**RESEARCH ETHICS BOARD – TERMS OF REFERENCE**

# POLICY

* 1. The Board of Trustees of the Royal Ottawa Health Care Group (ROHCG) delegates to the Royal’s Research Ethics Board (REB) responsibility for the review and ethics oversight of all research involving human participants at The Royal Ottawa Mental Health Centre (ROMHC), The Institute of Mental Health Research (IMHR), The Royal Brockville Mental Health Centre (BMHC), the Community Mental Health Program (Carlingwood), and the Atlas Institute for Veterans and Families (Atlas). This delegation may extend to other institutions such as for applications submitted by members of the University of Ottawa (UO) and Carleton University (CU) who are involved in partnerships with the ROHCG.
	2. The ROHCG Board of Trustees, through this policy, establishes a structure to provide the REB with the mandate, autonomy, jurisdiction and authority to provide research ethics oversight of research investigations, and takes reasonable measures to ensure that the roles and responsibilities of the REB are defined, resources are available and processes are in place to ensure compliance with relevant guidelines and applicable regulatory requirements.
	3. The ROHCG Board of Trustees will receive quarterly updates on activities/issues of the REB from the REB Chair or their delegate at regular meetings.
	4. The REB will deliver a written report of its operations and the ensuing issues and mitigation strategies quarterly and annually to the ROHCG Board of Trustees to ensure continuing accountability of its mandate.
	5. Given the specific institutional eligibility requirements to administer grants funds (e.g. Canadian federal funding agencies (Tri-Council CIHR, NSERC, SSHRC \* see section 2.0), and in line with the institutional policies on Responsible Conduct of Research (ROHCG CORP III – 140, UO Policy 115), there is an indirect ad hoc reporting arrangement in which the ROHCG REB and the University (UO) agree to inform each other, via the IMHR, of any issues arising relating to University research of which they become aware, including those relating to ethics, participant safety or scientific integrity. The reporting line is expressed in a MOU Authorization Agreement with regard to the University’s recognition of ethical approvals granted by the ROHCG REB, which involves research grant funding flowing from/to the University in which research is conducted by University of Ottawa-affiliated employees, academic staff, trainees, postdoctoral fellows and students at the ROHCG.
	6. The REB is responsible to ensure that research involving human participants meets current scientific and ethical research standards for the protection of human research participants.
	7. The IMHR will provide staff and resources to support the administrative tasks of the REB office functions.

# 2.0 DEFINITIONS

**REB –** Research Ethics Board

**IMHR –** Institute of Mental Health Research **ROHCG –** Royal Ottawa Health Care Group **ROMHC -** Royal Ottawa Mental Health Centre

**Atlas –** Atlas Institute for Veterans and Families

**BMHC –** Brockville Mental Health Centre

**UO –** University of Ottawa

**CU –** Carleton University

**CIHR -** Canadian Institutes of Health Research

**NSERC -** Natural Sciences and Engineering Research Council of Canada

**SSHRC -** Social Sciences and Humanities Research Council

**FDA –** United States Food and Drug Administration

**HC –** Health Canada

**OHRP –** Office for Human Research Protections

**ICH-GCP –** International Conference on Harmonisation-Good Clinical Practice

**TCPS2 –** Tri-Council Policy Statement “Ethical Conduct for Research Involving Humans”

**QARE –** Quality Assurance for Research Excellence

**SOP –** Standard Operating Procedure

**PHIPA –** Personal Health Information Protection Act

# GOVERNANCE AND JURISDICTION

Through ongoing oversight and reporting activities, the REB is responsible for ensuring that research involving human participants meets current scientific and ethical research standards for the welfare, and experience of human research participants. The IMHR and the ROHCG will rely on the service of the 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 the IMHR, ROHCG, BMHCG, CU and the UO. All research involving human participants requires REB review and approval before the research can begin.

* 1. The purpose of the REB is to determine the ethical acceptability of all research involving human participants at the ROHCG or by the investigators/personnel of the institution. The REB will assume responsibility for the review of applications from members of CU and UO in accordance with agreements held with these universities. Ethical assessment will be provided by the REB, or if there is insufficient expertise, by experts not involved in the study within either the institution, or elsewhere. The REB has a responsibility to focus on the ethical implications of a proposed study rather than issues related to study content or scientific design. Unless there is a significant concern that impacts ethical acceptability, REB members must avoid critiquing the studies under review.
	2. The REB will meet at the ROMHC, virtually, or at locations external to the involved institutions at the call of the Chair and/or Vice Chair as deemed suitable to facilitate the work of the REB.
	3. The IMHR will provide administrative staff support for the activities of the REB including management of the application and review process for all submitted research projects. Administrative staff will work directly with the REB Chair/Vice-Chair and will report administratively to the IMHR President/ROHCG Vice-President Research via their delegate.
	4. The 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 the ROHCG.
	5. The REB will be responsible for the following tasks: reviewing all proposed research from ethical perspectives before the research is started; reviewing adverse event reports; conducting continuing annual review; and reviewing amendments before amendments are implemented.
	6. The REB may suspend research deemed not to meet the standards established by the regulations and/or guidelines and/or legislation listed in section 9.
	7. The REB is guided by the following core principles as defined in Article 1.1 of TCPS2 – Tri-Council Policy Statement “Ethical Conduct for Research Involving Humans” \*\*: 1) Respect for persons; 2) Concern for Welfare; 3) Justice.
	8. The REB and the IMHR shall monitor the activities of research involving human participants on an ongoing basis (including breaches of privacy, disclosures of conflict of interest or of perceived conflicts of interest related to human research). The REB fulfills this responsibility through continuing review of the research and review of unanticipated issues/problems. IMHR fulfills this responsibility through the conduct of internal audits (Quality Assurance for Research Excellence (QARE) Program).
	9. The REB reports to the highest body of the institutions, the ROHCG Board of Trustees.
	10. Any policies and SOPs for the REB will be written in compliance with Health Canada regulations, and adhere to existing guidelines (ICH-GCP), TCPS2, Personal health Information Protection Act (PHIPA). The REB will comply with American (FDA, OHRP) requirements, where applicable.

\*\* TCPS2 current version: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022)
[Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022) (ethics.gc.ca)](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html)

# MANAGEMENT OF THE REB

* 1. **REB Chair and Vice-Chair(s)**

The REB Chair/Vice-Chair should be experienced and respected REB member with at least two (2) years of experience serving 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 participant research undertaken within the jurisdiction of the REB.

# Responsibilities of the REB Chair

* + - Leads convened meetings
		- Performs delegated review, or delegates authority to perform delegated review to an appropriate REB member when appropriate.
		- Is empowered, pending REB review, to suspend the conduct of research if they determine that an investigator is not following the REB’s policies or procedures or if there is evidence that the investigator is non- compliant with the regulations and/or guidelines and or legislation listed in section 9.
		- Monitors the REB’s decisions for consistency and ensures these decisions are recorded accurately, and communicated clearly to the Investigators in writing as soon as possible.
		- May delegate any of their responsibilities to other suitably qualified individual(s) as appropriate. Such delegation must be in writing.
		- Convenes administrative meetings with the Vice-Chair(s), IMHR Clinical Research Support Manager, and IMHR President/ROHCG Vice-President Research or designate on a quarterly basis and notifies them of any major events.
		- Guides the IMHR Clinical Research Support Manager and the REB Office Coordinator(s) on correspondence to investigators.

# Responsibilities of the Vice-Chair

* + - Undertake the responsibilities of the Chair when the Chair is unable to do so.
		- Carry out the responsibilities assigned to them by the Chair.
		- Chair the REB meeting as required.
		- Assist in the overall operation of the REB.
		- Monitor the REB’s decisions for consistency and ensure that the decisions are recorded accurately and communicated clearly to the Investigators in writing as soon as possible.
		- Guide the Clinical Research Support Manager and REB Coordinator(s) on correspondence to investigators.

# Selection, Term and Evaluation

* + - Following a call for nominations, a short list of candidate(s) will be recommended by the ROHCG President/CEO, IMHR President/ROHCG Vice-President Research, ROHCG Psychiatrist-in-Chief/Chief of Staff, and Atlas President/CEO to the ROHCG Quality Committee, who in turn will provide the final recommendation to the ROHCG Board of Trustees.
		- The REB Chair and/or Vice-Chair(s) will undergo annual performance evaluations. Performance criteria will include the ability to fulfill the role, attendance at REB meetings, compliance with REB SOPs, guidelines and regulations, as per description of the role. Board discussions may occur in a closed or restricted session.
		- Performance evaluations: with input from the ROHCG President/CEO, IMHR President/ROHCG Vice-President Research, ROHCG Psychiatrist-in-Chief/Chief of Staff, and Atlas President/CEO, the ROHCG Quality Committee will report on the REB Chair performance evaluation to the ROHCG Board of Trustees. Evaluation may include a meeting between the REB Chair and the ROHCG Quality Committee.
		- The REB Chair and/or Vice-Chairs will serve a term of up to three (3) years, renewable twice, for up to a maximum of three (3) terms. Suitability for renewal: with input from the ROHCG President/CEO, IMHR President/ROHCG Vice-President Research, ROHCG Psychiatrist-in-Chief/Chief of Staff, and Atlas President/CEO, the ROHCG Quality Committee will recommend renewals to the ROHCG Board of Trustees.
		- REB members will serve a term of three (3) years. At the request of the Chair of the REB, and by mutual agreement between the REB member and the Chair of the REB, the REB member’s term may be renewed, for up to a maximum of three (3) consecutive terms.

# BOARD COMPOSITION

* 1. The membership of the 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 Council for Harmonisation Good Clinical Practice Guidelines (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), and the Office for Human Research Protections (OHRP) (46.107).
	2. 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 IMHR President/ROHCG Vice-President Research or delegate, REB Chair, and the IMHR Clinical Research Support Manager.
	3. Individual members of the REB must be qualified through training, experience, and expertise to assess the acceptability of proposed research in terms of ethical principles and applicable regulations, guidelines and standards related to human participants or human materials protection.
	4. Quorum shall consist of at least five (5) REB members (except REB Chair), including (at minimum):
* two (2) members with expertise in the relevant disciplines, fields and methodologies covered by the REB
* one (1) member who is primarily experienced in non-scientific disciplines
* one (1) member knowledgeable in ethics
* one (1) member from the community who has no affiliation with the organization(s) and who is not part of the immediate family of a person who is affiliated with the organization
* one (1) member knowledgeable in the relevant law (for biomedical research) additional representation as required by applicable legislation or guidelines

Exception: For research subject to the US Code of Federal Regulations, quorum shall consist of one half of REB voting members (except REB Chair) plus one.

* 1. All members shall be without conflict of interest in the review/approval process and shall disclose actual, perceived or potential conflicts of interest at the outset of the meeting. Only those REB members who are independent of the investigator and the sponsor of a trial should participate in the initial or continuing review of any protocol or provide an opinion on a protocol-related matter, expect to provide information requested by the REB.

In the event that the REB Chair and REB Vice-Chair are unable to fulfill their duties as chair due to a conflict of interest, the most senior REB member (based on years of membership) shall function as chair in their stead.

**5.6.** There shall be French-speaking representation on the REB

# MEETING FREQUENCY AND ATTENDANCE

* 1. Meetings will be held on a monthly basis, and additionally at the call of the Chair.
	2. REB members are expected to attend every REB meetings as well as scheduled educational events/opportunities. Failure to attend a minimum of 66% of the meetings without explanation may be grounds for membership termination from the REB.

# RECONSIDERATION

# Investigators have the right to request, and the REB has an obligation to provide, reconsideration of an REB decision.

Where a study is reviewed and not approved, or where approval is conditional upon revisions to the study which the investigator believes may compromise the feasibility or integrity of the proposed research, the Investigator has a right to request re-consideration by the REB on substantive or procedural grounds. Investigators and REB are expected to engage in meaningful discussions together to ensure high-quality, ethical research.

* 1. The investigator may seek reconsideration by submitting a written Request for Reconsideration to the REB Chair within thirty (30) calendar days of receipt of the REB’s written decision.
	2. The Request for Reconsideration letter must provide justification for the request based on substantive grounds (e.g. noncompliance with a specific article of TCPS2 or a relevant regulation or guideline), or substantive changes to the study from time of the REB’s original review and decision. The onus is on the investigator to justify the Request for Reconsideration by providing evidence of study changes or noted breaches to the research ethics review process.
	3. The REB Chair will ensure the requirements are met and confirm receipt of the request in a timely manner.
	4. The REB Chair will present the Request of Reconsideration at the next scheduled REB meeting.
	5. The REB will review the request and vote to approve, reject or request modifications to the research proposal in their reconsideration decision.

# NOTICE OF APPEAL

# Investigators and the REB must have fully exhausted the reconsideration process and the REB must have issued a final decision before an investigator initiates an appeal. The appeal process is not a forum to merely seek a second opinion.

* 1. Investigators must submit a written Notice of Appeal within thirty (30) calendar days of the REB’s final written decision.
	2. The appeal must be made in writing and must clearly state the grounds upon which the appeal is filed. An appeal must be based on procedural grounds (i.e. that the review or reconsideration process did not comply with the REB’s terms of reference, written procedures or policies) or substantive grounds (e.g., noncompliance with a specific article of the TCPS2 or a relevant regulation or guideline).
	3. The written Notice of Appeal should be accompanied by all supporting documentation including:
1. The original ethics application,
2. The original REB decision,
3. All subsequent written communications between the REB and the investigator,
4. The final reconsideration decision;
5. Written documentation of the evidentiary basis and rationale for the appeal including relevant
references or copies of pertinent guidelines, internal and external policies, and legislation; and
6. Any other relevant documents and records.
	1. The appeal documentation package will be reviewed by the Chair of the Quality Committee (or delegate) upon receipt. Incomplete appeals packages will be returned to the investigator and the investigator will be required to submit a complete package within fifteen (15) days or the appeal will be dismissed.
	2. The Chair of the Quality Committee will notify the investigator and the Chair of the REB once all documents are received.
	3. The ROHCG Board of Trustees, through the Quality Committee, if appropriate, will appoint a minimum of three (3) members to the Research Ethics Appeal Committee (“Appeal Committee”) for the purpose of hearing the appeal.
	4. The composition of the Appeal Committee must reflect the range of expertise and knowledge appropriate to the decision that is being appealed.
	5. All members of the Appeal Committee must be free of conflicts of interest in relation to the study under review. Members of the REB, involved in the initial review of the proposed study may not participate on the appeal committee.

Appeal Procedure

* 1. The onus is on the investigator making the appeal to justify the grounds on which the appeal is requested and to indicate any breaches to the research ethics review process or any elements of the REB decision that are not supported by the TCPS2 or the IMHR policy on the ethical conduct of research involving human participants.
	2. The Appeal Committee shall have the authority to approve, reject or request modifications to the research proposal. Its decision shall be final.
	3. The REB Coordinator will assemble and distribute the Notice of Appeal and supporting documentation (including the REB minutes pertaining to the submission) to the Appeal Committee for review, with a copy to the Chair of the REB whose decision is under review and to the investigator.
	4. The appeal committee will have thirty (30) days to review the file and a meeting will be scheduled on or before the final working day. The investigator and the REB Chair (or delegate) may appear before the Appeal Committee. Each party may be assisted by an advisor who may be present during the meeting. None of these parties will be present during the deliberation and decision-making by the Appeal Committee.
	5. During the meeting, the Investigator will present evidence to support the grounds for the appeal (article 8.3). The Chair of the REB will have an opportunity to respond. The Appeal Committee has the right to question both parties. Each party will be provided a single opportunity to summarize their respective statements, with the investigator speaking last. Both parties will be excused from the meeting, at which time deliberations will occur. The Chair of the Appeal Committee will provide a written decision of the Appeal Committee related to the grounds of the appeal with copies to the investigator and the REB within seven (7) working days after the meeting at which the decision was reached. The Appeal Committee will find one of the following:
* Approved as submitted, the decision of the REB is overturned
* Declined as submitted, the decision of the REB is upheld
* Modifications are proposed and the final decision is pending. In this case, the investigator will have thirty (30) days to make the modifications and submit updated documentation to the Appeal Committee for review.

If the investigator does not respond to the request for modifications within thirty (30) days, the notice of appeal will be declined and the REB decision will be upheld.

* 1. The Chair of the REB will be responsible for any implementation and follow up required through the REB.

# INTERNAL RECONSIDERATIONS AND APPEALS

# REB members have the right to request, and the REB Chair has an obligation to provide, reconsideration of an REB Chair decision (or acting Vice-Chair) made as an administrative decision. For the purposes of this process, an administrative decision is a decision made by the REB Chair (or acting Vice-Chair) without the consultation of any other REB member. Decisions made by REB members other than the REB Chair (or acting Vice-Chair), including Full Board, are not eligible for this process.

# Where a study is reviewed and a decision is made by the REB Chair which an REB member believes may violate the ethical integrity upheld by the REB, the REB member has a right to request re-consideration by the REB Chair on substantive or procedural grounds by providing a written request within thirty (30) calendar days of the decision. REB member and REB Chair are expected to engage in meaningful discussions together to ensure high-quality, ethical research.

# If the REB member and REB Chair have fully exhausted the reconsideration process, the REB Chair will present the written reconsideration request at the next scheduled REB meeting.

# The REB will review the request and vote on whether to uphold the original decision by the REB Chair or to provide a different decision. The decision made by the REB will be final.

# REB REVIEW DURING PUBLICLY DECLARED EMERGENCIES

* 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.
	2. Procedures will be developed by the REB to detail how reviews will be conducted during an emergency. The following will be taken into account: 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.
	3. The REB and investigators should ensure that the risks and potential benefits posed by any proposed research during an emergency are appropriately evaluated.

# RELATED POLICIES AND/OR LEGISLATION

* + - Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS Current Version)
		- The International Council for Harmonisation 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, and the Natural and Non-Prescription Health Product Regulations];
		- Ontario Personal health Information Protection Act (PHIPA)
		- US Food and Drug Administration (FDA) code of Federal Regulations, Title 21, Part 56.107;
		- US FDA Information Sheets, Guidance for Institutional Review Boards and Clinical Investigators
		- US office for Human Research Protections 45 Code of Federal Regulations title 46.107;
		- Canadian Association of Research Ethics Boards Guidance on Reporting Unanticipated Problems including Adverse Vents to Research Ethics Boards in Canada;
		- US FDA Guidance for Industry and Investigators Safety Reporting Requirements for INDs and BA/BE Studies (2010);