CORPORATE POLICY AND PROCEDURE MANUAL
MANUEL DES POLITIQUES ET PROCÉDURES DE L'HOPITAL D'OTTAWA

SECTION : /

NO. / N : **BOARD POLICY XXXX**

ISSUED BY / PRÉPARÉE PAR : V.P. Research / V.-p. recherche

APPROVED BY / APPROUVÉE PAR :
Senior Management Committee / Comité de Haute Direction
TOH Board of Governors/
Scientific Advisory Committee/
UOHI Board of Directors/

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1. POLICY

1.1 The Board of Governors of The Ottawa Hospital (TOH) and the Board of Directors of the University of Ottawa Heart Institute (UOHI), the "Governors/Directors" delegate to the **Ottawa Health Science Network Research Ethics Board** (**OHSN-REB**) responsibility for the review and ethics oversight of all research involving human subjects/participants at TOH and the UOHI. This delegation may extend to other institutions by way of jurisdictional agreements, such as for applications submitted by members of the University of Ottawa (UO) or under the aegis of Clinical Trials Ontario (CTO).

1.2 The Governors/Directors through this policy establish a governance structure to provide the OHSN-REB with the mandate, autonomy, jurisdiction and authority to provide research ethics oversight of investigations conducted under its auspices and take reasonable measures to ensure that the roles and responsibilities of the OHSN-REB are defined, resources are made available and processes are in place to ensure compliance with relevant guidelines, applicable statutory and regulatory requirements. The Governors/Directors in collaboration with TOH Vice President Research and UOHI Vice President Research shall identify the Chair of the OHSN-REB who shall also chair the OHSN-REB Operations Committee. Formal procedures shall be in place for the selection, appointment, performance evaluations and terms of the OHSN-REB Chair, and Vice-Chairs.

1.3 OHSN-REB Operations Committee will be the administrative mechanism for the OHSN-REB, within the authorities established by its terms of reference. This committee guides the mandate, operations and jurisdiction of the OHSN-REB through the authority of this written governance policy and approved standard operating

procedures (SOPs) for established operations and processes of the OHSN-REB, board composition, and management of real or perceived undue influence or conflict of interest with respect to the establishment, operations and decision making of OHSN-REB. The OHSN-REB Operations Committee will develop, review and approve OHSN-REB SOPs, common consent form templates and internally prepared guidance documents for all researchers who submit to the OHSN-REB. OHSN-REB Operations Committee will be chaired by the OHSN-REB Chair and will be comprised of OHSN-REB members (voting), inclusive of the Chair and Vice-Chairs, with administrative representation (ex-officio) from Ottawa Hospital Research Institute (OHRI) in the Director and Manager overseeing the OHSN-REB administrative office, from UOHI a representative of Clinical Research Administration (ex-officio) and a representative from the UO (ex-officio). Formal procedures shall be in place for the selection, appointment, training, and terms of OHSN-REB members. **1.4** The Clinical Research Governing Council (CRGC) with representation from OHRI, UOHI/OHIRC and UO will receive updates on activities/issues of the OHSN-REB from the OHSN-REB Chair or his/her delegate at regular meetings. Due to the autonomy of the OHSN-REB, CRGC may provide guidance to the OHSN-REB Chair and Administrative Director and for information purposes will review Standard Operating Procedures (SOPs), guidance documents and templates previously agreed to and approved by the OHSN-REB Operations Committee to ensure alignment with TOH/OHRI, UOHI/OHIRC and UO policy. **1.5** The OHRI Senior Management Team (SMT) and UOHI Internal Scientific Advisory Committee (SAC) may review documents previously approved by the OHSN-REB Operations Committee and reviewed by CRGC, and may advise or suggest administrative revisions to ensure compliance with TOH/OHRI and UOHI/OHIRC policies and requirements. Documents will not be revised which pertain procedurally to the OHSN-REB's review of submissions for ethics approval and/or continuing surveillance, in order to preserve the OHSN-REB's independence from institutional or personal interests while considering and reaching decisions on the ethical aspects of activities under its jurisdiction and surveillance. Policy pertaining to OHSN-REB Governance must be approved by the highest authority of the institutions, the Governors/Directors. **1.6** OHSN-REB shall deliver a written report of its operations and the ensuing issues annually to the 'Governors/Directors' to assure continuing accountability and fulfillment of its mandate. A copy of the report may also be provided to the UO and other institutions who may specify the OHSN-REB as their board of record and other interested parties. **1.7** OHSN-REB is responsible to ensure that research involving the participation of humans meets current scientific and ethical research standards for the protection of human	

research participants.

1.8 OHRI will provide staff and resources to support the administrative tasks of OHSN-REB functions.

2. DEFINITIONS – see organizational chart- Appendix 1

OHSN-REB –Ottawa Health Science Network Research Ethics Board

OHSN-REB Operations Committee – the administrative mechanism of the REB, within the authorities established by its terms of reference; composed of a subset of OHSN-REB members, inclusive of the Chair and Vice-chairs, and a community OHSN-REB member, with administrative representation (ex-officio and non-voting) from OHRI in the Director and Manager overseeing the OHSN-REB administrative office, Senior Contracts Officer and from UOHI/OHIRC a member of Clinical Research Administration and a representative from UO. This committee guides the OHSN-REB Chair, and Vice-Chairs to fulfil the mandate of the OHSN-REB.

TOH Vice President Research – The VP Research is also the CEO and Scientific Director of the OHRI responsible for oversight of all Research conducted at TOH.

CRGC – Clinical Research Governing Council - research leaders, OHRI CEO, Chief Operating Officer (COO), Director Clinical Epidemiology Program, OHRI Administrative Director for Clinical Research, with representation from UOHI in the VP Research and administrative representation from UO. Guides the conduct of clinical research for OHRI, with recommendations regarding regulations, guidelines, and training.

OHRI – Ottawa Hospital Research Institute

OHRI SMT – Ottawa Hospital Research Institute Senior Management Team

UOHI – University of Ottawa Heart Institute and its research arm, the Ottawa Heart Institute Research Corporation (OHIRC)

UOHI SAC – UOHI/OHIRC Internal Scientific Advisory Committee

FDA – United States Food and Drug Administration

HC - Health Canada Food and Drug Regulations

OHRP – Office for Human Research Protections

UO – University of Ottawa

3. GOVERNANCE AND JURISDICTION

TOH and UOHI will rely on the service of the OHSN-REB to ensure scholarly review by ensuring compliance with the Scientific Review policies and scholarly standards of research proposals submitted to it and conducted within or by members

of the professional staff of TOH, the OHRI, the UOHI, the OHIRC and the UO. All research involving human participants requires REB review and approval before the research can begin.

3.1. The purpose of the OHSN-REB is to determine the ethical acceptability of all research involving human subjects at TOH and UOHI or by the investigators/personnel and OHSN-REB may assume responsibility for the review of applications from members of the UO by way of an agreement from the University of Ottawa. Scientific and scholarly assessment may be provided by the OHSN-REB, or if there is insufficient expertise, by experts not involved in the study either within the institutions, the Faculty or elsewhere.

3.2. The OHSN-REB may meet at any of the three TOH campuses, the UOHI, or at locations external to the involved institutions, at the call of the Chair and/or Vice-Chair(s) as deemed suitable to facilitate the work of the OHSN-REB. Meetings may be held via teleconferencing during publically declared emergencies.

3.3. The OHRI will provide administrative staff support for the activities of OHSN-REB including management of the application and review process for all submitted research projects. OHSN-REB administrative staff will work directly with the Chair/Vice-Chair(s) and will report administratively to the responsible OHRI administrative director. In case of conflicting instructions, decisions will be made using applicable guidelines, regulations and legislation.

3.4 There will be one OHSN-REB review for all of TOH, OHRI, UOHI, OHIRC and Faculties of UO (by mutual agreement), but administrative impacts may be carried out by each of the individual institutions, when deemed necessary and appropriate.

3.5 Administrative review will take place at relevant areas/departments of TOH/OHRI, UOHI/OHIRC, UO impacted by the proposed studies. Administrative approval cannot force the approval of a study refused by the OHSN-REB.

3.6 The OHSN-REB has the mandate to approve, reject, propose modifications to, renew, or terminate any proposed or ongoing research involving human subjects/participants that is conducted within, or by members of these institutions.

3.7 The OHSN-REB shall be responsible for the following tasks: reviewing all proposed research from scientific and ethical perspectives before the research is started; reviewing adverse event reports; conducting continuing review; and reviewing amendments before amendments are implemented.

3.8 The OHSN-REB may also suspend research deemed not to meet the standards established by the regulations and/or guidelines and/or legislation listed in section 9.

3.9 The OHSN-REB is guided by the following core principles as defined in Article l.1 of the Tri-Council Policy

Statement, "Ethical Conduct for Research Involving Humans: 1) Respect for Persons; 2) Concern for Welfare; and 3) Justice.

3.10 The OHSN-REB, the OHRI, and the UOHI, OHIRC shall monitor the activities of research involving human subjects (including breaches of privacy, disclosures of conflict of interest or of perceived conflicts of interest relevant to human research). The OHSN-REB fulfils this responsibility through continuing review of the research and review of unanticipated issues/problems. OHRI and UOHI/OHIRC administrations fulfill this responsibility through the conduct of internal audits and monitoring visits.

3.11 The OHSN-REB reports to the highest body of the institutions, the Governors/Directors.

3.12 The OHSN-REB meeting conducted at UOHI will specifically review the ethical acceptability of applications related to activity at the UOHI and other relevant protocols submitted by TOH investigators (e.g. vascular, thoracic, critical care).

3.13 Any policies and SOPs for the OHSN-REB will be written in compliance with Health Canada regulations, and adhere to existing guidelines (ICH-GCP), policy statement (current version of the Tri-Council Policy), Personal Health Information and Protection Act (PHIPA) and Research Ethics Oversight of Biomedical Clinical Trials from the Canadian General Standards Board, when available. The OHSN-REB will comply with American (FDA, OHRP) requirements, where applicable.

3.14 Policies, SOPs, guidance documents and templates will be reviewed and approved at the OHSN-REB Operations Committee. Subsequent review is provided by CRGC. OHRI SMT and UOHI SMT may provide additional review of documents approved by the OHSN-REB Operations Committee and reviewed by CRGC/SAC, to ensure compliance with TOH/OHRI/UOHI/OHIRC respective policies and requirements, while preserving the absolute requirement for the OHSN-REB to have full independence from institutional or personal interests when the OHSN-REB is considering and reaching decisions on the ethical aspects of activities under its jurisdiction and surveillance. While maintaining an arm's-length relationship, the Institutions retain the authority to disallow the conduct of research even if approved by the OHSN-REB. Policy pertaining to OHSN-REB governance must be approved by the highest authority of the institutions, the 'Governors/Directors'.

4. MANAGEMENT OF THE OHSN-REB

4.1 OHSN-REB Chair and Vice-Chairs

The OHSN-REB Chair/Vice-Chairs should normally be experienced and respected OHSN-REB members with at least two years' experience on an REB, and shall have a broad and deep knowledge of research ethics literature and debates,

national and international guidelines, regulations, policies and their application to the human subject research undertaken within the jurisdiction of the OHSN-REB.

4.2 Responsibilities of the OHSN-REB Chair

- Leads convened meetings
- Chairs the OHSN-REB Operations Committee
- Performs delegated review, or delegates authority to perform delegated review to an appropriate OHSN-REB member, when appropriate
- Is empowered, pending OHSN-REB review, to suspend the conduct of research deemed to place individuals at unacceptable risk
- Is empowered, pending OHSN-REB review, to suspend the conduct of research if he/she determines that an investigator is not following the OHSN-REB's policies or procedures or if there is evidence that the investigator is noncompliant with the regulations and/or guidelines and/or legislation listed in section 9
- Monitors the OHSN-REB's decisions for consistency and ensures that these decisions are recorded accurately and communicated clearly to the researchers in writing as soon as possible
- May delegate any of his/her responsibilities to other suitably qualified individual(s), as appropriate. Such delegation must be in writing
- Convenes administrative meetings with the Vice-Chairs, OHSN-REB Manager, OHRI Administrative Director responsible for the OHSN-REB, and UOHI VP Research or designate on a quarterly basis and notifies them of any major events
- Guides Administrative Manager of the OHSN-REB and Protocol Officers on correspondence to investigators

4.3 Responsibilities of the OHSN-REB Vice-Chairs

- Discharge the responsibilities of the Chair when the Chair is unable to do so
- Discharge the responsibilities assigned to them by the Chair
- Chair OHSN-REB meeting at any site
- Assist in the overall operation of the OHSN-REB
- Monitor the OHSN-REB's decisions for consistency and ensures that these decisions are recorded accurately and communicated clearly to the researchers in writing as soon as possible
- Guide Administrative Manager of OHSN-REB and Protocol Officers on correspondence to investigators

4.4 Selection, Term and Evaluation

- Selection of the OHSN-REB Chair shall be made by the VP Research TOH on the recommendation of the OHSN-REB Operations Committee and in consultation with the UOHI VP Research and the OHRI Administrative Director responsible for the OHSN-REB and Clinical Research
- Chair and/or Vice-Chairs will undergo regular

performance evaluations by the VP Research TOH and/or UOHI VP Research. Performance criteria will include the ability to fulfill the role, attendance at the OHSN-REB Operations Committee meetings, OHSN-REB meetings, compliance with OHSN-REB SOPs, guidelines, regulations and "Research Ethics Oversight of Biomedical Clinical Trials" by the Canadian General Standards Board (CGSB).

- Chair and/or Vice-Chairs will serve a term of up to five years, renewable. Suitability for renewal will be determined by the VP Research TOH in consultation with the OHRI Administrative Director responsible for the OHSN-REB and Clinical Research, and where UOHI is involved, in consultation with the UOHI VP Research and if deemed appropriate, the OHRI Administrative Director for the OHSN-REB.

5. BOARD COMPOSITION

5.1 The membership of the OHSN-REB will be in compliance with Health Canada, current Tri-Council Policy Statement (TCPS) on Ethical Conduct for Research Involving Humans (Article 6.4), The International Conference on Harmonisation Good Clinical Practices (ICH GCP 3.2.1), the Ontario Personal Health Information Protection Act (PHIPA) (S. 15), U.S. Food and Drug Administration Code of Federal Regulations (US FDA CFR 56.107), the CGSB Research Ethics Oversight of Biomedical Clinical Trials, and the Office for Human Research Protections (OHRP) (46.107).

5.2 A series of standard operating procedures (SOPs) detailing Board composition, appointment, resignation and removal process, duties, term, training requirements, provisions for ad hoc advisory process, quorum requirements, signing authority, application/submission procedures, review criteria, conflict management, and confidentiality. These SOPs have been subject to agreement and approval by the OHSN-REB Operations Committee and reviewed by the CRGC, OHRI SMT and UOHI SAC.

5.3 Individual members of the OHSN-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.

5.4 The UOHI/OHIRC may identify and appoint one Vice-Chair and OHSN-REB members for the OHSN-REB meetings held at UOHI for the review of applications related to activities at the UOHI and other relevant protocols submitted by TOH investigators (e.g. vascular, thoracic, critical care) to distribute volume of reviews between the three meeting locations. This Vice-Chair identification is conducted in collaboration with the UOHI VP Research, in consultation with the OHSN-REB Chair, and if deemed appropriate, VP Research of TOH and the OHRI

Administrative Director for the OHSN-REB.

6. RELATIONSHIP TO OTHER REBS

In consultation with OHSN-REB, TOH and UOHI may authorize OHSN-REB to provide review to other institutions or accept reviews undertaken by an external REB on the ethical acceptability of research. This authorization should be based on an explicit agreement which specifies adherence to current TCPS, and where applicable, Health Canada and other relevant regulations (e.g. FDA, U.S. 'Common Rule'); approvals based on cross-institutional agreements should be documented and reported to the full OHSN-REB, through the Chair and disclosed in organization policy. Agreements are currently in place as specified in *Appendix 2* to this policy.

7. RECONSIDERATIONS AND APPEALS

Where a researcher does not receive ethics approval, or receive approval conditional on revisions that they find compromise the feasibility or integrity of the proposed research, they are entitled to reconsideration by the OHSN-REB on substantive or procedural grounds. If that is not successful, they may appeal using the established mechanism in accordance with the institutions' procedures.

7.1 Researcher and the OHSN-REB should make every effort to resolve disagreements they may have through deliberation, consultation or advice.

7.2 The OHSN-REB must have an established procedure in place for handling appeals promptly.

7.3 The researcher and the OHSN-REB must have fully exhausted the reconsideration process and the OHSN-REB must have issued a final decision before the researcher initiates an appeal.

7.4 The Governors/Directors must appoint an ad hoc appeal committee that reflects a range of expertise, but does not include the OHSN-REB members who originally reviewed the research.

7.5 The appeal committee shall have the authority to review negative decisions, approve, reject or request modifications to the research proposal. Its decision on behalf of the institutions shall be final.

8. REB REVIEW DURING PUBLICLY DECLARED EMERGENCIES

8.1 Research ethics review during publicly declared emergencies may follow modified procedures and practices, but must be particularly vigilant, enhance ethics oversight, and exercise special diligence in respecting ethical principles, standard operating procedures and the law. It is recognized that outbreaks may provide particular need for research, particular opportunity for research, and particular vulnerability of research participants.

8.2 The OHSN-REB shall develop procedures for reviews during emergencies that take into account the following: a) what research is "essential" research during an emergency; b) the initial ethics review process of new research projects arising from the emergency; c) continuing ethics review of research undertaken prior to the occurrence of the emergency; and d) the ethics review process for changes to approved research that may require action very rapidly during emergencies.

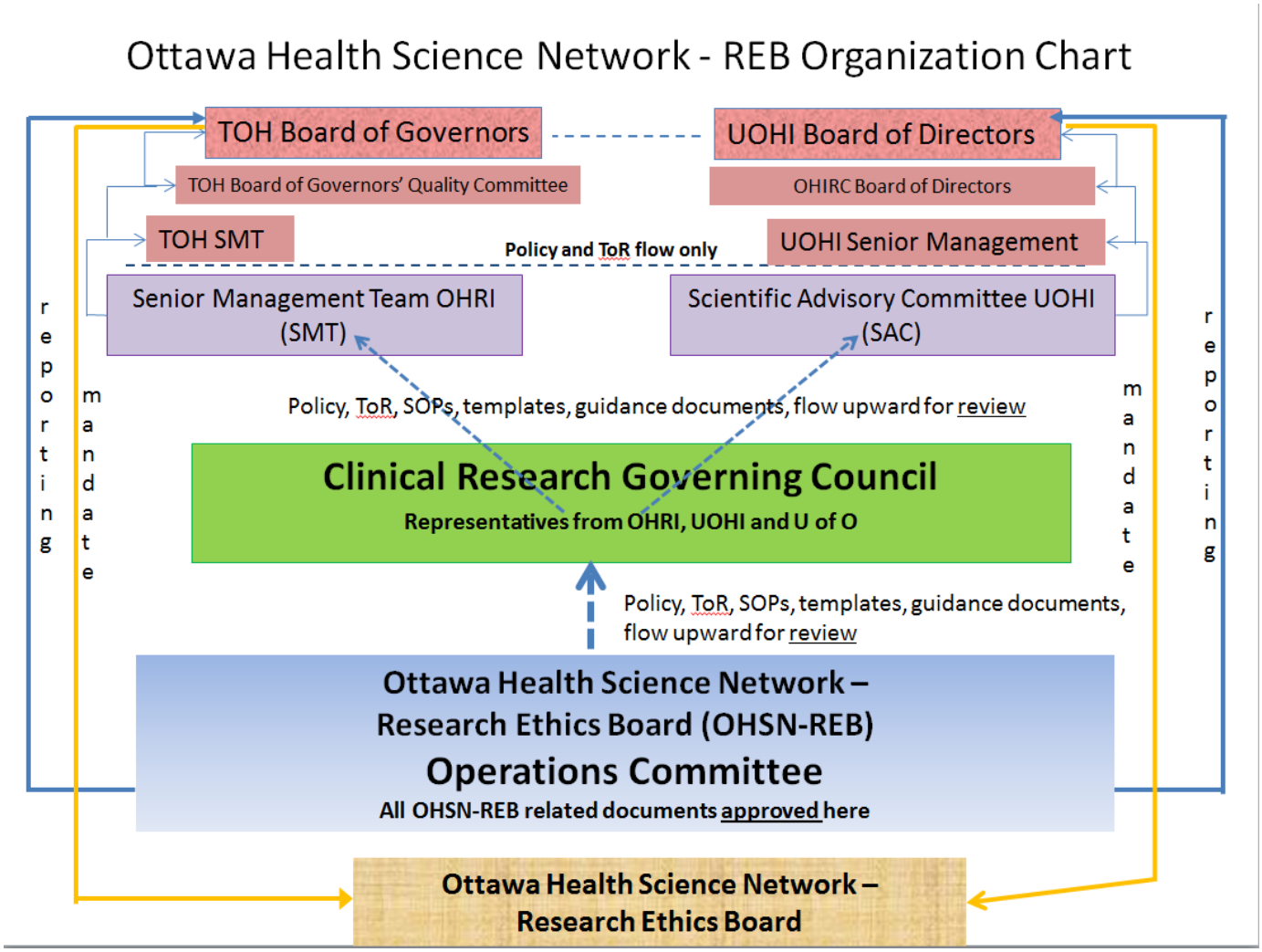
8.3 OHSN-REB procedures may warrant reasonable adjustments to address the timing, locale, expertise, form and scope of research ethics review, and the holding of OHSN-REB meetings during emergency situations. Special attention shall be given to procedures to review and approve research, quorum rules, or special agreements with other institutions, while considering the impact of the emergency on participants, researchers, REB members, institutional staff and others.

8.4 OHSN-REB and researchers should ensure that the risks and potential benefits posed by any proposed research during an emergency are appropriately evaluated.

9. RELATED POLICIES AND / OR LEGISLATION:

- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, (TCPS current version)
- The International Conference on Harmonization Guidelines for Good Clinical Practice, Section 3;
- Health Canada [Division 5, Part C.05.of the Food and Drug Act (clinical drug trials), Division 3 (PET tracers), Medical Device Regulations, Natural Health Product Regulations];
- Ontario Personal Health Information Protection Act (PHIPA)
- US Food and Drug Administration Code of Federal Regulations Title 21 Part 56.107;
- US Office for Human Research Protections 45 Code of Federal Regulations Title 46.107;
- US FDA Information Sheets, Guidance for Institutional Review Boards and Clinical Investigators
- Canadian Association of Research Ethics Boards Guidance on Reporting of Unanticipated Problems including Adverse Events to Research Ethics Boards in Canada (2010)
- US FDA Guidance for Industry and Investigators Safety Reporting Requirements for INDs and BA/BE Studies (2010)
- Research ethics oversight for biomedical clinical trials from the Canadian General Standards Board.

APPENDIX 1


Ottawa Health Science Network - REB Organization Chart
TOH Board of Governors
UOHI Board of Directors
TOH Board of Governors' Quality Committee
OHIRC Board of Directors
TOH SMT
Policy and ToR flow only
UOHI Senior Management
Senior Management Team OHRI (SMT)
Scientific Advisory Committee UOHI (SAC)
reporting
mandate
Policy, ToR, SOPs, templates, guidance documents, flow upward for review
Clinical Research Governing Council
Representatives from OHRI, UOHI and U of O
mandate
reporting
Policy, ToR, SOPs, templates, guidance documents, flow upward for review
Ottawa Health Science Network – Research Ethics Board (OHSN-REB)
Operations Committee
All OHSN-REB related documents approved here
Ottawa Health Science Network – Research Ethics Board

APPENDIX 2
RELATIONSHIP TO OTHER REBS

In consultation with the OHSN-REB, TOH /UOHI may authorize the OHSN-REB to accept reviews undertaken by an external REB on the ethical acceptability of research. This authorization should be based on an explicit agreement which specifies adherence to current TCPS, and where applicable, Health Canada and other regulations (e.g., FDA, U.S. 'Common Rule'). Approvals based on cross-institutional agreement should be documented and reported to the full OHSN-REB, through the Chair and disclosed in organization policy. Agreements are currently in place as specified:

1. The University of Ottawa - jurisdictional agreement
2. Ontario Cancer Research Ethics Board (OCREB) - reciprocity agreement
3. Bruyère Continuing Care agreement to serve as their appeals process committee; reciprocity agreement (pending) for minimal risk studies and OHSN-REB review of studies requiring full board review involving TOH and EBRI patients and investigators.
4. Clinical Trials Ontario (CTO) – reciprocity agreement (pending).
    a. OHSN-REB will participate in the rotational review process of multicentre trials submitted to CTO as a designated, qualified REB.
    b. TOH and UOHI will accept REB reviews done under the aegis of CTO for multi-centre trials in which TOH or UOHI investigators are involved.
    c. Investigators at TOH and UOHI may submit to CTO for the ethical review of their multi-centre investigations.
5. Children's Hospital of Eastern Ontario (CHEO) – reciprocity agreement (in-progress)
6. Royal College of Physicians and Surgeons – jurisdictional agreement (in-progress)

Additional agreements may be added as deemed appropriate by OHSN-REB Operations Committee.