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 by sending an email to researchoperations@thp.ca to confirm whether your study necessitates a research agreement. If any of the following criteria are met, a research agreement may be required:

- 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?
- Involves 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?

No, but we will provide you with a guidance document if requested.
For your reference, please find below items that should (if applicable) be included your consent form:

The consent form should include:

- 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 of the issue 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** or send an email to THPREB@thp.ca

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?

No, but we will provide you with a guidance document if requested.
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 meets the definition of human subject research?

In order to receive a determination, please complete and submit a copy of the "REB Determination Request Form (that you can request at THPREB@thp.ca)," as well as a copy of your protocol/project charter for review and determination by the REB. The REB also recommends that you complete and submit 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 a quality initiative or, 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/19345/5888802f72a7fbe0e67e4848737547ac

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

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

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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. 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.

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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@thp.ca

All research agreements or communications in relation to research agreements should be sent to the Research Operations Office at researchoperation@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. Is there a deadline for delegated reviews/submissions?

If a study is determined by the REB to be minimal risk there is no submission deadline. All studies that qualify for delegated review will be screened and once they have passed the screening process will be immediately assigned for review.

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

Depending on the quality of your submission, the Trillium Health Partners' REB currently aims to have a response to researchers within 2 weeks (10 business days) of the submission for delegated reviews (minimal risk studies) and 2 weeks following the full-board meeting 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?

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 the Research Operations office at Researchoperations@thp.ca and a research Analyst will be happy to 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?

For consistency in review, we are requesting that you use the THC forms until the new forms become available. Please check the THP website for future updates on the new forms (Sept. 2018).

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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).

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

1. A copy of the THP Research Ethics Report and Case Study Form should be completed and submitted with the following:
   a) A copy of the consent form that will be 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 should 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[1]
Renewals	$750.00

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[1] Effective Q_3 Fiscal 15/16