Ottawa Health Science Network Research Ethics Board (OHSN-REB) /
Conseil d'éthique de la recherche du réseau de science de la santé d'Ottawa (CÉR-RSSO)

Instructions for Full Board Applications

Studies that involve **more than minimal risk to participants** are reviewed by the full Board. For example:

- Clinical trials of drugs, devices, or natural health products
- Studies involving the collection of significant personal health information
- Studies where the participant/patient population is vulnerable

FOLLOWING THESE INSTRUCTIONS PRIOR TO SUBMISSION WILL ENSURE A TIMELY REB REVIEW PROCESS:

- **For complex studies,** arrange to meet with the OHSN-REB to discuss the study. Contact the REB Administrative Assistant (rebadministration@ohri.ca) to schedule a huddle meeting.

- **For OHRI and OHIRC investigator initiated regulated studies (including Phase IV studies),** contact your institution's Clinical Research Administration team; they review all study related documentation from a regulatory perspective.

- **Ensure all members of the research team have the applicable training** (TCPS 2, PHIPA, GCP, Health Canada, etc.) **required for the specific project and are familiar with the institution's policies** (SOPs, Privacy, IT, etc.)

- **Ensure the person completing the REB application has a complete understanding of the study from beginning to end to ensure they describe details accurately to the REB within the application.**
  They must be able to:
  - ✓ Ensure the REB application aligns with the Protocol and consent form.
  - ✓ Describe how identification of participants, initial contact, recruitment and consent will occur.
  - ✓ List all data sources and describe all study procedures.
  - ✓ Detail what confidential information will be collected/stored, what is leaving the institution, where it is going, why it is going and how it will be sent.
  - ✓ List all technologies (eCRFs, devices, Apps, online portals, electronic surveys, etc.) that will be used in the study, explain how they will be used as well as the privacy protections in place.

- **Principal Investigator must review the REB application for completeness and accuracy.**
  - **The REB will not review incomplete or incoherent applications.** Research team members responsible for REB correspondence must ensure the completed application is reviewed by the investigator prior to sign-off and submission. If the application is not ready for Board review, a corrected or, in some cases, a brand-new application will be required after the research staff have been appropriately trained on the Protocol and/or REB application process.

- **Review the full Board submission deadlines and meeting dates**: The application must be received by the REB no later than midnight on the submission deadline date. There is a maximum of 6 applications reviewed at each board meeting. The submission deadline is the FINAL date for submission; early submissions are encouraged to ensure the study is added onto the meeting agenda.

- **Be prepared to present at the full Board meeting**: Investigators and study teams should note the date of the Full Board meeting in their Outlook calendars and they should attend via MS Teams for approximately 15 to 30 minutes to present their project and address questions from the Board. An exact time will be arranged after submission.

IMPORTANT

The REB will **conduct a preliminary review** which consists of screening the application for completeness prior to assigning to Board members for review**.** Following submission, research team members listed on the REB application must be responsive to requests for clarification to address the Research Ethics Coordinator's (REC) preliminary concerns. Applications will not proceed to the board's agenda when requested clarification has not been provided.

- If preliminary concerns are issued, research teams will be notified via an email with instructions and a deadline by which to respond.
- If the study team is not able to make the requested edits within the time frame provided by the REB, the application may need to be withdrawn.

Process Map for Full Board Applications

New application received by OHSN-REB
(on or prior to submission deadline; ≥ 15 business days prior to meeting date)
or
Re-submission received by OHSN-REB (≥ 7 business days prior to meeting date)

OHSN-REB Research Ethics Coordinator (REC) conducts a preliminary review (screens application for completeness)
(within 1- 2 business days)

Application Complete - Ready for Board review

Application added onto Full Board meeting agenda

Meeting occurs;
Investigator attends to present study
and address questions from the Board (recommended)

APPLICATION INCOMPLETE –
NOT READY FOR BOARD REVIEW

Incomplete or incoherent applications will **not** be added to a meeting agenda; they are returned to Investigator with prelim concerns to be addressed within 1-2 business days.

Investigator/delegate responds to prelim concerns **in FULL**
(within 1- 2 business days; deadline will be in email)

STOP

If prelim concerns cannot be addressed within this timeframe, the Investigator must inform the REC of the next step:

- Withdrawal of application
- Meet with REB ASAP (note, REB may determine that the application needs to be withdrawn)

Meeting Decisions:

- Approved
- Approved pending revisions
- Subcommittee
- Re-Submit to Full Board
- Rejected

REB Review Letter (RL) issued
(within 7 calendar days of meeting)

Note: If a 2nd RL is warranted, Investigators & study teams may be asked to meet with the REB to facilitate resolution of outstanding items.

Investigator responds to the REB's RL **in FULL**
(within 14 calendar days; deadline will be in RL)

If all concerns have not been addressed, subsequent RL issued

REB reviews Investigator's response to the RL in accordance with meeting decision
(see 3 options below for days)

- REC & Chair Review **(within 7 calendar days)**
- REC & Subcommittee Review **(within 14 calendar days)**
- Re-Submit to Full Board **(return to top of diagram)**

Once all concerns have been addressed, ethics approval is issued
(standard turnaround time to approval is within 90 calendar days)

Ethics approval does not permit the study to start. **An Institutional approval letter is required prior to study start.** Institutional approval is granted by the OHSN-REB or Contracts Office once the Ethics, Contracts and Department Notifications tabs of the CRRF have been reviewed and marked complete.

If you wish to meet with the REB, contact REBadministration@ohri.ca to schedule a remote MS Teams meeting. Collaborative meetings with Facilitation, Contracts, Privacy, IT, etc. can also be arranged.