Science and Research Ethics Board Review Process

**Important:** Applications to the Holland Bloorview Research Ethics Board should identify a Bloorview Research Institute scientist, Clinical Team Investigator or Clinical Study Investigator as the Local Principal Investigator. Exceptions to this must be reviewed and approved by the Holland Bloorview VP Research/BRI Director before submitting a research ethics application.

All REB forms can be found in the "Forms" section [http://research.hollandbloorview.ca/ResearchEthicsBoard/Forms](http://research.hollandbloorview.ca/ResearchEthicsBoard/Forms)

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Prepare research proposal.

Check the [Science Review Process at Holland Bloorview](http://research.hollandbloorview.ca/ResearchEthicsBoard/Forms) to determine the relevant requirements. Submit your research proposal to the primary science reviewer for formal review.

Receive the completed [Science Review Form](http://research.hollandbloorview.ca/ResearchEthicsBoard/Forms) from the primary science reviewer.

Make the appropriate changes and submit a written itemized response to the primary science reviewer.

Receive approval/signoff from the primary science reviewer.

Prepare [TAHSN Application Form](http://research.hollandbloorview.ca/ResearchEthicsBoard/Forms) and obtain signatures from all investigators.

**Note:** A research proposal that is still under review by a granting agency is usually not reviewed by the Holland Bloorview REB until after funding is awarded. Check with the REB Office Staff before you submit your proposal for ethics review.

Prepare Research Ethics Board Application Package. Submit 2 hard copies of the following documents (where applicable) to the BRI Operations Office for review. **Check monthly deadlines for submissions.** BRI Operations Office will forward your REB application to the REB Office.

- a. REB Application Checklist
- b. TAHSN Application Form
- c. Study Protocol
- d. Informed Consent Forms
- e. Assent Forms
- f. [Departmental Approval Form](http://research.hollandbloorview.ca/ResearchEthicsBoard/Forms)
- g. Scientific Review Form + Response
- h. Non-standard forms, scales, and questionnaires
- i. Participant Documents
- j. Approval letters from other REBs
- k. Investigator Brochure or Product Monograph
- l. Health Canada NOL/ITA, FDA Approval
- m. Risk Assessment Documentation (Devices)
- n. Data & Biological Sample Transfer Agreements
Continued...

REB Office Staff screens package for completeness. Application assigned to receive either a Full or Delegated REB Review. REB notifies researcher of decision and requests additional copies as needed.

**Full REB Review:** Submit additional copies of the complete application package to the REB Office.

**Delegated REB Review**

Attend REB meeting.

Receive written comments from the REB. Prepare itemized response to REB comments and amend documents as required. Submit both to the REB Office for review.

*Further revisions may be required.* Make necessary changes and resubmit to REB Office Staff.

**Receive REB Approval**

- Submit Annual Renewal Form each year that your study continues
- Submit Amendment Request to seek REB approval for any changes to your application.
- Report all unanticipated problems
- Report all Primary protocol deviations

Submit Study Completion Form to REB Office.