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 Secondary Use Applications

Secondary Use research refers to the use of information and/or human biological materials originally collected for a purpose other than the current research purpose (i.e.: use of data and/or samples that already exist). The OHSN-REB Secondary Use application contains 2 options for this type of research:

1. **Retrospective research on human data/records (example: Retrospective chart review)**
   - In order for a study to be considered retrospective, the end date of data collection must be prior to the date of submission to the REB. *Not to be confused with the dates the study team will physically be accessing the records but rather, the dates on the records that will be reviewed.*
2. **Retrospective research on human samples (example: Secondary use of biobank samples)**
   - In order for a study to be considered retrospective, the end date of sample collection must be prior to the date of submission to the REB. *Not to be confused with the dates the study team will physically be accessing the samples but rather, the dates on the samples that will be analyzed.*

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

- **For assistance in setting up your study,** contact your institution's Clinical Research Administration team; they can provide guidance from pre-grant submission to study close-out.
- **Ensure all members of the research team have the applicable training** (TCPS 2, PHIPA, 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.** They must be able to:
  - ✓ Ensure the REB application aligns with the Protocol.
  - ✓ List all data/sample sources
  - ✓ 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.
- **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 review, a corrected or, in some cases, a brand-new application will be required after research staff have been appropriately trained on the Protocol and/or REB application process.
- **Assess whether a huddle with the REB could be beneficial.** The REB Office holds huddles to discuss REB submissions; you can request a huddle by contacting REBAdministration@ohri.ca.
  - Note, upon review, the REB Office may determine a huddle is required if clarification is needed and/or if the application is of poor quality. Should a collaborative discussion be required, the Contracts Officer, Facilitators, Privacy Office, IT, and/or Director of Clinical and Research Administration may also be invited to the huddle.

IMPORTANT

The REB will **conduct a preliminary review** which consists of screening the application for completeness prior to 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.

- 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 Secondary Use Applications

New application received by OHSN-REB
Optional: Investigator/delegate emails REBAdministration@ohri.ca to request a huddle with REB

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

Application Complete- ready for review

REC Review **(within 4 business days)**

If applicable, Chair Review **(within 2 business days)**

Huddle Date (if applicable)

REB Review Letter (RL) issued **(within 1 business day of REC review, Chair review or huddle date)**

Investigator responds to the REB's RL **in FULL** **(within 3 business days; deadline will be in RL)**
RLs not addressed in full will be returned to the Investigator, without further review

REB reviews Investigator's response to RL **(within 3 business days)**

Once all concerns have been addressed, ethics approval is issued **(standard turnaround time to approval is within 28 calendar days)**

APPLICATION INCOMPLETE – NOT READY FOR REVIEW
Incomplete or incoherent applications will **not** be reviewed; they are returned to Investigator with prelim concerns to address within 1-2 business days.

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

If 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)

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

If all concerns have not been addressed, subsequent RL issued

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 Contracts, Facilitation, Privacy, IT, etc. can also be arranged.