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 stands for the "Research Ethics Board". The Trillium Health Partners (THP) REB is a body established by the Board of Directors to independently protect the rights and welfare of human research subjects. This is done by ensuring that all human subject research meets current ethical and scientific standards, and is in compliance with the applicable legislation, guidelines, policies and regulations.

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

You will need to contact the Research Operations department at **(905) 848-7580 ext. 1610**, in regards to executing a research agreement if any of the following criteria are met:

- Does the study involve collaboration with external institutions and/or individuals?
- Is the study being initiated by an external organization and/or individual?
- Is the Principal Investigator (PI) or site investigator involved in the study a member of the THP privileged staff (i.e. Medical Staff, Dental Staff, Midwifery staff and members of the Extended Class Nursing Staff who are not employees of the hospital)?
- Is the study being conducted within or under the auspice of an external organization and specifically requesting use of the THP REB?
- The transfer of material outside of Trillium Health Partners. Materials can include human samples, clinical interpretations of human samples or pathology images, clinical interpretations of laboratory results, pathology images and/or samples, pathology reports and laboratory results.

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3. Is there a consent form template?

We do not have a consent form template. Please find below items that should (if applicable) be included your consent form:

The consent form should have:

- The Trillium Health Partners (THP) logo.
- The Investigator(s)/funder(s) and sponsor(s): name, role, institution and contact information
- The study title and page numbers
- The version number and date should be inserted in the footer of the consent document. This assists with document control.

The consent form should contain the following sections and information:

INTRODUCTION:

- Inform potential participants of the importance of reading the consent form thoroughly so they can make an informed decision on whether or not to participate in the study.
- Explained why they are being asked to participate in the study and what they are being asked to do.
- Provide a brief explanation as to what the issue is that is being investigated (a more condensed version of the background section in your protocol).

PURPOSE:

- Explain the significance of conducting the study (e.g. does the area being studied affect many people? Is it a serious problem and why?)

PROCEDURE:

- Provide a brief explanation about how the study will be conducted with reference to what the participant's involvement will be, (e.g. where the study is taking place, what is the participant's time commitment to this study, study visits).
- Explain what the difference is between what is taking place in the study and standard practice for this population at the hospital.
- Include information about what data will be collected and how the data will be collected from the participant (e.g. answers to survey questions, DNA samples, etc.) and how it will be used (e.g. for statistical analysis, for experimental testing, etc.)
- Include information as to whether there will be any costs, compensation, incentives or reimbursements for the study (e.g. Parking, gift cards, etc.).

ELIGIBILITY:

- Include the demographics that are being targeted for the study (e.g. Heritage, gender, age and/or health issues).
- Samples size required for the study.

RISKS AND BENEFITS:

- This section should cover whether there are any risks and/or benefits involved in participating in this study?
- If there are any risks, how will they be mitigated?
- Who will cover liability?
- Will there be any resources or supports that will be available?
- Do participants have the option to withdraw from the study at any point?

CONFIDENTIALITY:

- How will confidentiality be maintained?
- Will the information be destroyed afterwards (e.g. paper copies shredded after 5 years, etc. Please see THC policies on retention)?
- Where will the information be stored?
- Who will have access to participant information and why?
- Will the information be password protected or encrypted to prevent unauthorized access?
- Will the data be anonymous or de-identified during analysis or when released for publication?

- If information is being released to the public or to a research journal. What information is being released?
- Is there any way the information can be traced back to the participant after the study is completed?
- Explain whether the data is only being used for the purpose of this study.

VOLUNTARY PARTICIPATION:

- Is the participant allowed to withdraw from the study?
- Is the participant only allowed to withdraw before or after a certain point in the study?
- If the participant wants to withdraw, what will happen to their data (will it be destroyed, or will it still be used)?
- If surveys or interviews are part of the study, do participants have the option to skip any questions they feel uncomfortable answering?
- Will withdrawal from the study impact their usual care?

QUESTIONS ABOUT THE STUDY:

- Indicate that the research study has been approved by THP or another ethics board and if they have any questions about this study, please feel free to contact…[the research coordinator or the study PI] @XXX-XXX-XXXX or email @…. If they have any concerns about their rights as a participant in this project, they can call the **Trillium Health Partners Research Ethics Board** at **905-848-7580, ex.1682**.

SIGNATURE PAGE:

- Include information about what the participant is consenting to by signing the consent form.
- Include a signature section (name, signature and date) for participants and the study personnel responsible for obtaining consent.
- If the study is seeking consent from a substitute decision maker or someone consenting on behalf of the participant, please include a section for them to print, sign and date.

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4. Is there a protocol template?

We do not have a protocol template. Please find below items that should (if applicable) be included in your protocol:

Your study protocol should contain at least the following information about your study:

- The study title
- The Investigator(s)/funder(s) and Sponsor(s): Name and Institution.
- The version number and date should be inserted in the footer of the protocol document.

Your study protocol should contain at least the following sections:

1. Background
2. Research Question/Objective
3. Study Design
4. Ethical considerations
5. Dissemination plan

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5. How do I obtain a formal determination regarding whether my project is considered a research study or a quality initiative?

There is a publicly available tool known as the ARECCI Ethics Screening Tool which will assess whether your project is research or quality. Once you have completed the ARECCI Tool, you will need to submit a copy of the results of the assessment and a copy of your protocol/project charter for review and determination by the REB. If the study is determined to be quality, and in some instances, non-human subjects research, a determination letter will be issued.

The link to the **ARECCI Ethics Screening Tool** has been provided below:

http://www.aihealthsolutions.ca/arecci/screening/39438/b0e2818edfa3f552eafcfd8469df7834

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6. Where are the REB application submission forms located?

Each of the 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

You can also access the Tri-Council Policy Statement 2 Research Ethics training module (Tri-Council Policy Statement 2 (TCPS2) Course on Research Ethics) through the following link:
http://tcps2core.ca/welcome)

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7. What is the difference between application A and application B?

The application package that you will need to complete will depend on whether or not there are human participants (i.e. active participation of study subjects). If there are human participants, you must complete application package A; if not, you will need to complete Application Package B

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

Please complete Application Package D and ensure that signatures are obtained from the manager(s)/director(s) of all departments involved in the advertisement of this study. The posting of flyers/posters on public notice boards will require approval from the communications department.

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9. How do I complete the Health System(s) Review section of the application and the Resource Impact form?

You will need to fill out the Resource Impact form included in the application (Appendix A) for all departments that will be impacted by the study; a separate Appendix A document is also available on the website for your use in the event that more than one department is impacted by the study. It should be signed by the director/manager (as applicable) of the impacted department and the principal investigator. The form should indicate whether there are any impacts on the department and whether there will be any fees associated with the impact. Please also ensure that section 27 (application A) or 13 (application B) of the application: Health System(s) Review is signed by the administrative lead of the impacted department (Director or VP). Please note that the REB will not review studies that have not received administrative sign-off.

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10. Where do I submit the completed application package?

You will need to submit your completed application package, study protocol, signed impact forms, consent documents (if applicable), and data collection forms to the REB Coordinator at: THPREB@trilliumhealthpartners.ca

All research agreements or communications in relation to research agreements should be sent to Delilah Ofosu-Barko, Research Operations Manager: Delilah.Ofosu-barko@trilliumhealthpartners.ca

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

Electronic copies are accepted and preferred. Please ensure that all submissions, regardless of submission format include all of the required signatures and attestations. Please send all hard copy submissions to the following address:

Mississauga Hospital site
100 Queensway West
Clinical and Administrative building - 6th Floor
Mississauga ON
L5B 1B8
Attention: THP REB

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12. Is there a deadline for expedited reviews/submissions?

Submission deadlines are only applicable to studies that require full board review (greater than minimal risk presented by the study). Research submissions for studies requiring full board review

are due on the first business day of each month. However, there is no deadline for expedited reviews. They can be submitted to the REB at any time.

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

This depends on the quality of your submission. The REB's standard turnaround time for a response to an initial submission is 10 business days from:

- The date of final submission (all required documentation, signatures and attestations received) for those studies that qualify for expedited/delegated review.
- The full board REB meeting for studies requiring full board review.

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

As long as identifiable data that is collected at THP is being sent to another location off site that is not a part of THP, a data sharing agreement is required. If you are collaborating with an external institute/individual, please contact Delilah Ofosu-Barko, the Research Operations Manager at **(905) 848-7580 ext. 1610** or by email at *Delilah.Ofosu-Barko@trilliumhealthpartners.ca* who will support you in implementing the appropriate agreement for your study.

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15. What do I do if there is a change in my project timeline or specific elements of my REB approved study?

If it is the same study and you are not changing the study design or research question, you are able to submit this to the REB as an amendment to the study using the REB Amendment Submission Form. In addition, in order to obtain continued REB approval for the proposed amendment in study conduct, a letter explaining the amendment can be submitted. When any study document (protocol, consent form, data collection form, questionnaires etc.) requires a revision both a clean and track-change version of the revised document must be submitted.

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

This is dependent on the nature of the study and the components of study activities that will occur at this site (THP). A local study investigator is required if any of the following are true:

- Full study conduct is occurring at Trillium Health Partners
- The study is a Clinical Trial (exception being for studies where only recruitment is happening at THP, in this case a local investigator is not required)

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17. Is there a difference between THP and CVH applications? Can they be used interchangeably?

There is no difference between THP and CVH forms. The legacy forms for both sites can be completed and submitted to the REB until new forms become available. Please check the THP website for future updates on the new forms.

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18. What are the requirements for a case study report?

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

A case report submission to the REB would require the following:

1. A copy of the consent form that will be used to obtain the patient's consent to conduct the case study
2. A cover letter detailing:
   a) What you are wanting to do and why
   b) How consent will be obtained (the process and who will obtain consent from the patient)
3. Prior to publishing, you should provide the REB with a copy of the report you intend to publish
4. You can email THPREB@trilliumhealthpartners.ca for a "*Case Report Publication Request*" and a "*Case Report Consent Form Template*" which will be necessary for submission.

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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[1]
Renewals	$750.00

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[1] Effective Q_3 Fiscal 15/16