OTTAWA HEALTH SCIENCE NETWORK RESEARCH ETHICS BOARD GOVERNANCE POLICY

APPROVED BY:	APPROVAL DATES
TOH Board of Governors	Date Initially Issued: 2013/April/03
UOHI Board of Directors/OHIRC Board of Directors	Date Last Reviewed/ Revised:2025/April/30
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Policy Purpose:
In compliance with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)*, institutions must establish a Research Ethics Board (REB) to review the ethical acceptability of all human research conducted under their authority.

The Ottawa Health Science Network Research Ethics Board (OHSN-REB) has been established to oversee the ethical review and approval of all human research conducted at The Ottawa Hospital (TOH) and the University of Ottawa Heart Institute (UOHI). The Ottawa Heart Institute Research Corporation (OHIRC) is the research and contracts arm of UOHI.

Scope:
This policy applies to the governance, oversight, and management of the OHSN-REB, including the roles and responsibilities of individuals and bodies involved in governing the ethical review process for human research at TOH and UOHI.

1. GOVERNANCE STRUCTURE

1.1. **Delegation of Authority:**
The Board of Governors of TOH and the Board of Directors of UOHI ("Governors/Directors") delegate to the **OHSN-REB** responsibility for the review and ethics oversight of all research involving human participants at TOH and the UOHI or conducted under their auspices; by their faculty, staff or students, regardless of where the research is conducted. This delegation may extend to other institutions, by way of jurisdictional agreements, or under the aegis of Clinical Trials Ontario (CTO).

1.2. **Governance:**
The Governors/Directors, through this policy and in collaboration with the TOH Executive Vice President, Research and Innovation (TOH EVP Research & Innovation) and UOHI Vice President Research / OHIRC Chief Scientific Officer (UOHIVP Research/OHIRC CSO), 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 OHSN-REB Chair, established through a formal process, also Chairs the OHSN-REB Operations Committee which guides administrative operations and procedures. Formal procedures shall be in place for the selection, appointment, performance evaluations and terms of the OHSN-REB Chair, and Vice-Chairs (refer to Selection, Term and Evaluation below).

1.3. **Operations Committee:**
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, 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.

OHSN-REB Operations Committee will be chaired by the OHSN-REB Chair with representation from OHSN-REB board members (voting), inclusive of the Chair and Vice-Chairs, a TOH Ethicist/delegate (voting) and with administrative representation (ex-officio) from Ottawa Hospital Research Institute (OHRI) in the Director and Manager overseeing the OHSN-REB administrative office, from OHIRC a representative of Clinical Research Administration (ex-officio) and a representative from the University of Ottawa (UO) (ex-officio). Formal procedures shall be in place for the selection, appointment, training, and terms of OHSN-REB board members.

The OHSN-REB Operations Committee (or delegated working group under its auspices) 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.

1.4. **Reporting:**
The TOH EVP Research & Innovation and UOHI VP Research/OHIRC CSO will receive updates on activities/issues of the OHSN-REB from the OHSN-REB Chair or their delegate and may provide guidance to the OHSN-REB Chair and OHSN-REB Administrative Director and for information purposes may review SOPs, guidance documents and templates previously agreed to and approved by the OHSN-REB Operations Committee to ensure alignment with TOH,OHRI, UOHI and/or OHIRC policies.

The OHRI Senior Leadership Team (SLT) and UOHI Scientific Advisory Committee (SAC) may review documents previously approved by the OHSN-REB Operations Committee and may advise or suggest administrative revisions to ensure compliance with TOH, OHRI, UOHI and OHIRC policies and requirements.

OHSN-REB shall deliver an annual report to the Governors/Directors (via the TOH Governance & Partnerships Committee and OHIRC Board of Directors) addressing governance and operational matters including non-compliance with legal and ethical standards (including TCPS2) and performance/fulfillment of the REB's mandate pursuant to the delegated authority. A copy of the report may also be provided to other institutions who may specify the OHSN-REB as their board of record.

1.5. **Autonomy:**
The OHSN-REB operates with full autonomy in its ethical review and decision-making processes. It is independent from institutional or personal interests, ensuring that all research involving human participants is evaluated solely on current scientific and ethical research standards for the protection of human research participants.

OHSN-REB members and the REB's decisions are free from undue influence by researchers, sponsors, or institutional administration. The board's authority includes the ability to reject, approve, propose modifications to, renew, or terminate any proposed or ongoing research involving human participants, as necessary, to protect participants and maintain ethical standards.

Policy pertaining to OHSN-REB Governance must be approved by the highest authority of the institutions - the Governors/Directors. Any governance or policy-related changes must preserve REB's independence.

2. JURISDICTION AND MANDATE

2.1. The OHSN-REB is guided by the following core principles as defined in TCPS2 1) Respect for Persons; 2) Concern for Welfare; and 3) Justice.

2.2. 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 the professional staff of TOH, the OHRI, the UOHI, the OHIRC, and the UO who hold a research appointment with OHRI and/or OHIRC. All research involving human participants requires REB review and approval before the research can begin.

2.3. OHSN-REB is responsible for determining the ethical acceptability of all research involving human participants at TOH and UOHI or conducted by the investigators/personnel at TOH and UOHI and OHSN-REB may assume responsibility for the review of applications from other institutions by way of an agreement.

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

2.5. The OHSN-REB members may convene in-person or virtually, at the call of the Chair and/or Vice-Chair(s) as deemed suitable to facilitate the work of the OHSN-REB.

2.6. There will be one OHSN-REB ethics review for all TOH, OHRI, UOHI, OHIRC and Faculties of UO (by mutual agreement when research involves staff or patients at TOH and UOHI). Administrative impacts/review or registration may be carried out by each of the individual institutions, when deemed necessary and appropriate.

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

2.8. The OHSN-REB may also suspend research deemed not to meet the standards established by the guidelines, regulations and/or legislation listed in section 8 of this policy.

2.9. The OHSN-REB, the OHRI, and the UOHI, OHIRC shall monitor the ongoing activities of research involving human participants for instances of 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.

2.10. Any policies and SOPs for the OHSN-REB will be written in compliance with Health Canada regulations and adhere to existing guidelines (International Conference on Harmonization Guidelines for Good Clinical Practice), policy statements (TCPS2), and Personal Health Information and Protection Act (PHIPA). The OHSN-REB will comply with American (Food and Drug Administration (FDA) and Office of Health Research Protections (OHRP)) requirements, where applicable.

3. MANAGEMENT OF THE OHSN-REB

3.1. **OHSN-REB Chair and Vice-Chairs**
The OHSN-REB Chair/Vice-Chairs should normally be experienced members of OHSN-REB and/or shall have a broad and deep knowledge of research ethics national and international guidelines, regulations, policies, and their application to human participant research undertaken within the jurisdiction of the OHSN-REB.

3.2. **Responsibilities of the OHSN-REB Chair**
The Chair leads OHSN-REB meetings and the Operations Committee, performs or delegates reviews, and can suspend research for safety or noncompliance. They ensure decisions are consistent, recorded, and communicated promptly, and may delegate tasks to qualified OHSN-REB board members. The duties of the Chair are further detailed in the OHSN-REB SOPs.

3.3. **Responsibilities of the OHSN-REB Vice-Chairs**
The OHSN-REB Vice-Chairs assume the Chair's responsibilities when needed, perform tasks assigned by the Chair, chairs OHSN-REB meetings at any site, and assist in the REB's overall operations. They ensure decisions are consistent, accurately recorded, and clearly communicated to researchers, and guide administrative staff on correspondence with investigators. The duties of the Vice-Chair are further detailed in the OHSN-REB SOPs.

3.4. **Selection, Term and Evaluation**

3.4.1. The OHSN-REB Chair shall be identified jointly by the TOH EVP Research & Innovation and the UOHI VP Research/OHIRC CSO, based on the recommendation of the OHSN-REB Operations Committee and in consultation with the OHSN-REB Administrative Director. The appointment will proceed with the approval of both the TOH EVP Research & Innovation and the UOHI VP Research/OHIRC CSO.

3.4.2. OHRI will identify and appoint one Vice-Chair responsible for reviewing applications primarily related to activities at TOH and other relevant protocols submitted by UOHI investigators. Identification and appointment of this Vice-Chair is conducted by the TOH EVP Research and Innovation, in consultation with the OHSN-REB Chair and OHSN-REB Administrative Director.

3.4.3. The UOHI and OHIRC will identify and appoint one Vice-Chair that will be responsible for OHSN-REB meetings held at UOHI for the review of applications primarily related to activities at the UOHI and other relevant protocols submitted by TOH investigators. Identification and appointment of this Vice-Chair is conducted by the UOHI CSO & VP Research, in consultation with the OHSN-REB Chair, OHSN-REB Administrative Director.

3.4.4. Chair will undergo annual performance evaluations by the TOH EVP Research & Innovation and UOHI VP Research/OHIRC CSO. Vice-Chair of TOH activities will undergo annual performance evaluations by the TOH EVP Research & Innovation. Vice-Chair of UOHI activities will undergo annual performance review by the UOHI VP Research/OHIRC CSO.

3.4.5. Chair will serve a term of up to five years, renewable. Suitability for renewal of Chair will be determined by the TOH EVP Research & Innovation and the UOHI VP Research/OHIRC CSO in consultation with the OHSN-REB Administrative Director. Suitability for renewal of Vice-Chair of TOH activities will be determined by the TOH EVP Research & Innovation, in consultation with the OHSN-REB Administrative Director. Suitability for renewal of Vice-Chair of UOHI activities will be determined by the UOHI VP Research/OHIRC CSO in consultation with the OHSN-REB Administrative Director. The Chair and Vice-Chairs will fulfill their duties in accordance with their employment contract.

3.5. Operational Support:

OHRI and OHIRC will provide proportionate funds to employ administrative staff support for the administrative and operational activities of OHSN-REB including OHSN-REB Administrative Director, REB Manager and Research Ethics Coordinators and support staff. OHSN-REB administrative staff will manage the application and review process for all submitted research projects, working directly with the Chair/Vice-Chair(s) and will report administratively to the responsible OHSN-REB Administrative Director .

OHRI will provide technical oversight of the electronic application system developed by OHRI Digital Solutions and overseen by the responsible OHRI Director. The Operations Committee (or delegated working group under its auspices) will create and approve the research ethics content and technical flow of the electronic application system. OHRI and OHIRC will create and approve the institutional content and technical flow of the electronic application system.

4. BOARD COMPOSITION

4.1. OHSN-REB operates in compliance with, and is constituted in accordance with, the requirements of TCPS2 and all other policies, regulations and legislation detailed in section 8 of this policy.

4.2. OHSN-REB is qualified through the CTO REB Qualification Program and is registered with the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protection (OHRP).

4.3. A series of SOPs details requirements for 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.

4.4. 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 participants or human materials protection.

5. RELATIONSHIP TO OTHER REBS

5.1. OHSN-REB provides reviews to other institutions and accepts reviews undertaken by external REBs on the ethical acceptability of research through its qualification and agreement with CTO.

5.2. Jurisdictional Agreements: TOH and UOHI may enter into agreements with other institutions on behalf of OHSN-REB, to review or accept reviews from external REBs. Such agreements specify adherence to current TCPS, and where applicable, Health Canada and other relevant regulations (e.g. FDA, U.S. 'Common Rule'). TOH has delegated its contract review and negotiation responsibility for jurisdictional agreements to the OHRI Contracts Office. UOHI has delegated its contract review and negotiation responsibility for jurisdictional agreements to OHIRC Legal Affairs.

6. RECONSIDERATIONS AND APPEALS

6.1. Where a researcher does not receive ethics approval or if approval is conditional on revisions that limit or compromise the feasibility or integrity of the proposed research, they are entitled to reconsideration by the OHSN-REB on substantive or procedural grounds. All approvals or refusals will be issued in writing, including the reasons for the decision. If reconsideration has been fully exhausted, they may appeal using the established appeals procedures.

6.2. The OHSN-REB Operations Committee, under the authority delegated by the Governors/Directors, will establish an appeal process that will ensure fair and unbiased review of OHSN-REB decisions.

7. REB REVIEW DURING PUBLICLY DECLARED EMERGENCIES

7.1. Research ethics review during publicly declared emergencies may follow modified procedures and practices, but must exercise special diligence in respecting ethical principles, OHSN-REB SOPs, and applicable laws and policies (including public health guidance). It is recognized that outbreaks may provide particular need for research, particular opportunity for research, and particular vulnerability of research participants.

7.2. 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.

7.3. 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.

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

8. RELATED POLICIES AND LEGISLATION:

OHSN-REB operates under a broad range of policies, regulations, and legislation, including:

- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, (TCPS 2 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)
- Canadian Association of Research Ethics Boards (CAREB) Standard Operating Procedures

RESEARCH ETHICS BOARD GOVERNANCE

APPENDIX 1