	RESEARCH ETHICS BOARD **STANDARD OPERATING PROCEDURES**	
	SOP Number	204
	REB Office Personnel Serving as REB Members	
	Date of Issue **Date of Revision**	2014 05 13 2018 03 30 2021 05 20 2022 07 13

Purpose: This standard operating procedure (SOP) describes the duties of REB Office Personnel serving as members of the Research Ethics Board (REB).

Directive: Fraser Health Policy "The Ethical Conduct of Research and Other Studies Involving Human Participants"

Reference: 2019 10 08 CAREB SOP 204.003

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.

Procedure

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

1.0 Duties

1.1 REB Office Personnel who are designated as Board members may attend convened meeting and participate in discussions, but the shall not be counted in determining quorum and they shall note participate in any votes;

1.2 REB Office Personnel that have been appointed to serve as REB members may perform delegated review in accordance with the delegated review procedure;

1.3 The assignment of these tasks to REB Office Personnel will be documented.

2.0 Appointment Criteria

2.1 The REB Office Personnel Serving as REB members shall have knowledge, experience, and training comparable to what is expected of REB members. The REB shall ensure that Office Personnel can fulfill their responsibilities as REB members independently.

3.0 Training and Education

3.1 REB Office Personnel serving as REB members are expected to additionally follow training and education procedures for REB members.

4.0 Conflict of Interest

4.1 REB Office Personnel serving as REB members are additionally expected to follow conflict of interest procedures for REB members.

5.0 Delegated Responsibilities to REB Office Personnel

5.1 New Submissions

- The following types of new minimal risk submissions may be delegated to the REB Office Personnel under the delegated review process:
  - New minimal risk applications involving chart reviews or anonymous surveys as the sole methods of data collection, with input of REB Chairs/members as needed at the discretion of the REB Office Personnel;
  - New minimal risk submissions undergoing harmonized review in which Fraser Health is not the board or record.

5.2 Amendments

- Changes in the following study personnel (if there is no resultant change to the conflict of interest of the team members):
  - Principal Investigator
  - Primary Contact
  - Co-Investigators
  - Study Team Members
- Administrative changes:
  - Addition of Research Site(s)
  - Change in Research Funding that does not result in a new conflict of interest
  - Editorial changes to documents
  - Editorial changes to study title
- Minor Amendments to the study procedures or documentation that do not alter the risk/benefit of the study.

5.3 Acknowledgements

- Completion of Study: The REB Office Personnel may issue an acknowledgement of notification of study completion. If there is any question or concern regarding the researcher's compliance with study closure guidelines, the REB Office Personnel will ask the researcher for clarification and/or refer the application to the REB Chair;
- Health Canada Letters of No Objection: The REB Office Personnel may issue an acknowledgement for a Health Canada Letter of No Objection if the application clearly states that the Health Canada NOL is issued for an approved protocol or a protocol amendment under review;
- Notification of study closed to accrual: exception - closed or on/off hold for safety reasons;
- Six monthly periodic safety summary reports: if there is a clear position statement that there is no change to the safety profile of the study treatment or risk/benefit ratio;
- Data Safety Monitoring Board reports in which there is a clear an unambiguous recommendation the trial continue unmodified and no safety concerns are raised;
- Administrative acknowledgement requests that do not pertain to the safety or conduct of the study, such as typo corrections in study documents, notifications of change of address for investigator or sponsor personnel, and translation certificates for study questionnaires.

5.4 Renewals

- The REB Office Personnel may review and issue an Annual Renewal Certificate without review by the REB Chair if:
  - The application for renewal meets the criteria for expedited/delegated review and is continuing according to plan, and there are no changes to the study that entail either increased risk or change the risk/benefit ratio of the study;
  - The study is required to comply with US regulations and meets the criteria for expedited continuing review in accordance with 21CFR 56.110.

5.5 Response to Modifications/Provisos

- For modifications/provisos arising from a submission receiving delegated review, the response to modifications/provisos may be delegated by the REB Chair to REB Office Personnel;
- For modifications arising from a submission receiving full board review, the REB may vote to delegate response to modifications for minor changes requested. This must be documented in the review decision in the meeting minutes.

6.0 Caveat

In all cases of delegated acknowledgement or approval, if the REB Office Personnel staff has any concern about the application, they will either consult with or assign the

submission to the REB Chair. Consultations with the REB Chair will be documented in the study file.

7.0 U.S. Federally Funded or Regulated Research

Studies that are funded or supported by the U.S. Federal government or regulated by the U.S. Food and Drug Administration may not be delegated for review in the manner suggested by this SOP. According to U.S. regulations, under an expedited review procedure, the review may only be carried out by the REB Chair or by one or more experienced reviewers designated by the chairperson from among members of the REB.

Studies that are funded or supported by the U.S. federal government or regulated by the U.S. Food and Drug Administration, are eligible for expedited/delegated review if listed in the OHRP and FDA guidances and are no more than minimal risk or include only minor changes in previously approved research as defined by the applicable regulations. Any study that was reviewed and received initial approval at a convened REB meeting will be reviewed by the convened REB at annual renewal, unless the study meets one of the conditions described in the FDA or DHHS guidances as applicable.