





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 Delegated Prospective Applications

"Minimal risk" research is defined as research in which the probability and magnitude of possible harms implied by participation in the research are no greater than those encountered by participants in those aspects of their everyday life that relate to the research.

Prospective studies that are minimal risk to participants may undergo delegated review; which may include:

- Observational studies involving questionnaire(s), survey(s), interview(s) and/or focus group(s)
- Prospective sample and/or data collection

FOLLOWING THESE INSTRUCTIONS <u>PRIOR TO</u> SUBMISSION WILL ENSURE A TIMELY REB REVIEW PROCESS:

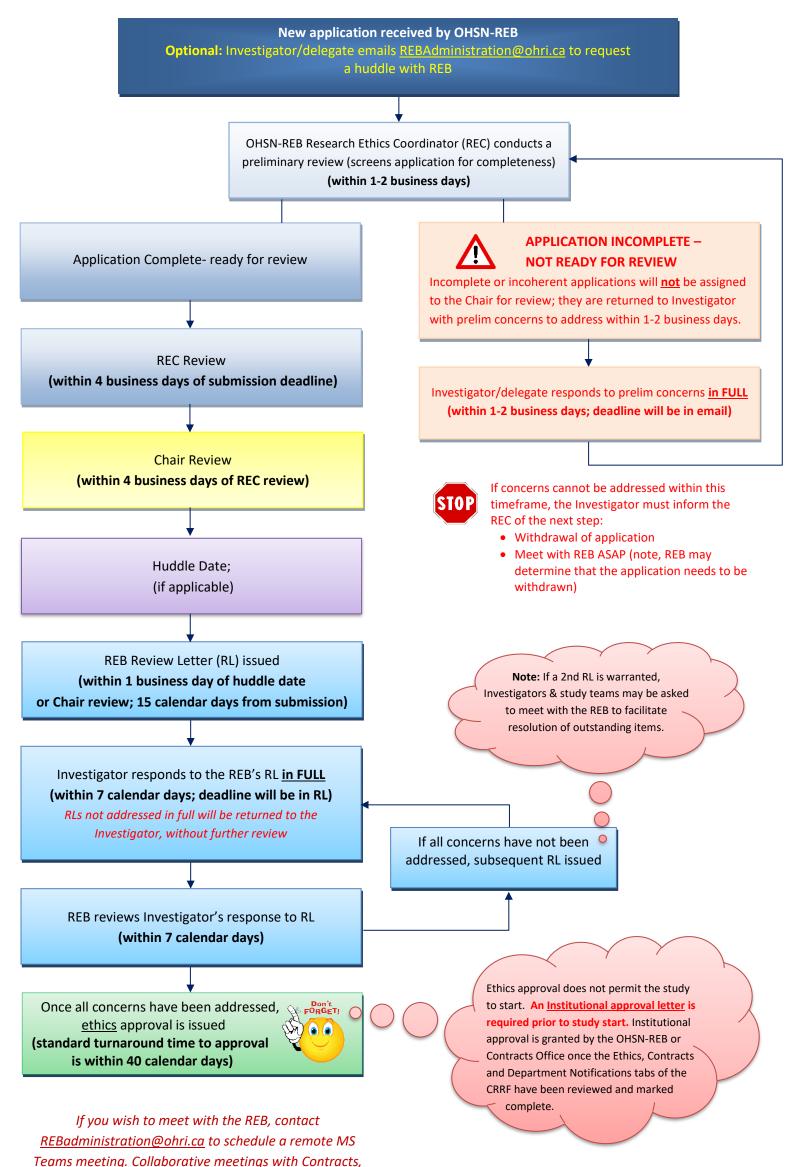
- For complex studies, arrange to meet with the OHSN-REB to discuss the study. Contact the REB Administrative Assistant (<u>rebadministration@ohri.ca</u>) to schedule a huddle meeting.
- For required assistance in setting up your study, contact your institution's Clinical Research Administration team; they can provide guidance from pre-grant submission to study close-out.
- Ensure <u>all members</u> 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 <u>complete</u> 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 and/or survey.
 - ✓ 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 <u>must</u> 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 Chair 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 <u>REBAdministration@ohri.ca</u>.
 - Note, upon review, the REB Office may determine a huddle is <u>required</u> 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.



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

- 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 Delegated Prospective Applications



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