Research Ethics Board:

Terms of Reference

Prepared by:

Research Ethics Office

Original Terms of Reference: Approved March, 2008;
Version # 2: Updated and Approved February 2010;
Version # 3: Updated and Approved September 21, 2011;
Version # 4: Updated and Approved June 17, 2015.

Mission Statement

St. Joseph's Care Group is a Catholic organization
committed to provide compassionate and holistic care and services
to the people of Northwestern Ontario.

Vision Statement

St. Joseph's Care Group will identify and respond to the unmet needs of our region
as a way of continuing the healing mission of Jesus in the tradition
of the Sisters of St. Joseph of Sault Ste. Marie.

Core Values

Commitment
Compassionate and Holistic Care
Dignity and Respect
Excellence
Faith-Based Care
Inclusiveness
Truthfulness and Trust

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A: Preface

i. Abbreviations Used within this Document

Board	Board of Directors, St. Joseph's Care Group
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
REO	Research Ethics Office
SJCG	St. Joseph's Care Group
SOP	Standard Operating Procedures
TCPS 2	Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

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 2014:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

Catholic Health Alliance of Canada Health Ethics Guide:
http://www.chac.ca/resources/ethics/ethicsguide_e.php

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-lois.justice.gc.ca/eng/regulations/C.R.C.%2C_c._870/page-281.html#h-255

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.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04q03_e.htm

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

1. Terms of Reference

1.1 Introduction:

The Research Ethics Board (REB) of St. Joseph's Care Group (SJCG) functions to ensure that all research involving humans at the Care Group meets the highest ethical standards prior to study initiation in accordance with the TCPS 2 Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.

The REB will ensure that all research reviewed demonstrates respect for the Core Values, Mission and Vision statements articulated by the Care Group.

The REB will endeavour to safeguard the rights, safety and well-being of patients, clients, residents, staff, volunteers, SJCG 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 Care Group, researchers having an association with the Care Group and any research involving patients, clients, residents, volunteers, health records, human biological materials of living or deceased individuals, staff or programs of the Care Group.

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 Care Group using the criteria described in the following documents as the minimum standards:
    - Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2),
    - 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, and
    - Quality of Care Information Protection Act (QCIPA), 2004.
- to review membership regularly to ensure composition and function according to the TCPS 2, 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 Care Group, 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 St. Joseph's Care Group which operates at arm's length from administrative, governance, programmatic, and research structures within St. Joseph's Care Group. 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.

St. Joseph's Care Group 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 current ethical and social teachings of the Catholic Church. Research protocols reviewed and approved by the REB may be subject to further feasibility reviews by the Leadership Team and/or the Board.

1.5 Appointment to the REB:

Members of the REB are appointed by the Board. Normally, REB members are appointed for a three year term, but shorter terms may be considered. Members may seek to serve multiple consecutive terms.

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 experience as a REB member. Normally, the REB Chair is appointed for a minimum of a two year term, renewable once.

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,
- at least one community representative having no affiliation with the Care Group*, and
- a staff member from the Research Ethics Office (permanent non-voting member).

* Due to the diversity of services provided by SJCG, 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 SJCG policies and relevant guidelines;
- to be available for expedited reviews and consultation regarding REB issues;
- to monitor the REB's decisions for consistency, to ensure that these decisions are recorded properly, and to ensure that researchers are given written communication of the REB's in a timely fashion.
- to recruit an 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 representatives 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 inform the REB Chair of required policies and procedures 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;
- to facilitate the application process for researchers submitting to the REB; and
- to monitor continuing ethics review.

1.9 Quorum:

Quorum is defined as a simple majority of REB members (50%+1), who collectively have sufficient expertise in the scientific, methodological and clinical areas of the research under review and are knowledgeable about relevant ethical and legal matters. The quorum will include at least one community member and a member whos primary experience and expertise are in a non-scientific discipline. Quorum includes REB members participating by telephone or video conference. Quorum also includes alternate REB members substituting for regular REB members in the same membership category.

1.10 Voting:

There shall be a requirement of a minimum of fifty percent (50%) plus one favourable vote of those member representatives 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 and/or human biological materials from living or deceased individuals 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 require expedited review,
   - B.2 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 protocol, re-approval, amendment or other submission to the REB:

1. approval, no revisions required.
2. minor clarifications/revisions requested by the REB, to be submitted and accepted 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 meeting.
5. not recommended for approval. Principal Investigator may request reconsideration.
6. decision deferred.
7. to suspend or terminate existing study approvals.

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.