

**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 Amendments

If there are any changes to what is currently on file with, and approved by, the OHSN-REB, the investigator must submit an Amendment Form to the OHSN-REB. For example:

- Changes to the REB approved ethics application and/or REB approved documents (i.e. Protocol, Investigator's Brochure, Product Monograph, recruitment materials, consent forms, questionnaires/surveys, other participant facing documents, etc.).

If the proposed change represents more than minimal risk, it must be reviewed by the REB at a Full Board meeting. Examples of Amendments that may be classified as more than minimal risk include:

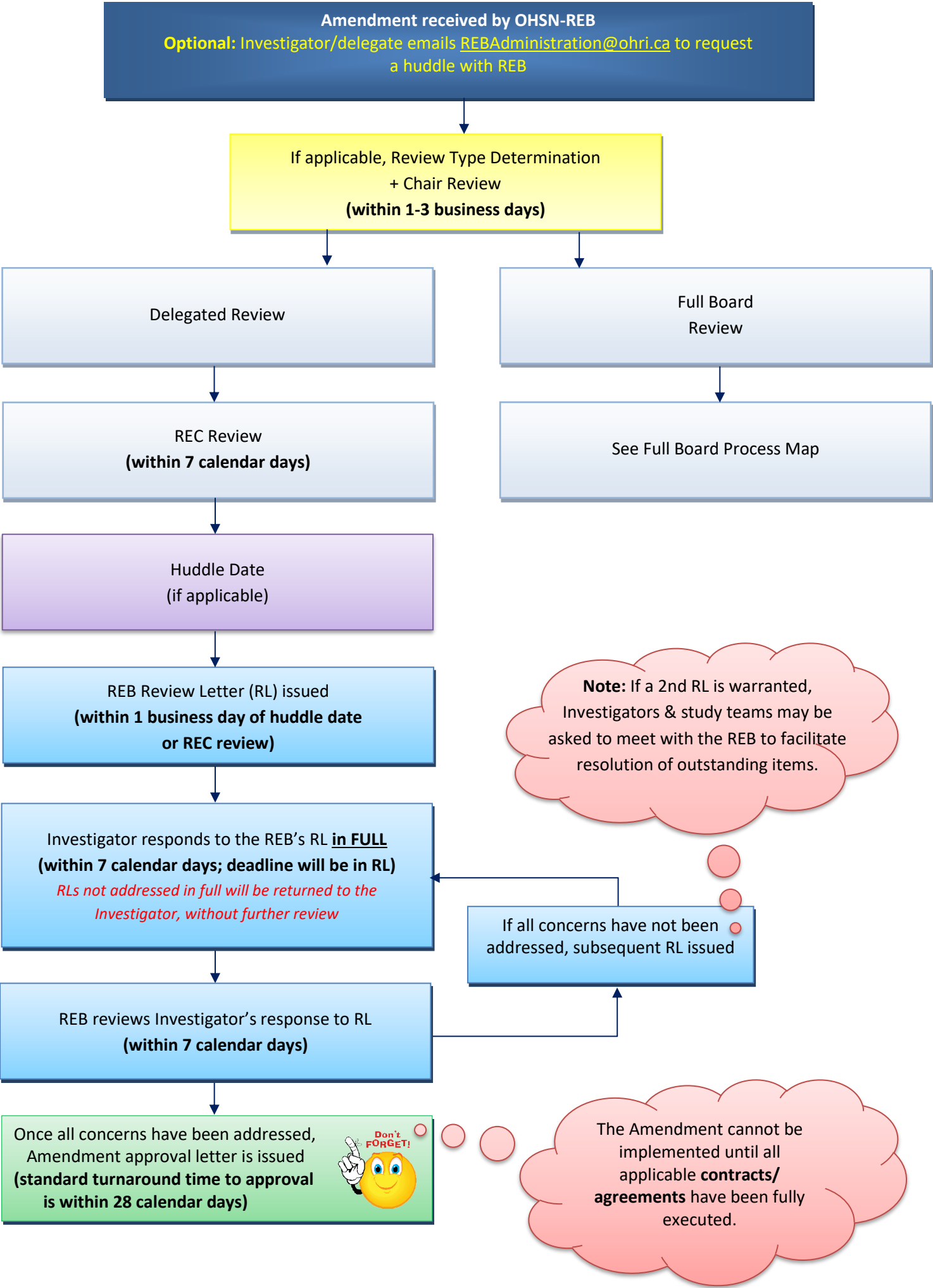
- Significant changes to study design (for example, addition of new study population or treatment arm).
- Increase in dosage or frequency of investigational product
- New risk information that is substantial and/or increases risk to participants or risk/benefit ratio study (e.g.: increase in physical risks, psychological risks, and/or privacy/confidentiality risks)
- Reduced safety monitoring
- New/additional genetic testing or tissue banking where genetic testing may/will be performed

The amended research may not be implemented prior to REB approval, except when necessary to eliminate immediate hazards to participants. If changes are made to eliminate immediate hazards, the Researcher must notify the REB immediately.

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

- **Ensure the person completing the Amendment Form has a complete understanding of the changes.** They must be able to:
 - ✓ Describe all changes & know whether they require authorization from Health Canada
 - ✓ Enclose tracked (showing the changes) and clean copies of all revised documents
 - ✓ Enclose all new documents
- **Principal Investigator must review the submission for completeness and accuracy.**
 - **The REB will not review incomplete or incoherent submissions.** 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 submission is not ready for review, a corrected or, in some cases, brand new Amendment Form will need to be completed once research staff has been appropriately trained on the changes and/or REB application process.
- **For Amendments eligible for delegated review:**
 - **Assess whether a huddle with the REB could be beneficial.** The REB Office holds huddles to discuss REB submissions; 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 submission is of poor quality.
- **For Amendments requiring full Board review:**
 - **Review the full Board submission deadlines and meeting dates:** If full Board review is required, the submission must be received by the REB no later than midnight on the submission deadline date. The submission deadline is the FINAL date for submission; early submissions are encouraged.
 - **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 calendar as they may be required to attend via MS Teams for approximately 10 to 15 minutes to present the Amendment and address questions from the Board. An exact time will be arranged after submission.

Process Map for Amendments



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.