigator responsible for a single site study, or the lead investigator within the institution for a multi-site study. An external PI leading a multi-site study may require a local co-applicant.

Privacy: in the context of personal information, privacy is about having the ability to control or influence the way in which information about a person is collected, used and disclosed.

Policy: a written statement that provides direction for decision-making, prescribes limits, identifies responsibility and accountability, and is secondary to existing legislation and bylaws. Policy statements describe what the Research Ethics Board (REB) is committed to and will typically contain words such as "must" or "will".

Proportionate review: based on the general principle that the more invasive or harmful the proposed and ongoing research, the greater the care in assessing the research. Proportionate review reserves the most intensive scrutiny, and correspondingly more protection, for the most ethically challenging research.

Procedure: written statements that typically describe a series of specific steps (action verbs) required to complete various tasks.

Qualified Investigator (QI): for Health Canada trials**,** the person responsible to the sponsor for the conduct of the clinical trial at a clinical trial site, who is entitled to provide health care under the laws of the province where that clinical trial site is located and who is:

(a) in the case of a clinical trial respecting a drug to be used for dental purposes only, a physician or dentist and a member in good standing of a professional medical or dental association; and

(b) in any other case, a physician and a member in good standing of a professional medical association.

Quorum: the minimum number of members that must be present (physically, via videoconference or teleconference) in order for the REB to review and make its determination regarding submitted research applications. Quorum is defined as fifty percent (50%) plus one of voting REB members to be present. However, where there is less than full attendance, decisions will be adopted only if the members attending the meeting possess the appropriate background and expertise in the area of research being considered. In exceptional circumstances, a member may submit their written review in advance to the REB Chair, and the Chair will document their proxy vote.

Re-approval Application: written summaries of the study/research status which may include: a recruitment summary, a summary of local serious adverse events, a notification of protocol deviations requiring reporting, updated conflict of interest information, relevant ethical and scientific information outside of an amendment, attachment of the current approved informed consent form, and Data Safety Monitoring Board reports.

Research Ethics Board (REB): a group of volunteers appointment by the Board of Directors to review research involving humans and/or human biological materials which is to be conduct under the auspices of the organization. At a minimum, membership is guided by the Tri-Council Policy Statement 2 (December, 2010) and the Terms of Reference.

Research Ethics Office: is a shared administrative service between St. Joseph's Care Group and Thunder Bay Regional Health Sciences Centre to support the duties of the Research Ethics Board of each organization.

REB Membership: the composition of the REB is outlined in the Terms of Reference following the guidance of TCPS 2: Chapter 6. It will consist of a minimum of seven voting members, both men and women, including representation from each category listed:

- two members with broad expertise in the methodology
- a member knowledgeable in ethics
- a member knowledgeable in health law
- a member knowledgeable in privacy issues
- a member from the community having no affiliation with the Corporation, and
- a member from the Research Ethics Office (non-voting member).

REB of Record: the Research Ethics Board that has been granted the authority for the ethics review and oversight of a research study.

REB Policy & Procedure Committee: is comprised of REO staff, and the REB Chairs for St. Joseph's Care Group and Thunder Bay Regional Health Sciences Centre.

Signing Authority: individual(s) authorized to sign documents on behalf of the REB. Also referred to as "authorized signatory".

SOP: standard operating procedure. For the purpose of this document, SOP will include both policies and procedures unless otherwise specified.

SOP Template: document used to standardize the format of all standard operating policies and procedures.

SOP Index: list of the current, finalized standard operating policies and procedures for REB members and Research Ethics Office (REO) staff.

Sponsor-Investigator: an individual who both initiates and conducts a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a research participant. The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

Standard REB Review Package: includes the meeting agenda, minutes from the previous meeting, documents related to 'business arising' (e.g., PI responses for revisions/clarifications and resulting actions), REB applications and continuing ethics review (e.g., new projects, amendments, re-approvals), reports (e.g., investigator brochures, safety reports) and administrative items (e.g., REB member recruitment, update on Standard Operating Policies and Procedures).

Suspension: a temporary or permanent halt to all or part of research activities pending future action by the REB or by the investigator of his/her study personnel.

Task Delegation Log: a document that lists the delegation of trial specific duties by the Principal Investigator to other research personnel in the team.

TCPS 2: 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, 2012].

Termination: a permanent halt by the REB to all or some research activities.

Training Record: document used to document the training for REB members and REO staff.

Unique Study Identifier: a unique number or unique combination of letter, numbers and/or symbols used to identify a research participant. Also known as a "unique study code".

Vulnerable Population: Vulnerability is often caused by limited capacity (temporary or permanent), or limited access to social goods, such as rights, opportunities and power. Individuals or groups in vulnerable circumstances have historically included children, the elderly, women, prisoners, those with mental health issues and those with diminished capacity for self-determination. Ethono-cultural minorities and those who are institutionalized are other examples of groups who have at times been treated unfairly and inequitably in research. (TCPS 2, page 10). Vulnerability needs to be assessed within the context of the proposed research.

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SOP Title:	Relationship of Research Ethics Office to Research Ethics Boards
Issued By:	Research Ethics Office
Approved By:	SJCG Research Ethics Board ~ June 2012 TBRHSC Research Ethics Board ~ May 2012

1.0 PURPOSE

The purpose of this standard operating policy and procedure (SOP) is to describe the relationship between the Research Ethics Office (REO) and the Research Ethics Boards (REBs), the overall management of REO staff and their responsibilities in supporting the work of the REBs.

2.0 POLICY STATEMENT

St. Joseph's Care Group and Thunder Bay Regional Health Sciences Centre endorse an accountable and transparent research review process based on the national standards for research.

The Research Ethics Office (REO) is a shared service of St. Joseph's Care Group (SJCG) and Thunder Bay Regional Health Sciences Centre (TBRHSC). The REO staff provides expertise and administrative support to facilitate the work of the SJCG and TBRHSC Research Ethics Boards (REBs).

3.0 RESPONSIBILITY

St. Joseph's Care Group and Thunder Bay Regional Health Sciences Centre shall provide sufficient resources (e.g., staffing, office space, meeting space, educational funding, computer hardware and software) to adequately support the functions of the REO and their respective REBs.

The goal of a shared REO is to develop consistent and harmonized processes for research ethics review for the two organizations, and to serve as a daily link between the REBs and the research community. The REO staff are vital to ensuring the efficient and effective administration and enforcement of REB decisions, thus the highest level of professionalism and integrity is expected.

4.0 PROCEDURES

4.1 Roles and Responsibilities

4.1.1
For SJCG REB, the primary responsibility is to conduct the ethical assessment of all research proposed to the Care Group, researchers having an association with SJCG, and any research involving patients, clients, health records, human biological materials of living or deceased individuals, staff or programs of SJCG as outlined in the SJCG Terms of Reference [Article 2.1].

For TBRHSC REB, the primary responsibility is to conduct the ethical assessment of all research proposed to the Health Sciences Centre, researchers having an association with TBRHSC, and any research involving patients, clients, health records, human biological materials of living or deceased individuals, staff or programs of TBRHSC as outlined in the TBRHSC Terms of Reference [Article 2.1].

4.1.2
The REB Chair is to be an advocate for ethical conduct of research within the organization and ensure the efficient and effective functioning of the REB by carrying out their responsibilities as outlined in the Terms of Reference [Article 1.7].

4.1.3
The Manager is to be an advocate for ethical conduct of research within the organization, oversee effective and efficient administrative support for the REB, and establish the roles and responsibilities for the REO staff as outlined in the REB Terms of Reference [Article 1.8]. The Manager is responsible for determining staffing requirements and for hiring and evaluating the ongoing performance of REO staff in accordance with the Human Resource policies of the St. Joseph's Care Group and Thunder Bay Regional Health Sciences Centre.

4.2 Delegation of Authority or Responsibility

4.2.1
The REB Chair may only delegate appropriate tasks or responsibilities to a REO staff member if the individual has the expertise to carry out the task(s) and the task delegation has been agreed to by both the staff member and the Manager of REO. Delegation of tasks should be either documented in writing or outlined in an SOP.

4.3 Evaluation of REO Resources

4.3.1
The Manager shall conduct a periodic evaluation of all REO resources, including the budget.

4.3.2
The evaluation will assess whether the REO staffing, equipment, finances and space are adequate to carry out its function in support of REO and REB. The assessment takes into consideration the volume, complexity and types of human research projects administered by the staff and whether activities in support of the REB can be completed in a timely manner.

4.3.3
The REO will follow institutional policies and procedures for identifying, documenting and retaining formal staff interactions (such as performance evaluations). Input from the research community, office colleagues, REB members and the REB Chair may be gathered as part of the performance evaluation process. Performance feedback will be provided on an ongoing basis; formal performance evaluations will be conducted at least every two years.

4.3.4
The Manager discusses the need for additional resources with their responsible supervisor(s), as appropriate.

4.3.5
The Manager and REB Chair will jointly submit an annual report to the Board of Directors for each institution which will include a statement on administrative resources to support the work of the REB.

5.0 REFERENCES

1. *St. Joseph's Care Group Terms of Reference for the Research Ethics Board, Version # 3, September, 2011*
2. *Thunder Bay Regional Health Sciences Centre Terms of Reference for the Research Ethics Boar, Version # 2, September 2011*
3. *REO Staff job descriptions*

Research Ethics Board	SOP Development and Maintenance REB-SOP-II-02.01

DISCLAIMER: The Research Ethics Webpage version of this document is considered the most current. Please ensure that you have reviewed all linked documents and other referenced material within this guideline.

SOP Title:	Standard Operating Policy and Procedure Development and Maintenance
Issued By:	Research Ethics Office
Approved By:	SJCG Research Ethics Board ~ June 2012 TBRHSC Research Ethics Board ~ May 2012

1.0 PURPOSE

The purpose of this standard operating policy and procedure (SOP) is to describe the processes necessary to establish and maintain written SOPs to facilitate agreement with and consistent application of the principles, guidelines and regulations applicable to the ethical review and oversight of research involving humans.

2.0 POLICY STATEMENT

All SOPs are developed to operationalize the understanding of the principles outlined in the Tri-Council Policy Statement. If there are any discrepancies between the national standards and an SOP, the national standards shall prevail.

Written SOPs provide the framework to promote ethical standards in the review, oversight and conduct of research involving human subjects and/or human materials. SOPs describe the processes that must be followed and documented to assure that the rights and welfare of the human subjects of such research are overseen and protected in a uniform manner.

3.0 RESPONSIBILITY

This SOP applies to all REB members, Manager, and REO staff. The Manager (or designee) is responsible for coordinating the development, review and revision of the SOPs. The Manager and REB Chairs are responsible for granting final SOP approval.

4.0 PROCEDURES

4.1 Development, Review, Revision and Approval of Policies & Procedures

4.1.1
The Manager or designee will review the SOPs annually. Applicable SOPs will be reviewed earlier if changes to regulations, guidelines, or standard practice warrant revisions or the creation of new SOPs.

4.1.2
Standard Operating Procedure(s) may be revised due to: changes to applicable regulations or guidance documents; new policies determined by the Manager or REB Chair; or changes to REB or REO administrative practices.

4.1.3
The Manager or designee will make the necessary modifications to existing SOPs, or draft new SOP(s). Standard Operating Procedure(s) are controlled documents and new drafts will be indicated by the addition of DRAFT version date, and removal of the previous version date.

4.1.4
New or revised SOP(s) will be circulated by the REO staff to all REB members (as appropriate) for review at either a convened meeting or through electronic communication. Approval of the new or revised SOP will be by vote and documented in the minutes.

4.1.5
Each SOP will be identified by a number. The number format follows the sequence:

- The letters REB, followed by the letters SOP, followed by the section number, followed by the SOP number and version number (i.e. REB-SOP-II-01.01). For revisions to previous SOPs, the version number must be revised to the next consecutive number (e.g. 01.01 becomes 01.02). This new version supersedes any previous versions.

4.1.6
Once the final draft is approved, the draft version date will be removed and the date of the approved revision will be entered. For an original Policy or Procedure, the original issue date will be recorded in the header. For subsequent Policies or Procedures, the version date will be recorded in the header.

4.1.7
A Policy/Procedure Development and Approval Form will be used to track approval for both original and revised policies and procedures. Terms of Reference are approved by the Board of Directors, St. Joseph's Care Group and Thunder Bay Regional Health Sciences Centre respectively. Standard Operating Procedure(s) are approved by each of the Research Ethics Boards.

4.1.8
Standard Operating Procedure(s) will be archived as per Health Canada requirements in the Research Ethics Office or designated storage facility.

4.2 Distribution and Communication

4.2.1
The Manager and/or REB Chair is responsible for ensuring new or revised policies and associated guidance documents will be communicated and disseminated to all individuals identified in the Responsibilities section of each SOP.

4.2.2
Training will be provided to all members of the REBs and REO staff for any new or revised policy or relevant procedure as applicable.

4.2.3
Each new REB member must review all applicable policies and procedures prior to undertaking their responsibilities as an REB member.

4.2.4
Each new REO employee must review all applicable policies and procedures within the first month of undertaking their responsibilities with the REO.

4.2.5
The REO shall maintain all documentation of training in the SOP training record.

4.3 Forms

4.3.1
Forms, including checklists and worksheets, are used to facilitate adherence with SOPs and to ensure that policies and procedures are integrated into daily operations. Forms are either controlled or non-controlled.

- Controlled forms are documents that require formal change control through use of version dates and form part of the permanent record of REB operations and processes.

- Non-controlled forms are management tools that are not part of the permanent record of REB operations and processes. Non-controlled forms will also contain version dates.

5.0 REFERENCES

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 2010: *(short name: TCPS 2);*
2. *International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines as adopted by Health Canada;*
3. *Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials, Division 5;*
4. *US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21, Parts 56.108, 56.115;*
5. *US Department of Health and Human Services (HHS) CFR Title 45 Part 46.103, 46.108.*

DISCLAIMER: The Research Ethics Webpage version of this document is considered the most current. Please ensure that you have reviewed all linked documents and other referenced material within this guideline.

SOP Title:	Training and Education: Research Ethics Board Members and Research Ethics Office Staff
Issued By:	Research Ethics Office
Approved By:	SJCG Research Ethics Board ~ June 2012 TBRHSC Research Ethics Board ~ May 2012

1.0 PURPOSE

The purpose of this standard operating policy and procedure (SOP) is to describe the training and education requirements for Research Ethics Board (REB) members and Research Ethics Office (REO) staff.

2.0 POLICY STATEMENT

Research Ethics Board members and REO staff charged with the responsibility of reviewing, approving and overseeing human research should be well-versed in the regulations, guidelines, policies and ethical principles applicable to human research. Adequate training and education in these areas is essential for the REB to fulfill its mandate of protecting the rights and welfare of human research subjects and human materials in a consistent manner.

3.0 RESPONSIBILITY

This SOP applies to the REB Chairs, Manager, REB members and REO staff.

The REB Chairs and the Manager, or designee, are responsible for establishing the training and education requirements for REB members and REO staff. The Manager, or designee, will ensure that initial and ongoing training is provided and documented in accordance with such requirements.

4.0 PROCEDURES

4.1 Initial Training and Education – REB Members

4.1.1
The REB Chair, or designee, will provide new members with a general orientation of the policies and procedures pertinent to REB meeting functions and REB member expectations.

4.1.2
New REB members will receive an orientation binder. Before beginning their formal duties on the REB, members are expected to read and become familiar with the information. The orientation binder will include, but is not limited to:

- Welcome Letter, Checklist and Confidentiality Agreement
- Research Ethics Board Terms of Reference
- Research Ethics Office Contact Information
- Research Ethics Board Meeting Schedule (including agenda cut-off dates)
- Confidential REB Membership List

- REB Protocol Review Procedure (Guidelines and Application Forms and Report Forms)
- Regulatory and Guidance Documents (Tri-Council Policy Statement: Ethical conduct for Research Involving Humans [TCPS II, 2010]; ICH Good Clinical Practice Guidelines as adopted by Health Canada)
- List of electronic resources/websites related to review of research involving humans
- Educational Resources
- Articles

4.1.3
As part of the orientation, new REB members will observe at least one REB meeting prior to commencing their REB member duties.

4.1.4
All REB members should complete the online TCPS 2 Course On Research Ethics (CORE) tutorial within the first six months of their appointment to the REB. A certificate of completion will be made available to the Research Ethics Office.

4.2 Initial Training and Education – REO Staff

4.2.1
The Manager or designee will provide new REO staff with a general orientation to the REO with an overview of the policies and procedures pertinent to their role in support of the REB.

4.2.2
New REO staff will receive an orientation to their role. Before commencing their official duties REO staff are expected to read and become familiar with the standard operating policies and procedures (SOPs).

4.2.3 All REO staff must complete the online TCPS introductory tutorial within the first 3 months on the job.

4.3 Continuing Education – REB Members and REO Staff

4.3.1
Conferences: REB members (including the Chair & Acting Chair) and REO staff are encouraged to attend conferences pertaining to human participant research protection, such as the Canadian Association of Research Ethics Board (CAREB) annual general meeting. The REO will support such activities to the extent possible and as appropriate to the responsibilities of REB members and REO staff. Conference attendance is based on availability of funding and other practical considerations (e.g., timing, conference location).

4.3.2
Workshops and Seminars: REB members and REO staff are encouraged to attend (in person or via teleconference/webinars) other relevant local workshops and educational sessions such as research ethics education sessions (e.g., Centre for Health Care Ethics located at Lakehead University).

4.3.3
Research Ethics Board members who have received funding from the REO to attend a workshop or conference will be asked to present the relevant conference/workshop information at the next REB meeting, time permitting. Research Ethics Office staff will be asked to present relevant conference/workshop information to their colleagues at the next team meeting and/or at an REB meeting, as appropriate.

4.3.4
Other Educational Opportunities: The REB Chair and Manager, or designee, will distribute articles related to human subject protections, trends in research or updated guidance documents as appropriate. Research Ethics Board members and REO staff are encouraged to submit relevant articles to the REB Chair, Manager or REO staff for distribution.

4.4 Documentation of Training and Education - REB Members and REO Staff

4.4.1
The REO will keep copies of REB members and REO staff biosketches or CVs on file.

4.4.2
Research Ethics Board members will be asked to provide the REO with details of relevant training and education and to submit copies of any certificates of completion. A copy of the TCPS certificate of completion must be submitted to the REO.

4.4.3
Research Ethics Office staff must submit a copy of the TCPS certificate of completion to the Manager, or designee.

4.4.4
Research Ethics Board members and REO staff are encouraged to retain copies of agendas for relevant workshops, seminars and conferences attended as evidence of continuing education.

4.4.5
Research Ethics Board member and staff training records will be kept on file in the REO.

4.4.6
Documentation of the distribution of educational materials will be kept in the education file located in the REO.

5.0 REFERENCES

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 2010: (TCPS 2);*
2. *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) Course On Research Ethics [CORE] online tutorial;*
3. *US Department of Health and Human Services (HHS) CFR Title 45 Part 46.107;*
4. *US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21, Part 56.107;*
5. *National Institutes of Health (NIH) NOTICE: OD-00-039 Required Education in the Protection of Human Research Participants: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.*

DISCLAIMER: The Research Ethics Webpage version of this document is considered the most current. Please ensure that you have reviewed all linked documents and other referenced material within this guideline.

SOP Title:	Composition and Management of the Research Ethics Board
Issued By:	Research Ethics Office
Approved By:	SJCG Research Ethics Board ~ June 2012 TBRHSC Research Ethics Board ~ May 2012

1.0 PURPOSE

The purpose of this standard operating policy and procedure (SOP) is to describe the membership composition and management requirements of the St. Joseph's Care Group and Thunder Bay Regional Health Sciences Centre Research Ethics Boards (REBs).

2.0 POLICY STATEMENT

Individual members of a REB must be qualified through training, experience and expertise to ascertain the acceptability of proposed research in terms of ethical principles and applicable regulations, guidelines and standards pertaining to human subjects or human materials protection.

3.0 RESPONSIBILITY

The Manager and REB Chair are responsible for ensuring that the composition of the REB meets the applicable regulatory requirements.

4.0 PROCEDURES

To promote complete and adequate reviews of the types of research commonly reviewed by the REB, the REB must include appropriate diversity; therefore, selection of members must include consideration of professional expertise, clinical and research experience, scientific and non-scientific expertise, sex, and sensitivity to such issues as community attitudes to assess the research submitted for review.

Ensuring compliance as outlined in the TCPS 2, the composition of the REB will consist of a minimum of seven voting members, both men and women, including:

- at least two members with broad expertise in the methodology
- at least one member knowledgeable in ethics
- at least one member knowledgeable in health law
- at least one member knowledgeable in privacy issues, and
- at least one community representative having no affiliation with the designated organization*, and
- a staff member from the Research Ethics Office (permanent non-voting member).

* Due to the diversity of services provided by each of these organizations, the REB membership would be strengthened by the inclusion of a second community representative.

4.1 Selection of REB Members

4.1.1
In the selection of REB members, equal consideration shall be given to qualified persons of both sexes. No appointment shall be made solely on the basis of sex.

4.1.2
The REB will make every effort to include cultural and ethnic minorities to represent the population cared for by the research community in Thunder Bay and Northwestern Ontario, within the scope of available expertise needed to conduct its functions.

4.1.3
Research Ethics Board membership will not consist entirely of members of one profession.

4.1.4
Members will be selected based on the needs of the REB as outlined below and per applicable regulations, guidelines and standards.

4.2 Composition of the REB

4.2.1
The membership of the REB will be in compliance with 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 2010 (Article 6.4). If clinical trials are reviewed by the REB, membership will also be in compliance with Health Canada Division 5, Part C.05.001 of the Food and Drug Act and the Office for Human Research Protections (OHRP) (46.107).

4.2.2
The Manager and REB Chair monitor the REB membership composition for appropriate membership in relation to the volume of protocol submissions.

4.2.3
The REB will include at least seven members, include both men and women, the majority of whom are Canadian citizens or permanent residents of Canada and who collectively have the qualifications and experience to review and evaluate the science, clinical aspects and ethics of the proposed research.

4.2.4
The REB should consist of broad representation from across therapeutic areas and include health care providers with clinical and/or research experience, informed community members, and members with expertise in research ethics, health law, privacy legislation and may consist of other related disciplines such as pharmacy, epidemiology, and biostatistics.

4.3 REB Chair for each institution

4.3.1
For each institution, the Chair of the REB will be nominated by its REB membership, and approved by the appropriate institution's Board. The REB Chair should have a minimum of one year experience as a REB member.

4.3.2
The term of office of the REB Chair is two years and is renewable.

4.3.3
The REB Chair and Manager recruit REB members as needed. Membership to the REB is approved by the appropriate institution's Board.

4.3.4
An REB member is appointed by the Chair to serve as Acting Chair. The role of Acting Chair is to assume the duties of the REB Chair in the REB Chair's absence or declared conflict of interest.

4.4 Consultants

4.4.1
At his/her discretion, the REB Chair may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the REB.

4.4.2
The consultant may be asked to provide a written report and to participate via teleconference, or to attend the meeting to lend his/her expertise to the discussions.

4.4.3
Consultants shall sign a Confidentiality and Conflict of Interest Agreement.

4.4.4
These individuals may not contribute to the REB's decision and their presence or absence shall not be used in establishing a quorum.

4.4.5
Documentation of key information provided by consultants shall be summarized in the REB minutes and if available, the written report shall be placed in the specific study's REB file in the REO.

4.5 Terms of Appointment – REB Members

4.5.1
For each institution's REB, an REB member may serve for three consecutive three-years terms [a total of nine years].

4.5.2
Terms will be overlapping to preserve experience and continuity of function of the REB. Experience with previous research ethics review committees/teams will be recognized.

4.6 Resignations and Removals

4.6.1
An REB member may resign before the conclusion of his/her term upon provision of notice to the Manager or REB Chair;

4.6.2
Attendance and active participation is important. A member may be asked to step down if they miss more than 25% of the scheduled REB meetings. If circumstances prevail where a member will have a known absence over a significant period of time, the member should notify the REB and request a leave of absence.

4.6.3
The REB Chair may otherwise remove members if they are not fulfilling their duties.

4.6.4
Every effort will be made to recruit a similarly qualified replacement prior to the departure of a member to preserve experience and continuity of function of the REB.

4.7 Compensation

4.7.1
Research Ethics Board members may be reimbursed for parking and other miscellaneous expenses associated with full REB meeting attendance.

4.7.2
Research Ethics Board members are not provided with an honorarium.

4.8 Liability Coverage

Research Ethics Board members are insured for errors and omissions in the performance of their role as REB members under the insurance policy of St. Joseph's Care Group and Thunder Bay Regional Health Sciences Centre, respectively.

4. 9 Confidentiality Agreement

All REB members sign a Confidentiality Agreement per term, agreeing to abide by the REB confidentiality agreement.

4.10 Documentation and Posting of the REB Membership List

4.10.1
The REO staff will maintain an updated electronic REB membership list.

4.10.2
The REB membership list is reviewed and updated as required or with the initiation of new or conclusion/termination of existing terms. The effective date of the updated REB membership list will be consistent with an REB full board or convened meeting date.

4.10.3
The REO staff may provide a listing of REB composition stating expertise, role and sex ratio when requested for research purposes. This is referred to the publicly available membership list. Names and contact information will remain confidential, except when required (e.g., Federal Worldwide Assurance Registration).

4.10.4
A detailed membership list will be stored and locked in the REO. This list will contain member contact information. It will be kept confidential for access by REB members and REO staff.

4.10.5
The Manager, Research Ethics Office updates the REB membership roster and OHRP registration to reflect any membership changes. OHRP will be notified within 60 days of any change. Previous versions will be archived.

4.11 Contents of REB Member Personnel Files

4.11.1
The contents of the personnel files for all current and past REB members may contain:

- Curricula Vitae, other supporting documents related to education and expertise, and member's letters of appointment
- Proof of Canadian citizenship (if applicable)
- Copy of signed and dated Welcome Letter,
- Original signed and dated Confidentiality of Information Agreement
- TCPS 2 tutorial completion certificate,
- Record of attendance at educational events,
- Thank you letters,
- Notes to file,
- Any other relevant information.

4.12 Creating and Maintaining REB Member Personnel Files

4.12.1
All REB membership documentation will be stored and locked in the Research Ethics Office. Files will be kept securely up to 25 years from when a member resigns for the Research Ethics Board.

4.12.2
The REO creates REB member personnel files as directed by the REB Chair.

4.12.3
The REO reviews REB member personnel files twice yearly, in April and October, for completeness and updates accordingly. Additionally, each member's attendance rate is calculated and recorded in his/her personnel file.

5.0 REFERENCES

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 2010: (TCPS 2), Chapter 6;*
2. *Health Canada (Division 5, Part C.05.001 of the Food and Drug Act);*
3. *Ontario Personal Health Information Protection Act (PHIPA), S.15;*
4. *The International Conference on Harmonization Good Clinical Practices, Section 3.2.1;*
5. *US Office for Human Research Protections 45 Code of Federal Regulations Title 46.107;*
6. *US Food and Drug Administration Code of Federal Regulations Title 21 Part 56.107;*
7. *FDA Information Sheets, FAQ Section II, Questions 14 and15.*

DISCLAIMER: The Research Ethics Webpage version of this document is considered the most current. Please ensure that you have reviewed all linked documents and other referenced material within this guideline.

SOP Title:	Duties of Research Ethics Board members
Issued By:	Research Ethics Office
Approved By:	SJCG Research Ethics Board ~ June 2012 TBRHSC Research Ethics Board ~ May 2012

1.0 PURPOSE

The purpose of this standard operating policy and procedure (SOP) is to describe the duties of the St. Joseph's Care Group and Thunder Bay Regional Health Sciences Research Ethics Board (REB) members.

2.0 POLICY STATEMENT

Each Research Ethics Board (REB) member's primary duty is the protection of the rights and welfare of the individual human beings who are serving as the participants of research. In order to fulfill his or her duties, REB members must be versed in regulations governing human participants' protection and biomedical research ethics, and policies relevant to human research participant protection.

3.0 RESPONSIBILITY

This SOP applies to the REB Chair, Manager, all REB members, and REO staff.

The REB Chair and Manager or designee are responsible for clearly articulating all required duties associated with membership on the REB to potential and current REB members.

4.0 PROCEDURES

4.1 Attendance

4.1.1
Research Ethics Board members are expected to attend all regularly scheduled meetings as well as educational events. Members may be asked to step down if they consistently miss more than 25 percent of the scheduled meetings.

4.1.2
Research Ethics Board members are expected to be available for the complete meeting, not just the sections for which they have been assigned as reviewers.

4.2 Term of Duty

All REB members including the REB Chair and Acting Chair, are expected to commit to terms of their appointment as outlined in their appointment letter.

4.3 Duties

All REB members are expected to review all distributed materials and be prepared to discuss each project and provide his/her input at convened meetings. Each REB member is expected to fulfill specific duties based on their role(s) on the REB as outlined below. More than one member may fulfill each role.

4.3.1
Community Member(s): are expected to provide input regarding their knowledge about the local community and be able to discuss issues and research from that perspective. Community members should advise the REB of the need for additional review by a specific community of interest.

4.3.2
Members knowledgeable in relevant methodology: are expected to contribute to the evaluation of a study on its ethical, scientific and statistical merits, and standards of practice. These members should also advise the REB if additional expertise in a scientific or non-scientific area is required to assess whether the research protocol, consent document and other research materials adequately protect the rights and welfare of participants.

4.3.4
Member(s) knowledgeable in relevant law: are expected to inform the review process regarding potential legal issues and their implications, not to provide formal legal opinion or serve as legal counsel for the REB.

4.3.5
Member(s) knowledgeable in research ethics: are expected to inform the review process regarding potential ethics issues and options.

4.3.6
Member(s) knowledgeable in privacy: are expected to inform the review process regarding privacy issues.

4.3.7
Consultants: individuals with competence in special areas may be asked to assist in the review of issues that require expertise beyond or in addition to that available on the REB. The consultant may be requested to submit a written report and/or participate via teleconference, or to attend the meeting to lend his/her expertise to the discussions. The consultant's attendance will not be counted towards quorum and the consultant will not contribute to the REB's decision.

4.3.8
REB Chair is responsible:

- to convene the REB meetings in compliance with relevant policies and guidelines
- to perform, or delegate to an appropriate REB member the authority to perform delegated reviews of applications when appropriate
- to be available to the REO staff for consultation regarding REB issues
- to monitor the REB's decisions for consistency, to oversee the proper documentation of all decisions, and to ensure that researchers are given written communication of the REB's decisions (with reasons of negative decisions) in a timely fashion
- to suspend the conduct of REB approved research deemed to place individuals at unacceptable risk
- to suspend the conduct of REB approved research if he/she determines an investigator is not following the REB's policies or procedures, and
- when necessary, to document the delegation of any of his/her responsibilities, as appropriate, to other qualified individual(s). Such delegation should be in writing.

In addition to the duties described above, the REB Chair

- will recruit an REB member in good standing with at least one year experience to be appointed as Acting Chair. The role of Acting Chair is to assist or act on behalf of the Chair in particular REB matters and at REB meetings, either as a general procedure, or on a case-by-case basis. Minutes will reflect when the Acting Chair performed the duties on behalf of the REB Chair.

4.4 Reviewers

In addition to the duties described in section 4.3 above, REB members may be appointed as primary reviewers to review assigned research projects in greater detail and lead the related discussion at the meeting. The REB utilizes the primary and secondary reviewer model for initial review. Reviewers are assigned by the Chair or designee based upon the member's expertise and experience, with consideration of distribution of workload among REB members.

4.4.1
Primary Reviewers:

- conduct an in-depth review of all documents related to the assigned research project,
- present their assessment of the research at the convened meeting, lead the discussion of the application, and contribute toward the decision regarding approval or disapproval of the research, and
- may be required to review additional material (e.g., investigator responses) for the purpose of research ethics approval.

Primary reviewers who are not able to participate in a meeting should forward a complete written review to the Research Ethics Office prior to the convened meeting. REO staff will speak for any reviewers not in attendance but who have provided feedback/questions/comments.

4.4.2
Secondary Reviewers:

- conduct an in-depth review of the assigned research project(s) REB application and informed consent,
- speak to their assessment of the research at the convened meeting, add to the discussion as appropriate, and contribute toward the decision regarding approval or disapproval of the research, and
- may be required to review additional material (e.g., investigator responses) for the purpose of research ethics approval.

Secondary reviewers who are not able to participate in a meeting are encouraged to forward a written review to the Research Ethics Office prior to the convened meeting. REO staff will speak for any reviewers not in attendance but who have provided feedback/questions/comments.

4.5 Continuing Education

All REB members are expected to participate in continuing education activities, including attendance during REB Training and Education Sessions, conferences, seminars and/or reading pertinent articles/books. (Refer to REB-SOP-II-03.01).

4.6 Conflict of Interest

4.6.1
All REB members and consultants are expected to disclose any conflict of interest on an item by item basis prior to the review and/or discussion of items on the meeting agenda. If a member is unsure if a conflict exists, he/she should disclose the issue to the membership, and seek advice and agreement from the membership.

4.6.2
All REB members are expected to follow recusal requirements. If the conflict of interest is declared by:

- the REB Chair, he or she must surrender their duties of Chair to the Acting Chair or other designate for the portion of the meeting in which conflict has been declared.
- an REB member, he or she may choose to remain for the presentation of the project, as his or her expertise may contribute to the understanding of the project. During the study presentation phase of the review, the person who has declared conflict should refrain from exerting undue influence on the decision to be made by the remaining REB members. The REB member who declared conflict must leave the meeting for the discussion and decision portion of the review process for an identified application.

5.0 REFERENCES

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 2010: (TCPS 2;*
2. *Health Canada (Division 5, Part C.05.001 of the Food and Drug Act);*
3. *The International Conference on Harmonization Good Clinical Practices, Section 3;*
4. *US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.107;*
5. *US Food and Drug Administration (FDA) CFR Title 21 Part 56.107;*
6. *FDA Information Sheets: FAQ Section II, Question 17*

DISCLAIMER: The Research Ethics Webpage version of this document is considered the most current. Please ensure that you have reviewed all linked documents and other referenced material within this guideline.

SOP Title:	Authorized Signatory/Signing Authority
Issued By:	Research Ethics Office
Approved By:	SJCG Research Ethics Board ~ June 2012 TBRHSC Research Ethics Board ~ May 2012

1.0 PURPOSE

The purpose of this standard operating policy and procedure (SOP) is to specify who has the authority to sign documents on behalf of the Research Ethics Board (REB), and to describe the responsibilities of such individuals, and the circumstances under which signing authority may be delegated.

2.0 POLICY STATEMENT

Research Ethics Boards (REBs) are accountable for their activities and decisions, and appropriate controls must be applied to ensure that documents related to REB review and approvals of research are signed by a person or persons having the appropriate authority to do so.

3.0 RESPONSIBILITY

This SOP applies to the REB Chair and Acting Chair, REB members, Manager and REO staff.
The REB Chair is responsible for signing documents related to the REB review and approval of research conducted by their respective REB membership. In the event of absenteeism or conflict of interest, the appointed Acting Chair performs these duties on behalf of the REB Chair. For agenda items which are categorized as “REPORT ONLY” to the REB, acknowledgement of receipt of these documents may be delegated to the Manager, Research Ethics Office, but the responsibility for oversight remains with the REB Chair.

4.0 PROCEDURES

4.1 Delegation of Signing Authority

4.1.1
The REB Chair may delegate signing authority for documents related to REB review and approval.

4.1.2
The REB Chair may only delegate signing authority to REB members or REO staff with the skill and knowledge necessary to effectively exercise the authority.

4.1.3
The REB Chair may not delegate his/her signing authority to consultants or independent contractors.

4.1.4
The REB Chair should clearly define the parameters of the delegated authority using a task delegation log.

4.1.5
The REB Chair may delegate signing authority for the length of their term, or for defined periods of time (e.g., for absences).

4.1.6
Delegation of signing authority should be recorded and kept on file.

4.2 REB Reviews, Approvals and Other Correspondence with the Investigator

4.2.1
The results of reviews and decisions made by the REB, either by the Full Board or delegated review, including investigation of ongoing research, that grant or may appear to grant investigators with initial or continuing approval of research involving humans, or suspends or terminates such research, must be signed by the REB Chair or Acting Chair, or as otherwise designated in writing by the REB Chair.

4.2.2
Any letters, memos, or e-mails between the REB and/or REO and investigators that provide information concerning the review of research (e.g., requests for consent form changes, requests for additional information, renewal reminder notices) and that do not grant or appear to grant approval of the research, may be signed by the appropriate REO staff member.

4.2.3 Individuals must sign their own name. The individual's title must be documented.

4.3 Correspondence with External Agencies

4.3.1
The REB Chair or designee signs all correspondence to federal government agencies (e.g., Health Canada, OHRP, Federal Worldwide Assurance) and funding agencies or sponsors as applicable.

5.0 REFERENCES

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 2010: (TCPS 2), Article 6.17;*
2. *The International Conference on Harmonization Guidelines for Good Clinical Practice, Section 3;*
3. *US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.115;*
4. *US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.108, 56.115.*

Research Ethics Board	Submission Requirements REB-SOP-IV-01.01

DISCLAIMER: The Research Ethics Webpage version of this document is considered the most current. Please ensure that you have reviewed all linked documents and other referenced material within this guideline.

SOP Title:	REB Submission Requirements and Administrative Review
Issued By:	Research Ethics Office
Approved By:	SJCG Research Ethics Board ~ June 2012 TBRHSC Research Ethics Board ~ May 2012

1.0 PURPOSE

The purpose of this standard operating policy and procedure (SOP) is to describe the Research Ethics Board (REB) submission requirements, and the administrative review procedures conducted by the Research Ethics Office (REO). This SOP applies to all submissions including but not limited to: new research projects for initial review, amendments or modifications to approved research and consent forms, updated safety information, applications for continuing approval, reports of unanticipated problems including serious adverse events, and protocol deviations.

2.0 POLICY STATEMENT

Research Ethics Board members must rely on the documentation provided by the principal investigator for initial and continuing review. Therefore, the materials submitted must provide sufficient information to conduct the review and make the required determinations. The REB is supported by administrative procedures that assure that REB members not only have adequate time for assessment of proposed research, but that the materials they receive allow them to adequately assess whether the research meets the criteria for REB approval.

3.0 RESPONSIBILITY

This SOP applies to the REB Chair, Manager, REB members, REO staff and research teams.

4.0 PROCEDURES

The Manager or designee is responsible for maintaining the submission requirements, and for making such information available to investigators. The instructions to investigators regarding submission requirements, including deadlines and meeting dates, are available on the REO webpages or by contacting the REO.

4.1 Submission Requirements

4.1.1
All required documents, submission guidelines and submission procedures are outlined on the webpages for each institution. REB application forms have been standardized for the two organizations. The initial application is a shared form for St. Joseph's Care Group and Thunder Bay Regional Health Sciences Centre. Accompanying documentation and continuing ethics review applications and forms, while similar, are institution specific.

For new studies, REB application forms and checklists include:

- Research Ethics Application
- SJCG Organizational Impact Form/TBRHSC Research Development Committee
- Declaration of Conflict of Interest (supplemental, if more than one investigators per application).

When the study has been completed, a Study Completion Report is required to be submitted to the REB.

For continuing ethics review, the following applications and forms may be required:

- Amendment Application
- Re-approval Application
- Local Serious Adverse Event Report Form
- Non-local Serious Adverse Event Report Spreadsheet
- Protocol Deviation/Violation Report Form
- Study Report Form (to be used for information that is report only, no REB approval required).

4.2 Administrative Review

4.2.1
Upon receipt of a submission, the Research Ethics Office staff date stamps the package, creates a new labeled project file folder, and enters the preliminary study information into the REB database which automatically assigns a unique REB number and file status as submitted.

4.2.2
The assigned REB number is used for all communication regarding the specific project.

4.2.3
The Research Ethics Office staff screens the application for completeness and clarity. If a submission is incomplete, the REO staff will follow-up with the investigator to request the required information for inclusion with the submission. Feedback/suggestions for clarifications may be provided to the investigator during this screening process to facilitate the review process.

4.2.4
Complete applications are assessed for review pathway: full REB review or delegated review using the risk matrix described in REB-SOP-V-02.01.

4.2.5
The Research Ethics Office staff notifies the research team of the review pathway. If full REB review is required, arrangements are made for the Principal Investigator to present their project at the next REB meeting.

4.2.6
The review packages are prepared and distributed to the REB members for the full board meeting and/or delegated review.

4.2.7
Original signed submission materials are retained in the REO office.

5.0 REFERENCES

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 2010*;
2. *The International Conference on Harmonization Guidelines for Good Clinical Practice, Section 3;*
3. *US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.108, 46.115;*
4. *US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.107, 56.108; 21 CFR 312, 812*
5. *OHRP Guidance on Written IRB Procedures;*

DISCLAIMER: The Research Ethics Webpage version of this document is considered the most current. Please ensure that you have reviewed all linked documents and other referenced material within this guideline.

SOP Title:	Research Ethics Board Meeting Administration
Issued By:	Research Ethics Office
Approved By:	SJCG Research Ethics Board ~ June 2012 TBRHSC Research Ethics Board ~ May 2012

1.0 PURPOSE

The purpose of this standard operating policy and procedure (SOP) is to describe the required activities for the preparation, management and documentation of convened Research Ethics Board (REB) meetings.

2.0 POLICY STATEMENT

Except when a delegated review procedure is used (REB-SOP-V-02.01), the REB will review proposed research studies at convened meetings at which a quorum is present. There will be a minimum of eight meetings scheduled per year, with additional meetings convened by the Chair, when necessary.

The REB meeting agenda provides the meeting content, establishes a sequence of review and provides the foundation for the REB meeting minutes. It also includes an attachment of all items that have been reviewed and approved by delegated review procedures since the last convened meeting, a list of items that are pending review by the convened REB. The REB meeting minutes document the actions that occur during an REB meeting and should provide the REB with sufficient detail to help it reconstruct its discussions at a later date, if necessary. The detailed feedback communicated to each research team listing the requested revisions/clarifications will serve as an appendix for each set of minutes.

3.0 RESPONSIBILITY

This SOP applies to the REB Chair, Manager, all REB Members, REB consultants, REB meeting guests and REO staff involved in REB Meeting Administration.

4.0 PROCEDURES

4.1 Agenda and Meeting Preparation

4.1.1
The Research Ethics Office staff, in consultation with the REB Chair as necessary, drafts the meeting agenda according to the REB Meeting Agenda Template. The agenda includes but is not limited to all items that require full REB review (e.g., new studies, amendments, re-approvals and local serious adverse events) and all items that were reviewed and approved via delegated review procedures, a list of reports and receivables and any other items for information or discussion (e.g. Administrative reports, SOPs, educational articles).

4.1.3
The Research Ethics Office staff, in consultation with the REB Chair or Manager, reviews the agenda, assigns the reviewers for each project, posts the reviewer assignment to the agenda and notifies the REB members of the reviewer assignment, requests declarations of conflicts with the assignment and confirms meeting attendance.

4.1.4
The agenda should be completed a minimum of 7 days prior to the REB meeting date.

4.1.5
The Research Ethics Office staff ensures the REB meeting packages which includes the meeting agenda, reading assignments plus all supporting documentation is distributed to all REB members 7-10 days prior to the REB meeting.

4.1.6
While the entire REB membership will have access to the entire REB package, for a given application, the Primary Reviewers will review the assigned research project in depth and be prepared to lead the discussion at the convened meeting. All other REB members will review the REB application form, informed consent and budget and be prepared to contribute to the discussion at the convened meeting.

4.2 During the REB Meeting

4.2.1
Attendance is recorded using the attendance tracking record. Meeting time, recusal, departure and return to meeting will be noted for each member.

4.2.2
To conduct a convened meeting for review of research projects and continuing ethics review, REB members must attend in person or via teleconference to establish quorum.

4.2.3
Should quorum fail during a meeting (e.g., through recusal of members with conflicts of interest or early departures), the REB may continue discussion to further the review of the application, but may not make a decisions until quorum can be restored.

4.2.4
Consultant(s) will not be used to establish a quorum.

4.2.5
Members recusing themselves due to conflicts of interest are not counted toward quorum.

4.2.6
Under unusual circumstances (e.g., public health alerts and quarantines) the REB Chair may, at his/her discretion, conduct an REB meeting with all members attending via simultaneous videoconference or teleconference, provided everyone has received the review materials and quorum is met.

4.2.7
Principal investigators are required to attend the REB meeting to present their project and respond directly to any comments or questions raised by the REB. If required, teleconferencing is made available for Principal Investigators and/or their research team to present their study. A designate for the Principal Investigator may present the research study, if it has been pre-approved by the REB Chair or Manager.

4.2.8
Guests may be invited or permitted to attend REB meetings, subject to the agreement of the REB Chair and execution of a Confidentiality and Conflict of Interest Agreement. Guests must disclose any vested interest in, or scientific or management responsibility for any applications being considered at the meeting.

4.2.9
Any individual not listed on the current REB membership list may not participate in the decisions of the REB.

4.3 Meeting Minute Preparation

4.3.1
The REB recording secretary creates the outline of the meeting minutes according to the REB Meeting Minutes Template and incorporates the meeting agenda.

4.3.2
The REB recording secretary drafts the portions of the meeting minutes relevant to their assigned projects.

4.3.3
The REO staff records the key REB discussions.

4.3.4
The REO staff prepares a list of requested clarifications/revisions as outlined at the REB meeting. This document may be reviewed by the REB Chair and or members before it is submitted to the Principal Investigator. This communication will include directions and time lines for response from the research team. The information documented in the request for clarifications/revisions should be reflected in the meeting minutes.

4.3.5
The REB Chair and/or Manager reviews the minutes for accuracy and completeness.

4.3.6
REB meeting minutes are reported to the respective Board of Directors for each institution usually within one month of the convened meeting.

4.4 Meeting Minute Approval

4.4.1
The REB minutes are included in the next convened REB meeting packages for distribution to the REB members.

4.4.2
The minutes are presented at the next convened REB meeting for review and approval.

4.4.3
It is the responsibility of the REB members to review, recommend changes, and approve the meeting minutes.

4.4.4
If modifications to the minutes are required, the corrections are noted in the meeting at which the corrections/modifications/issues were discussed.

4.5 Documentation

4.5.1 The meeting minutes and/or attendance record include the following items:

- Time meeting commenced and adjourned
- Names of REB members in attendance (present, teleconference, videoconference)
- Names of REB members absent
- Presence of guests and ex-officio members
- Use of expert consultants and their specialty as applicable
- List of declared conflicts of interest by agenda item or a note that none were declared
- A summary of key discussions and issues including the basis for requiring changes in or for rejecting a research study
- The decisions taken by the REB regarding approval
- The number voting for, against or abstaining for each vote recorded.

5.0 REFERENCES

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 2010*;
2. The International Conference on Harmonization Guidelines for Good Clinical Practice, Section 3;
3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103; 46.107; 46.108, 46.109, 46.115;
4. US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.107, 56.108, 56.109, 56.115;
5. OHRP Guidance on Written IRB Procedures;

DISCLAIMER: The Research Ethics Webpage version of this document is considered the most current. Please ensure that you have reviewed all linked documents and other referenced material within this guideline.

SOP Title:	Documentation Management
Issued By:	Research Ethics Office
Approved By:	SJCG Research Ethics Board ~ June 2012 TBRHSC Research Ethics Board ~ May 2012

1.0 PURPOSE

The purpose of this standard operating policy and procedure (SOP) is to describe the requirements for document management, including document retention and archiving. This SOP applies to documents submitted to and reviewed by the Research Ethics Board (REB), as well as REB administrative documents.

2.0 POLICY STATEMENT

The Research Ethics Office (REO) must retain all relevant records (e.g., documents reviewed and approved or rejected, meeting minutes, correspondence with investigators, written SOPs, membership lists) to provide a complete history of all actions related to REB review, approval and oversight of submitted research. Relevant records must be made accessible to authorized regulatory authorities, representatives of the institutions, researchers and funding agencies within a reasonable time upon request.

3.0 RESPONSIBILITY

This SOP applies to the REB Chair, Manager, all REB members, REO staff. The REO staff is responsible for maintaining complete files on all research submitted to and reviewed by the REB, and for maintaining administrative documents related to such research (e.g., agendas, minutes, correspondence). The Manager or designee is responsible for retention and archiving of the REB files. The REB Chair, Manager, all REB members and REO staff are responsible for maintaining the confidentiality of the REB files. The Manager is responsible for the back-up and security of the REB database.

4.0 PROCEDURES

4.1 Study-Related Documents

4.1.1
Upon receipt of an initial submission, the Research Ethics Office staff enters the initial study information into the REB database, which generates a unique REB application number.

4.1.2
The REO staff creates a research project-specific paper file identified by the unique REB number.

4.1.3
The REO staff creates a research project-specific electronic file identified by the unique REB number and the Principal Investigators surname (e.g., 2010123 Smith). Subfolders are generated using the standardized Electronic File Folder template. Subfolders are dated to keep version dates sorted.

4.1.4
The REO staff adds any research-related documents received throughout the course of the research project to the paper files and electronic files.

4.1.5
The REO staff retains records of all research studies submitted for REB review, regardless of whether the research is reviewed and/ or approved by the REB. Applications which are closed by the investigator or REO staff which were not reviewed and/or final decision made by the REB will be marked as withdrawn in the REB database.

4.1.6
Research-related documents that must be retained include, but are not limited to, the following (as applicable):

- Signed REB application forms
- Research protocol
- Scientific evaluations
- Investigator brochures or product monographs
- Participant recruitment materials, survey instruments and questionnaires
- Approved consent documents
- Research budgets
- Health Canada No Objection Letters or Investigational Testing Authorizations
- Correspondence between the REB and the Investigator
- Records of continuing ethics review such as:
    - reports of unanticipated problems involving risks to participants and others, including reports of local serious adverse events
    - amendments or modifications to the research protocol
    - reported significant deviations /violations from the research protocol
    - reports of significant new findings provided to participants
- REB monitoring reports:
    - Progress reports and study completion reports
    - Copies of correspondence between the REB and regulatory agencies
    - Reports of any complaints received and their resolution.

4.2 REB Administrative Documents

4.2.1
The Research Ethics Office retains all administrative records related to the REB review activities.

4.2.2
Research Ethics Board administrative documents that must be retained include, but are not limited to, the following:

- Agendas and minutes of all REB meetings
- Submitted REB member reviews/reports
- REB member records:
    - Current and archived membership lists
    - Curriculum Vitae and training records of current and past REB members
    - Signed Confidentiality Agreements
- Current and archived Standard Operating Procedures
- Current and archived documentation of the REB Chair's delegation of authority, responsibilities or specific functions
- Records of registration of the REB with the US Office of Human Research Protection.

4.3 Document Storage and Archiving

4.3.1
Paper copies of REB documents are retained onsite in a secure file cabinet accessible to the REB Chair, Manager and REO staff.

4.3.2
For TBRHSC, closed REB files are archived in the TBRHSC secure storage facility; For SJCG, closed REB files are archived in a secure filing cabinet in the Research Services/Research Ethics Office.

4.3.3
The REB database stores both current and historical data for all open REB approved research projects backdating to 2004.

4.4 Confidentiality and Document Destruction

4.4.1
All materials received by the REB are considered confidential and are distributed only to REB members, consultants (as appropriate), REB Chair, Manager and REO staff.

4.4.2
The REB Chair, Manager, REO staff, all REB members, consultants and guests must sign a Conflict of Interest and Confidentiality Agreement.

4.4.3
All relevant documents are stored in REB files with access limited to the REB Chair or designate, Manager, REO staff, and REB members (upon request).

4.4.4
Paper files are stored in cabinets in a locked, secure area at the end of each day.

4.4.5
Electronic data for REB projects is stored in the institution- specific Research Ethics Office shared drive and is accessible only to the Manager, REO staff and the REB Chair of each institution respectively.

4.4.6
Guests of the REB are not allowed access to the REB files unless they are members of regulatory agencies, or representatives of the sponsor or Principal Investigator and are reviewing the files related to their specific research.

4.4.7
All confidential materials received in excess of the required documentation will be shredded. REB members without access to secure disposal should return their REB materials to the REB office for disposal.

5.0 REFERENCES

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 2010;*
2. *The International Conference on Harmonization Guidelines for Good Clinical Practice, Section 3.4;*
3. *US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.115;*
4. *US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.115;*
5. *OHRP Guidance on Written IRB Procedures;*
6. *FDA Information Sheets.*

DISCLAIMER: The Research Ethics Webpage version of this document is considered the most current. Please ensure that you have reviewed all linked documents and other referenced material within this guideline.

SOP Title:	REB Review Determinations
Issued By:	Research Ethics Office
Approved By:	SJCG Research Ethics Board ~ June 2012 TBRHSC Research Ethics Board ~ May 2012

1.0 PURPOSE

The purpose of this standard operating policy and procedure (SOP) is to describe the decisions that the Research Ethics Board (REB) may make resulting from its review of proposed research.

2.0 POLICY STATEMENT

As a result of its review, the REB has the authority to approve, reject, or require modifications to submitted research projects. If there are questions that must be addressed prior to a determination, the REB may defer the action. When the full board review procedure is used, decisions will be made by consensus of the REB members in attendance at a convened meeting with quorum present. If consensus cannot be achieved, a vote will be taken.

REB members with a conflict of interest regarding the research will recuse themselves and not be present during the discussion and decision. When the delegated review procedure is used, the REB Chair or designee can make any of the determinations except to reject the research (Refer to REB-SOP-V-02.01 – Delegated Review). Principal Investigators have the right to appeal the decision of the REB.

3.0 RESPONSIBILITY

This SOP applies to the REB Chair, Acting Chair, Manager, all REB members, and REO staff. The REB Chair, or designee, is responsible for ensuring that a decision is made on every submission reviewed by the REB, that the decision is clearly understood, and that the delegation of responsibility for considering any further information prior to issuing approval is clearly agreed to. The REB Chair is responsible for signing documents related to the REB review and approval of research. The REB Chair may delegate signing authority; however, the responsibility for oversight rests with the REB Chair. Delegation of signing authority must be in writing (Refer to REB-SOP-III-03.01- Authorized Signatory).

4.0 PROCEDURES

4.1 REB Decisions

The REB should reach one of the following decisions as a result of its review and deliberation of research submitted for initial or for continuing review.

4.1.1
Approval by Full Board Review:

- When an acceptable risk/benefit ratio exists and the regulatory criteria required for approval are satisfied, the research may be approved as submitted

- This decision is made by a consensus of the members present, except for those who have recused themselves due to conflict of interest
- If consensus cannot be achieved, a vote will be taken
- The approval date is defined as the REB meeting date when the application was last reviewed by the full membership. The expiration date is not more than one year from the approval date.

4.1.2
Minor Clarifications/Revisions required:

- When an acceptable risk/benefit ratio exists, the regulatory criteria required for approval are satisfied or forthcoming, but the REB requires modifications to secure approval
- This decision is made by a consensus of the members present, except for those who have recused themselves due to conflict of interest
- If consensus cannot be achieved, a vote will be taken
- REB Chair should ensure that the required modification(s) is specifically identified at the meeting;
- Written comments are prepared by the REO staff outlining the required revisions/clarifications required;
- Revision/clarifications are reviewed by the Manager , REB Chair or REB members involved in the discussion and sent by the REO staff to the Principal Investigator for response
- If the Principal Investigator's response is deemed complete and satisfactory by the REB Chair (with input from the reviewers as applicable), approval can be issued by the REB Chair
- If the investigator's response is incomplete and does not fully address the matter raised, requests for further information or clarification are sent to the principal investigator
- The approval date is defined as the REB meeting date when the application was last reviewed by the full REB membership. REB approval is granted for no greater than one year. The approval period will be clearly indicated on the original approval letter and subsequent continuing ethics review.

4.1.3
Major Clarifications/Revision required for review at Subsequent Convened REB meeting:

- The REB may defer its decision pending receipt of clarifications/revisions at a subsequent convened meeting when significant questions are raised during its review of the research
- The REB may request the Principal Investigator to attend the next convened REB meeting to respond to questions and provide clarification around the issues raised by the REB
- Upon consideration of the complete response from the investigator at the meeting, the REB should issue its determination (approval, further revision/clarifications, deferral to subsequent full board meeting or rejection)
- This decision is made by a consensus of the members present, except for those who have recused due to conflict of interest
- If consensus cannot be achieved, a vote will be taken
- The approval date is defined as the REB meeting date when the application was last reviewed by the full REB membership. REB approval is granted for no greater than one year. The expiry date will be clearly indicated on the original approval letter and subsequent continuing ethics review.

4.1.4
Rejection/Not Approved:

- The REB may reject a project when the research fails to meet its ethical or scientific standards, or is contrary to the mission, vision and values of the organization, and where revision is unlikely to enable the REB to reach a positive determination
- This decision is made by a consensus of the members present, except for those who have recused themselves due to conflict of interest
- If consensus cannot be achieved, a vote will be taken
- Rejection cannot be decided through the delegated review procedure

- The REB Chair should ensure that the reasons for rejection are identified at the meeting for communication to the Principal Investigator
- If the research is rejected, the reasons for rejection (not approving) will be communicated to the Principal Investigator and the Principal Investigator will be given an opportunity to respond in person or in writing.

4.1.5
Delegated Reviews [reviews completed outside the regularly convened REB meetings]:

- When the research qualifies for delegated review and delegated review procedures are followed, approval is effective on the date of the letter confirming the study is approved by the REB Chair. REB approval is granted for no greater than one year. The expiry date will be clearly indicated on the original approval letter and subsequent continuing ethics review.
- This process may involve the request, receipt and review of additional information from the Principal Investigator
- The REB Chair has the authority to approve, require modifications, or defer the decision to a convened meeting
- Rejection cannot be decided through the delegated review procedure
- If the research is felt to be more than minimal risk or cannot be approved through the delegated review procedure, it must be reviewed by the full REB at a convened meeting.

4.2 Documenting REB Decisions

4.2.1
For each study, the REO staff ensures that the meeting minutes and/or attendance record includes the following:

- The REB's decision
- If a consensus is not achieved, the disputed matters and the outcome of a vote (i.e., the number of members in agreement, opposed, abstained)
- REB members recused due to conflicts of interest
- Any modifications required by REB including additional information requested from the Principal Investigator, and the agreed procedures for review and potential approval of the information requested.

4.2.2
The REB Chair or REO staff shall notify the Principal Investigator of the REBs decision in writing of the REBs decision to approve or reject (not approve) the proposed research.

4.2.3
If the REB requests minor revisions/clarifications with the final review and decision delegated to the REB Chair or designate, the requested information will be documented and communicated to the Principal Investigator by the REO staff. Clear directions will be provided for submission of required revisions/clarifications and the steps needed for final review.

4.2.4
If the REB defers its decision to the next meeting, the letter to the Principal Investigator should include the issues of concern, what further information is required, and notification that the information will be discussed at a subsequent convened REB meeting. The REB meeting schedule and deadlines for submission are posted on the webpages.

4.2.5
Investigators have the right to appeal the REB's decisions.

4.2.6
The final approval letter should include standard conditions of approval to which the Principal Investigator must adhere and the period for which the REB approval is granted.

4.2.7
The REB Chair is responsible for signing documents related to the REB approval of research. The REB Chair may delegate signing authority however, the responsibility for oversight rests with the REB Chair. Delegation of signing authority must be in writing (Refer to REB-SOP-III-03.01 – Authorized Signatory).

5.0 REFERENCES

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 2010*;
2. *International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines as adopted by Health Canada, Section 3.0;*
3. *US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21 CFR 50 and 56;*
4. *US Department of Health and Human Services (HHS) Title 45 CFR 46.109, 46.111*

Research Ethics Board	Delegated Review REB-SOP-V-02.01

DISCLAIMER: The Research Ethics Webpage version of this document is considered the most current. Please ensure that you have reviewed all linked documents and other referenced material within this guideline.

SOP Title:	Delegated Review
Issued By:	Research Ethics Office
Approved By:	SJCG Research Ethics Board ~ June 2012 TBRHSC Research Ethics Board ~ May 2012

1.0 PURPOSE

The purpose of this standard operating policy and procedure (SOP) to describe the processes for determining if research meets the criteria for delegated ethics review and the delegated review procedures.

2.0 POLICY STATEMENT

Research Ethics Boards (REBs) should adopt a proportionate approach to ethics assessment based on the general principle that the more invasive or harmful the proposed and ongoing research, the greater the care in assessing the research. Full review by an REB is the default requirement for all research involving human subjects unless the REB decides to authorize delegated review based primarily on the risk matrix that is expected to arise from the research. While all research must be reviewed adequately, proportionate review is intended to reserve the most intensive scrutiny, and correspondingly more protection, for the most ethically challenging research. In practice, proportionate review implies different levels of REB review for different research studies. The two levels utilized by the REB are full review at a convened REB meeting, or delegated review by one or more experienced REB members as determined by the REB Chair or designee.

3.0 RESPONSIBILITY

This SOP applies to the REB Chair, Acting Chair, Manager, REB members, and REO staff. The REB Chair, or designee, is responsible for determining if research is eligible for delegated review. If the REB Chair delegates this task to an REO staff member, the responsibility for oversight remains with the REB Chair.

The REB Chair, Manager, and/or subgroup of the REB are responsible for conducting the delegated review.

4.0 PROCEDURES

4.1 Determination of Eligibility for Delegated Review

4.1.1
Full review by the convened REB is the default for research involving human participants submitted to the REB; however, some research may be eligible for delegated REB review based on a risk matrix below.

Risk Matrix	Vulnerability	Research Risk		
		None to Low	Medium	High
	No	delegated	delegated	full
	Possibly	delegated	delegated	full
	Definitely	full	full	full

4.1.2
The REB may authorize a delegated ethics review for research that meets the following criteria:

- Research activities that are expected to involve no more than minimal risk and do not involve vulnerable populations
- Minimal-risk changes or no changes to previously approved research
- Continuing review of approved research.

4.1.3
When a research study is submitted for delegated review, the REO staff will perform an initial screening of the research application to determine if the activities may qualify for delegated review.

4.1.4
The REB Chair or designee will make the final determination if the research activities meet the requirements for delegated review.

4.1.5
When determining if initial review of research or modifications to previously approved research are eligible for delegated REB review, the REB Chair, or designee, will take into consideration the methods used to conduct the research, recruitment practices, participant population, confidentiality of data, involvement and training of the research staff.

4.2 Authority of the Delegated Reviewer(s)

4.2.1
For research that meets the criteria, delegated REB review may be conducted by the REB Chair plus one or more of the REB members as delegated by the REB Chair or the convened REB.

4.2.2
The REB Chair, or designee(s), may exercise all of the authorities of the REB, except that they may not reject the research. A research study may be rejected only after full review by the convened REB.

4.2.3
The REB Chair, or designee(s), reviewing research under delegated review must not have a conflict of interest for the research.

4.2.4
Research Ethics Board members conducting a delegated review will contact the REB Chair to request the expertise of a consultant, if applicable. Consultants may not participate in the final decision regarding approval of the research.

4.2.5
The REB Chair, or authorized signatory, will sign the REB review and approval letters associated with delegated REB review.

4.3 Continuing Review: Proposed Revisions to the Protocol and/or Informed Consent Form, Amendments and Renewals

4.3.1
Research that was previously reviewed by delegated review procedures may be reviewed at the time of continuing review using delegated review procedures. Research that was previously reviewed by the convened REB may be reviewed at the time of continuing review using delegated review procedures when there are minimal-risk changes,

or no changes to previously approved research. However, if the REB Chair, or designee, determines that the risks are now more than minimal, he/she must refer any study for full review at a convened REB meeting.

4.3.2
The REB Chair, or designee, may use delegated review procedures for changes proposed to consent documents that do not affect the rights, safety and welfare of study subjects and do not involve increased risk or significant changes in study procedures.

4.4 Local and Non-Local Serious Adverse Events and Safety Updates

4.4.1
The REB Chair or designee signs receipt of all local and non-local Serious Adverse Event (SAE) Reports.

4.4.2
If the REB Chair, or designee, receives reports of unanticipated problems (including serious adverse events) and/or safety updates such as reports from Data Safety Monitoring Committees, and subsequently considers that action is needed to protect the safety of research participants, he/she may take such action and/or request that the full REB or designated subcommittee review reports of unanticipated problems or safety updates to determine what further action, if any, is required.

4.5 Additional Items

4.5.1
The REB Chair, or designee, may use delegated review procedures for other types of minor changes to previously approved research and miscellaneous items, including the following:

- Participant materials such as: recruitment posters or scripts, diaries, validated questionnaires, clinical trial identification/wallet cards
- Protocol deviations
- Translations of English documents previously-approved by the REB
- Correspondence from the Principal Investigator
- REB minutes contingently approved by the convened REB.

4.6 Notification of the REB

4.6.1
The REB is informed at the next convened meeting of all research submissions that were approved using delegated review procedures.

4.7 Documentation

4.7.1
The type of REB review conducted (i.e., full or delegated) will be noted in the review and approval letters sent to the Principal Investigator.

4.7.2
The REB minutes and or attachments will include documentation (list) of research that was approved using delegated review procedures.

5.0 REFERENCES

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 2010;
2. The International Conference on Harmonization Guidelines for Good Clinical Practice, Section 3;
3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.102, 46.110;
4. US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.102, 56.110;
5. Department Of Health And Human Services (DHHS) Federal Register: *Categories of Research That May Be Reviewed by the Institutional Review Board through an Delegated Review*;
6. DHHS/OHRP Guidance on the use of Delegated Review Procedures.

DISCLAIMER: The Research Ethics Webpage version of this document is considered the most current. Please ensure that you have reviewed all linked documents and other referenced material within this guideline.

SOP Title:	Initial Review – Criteria for REB Approval
Issued By:	Research Ethics Office
Approved By:	SJCG Research Ethics Board ~ June 2012 TBRHSC Research Ethics Board ~ May 2012

1.0 PURPOSE

The purpose of this standard operating policy and procedure is to describe the minimum requirements of research proposals involving human participants for approval by the Research Ethics Board (REB), independent of the review pathway (full REB or delegated review).

2.0 POLICY STATEMENT

All research involving humans must meet certain criteria before REB approval may be granted. The approval criteria are based on the guiding ethical principles of the Tri-Council Policy Statement (TCPS 2) and applicable regulations and guidelines. Initial REB approval of the research is based on assessment of a complete application package. The REB may consult the Principal Investigator for additional information as necessary. In addition to REB approval, the requirements of the institution must also be met before the research can begin (e.g., approval for resource utilization, signed researcher agreement/contract).

3.0 RESPONSIBILITY

This SOP applies to the REB Chair, Manager, all REB members, and REO staff.

The REB members are responsible for determining whether or not a research study meets the criteria for approval based on ethical principles.

The REB Chair or designee is responsible for ensuring the REB members have adequate training, expertise and guidance to conduct their reviews and to make decisions regarding the approvability of the research.

4.0 PROCEDURES

4.1 Minimal Criteria for Approval of Research

In order for a research study to receive REB approval, the REB must find that:

4.1.1
Risks to participants are minimized by:

- using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk, and

- by using procedures already being performed on the participants for diagnostic or treatment purposes, whenever appropriate.

4.1.2
Risks to participants are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the REB will consider those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that participants would receive even if not participating in the research).

4.1.3
Selection of participants is equitable. In making this assessment, the REB will take into account the purposes of the research and the research setting. If applicable, the REB considers the scientific and ethical reasons for including vulnerable populations.

4.1.4
There are sound scientific and ethical reasons for excluding classes of persons who might benefit from research:

- Non-English speaking participants should not be systematically excluded because of inconvenience in translating informed consent documents
- Participants should not be taken from one group simply because it is convenient
- The research includes both women and men when appropriate, and does not arbitrarily exclude the participation of persons of reproductive ages

4.1.5
When some or all of the participants are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study and in the REB review process to protect the rights and welfare of these participants

4.1.6
Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with and to the extent required by applicable regulations and guidelines

4.1.7
The informed consent form accurately explains the research and contains the required elements as outlined in TCPS 2 (Refer to REB-SOP-VII-01.01- Communication – Study Participants).

4.1.8
The informed consent process is clearly described in the application.

4.1.9
When appropriate, or required by Health Canada, there are provisions for on-going data and safety monitoring, as evidence by a data safety monitoring plan (DSMP), that are appropriate to the size, complexity, phase, and level of risk of the study. The REB may recommend the use of a data and safety monitoring board (DSMB) for any study to enhance participant protection.

4.1.10
There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

4.1.11
There are adequate provisions for continued access to the agent or device, or adequate replacement, after the study is completed, when appropriate.

4.1.12
The research has been submitted to Health Canada if applicable, and the Health Canada No Objection Letter or Investigational Testing Authorization Notice has been issued.

4.1.13
Where pharmaceutical interventions are being compared, there is a state of clinical equipoise.

4.1.14
The research will generate knowledge that could be generalized and lead to improvements in health or well-being.

4.1.15
For greater than minimal risk studies, the methodology is scientifically sound and capable of answering the research question.

4.2 Additional Criteria

4.2.1
Studies proposing access to or collection of personal health information require consideration of additional items to protect the privacy of the personal health information. Therefore the REB must find that:

- authorization is obtained from participants or their legally authorized representative for the collection, use or disclosure of their personal health information, or the REB has approved a waiver of such authorization
- personal health information will be contained in a de-identified limited data set with appropriate safeguards to maintain privacy.

4.3 Minimal Criteria for Approval to Conduct the Research

In order to receive approval to participate in research, the REB must be satisfied that:

4.3.1
The application has been signed by the Principal Investigator.

4.3.2
The Principal Investigator has the qualifications to conduct the research as attested to by the hospital procedures.

4.3.3
Any potential conflicts of interest are managed appropriately to prevent any compromises to the safety or well-being of participants or the integrity of the data.

4.3.4
The recruitment methods respect the privacy of individual participants.

4.3.5
The informed consent form(s) accurately explains the research and contains the required elements.

4.3.6
Informed consent process is clearly described in the application.

4.3.7
There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

4.3.8
There are no restrictions on timely publication and dissemination of the research results.

4.4 Length of Approval Period

4.4.1
The REB shall approve research studies for a maximum period of one year.

4.4.2
The REB may consider review of research more often than annually when any of the following are true:

- Proposed procedures have not been used in humans
- The stage of the research is such that many of the risks are unknown
- More than minimal risk exists to vulnerable populations with no prospect of direct benefit
- There have been previously confirmed instances of serious or continuing non-compliance with the applicant Principal Investigator, and/or
- The REB documents other reasons for more frequent review.

5.0 REFERENCES

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 2010:
2. *The International Conference on Harmonization Guidelines for Good Clinical Practice, Sections 3, 4.1, 4.8;*
3. *Ontario's Personal Health Information Protection Act (PHIPA);*
4. *Personal Health Information Protection and Electronic Documents Act (PIPEDA);*
5. *Canadian Institutes for Health Research (CIHR) Best Practices for Protecting Privacy in Health Research (September 2005);*
6. *US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.111;*

DISCLAIMER: The Research Ethics Webpage version of this document is considered the most current. Please ensure that you have reviewed all linked documents and other referenced material within this guideline.

SOP Title:	Continuing Ethics Review
Issued By:	Research Ethics Office
Approved By:	SJCG Research Ethics Board ~ June 2012 TBRHSC Research Ethics Board ~ May 2012

1.0 PURPOSE

The purpose of this standard operating policy and procedure (SOP) is to describe the procedures for continuing review of research overseen by the Research Ethics Board (REB) and the criteria for continuation of REB approval.

2.0 POLICY STATEMENT

Research Ethics Boards must establish procedures for conducting continuing review of approved research involving human subjects, at intervals appropriate to the degree of risk, but not less than once a year. Periodic review of research activities is necessary to determine whether approval should be continued or withdrawn. Although many activities comprise ongoing review; a formal, substantive, and meaningful continuing review and determination regarding re-approval must be completed prior to the end of the REB approval period. The criteria for approval that must be satisfied at the time of initial review must also be satisfied at the time of continuing review. Failure by the Principal Investigator to ensure timely submission of progress reports for continuing review is a serious matter that may lead to suspension or termination of the research or expiration of REB approval. If any new information is received through continuing review that might affect the rights and welfare of research subjects, the REB may require that the research be modified, suspended or terminated. The REB will also consider if this new information should be communicated to research subjects.

3.0 RESPONSIBILITY

This SOP applies to the REB Chair, Manager, all REB members, and REO staff. The REB Chair and the assigned reviewers (if applicable) are responsible for conducting proportionate reviews of the progress report(s) for their assigned research studies. For research requiring continuing review at a convened REB meeting, appropriate documentation for the review will be available to the REB members.

4.0 PROCEDURES

4.1 Continuing Review by the Convened REB

4.1.1
A fixed anniversary date is maintained whenever possible. Investigators are required to submit research progress reports using the *REB Re-Approval Application Form* at a frequency determined by the REB at the time of initial approval or the previous Continuing Ethics Review. At a minimum, the REB requires a progress report once per year until all data have been collected and contact with study subjects or patient charts has concluded.

4.1.2
To preserve a fixed anniversary date, application for re-approval should be submitted by the Principal Investigator no greater than 60 days prior to the end of the approval period.

4.1.3
Research must be reviewed by the REB within no more than 30 days prior to the end of the approval period. If it is necessary to conduct continuing ethics review before 30 days to expiry, approval will be granted for no more than one year from the date of the convened REB meeting where the decision to approve with or without further clarifications was determined.

4.1.4
It is the Principle Investigator's responsibility to submit progress reports on time. To assist the investigators with this responsibility, the REO staff will send a courtesy notice reminding the Principal Investigator to submit the progress report approximately eight weeks before the end of the approval period.

4.1.5
The documents for Continuing Ethics Review must be submitted by the agenda submission cut-off date to be considered at the next convened REB meeting.

4.1.6
The REO staff review the continuing ethics review submission and request any clarifications, or missing documents or information.

4.1.7
Continuing Ethics Reviews will be scheduled for the REB meeting that occurs immediately prior to the end of the approval period, to preserve the fixed anniversary expiry date. The REO staff adds the research study to the REB meeting agenda and assign to the REB Chair or designate. The REB Chair may assign review of the study to the original primary and secondary reviewers as well.

4.1.9
The research progress report may be discussed at a convened meeting whereby the REB makes its decision regarding the approvability of the research and additional determinations regarding the conduct of the study.

4.1.10
Extensions of approval beyond the end of the approval period are not granted. If however, the continuing ethics review requires additional revisions/clarifications before final approval, the study is not considered expired while this information is obtained. Renewal dates will be determined similar to the process outlined in section 4.1.2 of this document. Exception to this is at the discretion of the REB Chair.

4.2 Continuing Review by Delegated Review Procedures

4.2.1
Principal Investigators are required to submit research progress reports using the *REB Re-Approval Application Form* at a frequency determined by the REB at the time of initial approval or the previous Continuing Ethics Review. At a minimum, the REB requires a progress report once per year until all data have been collected and contact with study subjects or patient charts has concluded.

4.2.2
To preserve a fixed anniversary date, the research must be reviewed through the REB delegated review process within no more than 30 days prior to the end of the approval period.

4.2.3
It is the Principle Investigator's responsibility to submit progress reports on time. To assist the investigators with this responsibility, the REO staff will send a courtesy notice reminding the Principal Investigator to submit the progress report approximately eight weeks before the end of the approval period.

4.2.4
Research that was previously reviewed by delegated review procedures is reviewed at the time of continuing review using delegated review procedures. However, using the risk matrix, if the REB Chair, or designee, determines that the study has shifted, the REB Chair may refer the study for full board review at a convened REB meeting.

4.2.5
Research that was previously reviewed by the convened REB may be reviewed at the time of continuing review using delegated review procedures when there are minimal-risk changes or no changes to the previously approved research.

4.2.6
The REO staff will distribute the progress reports, to the Chair, or designee, for review.

4.2.7
The REB Chair, or designee, makes a decision regarding the approvability of the research and additional determinations regarding the conduct of the study.

4.3 REB Determinations

4.3.1
To grant continuation of approval, the REB must determine that:

- there have been no material changes to the study protocol or consent form that have not been previously submitted and approved
- there is no conflict of interest or new information that has emerged that might adversely affect the safety or well-being of study participants
- informed consent forms continues to be compliant with applicable guidelines, regulations and policies.

4.3.2
The REB may also make additional determinations, including:

- requiring changes to the informed consent form(s)
- requiring changes for the continuing review interval (based on risks)
- imposing special precautions (e.g., frequency of monitoring, the requirement for interim reports
- or duration of approval period)
- lifting or relaxing special precautions
- requiring modifications to the research
- suspending or terminating REB approval.

4.4 Documentation and Communication

4.4.1
REB continuing ethics review activities will be documented, filed and retained per REO operational procedures (Refer to REB-SOP-IV-03.01 - Document Management).

4.4.2
Research Ethics Board notice of continuing approval or changes required to obtain continuing approval will be distributed to Principal Investigators in a timely manner.

4.4.3
If the progress report is not received, reviewed and approved by the REB by the end of the approval period, the REB Chair will determine the appropriate action to take. This may include suspension of study activities and enrollment. Participants already enrolled in the study should receive appropriate medical care to ensure their safety and well-being. The REB Chair will decide whether prospective research data collection (except safety data) will be allowed and whether procedures that are being performed only for the purposes of the study should be undertaken until REB approval is reinstated.

4.4.4
The Principal Investigator is responsible for promptly notifying the REB if there is a need to continue study-related medical treatment of current study participants for their safety and well-being.

4.4.5
These activities will be documented and filed in the REO study file.

5.0 REFERENCES

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 2010*;
2. *The International Conference on Harmonization Good Clinical Practices, Sections 3, 4.4, 4.5, 4.10, 4.11, 4.12;*
3. *US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.109, 46.111, 46.113, 46.115;*
4. *OHRP Guidance on Continuing Review;*
5. *US Food and Drug Administration (FDA) CFR Title 21 Part 56.108, 56.109, 56.110, 56.111, 56.115;*

Research Ethics Board	Amendment Application and Review REB-SOP-V-05.01

DISCLAIMER: The Research Ethics Webpage version of this document is considered the most current. Please ensure that you have reviewed all linked documents and other referenced material within this guideline.

SOP Title:	Amendment Application and Review
Issued By:	Research Ethics Office
Approved By:	SJCG Research Ethics Board ~ June 2012 TBRHSC Research Ethics Board ~ May 2012

1.0 PURPOSE

The purpose of this standard operating policy and procedure (SOP) is to describe the process for submission and review of amendments to Research Ethics Board (REB) approved research.

2.0 POLICY STATEMENT

In addition to the formally scheduled continuing ethics review, the REB must receive and review all new information and changes (amendments) generated throughout the course of the research.

The REBs has adopted a proportionate approach to ethics assessment based on the general principle that the more invasive or harmful the proposed and ongoing research, the greater the care in assessing the research. Proportionate review reserves the most intensive scrutiny, and correspondingly more protection, for the most ethically challenging research.

In addition, the **Three R checklist** has been developed to guide whether changes to a REB approved research study may constitute a new research study and application as opposed to an amendment. Changes to an existing protocol may constitute a new study when there are significant changes to:

- the **R**esearch Question
- the **R**ecruitment strategy or eligibility criteria
- the **R**isk to participants.

3.0 RESPONSIBILITY

This SOP applies to the REB Chair, Manager, all REB members, REO staff and research teams.

4.0 PROCEDURES

4.1 Continuing Ethics Review of Changes to Approved Research

4.1.1
Principal Investigators must submit to the REB any new information and changes to the approved protocol and associated study documents using the *REB Amendment Application Form*;

4.1.2
The REB Chair or designate reviews the amendment to determine if the degree of changes constitute an amendment or a new study.

4.1.3
The REB Chair or designate reviews the amendment to determine the appropriate level of REB review required. Delegated review of an amendment may be done when the proposed changes are minor or involve no more than minimal risk (as defined above).

4.1.4
The REB Chair or designate has the authority to direct any delegated review request to the full board for review.

4.1.5
Full board review of an amendment may be required when the proposed change(s) represents more than minimal risk (as defined above) AND is determined by the REB Chair to require more intense scrutiny by the full REB, or is required by the regulatory body. Examples of amendments that may require full board review may include:

- Proposed changes to the scientific intent of the research
- Reports of any changes significantly affect the conduct of the research or increasing the risk to research participants
- New information that may adversely affect the safety of the research participants or the conduct of the research.

4.1.6
The REB must find that the criteria for approval are still met in order to approve the amendment.

4.1.7
Modifications to approved research may not be initiated without prior REB review and approval except where necessary to eliminate apparent immediate hazards to human subjects. If changes are made to eliminate immediate hazards, the Principal Investigator must notify the REB Chair immediately. The REB Chair will notify the REB membership of the modifications at the next convened REB meeting.

4.2 Documentation and Communication

4.2.1
REB review activities related to any amendments will be documented, filed and retained per REO operational procedures (Refer to REB-SOP-IV-03.01 - Document Management).

4.2.2
Research Ethics Board notice of approval or changes required to obtain continuing approval will be distributed to Principal Investigators in a timely manner.

5.0 REFERENCES

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 2010*;
2. *The International Conference on Harmonization Good Clinical Practices, Sections 3, 4.4, 4.5, 4.10, 4.11, 4.12;*
3. *US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.109, 46.111, 46.113, 46.115;*
4. *OHRP Guidance on Continuing Review;*
5. *US Food and Drug Administration (FDA) CFR Title 21 Part 56.108, 56.109, 56.110, 56.111, 56.115.*

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SOP Title:	Study Completion
Issued By:	Research Ethics Office
Approved By:	SJCG Research Ethics Board ~ June 2012 TBRHSC Research Ethics Board ~ May 2012

1.0 PURPOSE

This standard operating policy and procedure (SOP) describes the procedures for the closure of a research study with the Research Ethics Boards (REBs).

2.0 POLICY STATEMENT

The completion of a research study is a change in activity that must be reported to the REB. Although research participants will no longer be at risk under the study, a final report allows the REB to close its files.

3.0 RESPONSIBILITY

This SOP applies to the REB Chair, Manager, all REB members, REO staff and research team.

The REO staff is responsible for verifying that all study completion documents are received, reviewed and signed by the REB Chair or designee. Reports are filed appropriately by the REO staff.

4.0 PROCEDURES

4.1 Determining When a Research Study Can be Closed

A Study Completion Report is submitted when there is no further participant involvement and all data collection, clarification and transfer is complete (including access to the participants' health record). Submission of this report indicates that these activities have ceased, the study does not require continuing ethics approval, and the REB study file can be closed.

4.1.1
For single centre research, a study may be closed with the REB when there is no further participant involvement and all data collection, clarification and transfer is complete (including access to the participants' health record).

4.1.2
For multi-centre research, an individual centre may be closed when contact with the research participants and data collection have ceased at the centre and the sponsor has conducted their study closeout procedures.

4.2 Study Completion Reports

4.2.1
When a study is ready to be closed, the Principal Investigator should submit the *Study Completion Report* to the REB.

4.2.2
If the research is prematurely terminated for any reason, the Principal Investigator should promptly submit the *REB Study Completion Report* to the REB. When the Study Completion Report indicating a premature termination of the study is received by the REO, the REO staff will notify the REB Chair or designee who will act according to the SOP on suspensions and terminations of research studies (Refer to REB-SOP-V-07.01 – Suspension or Termination of REB Approval).

4.2.3
The REO staff will perform an administrative review of the report and the files and request any outstanding information, clarification or documentation from the investigator if needed.

4.2.4
Once all outstanding issues have been addressed, the REB Chair or designee will review the report and sign the report indicating study closure with the REB. The REO staff will enter into the REB Database the study closure date as the date the REB Chair or designate acknowledges through signature the study has been closed.

4.2.6 The REO staff or designee sends the signed notice to the Principal Investigator acknowledging the study closure and closure of the REB files.

4.2.7 The REO staff coordinates storage of closed studies for archiving. Health Canada regulations are followed for appropriate studies.

5.0 REFERENCES

1. *The International Conference on Harmonization Good Clinical Practices, Section 4.13;*
2. *US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.109;*
3. *US Food and Drug Administration (FDA) CFR Title 21 Part 56.108, 56.109.*

DISCLAIMER: The Research Ethics Webpage version of this document is considered the most current. Please ensure that you have reviewed all linked documents and other referenced material within this guideline.

SOP Title:	Suspension or Termination of REB Approval
Issued By:	Research Ethics Office
Approved By:	SJCG Research Ethics Board ~ June 2012 TBRHSC Research Ethics Board ~ May 2012

1.0 PURPOSE

This standard operating policy and procedure (SOP) describes the procedures associated with suspension or termination of research previously approved by the Research Ethics Board (REB).

2.0 POLICY STATEMENT

As a result of ongoing review activities, the REB may require that research be modified or may suspend or terminate REB approval if the risks to the research participants are determined to be unreasonably high, for example, in cases in which there are high numbers of unexpected serious adverse events, or when there is evidence that the Principal Investigator is not conducting the research in compliance with applicable regulations and guidelines. The REB also has the authority to suspend new enrolment while additional information from the Principal Investigator is requested. A decision to suspend or terminate REB approval of the research must include consideration of the safety, rights and well-being of participants already enrolled in the study, specifically whether and how to continue the care of enrolled participants, and how and when the notification of research participants will take place. The convened REB has the authority to suspend or terminate REB approval of research. The REB Chair or designee has the authority to suspend approval. Any requests to lift a suspension or re-approve research must be reviewed by the convened REB.

3.0 RESPONSIBILITY

This SOP applies to the REB Chair, Manager, all REB members, and REO staff.

The REB Chair or designee is responsible for determining whether any information received throughout the course of the research requires consideration of suspension or termination of REB approval for the research. The REB Chair alone is not authorized to terminate research; however, the REB Chair or designee is authorized to suspend research and is responsible for reporting any suspensions to the convened REB at the next available meeting. The REB is authorized to terminate research following review at a convened REB meeting. The REB Chair is responsible for requesting that the Principal Investigator report any suspension or termination or REB approval of research to the study sponsor, the appropriate Institutional Official and regulatory authorities. Alternatively, the REB Chair may choose to notify the Institutional Official and regulatory authorities directly.

4.0 PROCEDURES

4.1 Suspension or Terminations by the Sponsor

4.1.1
The sponsor of a study may place research activities on hold or terminate the research (e.g. following results of an interim analyses; inadequate drug availability; in response to a DSMB recommendation; or a pre-planned stopping criteria).

4.1.2
The Principal Investigator must immediately notify the REB and institution of any suspensions or terminations and the reasons for the action.

4.1.3
Reports of suspensions or terminations by the sponsor will be forwarded to the convened REB.

4.1.4
The REB has the authority to suspend or terminate REB approval, which will require REB review and approval prior to resuming the research following the Sponsor's lifting of a suspension.

4.2 Suspension or Terminations by the REB

4.2.1
If any concerns are raised during REB oversight of a research study related to new information of the conduct of research, the REB may suspend or terminate research at any time. These concerns include:

- research not being conducted in accordance with the REB-approved protocol or REB requirements,
- unexpected serious harm to patients, safety reports, unanticipated problems involving risks to participants or others, DSMB reports
- failure to submit a progress report and application for continuing approval by the end of the approval period,
- falsification of study records or data
- failure to comply with prior conditions imposed by the REB (i.e. under a suspension or approval with modification)
- repeated or deliberate failure to properly obtain or document consent from research participants
- repeated or deliberate failure to limit administration of the investigational drug or device to those research participants under the investigator's supervision
- repeated or deliberate failure to comply with conditions placed on the study by the REB, sponsor, or regulatory agencies
- repeated or deliberate failure to obtain prior REB review and approval of amendments or modifications to the research, or repeated or deliberate failure to maintain accurate study records or submit required adverse event reports to the REB.

4.2.2
The REB has the authority to suspend or terminate REB approval of research and the REB Chair or designee has the authority to suspend approval.

4.2.3
Prior to suspending or terminating REB approval, the REB, or the REB Chair or designee must consider:

- risk(s) to current participants
- actions to protect the safety, rights and well-being of currently enrolled participants
- the appropriate follow-up care and monitoring
- whether withdrawal of enrolled participants is warranted and the specific procedures for their safe withdrawal
- whether participants should be informed of the termination or suspension
- whether adverse events or outcomes should be reported to the REB
- corrective measures time frame in which the corrective measures are to be implemented.

4.2.4
If the REB Chair or designee suspends the research, he/she must notify the REB at the next convened REB meeting.

4.2.5
The REO staff drafts a formal notice to the Principal Investigator with the reason(s) for the REB action and the corrective measures proposed by the REB. The letter is reviewed, revised as necessary and signed by the REB Chair or designee and sent to the Principal Investigator.

4.2.6
Approval may be reinstated after corrective actions are completed to the REB's satisfaction.

4.3 Reporting Suspensions or Terminations

4.3.1
The REB Chair or designee will promptly report orally to the Principal Investigator any suspensions or terminations of REB approval, and the reasons for the decision. The decision will follow in writing.

4.3.2 The REB Chair or designee will request the Principal Investigator to report any suspension or termination of REB approvals for research to the study sponsor and the appropriate Institutional Official and regulatory authorities. Alternatively, the REB Chair may choose to notify the Institutional Official and regulatory authorities directly.

5.0 REFERENCES

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 2010;*
2. *US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103;*
3. *US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21 Part 56.108.*

DISCLAIMER: The Research Ethics Webpage version of this document is considered the most current. Please ensure that you have reviewed all linked documents and other referenced material within this guideline.

SOP Title:	External Safety Reports to the REB
Issued By:	Research Ethics Office
Approved By:	SJCG Research Ethics Board ~ June 2012 TBRHSC Research Ethics Board ~ May 2012

1.0 PURPOSE

The purpose of this standard operating policy and procedure (SOP) is to describe the procedures for submitting External Safety Reports to the Research Ethics Board (REB) and the criteria for review of these Reports. External Safety Reports are also known as non-local Serious Adverse Events (SAE).

2.0 POLICY STATEMENT

Research Ethics Boards must establish procedures for conducting continuing review of approved research involving human subjects. In addition to formally scheduled continuing review, in keeping with current regulations, the REB requires that Principal Investigators participating in multi-centre trials submit certain individual External Safety Reports that occur at any other centre involved in a study using the same investigational agent.

The Principal Investigator must submit to the REB, External Safety Reports that are:

- Serious, AND
- Unexpected, AND
- Related (unlikely, possibly, probably, definitely), AND
- Clinically significant for the participants in the study at the local institution.

It is the responsibility of the Principal Investigator to review all External Safety Reports and retain copies. Only those that are deemed by the Principal Investigator to meet ALL of the above submission criteria are to be submitted to the REB. All other Reports not meeting the submission criteria are to be kept on file in the Investigator Study File and available for review by the REB upon request. Failure by the investigator to ensure timely submission of External Safety Reports to the REB for review is a serious matter that may lead to suspension or termination of the research at the local institution.

It is the expectation of the REB that the Principal Investigator will notify the REB when the reported information is considered to affect the rights and welfare of research subjects, and the recommended actions to follow. In turn, through review of the new information, the REB may require that the research be further modified, suspended or terminated.

3.0 RESPONSIBILITY

This SOP applies to the Principal Investigator, REB Chair, Manager, all REB members, and REO staff.

4.0 PROCEDURES

4.1 Submitting External Safety Reports to the REB

4.1.1
Upon receipt of an External Safety Report from the sponsor, it is the Principal Investigators responsibility to review each Report.

4.1.2
The Principal Investigator must determine whether the Report is:

- Serious, AND
- Unexpected, AND
- Related (unlikely, possibly, probably, definitely), AND
- Clinically significant for the participants in the study at the local institution.

4.1.3
Reports determined by the Principal Investigator to meet ALL of the above criteria must be reported to the REB using the External Safety Report Submission Form located on the Research Ethics Office webpage under Forms and Guidelines.

4.1.4
The PI is required to include the Sponsors Report #, indicate the type of Report (i.e. initial or follow up), the type of event, and the recommended action.

4.2 Review of External Safety Reports by the REB

4.2.1
Upon receipt of the External Safety Report Submission Form and accompanying Reports that meet ALL of the above criteria, the REO staff will review the submission and request any clarifications, or missing documents or information.

4.2.2
The Reports will be reviewed by the REB Chair or designate and the submission form signed indicating receipt of the information.

4.2.3
If the reported information is considered to affect the rights and welfare of research subjects, the REB may require that the research be modified, suspended or terminated. The REB will also consider if this new information should be communicated to research subjects.

4.2.4
The signed original form will be returned to the Principal Investigator for filing.

4.2.5
If the REB receives External Safety Reports that do not meet the submission criteria, the REB reserves the right to return such Reports, without review, to the Principal Investigator.

4.3 Documentation and Communication

4.3.1
Research Ethics Board notice of receipt and review of the Reports that meet the submission criteria will be distributed to Principal Investigator in a timely manner.

4.3.2
External Safety Report REB review activities will be documented, filed and retained per REO operational procedures (Refer to REB-SOP-IV-03.01 - Document Management).

4.3.3
It is the Principal Investigator 's responsibility to review all External Safety Reports and to retain copies in the Investigator Study File.

5.0 REFERENCES

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 2010;*
2. *The International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, Sections 3, 4.4, 4.5, 4.10, 4.11, 4.12;*
3. *Health Canada Food and Drug Regulations, Division 5, C.05.014*
4. *US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21 Part 56.108, 56.109, 56.110, 56.111, 56.115;*
5. *US Department of Health and Human Services (HHS) CFR Title 45 Part 46.103, 46.109, 46.110, 46.111, 46.115;*
6. *US Office for Human Research Protections (OHRP) Guidance "Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events";*
7. *OHRP Guidance on Continuing Review;*
8. *FDA Draft Guidance on Adverse Event Reporting, April 2007.*

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SOP Title:	Communication between Investigators and Research Office Staff
Issued By:	Research Ethics Office
Approved By:	SJCG Research Ethics Board ~ June 2012 TBRHSC Research Ethics Board ~ May 2012

1.0 PURPOSE

This standard operating policy and procedure (SOP) describes the Research Ethics Board (REB) communications with the investigator and his/her research team.

2.0 POLICY STATEMENT

In the interest of enhancing human research participant protection, it is important for the REB to foster collaboration and open communication between and among the REB, Principal Investigators and research staff. This applies not only to communication related to a specific research study, but also communication related to ethical issues as well as REB processes, policies and procedures. Feedback from Principal Investigators and their research staff should also be encouraged and considered as quality improvement opportunities for REB and Research Ethics Office (REO) staff and processes.

3.0 RESPONSIBILITY

This SOP applies to the REB Chair, Manager, all REB members, and REO staff.

The REB Chair or designee is responsible for overseeing all communications with Principal Investigators conducted on behalf of the REB and for the content of all review and approval letters issued on behalf of the REB.

The REO staff is responsible for drafting correspondence on behalf of the REB following a convened meeting or delegated review procedures. The REO staff is responsible for distributing the REB correspondence to appropriate parties and for day-to-day operational communication with the Principal Investigator and his/her research staff.

4.0 PROCEDURES

4.1 Notification of REB Decisions

4.1.1
The REO will notify the participating investigators in writing of the REB's decision as soon as possible following review of new studies, modifications to currently approved studies, or applications for continuing review.

4.1.2
If the study is not approved or re-approved (for continuing review), the REB Chair or designee will notify the Principal Investigator of the REB's decision within 48 hours of the REB's determination. A written notice will follow.

4.1.3
Using the *REB Request for Revisions/Clarification Template,* the REO staff drafts the letter summarizing the REB determinations, any concerns or requests for clarification, the reasons for not approving (when appropriate).

4.1.4
The REB Chair or designee reviews the drafted REB request for revisions/clarifications, requests revisions as necessary, and authorizes the communication to be sent by email.

4.1.5
The REO staff sends the REB request for revisions/clarifications to the Principal Investigator(s).

4.1.6
Upon receipt of the Principal Investigator's response to the REB request for revisions/clarifications, the REO staff will follow-up with Principal Investigator or his/her research staff to request any additional clarifications as needed or as requested by the REB Chair or reviewers.

4.1.7
Once all of the REB conditions are satisfied, the REO staff will prepare the REB Approval Letter using the *REB Approval Letter Template* which clearly states the approval period for signature by the REB Chair or designee.

4.1.8
The REB Chair or designee reviews and signs the approval letter.

4.1.9
REO staff will send an electronic copy of the signed REB approval letter by email to the Principal Investigator. The original signed copy will be sent by mail. The Principal Investigator will be asked to use the unique REB number assigned in any subsequent correspondence with the REB.

4.1.10
The REO staff files a paper copy of the signed approval letter in the specific REB file in the REO office. The REB database is updated, and an electronic copy of the approval letter is filed in the appropriate electronic file.

4.2 Investigator Appeal of REB Decision

4.2.1
A Principal Investigator has the right to request, and REBs have an obligation to provide, prompt reconsideration of decisions affecting a research project. (TCPS 2: Article 6.18).

4.2.2
Appeals are conducted in accordance with the Appeal Process outlined in the TCPS 2 (Article 6.19).

4.2.3
Only the fully convened REB may lift restrictions or re-review a submission which was not approved. Delegated review procedures may not be used.

4.3 Other Communication with the Principal Investigator or his/her Research Staff

4.3.1
The REO staff will respond to queries in a timely and professional manner to encourage communication with the investigator and/or his research staff.

4.3.2
The Manager will communicate regularly with the REO Staff to modify the REO procedures for process improvement.

5.0 REFERENCES

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 2010*;
2. *US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.109, 46.115;*
3. *US Food and Drug Administration (FDA) CFR Title 21 Part 56.115List the applicable regulations and guidelines the SOP is governed by.*

Research Ethics Board	Communications Study Participants REB-SOP-VI-02.01

DISCLAIMER: The Research Ethics Webpage version of this document is considered the most current. Please ensure that you have reviewed all linked documents and other referenced material within this guideline.

SOP Title:	Communication – Study Participants
Issued By:	Research Ethics Office
Approved By:	SJCG Research Ethics Board ~ June 2012 TBRHSC Research Ethics Board ~ May 2012

1.0 PURPOSE

This standard operating policy and procedure (SOP) describes the Research Ethics Board (REB) communications with study participants involved in research overseen by the REB.

2.0 POLICY STATEMENT

In the interests of enhancing human research participant protection and harmonization of policies and procedure, it is important for the REB to foster collaboration and open communication. Research participants should be able to confidentially voice their concerns or questions, or request information regarding their participation or potential participation in a research project, to an informed individual on the REB or staff in the Research Ethics Office (REO).

3.0 RESPONSIBILITY

This SOP applies to the REB Chair, Manager, all REB members, and REO staff.

4.0 PROCEDURES

4.1 Communication with Research Participants

4.1.1
Research participants are encouraged to contact (by telephone, email or in writing) the REB with questions and concerns using the contact information provided in the informed consent document. If requested, the identity of the participant will not be recorded or shared.

4.1.2
Research Ethics Office staff relay communications immediately to the REB Chair or designee when the participant shares concerns or problems encountered while participating in a research project.

4.1.3
The Manager, along with the REB Chair or designee, works to resolve participant issues, which may include follow-up with the Principal Investigator or the Principal Investigator's supervisor or institutional official and appropriate federal agencies, as indicated.

4.1.4
The Manager and REB Chair or designee documents all communication with the research participant and keeps a record on file at the REO.

5.0 REFERENCES

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 2010*;
2. *US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.109, 46.115;*
3. *US Food and Drug Administration (FDA) CFR Title 21 Part 56.115;*

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SOP Title:	Informed Consent Requirements and Documents
Issued By:	Research Ethics Office
Approved By:	SJCG Research Ethics Board ~ June 2012 TBRHSC Research Ethics Board ~ May 2012

1.0 PURPOSE

This standard operating policy and procedure (SOP) describes the requirements for obtaining and documenting initial and ongoing informed consent.

2.0 POLICY STATEMENT

Free and informed consent lies at the heart of ethical research involving human research participants. The Research Ethics Board (REB) must review all consent documents and procedures, including recruitment methods. Principal Investigators must obtain informed consent from the potential research participant or from his/her authorized third part decision maker prior to conducting any study-related procedures, unless a waiver of informed consent has been granted by the REB.

3.0 RESPONSIBILITY

This SOP applies to the REB Chair, Manager, all REB members, and REO staff.

The Principal Investigator is responsible for providing the REB with a detailed description of the consent process, recruitment methods and a copy of the consent documents.

The Principal Investigator, the sponsor (if applicable) and the REB are jointly responsible for ensuring that the consent form contains all of the basic elements and the applicable additional elements.

The Principal Investigator is responsible for providing appropriately translated consent documents if applicable.

The REB is responsible for determining whether informed consent exemptions or waivers are applicable and appropriate.

4.0 PROCEDURES

4.1 Required Elements of Informed Consent

4.1.1
The REO staff will ensure that the informed consent documents are distributed to all REB members in the case of full REB review, or to the applicable reviewers under the delegated REB review process.

4.1.2
The REB members will review the proposed consent process for appropriateness, and the proposed consent form(s) for formatting and general readability, for appropriateness of the language and content, and for the inclusion of the applicable basic and additional elements per the *Consent Form Checklist(s)* and the *Consent Form Template(s)* as outlined in the Guidelines on the websites.

4.1.3
The REB requires a separate consent form for optional procedures whereby the research purpose is not yet known (e.g. tissue, blood, genetic testing or specimen banking for future research). Optional procedures for sub-studies directly related to the main research study may be included in the main study informed consent form.

4.1.4
Following the review, REB may approve the consent form(s) as submitted, or require changes.

4.1.5
When the changes meet the criteria for delegated review, the REO staff presents the revised consent to the REB Chair or designee for review and approval.

4.1.6
When changes do not meet the criteria for delegated review; the REO staff adds the revised consent to the agenda of the next full REB meeting.

4.2 Translation

4.2.1
The informed consent document should be in language understandable to the participant (or acceptable representative).

4.2.2
When a study participant is non-English speaking, documentation of informed consent can be by one of two methods:

- Written consent: The REB approved English version of the informed consent document is translated to the participant's native language. Translated informed consents must be accompanied by an attestation from the translator certifying that the translated informed consent accurately reflects the REB approved English informed consent.

- Oral consent: A translator fluent in both English and the participant's native language translates the REB approved English consent form orally to the participant. The translator should be a trained impartial person. When the person obtaining consent is assisted by a translator, the translator must sign and date the consent form.

4.2.3
The REB requires that the translated materials be submitted for review and approval prior to use in enrolling non-English speaking participants. The Principal Investigator must include a certificate or statement signed by the translator indicating that the translated materials are a true and accurate translation of the REB-approved English materials.

4.2.4
The REB may follow delegated review procedures to review and approve translated materials if the English language materials have already been approved and the signed translation certificate or statement is on file.

4.2.5
A translator should be available to the study participant throughout the study.

4.2.6
The translator must sign and date the consent form attesting that the study was accurately explained to, and appeared to be understood by the participant.

4.3 Re-Consenting Participants

4.3.1
The Principal Investigator must inform research participants of any new information that might affect their willingness to continue their participation in the research.

4.3.2
The Principal Investigator must obtain documentation of the participant's willingness to continue to participate if there is a significant change to the protocol or risk.

4.3.3
Written documentation of re-consent may be obtained by having the participant sign an updated REB approved version of the informed consent document or an REB approved addendum to the original consent form.

4.4 Recruitment Methods

4.4.1
Principal Investigator's Patients: If the patient is under the care of the Principal Investigator, the Principal Investigator may approach their patient directly to introduce the option of participating in a research study, [i.e., make aware of the opportunity], but in such a manner that the patient does not feel pressured or obligated in any way. In this instance, the patient's consent should be obtained by an individual other than the Principal Investigator.

4.4.2
Referrals: The Principal Investigator may send an REB-approved letter to colleagues asking for referrals of potential patients. The Principal Investigator may provide colleagues with an REB-approved study information sheet and/or consent form to give to patients. The patient will then be asked to contact the Principal Investigator directly, or, with documented permission from the patient, the Principal Investigator may initiate the call.

4.4.3
Health Records: The Principal Investigator may ask the Health Records Department to identify patients who appear to meet the study's eligibility criteria. The Principal Investigator should supply Health Records Department with an REB approved standard letter describing the study to give to the patient's physician, and asking whether the physician would be willing to approach his/her patients about participation. It is NOT acceptable for the Principal Investigator or his/her staff to contact patients identified through hospital records, clinic charts or other databases independently by phone or email, unless the patient has previously agreed, or is already under the medical care of the Principal Investigator.

4.4.4
Registries: If the REB has previously approved a patient research registry and the patient has provided permission to be contacted for potential studies, the Principal Investigator or his/her research team may contact these patients directly. The person contacting the patient should identify him/herself as associated with the patient's clinical caregiver, and remind the patient that they have agreed to be contacted. The patient must be offered the option of having his/her name removed from the research registry.

4.4.5
Advertising: The REB must first review and approve the text and the use of any advertisements, notices or media messages which are to be used as recruitment materials. Based on the risk matrix, and the level of involvement of the organization, this may be done through the delegated or full REB review pathway. Advertisements that are to be posted in the hospital must also be approved by Office of Communications of the appropriate organization.

4.5 Recruitment Materials

4.5.1
The REB reviews the recruitment materials (e.g., advertisements, letters, notices) for evidence of coercion or undue influence and consistency with the REB approved protocol and informed consent document.

4.5.2
Advertisements should be limited to the information that the prospective participant needs to determine their potential eligibility and interest. When appropriately worded, the following items may be included:

- Full study title
- The name of the Principal Investigator
- The name and phone number of the person or office to contact for further information
- Appropriate logos
- The condition under study and/or the purpose of the research
- In summary form, the eligibility criteria that will be used
- The time or other commitment required of the participants
- The location of the research
- Any payment and/or cost for study participants
- If recruitment is time limited, outline timing.

4.5.3
Advertisements may indicate that participants will be reimbursed for out-of-pocket expenses (e.g., parking) but this information should not be overly emphasized.

4.5.4
Advertisements should not name the study drugs or contain therapeutic claims.

4.5.5
All recruitment materials must be approved by REB and by Communications prior to their use.

4.6 Documentation of Informed Consent

4.6.1
The REB requires documentation of informed consent by the use of a written informed consent form approved by REB and signed and dated by the participant or the participant's authorized third party decision maker, and by the person obtaining consent, and by the Principal Investigator.

4.6.2
The Principal Investigator will give a copy of the signed consent form to the participant.

4.6.4
The REB may approve a process that allows the informed consent document to be delivered by regular mail, email or facsimile to the potential participant, and to conduct the consent interview by telephone when the participant can read the consent document as it is discussed. All other applicable conditions for documentation of informed consent must also be met when using this procedure.

4.7 Consent Monitoring

4.7.1
In considering the adequacy of informed consent procedures, the REB may require monitoring of the consent process by an observer appointed by the REB.

4.7.2
Such monitoring may be particularly warranted where the research presents significant risks to participants, or if participants are likely to have difficulty understanding the information to be provided.

4.7.3
Monitoring may also be appropriate as a corrective action where REB has identified problems associated with a particular Principal Investigator or a research project.

4.8 Waiver or Alteration of Informed Consent

4.8.1
In certain situations, the REB may approve a consent procedure that does not include, or which alters (e.g. deferral), some or all of the elements of informed consent, or waive the requirement to obtain informed consent. Examples are:

- The research involves no more than minimal risk to the participants
- The waivered or altered consent does not involve a therapeutic intervention
- The waiver or alteration is unlikely to adversely affect the rights and welfare of the participant
- The research could not practicably be carried out without the waiver or alteration
- The information is used in a manner that will ensure its confidentiality
- The public interest in conducting the research exceeds the public interest in protecting the privacy of the individuals
- The regulatory framework supports the waiver or alteration.

4.8.2
Whenever appropriate, the participants will be provided with additional pertinent information after participation.

4.8.3
These findings and their justifications shall be clearly documented in the REB minutes when REB exercises this waiver or alteration provision.

5.0 REFERENCES

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 2010*;
2. *Health Canada, Division 5 of the Food and Drug Act;*
3. *The International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP), Section 4.8;*
4. *US Food and Drug Administration (FDA) Code of Federal Regulations (CFR) Title 21 Part 50.20, 50.23, 50.24, 50.25, 50.27;*
5. *US Department of Health and Human Services (HHS) CFR Title 45 Part 46.116, 46.117.*