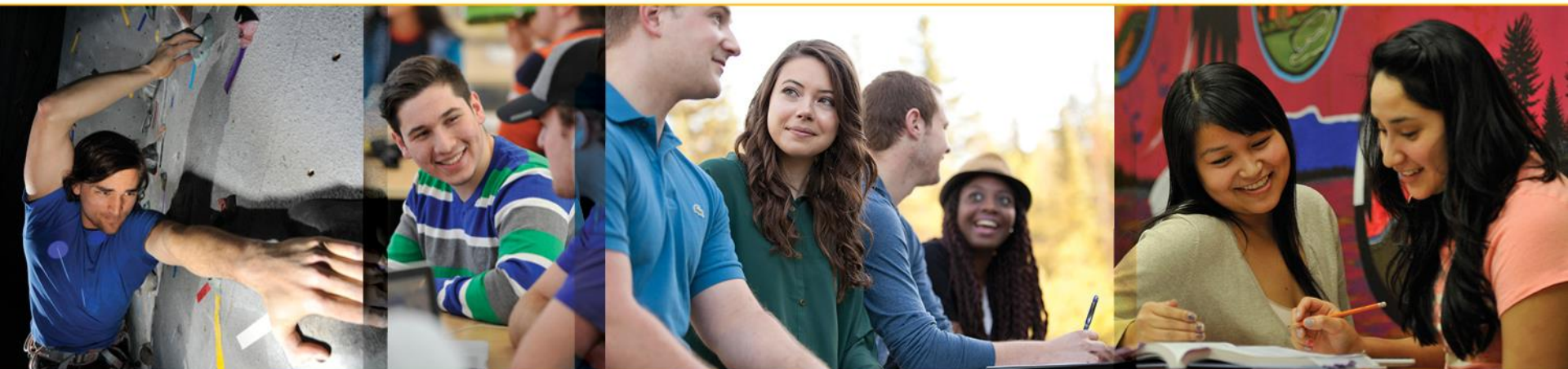


Demystifying the Process - Applying to the LU or TBRHSC REB? We Can Help

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Multi-Jurisdictional Research in Canada

The Canadian System:

- Canada has no “general” approval process for research across multiple sites
- Researchers must apply for REB approval from each and every site in which they wish to conduct research
- TCPS2 allows for the development of “alternative review models”

HUGE burden on researchers...

- lengthened timelines
- Paperwork, paperwork, paperwork
- Increased costs (hiring RA's)
- Unable to meet deliverables in contracts

HUGE burden on REBs

- Overload of reviews
- Repetitive work



Canadian examples

University Health Network in Toronto:

- If you belong to the Toronto Academic Health Sciences Network, you can defer your review to one of the qualified REBs and the others will accept the approval (non clinical trials)

Clinical Trials Ontario:

- Single ethics review for multi-centre clinical research in Ontario

Newfoundland/Labrador Health Research Ethics Authority:

- Government Act that mandates that all health research be reviewed and approved by the central REB

What is *our* process?

**** Approval by one REB is relevant for both LU and the TBRHSC****

The most appropriate REB is determined by the Research Ethics Offices and the application is routed through that appropriate REB. Determination is project-based, not researcher-based.

For example:

- A faculty member at LU conducting clinical research just requires the approval of the TBRHSC REB to conduct their trial (even if not taking place at the TBRHSC).
- An LU student wishing to interview nurses just requires the approval of the LU REB (even though this is taking place at the TBRHSC).

Why Reciprocity?

Lots of Reasons!

- Leverages the strengths of each of our institutions
- Increases coordination/collaboration
- Harmonization and streamlining of our processes
- Provides efficient review for our researchers
- Administrative burden was deterring researchers
- Researcher/REB errors become more of a possibility when duplicating processes
- Those with EXPERTISE need to review the projects



Why LU and TBRHSC?

- Growth of research partnerships between our institutions with the opening of NOSM
- Pan-Northern model proposed at the opening of NOSM
 - too big thus too logistically challenging
- Start small - where could the most impact be made?

Determined to be LU REB and TBRHSC REB

BUT...we need to trust each other...

- Get to know each other – review of REB Terms of Reference, REB Policies & SOPs, membership, ethical guidelines, office staff and processes etc...
- LEGAL AGREEMENT (of course!)



Legal Agreement

Most importantly it defines how to determine:

- the Most Responsible Institution (MRI)
- the REB of Record

And...all things which lawyers argue over...

Privacy and Confidentiality

Conflict of Interest

Party Obligations

Termination, Renewal

Liability, Indemnification

Insurances

Reporting

Breaches

Appeals



Getting Started – Scope of Review

Hospital REB

If the project involves any of the following:

- PHI for which the Hospital is the custodian
- Hospital medical facilities or equipment
- Regulation by Health Canada
- Investigational product(s) in humans
- The effect of a health related intervention on a health outcome

Lakehead REB

Everything Else!

Research Ethics Board (REB)

PROJECT INTAKE FORM

Please complete and submit to tbr_reo@tbh.net or research.ethics@lakeheadu.ca

Scope of Review

Project Intake Form

Available on our
websites

Principal Investigator (PI) Information		OFFICE USE ONLY
Name:		Date Received: dd/mm/yyyy
Email Address:		Most Responsible Institution:
Select ALL of the PI's affiliations below:		REB of Record:
<input type="checkbox"/> TBRHSC <input type="checkbox"/> TBRHRI <input type="checkbox"/> LU <input type="checkbox"/> NOSM		<input type="checkbox"/> Ad Hoc Reviewer Required <input type="checkbox"/> Notify Other REB upon Approval <input type="checkbox"/> Research Program Authorization Required
Other Affiliations:		
From the affiliations selected above, which will be the PI's Primary Affiliation for the conduct of THIS research project?		
<i>Please note: if the project is driven by a LU/NOSM learner to earn an academic credit, the PI's primary affiliation must be LU or NOSM</i>		
Primary Affiliation:		
STUDY INFORMATION		
Full Study Title:		
Funding will be Administered by: Name of Organization		<input type="checkbox"/> No Funding
Below, check ALL boxes that are TRUE :		
<input type="checkbox"/> This project is driven by a LU/NOSM learner to earn an academic credit		
<input type="checkbox"/> This project involves the use of any TBRHSC/TBRHRI resources (charts, patients/staff, space, equipment)		
<input type="checkbox"/> Someone on the research team has an affiliation with TBRHSC and/or TBRHRI		
<input type="checkbox"/> This project involves the use of any LU/NOSM resources (students/staff, space, equipment)		
<input type="checkbox"/> Someone on the research team has an affiliation with LU and/or NOSM		
This research project involves (select all that apply):		
<input type="checkbox"/> The use of TBRHSC personal health information		
<input type="checkbox"/> The use of TBRHSC medical facilities or equipment (e.g. MRI machine)		
<input type="checkbox"/> Regulation by Health Canada		
<input type="checkbox"/> The study of an investigational product in human participants		
<input type="checkbox"/> The effect of a health-related intervention on a health outcome		
<input type="checkbox"/> None of the above		
Additional Comments		

I've filled in the Project Intake Form...what next?

- Not sure where to send the Project Intake Form?
- Submit to either the LU REB (research.ethics@lakeheadu.ca) or TBRHSC REB (tbr_reo@tbh.net)
- We will determine which REB will be REB of Record and get back to you



REB Communication

Open communication process between each REB through the entire process, including:

- REB application process, including exchange of approval letters
- Amendments to approved project
- Adverse events
- Project renewals
- Project closure

We chat a lot!!



Submitting to the Hospital REB

Step 1) Submit Initial REB submission via email

- Submit to tbr_reo@tbh.net and researchprogram@tbh.net
- Submission prescreened by the REO (3-5 business days)

Should include:

- REB Application** (signed)
- Co-investigator COI forms** (signed)
- Stand-alone protocol**
- Localized budget**
- Other study documents as required (e.g. consent form, data collection tools, interview script)

Submitting to the Hospital REB

Why Research
Program?

Why a protocol?

What about a
paper copy?

What does
prescreen look
like?

What does prescreen look like?

- Prescreen entire submission for consistency & completeness
- Prescreen REB application against core principles of TCPS2
 - ❖ please see REO Prescreen form
- Prescreen consent form against core principles of TCPS2
 - ❖ please see ICF Prescreen checklist
- REO will provide prescreen comments or notify you of the review pathway via email (3-5 business days)

Submitting to the Hospital REB

Step 2) REB Review

Full Board (> Minimal Risk)

- Submit by the first Monday of the month (Sept-June)
- Sufficient response to prescreen comments must be received 12 days from the meeting date
- Meet on the forth Monday of the month (Sept-June)
- PI may be invited to the meeting to answer questions
- Full board comments / decision communicated within 3 days

Delegated (Minimal Risk)

- Submit at anytime
- 1 or 2 REB members are asked to submit their review comments within 2 weeks

Submitting to the Hospital REB

Step 3) Decision made by the REB

- 1) Approve as submitted
- 2) Approve pending minor clarifications, response to be reviewed by the REB Chair
- 3) Approve pending minor clarifications, response to be reviewed by sub-committee of the REB
- 4) Approve pending major clarifications, response to be reviewed by the Full Board
- 5) Reject the study (*VERY unlikely!*)

Submitting to the Hospital REB

NOW the paper copy is required before the Chair can sign off on the study:

- REB application (signed)
- Co-investigator COI forms (signed)
- All study documents
- Informed consent form & recruitment posters printed in colour (*stamped for distribution upon approval*)

High Quality Initial Submissions

- ☑ All necessary study documents are included and consistent
- ☑ Study documents are version controlled in the footer
- ☑ All participant information is written at a lowered reading level
- ☑ The researcher prescreened the REB application against the REO Prescreen form and all expectations were met
- ☑ The researcher prescreened the Informed Consent form against the ICF Prescreen Checklist and all expectations are met
- ❖ Specific guidance related to each section of the REB application can be found in the Researcher Guidance Document on our website

Submitting to the LU REB

Step 1) Submit Initial REB submission via Romeo

- PI is your Supervisor (if you are student)
- PI is local lead if a collaborative project
- Electronically routed through your Department Chair if you are LU faculty/student
- Submission prescreened by the research ethics office (3-5 business days), with changes routed back to you through Romeo

Must include:

- All study documents as required (e.g., info letter & consent form, interview script, survey, recruitment tools etc...**
- Signature page and TCPS2 Certificates for all project team members**

Submitting to the LU REB

Step 2) REB Review & Timelines

Minimal Risk

- Submit anytime
- Delegated review (2 members + Chair)
- Researcher will receive comments within 3 weeks

Greater than Minimal Risk

- Submit first week of the month
- REB will review at that months face-to-face meeting
- Researcher will receive comments by end of month

Submitting to the LU REB

Step 3) Decision made by the REB

- 1) Approve as submitted
- 2) Changes requested - response to be reviewed by the REB Chair
- 3) Changes requested - response to be reviewed by either the delegated committee or Full Board
- 4) Reject the study (*VERY unlikely!*)

Project will be routed back to you via Romeo for changes.

Participant Information Templates

We can help!

Both LU and TBRHSC REBs have templates:

TBRHSC template: <http://www.tbrhsc.net/regional-partners/research-ethics-board/forms/>

LU template: <https://www.lakeheadu.ca/research-and-innovation/ethics/human-subjects/resources>

Ensures documentation meets the requirements of the
TCPS2 for Information Letters and Consent Forms

Continuing REB Review

Amendments:

(through Romeo with LU, or paper with TBRHSC)

- We require:
 - Summary / Rationale for change
 - Tracked changes version of revised study documents
 - Clean version of revised study documents
 - Any new documents
- REBs **require** an amendment when you would like to add a **new team member, along with their signature and TCPS2 Certificate**

Continuing REB Review

Annual Renewals:

- Reminder email will be sent to best contact ~30 days before the approval expiry
- Funded projects must be renewed on time in order to avoid freezing of funds

Protocol Deviations and SAEs:

- Required as appropriate

Completion/Final Reports:

- Required when project completed

Questions

