



HEALTH SCIENCES NORTH RESEARCH ETHICS BOARD (HSN REB) LETTER OF INFORMATION TO INVESTIGATORS

Thank you for your interest in conducting research at Health Sciences North (HSN). All research involving human subjects at HSN is reviewed by the HSN REB. This requirement also applies to research involving human remains, cadavers, tissues, biological fluids, embryos, and fetuses.

In order to facilitate this review, it is essential that all the necessary documentation is included in your application. Please see the Application Package List below.

The HSN REB is constituted and operated in accordance with the Tri-Council Policy Statement for Conduct of Research Involving Humans (TCPS2), Canadian Food & Drug Regulations, Division 5 (Clinical Trials), ICH Good Clinical Practice Guidelines E6, Personal Health Protection Act, 2004 (PHIPA), U.S. Code of Federal Regulations Title 21 & 45. The HSN REB also holds a Federal Wide Assurance Registration with the U.S. Office of Human Research Protection.

For industry-sponsored research studies, there is a cost \$3000 associated with this review. Please provide the name and address of the Sponsor to be billed with your application.

There is no review fee associated with non-industry funded research.

Included in the REB application, is a hospital impact form to be completed and signed by the Principal Investigator, the Department Lead of any department impacted by the research being conducted, and a representative from Senior Management. Please see the application form for relevant details.

1. Full REB review

This level of review is required for all research that the REB regards as posing more than **minimal risk**. The REB may require this level of review for minimal-risk research as well if it judges that aspects of the research warrant doing so.

The HSN REB meets on the first Monday of every month at 1630 hours, but breaks for the month of August. Principal Investigators submitting an application for Full Board Review are requested to attend the Research Ethics Board meeting and will be given an appointment time. In order to allow sufficient time for research review, your completed application must be received by 15th of the month prior.

Send completed hard copy applications to:

Research Services Office
3rd Floor - Northeast Cancer Centre
Room 32007
Health Sciences North

41 Ramsey Lake Road
Sudbury, ON P3E 5J1
705.523.7100 ext. 2409

The application package should include:

- The original application form with appropriate signatures + 15 collated hard copies
- 4 hard copies of the study protocol
- 15 hard copy the consent form(s) (if applicable)
- 4 copies of the study budget
- 4 copies of the most recent Investigator Brochure, Product Monograph, or Device Manual (if relevant)
- 15 copies of all supplemental material (e.g., questionnaires and other assessment tools)
- 15 copies of any recruitment materials (i.e., posters, ads, etc.)
- 4 copies of any other relevant correspondence
- 1 scanned copy of the entire package to the Research Services Office email: reb@hsnsudbury.ca with the subject line indicating “*New submission for Full Board Review*”.

You will be notified of the REB decision within 10 business days after the meeting.

2. Delegated review by a member of the REB

Ethics applications filed with the REB normally receive delegated review by a member of the REB if the research poses only minimal risk (i.e., questionnaires, chart review, surveys, etc.). The REB member must report the results of such review for ratification by the full REB at a regular meeting.

Forward 1 hard copy of the *Research Ethics Committee Expedited/Delegated Form* with original signatures to the Research Services Office (address above) and scan 1 copy of the application directly to the REB office email: reb@hsnsudbury.ca for review. In the subject line, please indicate “*New submission for delegated review*”. Include all relevant documents with the submission (e.g. — data collection forms, budget, study summary, etc.).

There is no deadline for this type of submission. Applications are handled on a first- come, first-served basis. You will be notified of the REB decision approximately 15 business days of the date of receipt by the Research Services Office.

Please contact the Research Services Office if you have any questions about submission processes.