F.A.Q. – Frequently Asked Questions

We have compiled a list of common questions asked by clients and have displayed them here for your convenience. Please feel free to ask us about clarification of certain topics, errors within the document or suggestions for improvement.

Summary:
Click the question you wish to find the answer to. You will be redirected to a different part of the document.

1. What is the REB?

The REB is a body established by the Board of Directors to protect the rights and welfare of human research participants. As an independent body, the REB ensures that all research involving human participants meets current ethical and scientific standards and is in compliance with the applicable regulations, standards, guidelines and policies as they relate to the ethical conduct of research.

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2. How do I know if a research agreement is required?

You will need to contact the Research Operations department by sending an email to researchoperations@thp.ca to confirm whether your study necessitates a research agreement.

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3. Is there a consent form template?

There is no required standardized template; a guidance document is available for reference at the following link: Research Ethics Board under "Supporting Documents."

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4. Is there a protocol template?

There is no required standardized template; a guidance document is available for reference at the following link: Research Ethics Board under "Supporting Documents."

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5. How do I obtain a formal determination to ascertain if my project meets the definition of human subject research?

In order to receive a determination, please complete and submit the following three documents:

1. The REB Determination Request Form,
2. Your study protocol/project charter,
3. A copy of the publicly available tool known as the ARECCI Guidelines and Ethics Screening Tool. These are decision-support tools that will help you identify and manage risks to protect participants and assist in determining the appropriate review pathway for your project. If a determination is made that your project is not human subjects research, a determination letter will be issued.

Please note that the REB will not issue retroactive approval for research activities that have occurred in the absence of REB approval that are subsequently determined to be human subjects research.

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6. Where are the REB application submission forms located?

All REB submission forms and applications are available on the Trillium Health Partners website.

You can access these submission forms and application through the following link: https://trilliumhealthpartners.ca/researchandinnovation/Pages/Research-Ethics-Board.aspx

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7. What document(s) do I need to complete for an REB submission?

Please refer to the 'Trillium Health Partners Research Ethics Board Application Form Submission Guide document' located on the Trillium Health Partners website.

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8. What if I want to advertise my study for recruitment in the hospital or a specific department?

For External Research: Please complete the 'External Research Recruitment Application form'.

For Internal and External: Resource impact form(s) should be completed and signed by the director/delegate for each department involved in advertising the study and provided to your Research Operations Analyst (ROA). The posting of flyers/posters on public notice boards within the hospital require approval from the communications department. For more information, please contact your dedicated ROA or email researchoperations@thp.ca

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9. When do I complete the THP Research Study Impact Approval Form?

The THP Research Study Impact Approval Form should be completed for all human subject research studies that are taking place under the auspice of THP, in order to identify whether or not there are any financial impacts on any programs/departments in the hospital and to ensure all study-related costs are covered. A Research Study Impact Form must be completed for all impacted departments/programs with sign-off by the appropriate Director/delegate. Approval to conduct the study is also required at the Health Systems level, by the appropriate Director (or above). Please contact the Research Operations department at researchoperations@thp.ca for more information.

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10. When and where do I submit the completed application package?

Prior to submitting your application package to the THP REB for review, please contact the

Research Operations Office at researchoperations@thp.ca who will support you through the institutional approval process. The THP REB will not process your submission until the Research Operations department confirms study feasibility has been completed.

Once study feasibility is completed, please submit your completed application package to the REB Coordinator at: THPREB@thp.ca

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11. Does the REB require electronic or hard copy submissions?

Electronic. Please send all submissions electronically to THPREB@thp.ca

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12. What are the submission deadlines?

Full-board review - Studies must be submitted by the first business day of each month to be reviewed at the REB meeting that month.

Delegated review - Studies can be submitted at any time.

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13. What is the turnaround time for my submission to the REB?

The REB currently aims to have a response to researchers within 10 business days of the submission for delegated reviews (minimal risk studies) and 10 business days following the full-board meeting (3rd Thursday of each month) for studies determined to be above minimal risk.

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14. What are the requirements when sending data to parties outside of THP?

Please contact the Research Operations office at Researchoperations@thp.ca and a ROA will be happy to support you in determining where an agreement is required for your project.

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15. What do I do if I want to make a change to an element of my REB approved study?

Any changes being proposed to an approved study must be submitted to the REB using the THP REB Amendment Submission Form. A summary of the proposed changes and the rationale for the

changes are required. When changes are made to study documents (e.g. protocol, consent form, data collection form, questionnaires) both a clean and track-change version must be submitted.

If you are making changes to the overall study design or research question, a new REB study submission may be required. Please contact the Research Ethics Board Office for further direction: THPREB@thp.ca

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16. Is a local study investigator required for my study?

All studies that are being conducted under the auspices of THP require a local investigator and as per the THP Scientific and Complimentary Research Appointments policy and procedure, all local investigators are required to have an active Institute for Better Health (IBH) appointment in order to proceed with any research activities here at THP. For more information, please contact your ROA.

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17. When will the THP REB no longer accept the legacy THP forms?

As of February 6, 2023 we are requesting that all submissions are done using our new suite of THP REB forms. We will continue to accept the legacy THP forms during this transition timeframe to allow our users time to complete recent submissions and to familiarize themselves with the new forms. After April 10, 2023 the legacy forms will no longer be accepted.

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18. What is a Case Report/Study and what are the submission requirements?

A Case report/study involves descriptive information and anecdotal accounts about a particular patient/person or small group (three or fewer patients).

Case reports should be screened by the THP REB before any activities are initiated.

Submission requirements:

1. The THP REB Case Report and Case Study Form must be completed and submitted with a copy of the consent form that will be/was used to obtain the patient's consent.
2. All submission material should be sent to THPREB@thp.ca for review by the THP REB.
3. Prior to publishing, you must provide the REB with a copy of the report you intend to publish.

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19. Am I required to pay REB fees?

REB fees are required for all industry-sponsored research projects (i.e., those funded by industry such as pharmaceutical, biological or medical device company) or projects funded by other for profit or not-for profit organizations that are reviewed by the THP REB. Fees will be charged regardless of whether the proposed research project is investigator-initiated or sponsor-initiated. The fees are also charged regardless of the review's outcome. Invoices will be issued once your submission is received. Please find the REB fee schedule below:

Type of review	Amount
Initial REB Review Fee	$3,000.00
Amendments	$1,000.00
Renewals	$750.00

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20. Who is the study investigator(s), sponsor(s), and the funder(s)?

Lead Principal Investigator: the designated principal investigator who is responsible for the ethical conduct of the study for all sites

Local Investigator: the designated principal investigator who is responsible for the ethical conduct only at THP; this person must have a Faculty Appointment at IBH)

Sponsor: An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a project. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator. The sponsor may be, but is not required to be the investigator.

Funder: Receives grant applications, evaluating them, funds the most suitable ones, and evaluates research outputs.

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21. Is there someone that I can consult about my research?

A Research Ethics Consultation Service is available for Investigators and project teams who are seeking advice regarding ethical issues pertaining to their research study. Please contact the Research Ethics Board Coordinator at THPREB@thp.ca to set up a consultation appointment with a member of the Research Ethics Board should you require clarification or guidance about the REB review process and/or assistance in managing any ethical considerations of the study.

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22. Do I need to obtain Consent for Data Drop (registry)?

a. No known preference regarding deposit or re-contact:
If there was no prior mention of data deposit for future research use as part of the consent process, and participants' wishes about re-contact are unknown, researchers must re-contact them to seek their consent for the data deposit.

When seeking consent for a specific research project at the same time as seeking consent for storage of data and human biological materials for future unspecified research, prospective participants must be provided with an option to consent to each separately, either through separate consent forms or separate sections on the same form

b. No known preference regarding deposit or re-contact, but seeking consent is impracticable:
If there is no indication that participants have declined future use, but researchers cannot seek participants' consent because it is impracticable, the researchers can deposit the data subject to REB approval. "Impracticable" refers to undue hardship or onerousness in seeking participants' consent; it does not mean inconvenience for the researchers. It is impracticable when participants or their authorized third party may be deceased or difficult to track due to insufficient identifiers, cost, or time elapsed.

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23. Do research registries need REB oversight?

The creation of a repository requires REB review and is subject to continuing research ethics review, in accordance with a proportionate approach to research ethics review. Appropriate mechanisms and procedures should be clearly outlined in the governance and policies of the repository to ensure that subsequent use of the data and human biological materials is in accordance with the original terms of participant consent and to ensure safety, security and protection measures are in place.

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