Title	Duties of REB Members
SOP Code	203.004
Effective Date	15-May-2023

Site Approvals

Name and Title (typed or printed)	Signature	Date MM/DD/YYYY
Meera Sidhu, Research Ethics Manager	M Sidhu	12/01/2023
Steven Smith, Deputy Vice-Principal Research		12/04/2023

1.0 PURPOSE

This standard operating procedure (SOP) describes the duties of the Research Ethics Board (REB) members.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable regulations and guidelines.

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

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

REB members and alternates are responsible for fulfilling their duties as specified in this SOP.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

The primary duty of Each REB member is the protection of the rights and welfare of the individual human beings serving as the research participants. To fulfill their duties, REB members must be versed in regulations governing human participants' protection, biomedical research ethics, and policies germane to human research participant protection.

5.1 Attendance

5.1.1 Regular REB members are expected to attend the ~~**regularly**~~ scheduled REB meetings. REB members may be asked to step down if they consistently miss **50% or more of the** REB meetings **per calendar year.**

5.1.2 REB members must notify the REB Office if they will be absent from an REB meeting to ensure that quorum can still be met and/or that an appropriate alternate may attend.

5.1.3 Alternate REB members are expected to attend the identified REB meetings for which they have confirmed their availability to replace a regular REB member and/or at least two REB meetings annually.

5.1.4 REB members are expected to be available for the entire REB meeting.

5.2 Terms of Duty

5.2.1 All members of the REB, including the REB Chair and Vice-Chair, will be appointed for a term as specified by organizational policy.

5.3 Duties

5.3.1 All REB members attending an REB meeting are expected to review the relevant materials submitted for each item under review or consideration by the REB, submit comments before the REB meeting, and be prepared to discuss each agenda item and provide input at the Full Board meeting.

5.3.2 Each REB member is expected to fulfill specific duties based on the below-mentioned role. More than one REB member may fulfill each role.

5.3.3 **Scientific members** are expected to contribute to the evaluation of the research 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 adequately protects the rights and welfare of human participants.

5.3.4 **Non-scientific members** are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. Non-scientific members should advise the REB if additional experience in a non-scientific area is required to assess whether the research adequately protects the rights and welfare of participants and to comment on the comprehension of the consent document.

5.3.5 **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.

5.3.6 **Member(s) knowledgeable in relevant law** are expected to alert the REB to legal issues and their implications, but not to provide formal legal opinions nor to serve as legal counsel to the REB; **Member(s) knowledgeable in privacy issues are expected to alert the REB to privacy issues and their implications.**

5.3.7 **Member(s) knowledgeable in ethics** are expected to guide the REB in identifying and addressing ethics issues related to the research under review.

5.3.8 **Ad hoc advisors/affiliate members** are individuals with competence in special areas who may be required to provide input on issues that require expertise beyond or in addition to that available on the REB. The ad hoc advisor/affiliate member may be required to submit a written report and to participate via teleconference or to attend the REB meeting to lend their expertise to the discussions.

5.3.9 **REB Chair** provides overall leadership to the REB:

- They can delegate any of their responsibilities, as appropriate, to a Vice-Chair or other qualified designee,

- Any responsibilities that the REB Chair delegates must be documented **via a delegation log kept on file by the REB Office.**
- The REB Chair or designee facilitates the review process based on organizational policies and procedures, SOPs and applicable regulations and guidelines.
- The REB Chair or designee determines each research project's risk level.
- The REB Chair or designee monitors the REB's decisions for consistency and ensures that decisions are recorded accurately and communicated to Researchers in writing in a timely fashion,
- The REB Chair or designee ensures that all REB members are free to participate in discussions during the REB meetings. The REB Chair or designee can ask a substitute REB member to attend an REB meeting to draw their expertise in an area that may be relevant to the REB's review and deliberations of the research,
- The REB Chair or designee determines the appropriateness of a Full Board or delegated review of the research,
- The REB Chair or designee performs or delegates authority to (an) REB member(s) to perform a delegated review,
- The REB Chair or designee signs off on all REB decisions in writing,
- For REB approval of clinical trials approved by Health Canada, the REB approval letter, which includes the REB attestation, is signed by the REB Chair or designee,
- The REB Chair or designee can suspend the conduct of any research project that places participants at unacceptable risk pending discussion by the Full Board. The REB Chair or designee can suspend the conduct of the research if they determine that a Researcher is not adhering to the REB-approved protocol or the REB's policies and procedures,
- **In cases where Queen's University HSREB is not the Board of Record (i.e., a different CTO-qualified site is the Board of Record), where there is suspected misconduct, HSREB and/or the indicated Board of Record will notify the KHSC Vice-President Health Sciences Research as per the Affiliation Agreement between Queen's University and Kingston Health Sciences Centre. If a decision must be made, the KHSC Vice-President Health Sciences Research (in consultation with the Queen's Vice-Principal Research, REO/REB, Compliance, or other consultants) will submit recommendations for continuance or discontinuance of a project directly to the PI or applicant.**
- The REB Chair or designee will report on the activities of the REB to the organization on an annual basis,

- The REB Chair or designee, in conjunction with the REB Office Personnel and other organizational representatives as applicable, ensures the REB members are informed of all new legislation, regulations, policies and guidelines pertaining to human participant research and shall advise the organization on policies and procedures related to research conduct,

In conjunction with the REB Office Personnel, the REB chair shall assess the educational and training needs of the REB members and Office Personnel and will address any gaps identified. The REB Chair or designee reviews and approves REB policies and procedures at set intervals to ensure the REB SOPs meet all current standards.

5.3.10 **REB Vice-Chair** or equivalent is responsible for performing the responsibilities of the REB Chair when the REB Chair is unable to do so:

- The REB Vice-Chair performs all duties assigned by the REB Chair.
- The REB Vice-Chair assists with the overall operation of the REB.

5.4 Primary and Secondary Reviewers

5.4.1 REB members will act as primary and/or secondary reviewers for assigned ~~**research projects**~~ **research ethics applications** at Full Board meetings. The primary and secondary reviewers present their findings from a review of the REB submission materials, assess the soundness and safety of the research, and recommend specific action to the REB. They lead the discussion of the research project during the REB meeting. The primary and secondary reviewers review additional material(s) as requested by the REB to approve the research.

5.5 Training and Education

5.5.1 REB members are expected to follow training and education procedures.

5.6 Conflict of Interest

5.6.1 REB members are expected to follow conflict of interest procedures.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP203.001	15-Sept-2014	Original version
SOP203.002	08-Mar-2016	No revisions needed
SOP203.003	08-Oct-2019	No revisions needed
SOP203.004	15-May-2023	Changed his/her to their
SOP203.004	1-Dec-2023	Queen's Specific Revisions/Clarifications added to the N2 SOPs with modifications in bolded text