CLINICAL TRIALS ONTARIO

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Documented Institutional Ethics Requirements
Trillium Health Partners

Informed Consent Form Requirements

The Principal Investigator is responsible for ensuring the following requirements are met. (Not applicable for studies reviewed by the Ontario Cancer Research Ethics Board)

- Consent forms must include appropriate language (detail and consent statements) to account for any anticipated secondary use of personal information, personal health information, and biological material under the custody and control of an external organization (i.e. other than Trillium Health Partners) for the purpose of a patient's participation in the study. It is expected that this aspect of study participation (i.e. study conduct and activities following the patient journey, whereby a patient, in the course of their clinical care, may receive care from various institutions, and aspects of their care throughout their journey will be captured and/or leveraged for study purposes) are contemplated and factored into the consent process and consent documentation.
- Acceptable consent language include the following; note similar language that address each of the articulated scenario-based criteria are also acceptable:

Procedures section of Consent Form for Biological Material

- *"If you agree to take part in this study and sign this consent form, your [insert name of primary recruiting institution] study doctor will request that samples of your [insert detail of applicable biological material], which were collected from [insert details of relevant procedure from which biological material was originally obtained] that you had prior to the participation in this study, be sent to a special lab for testing. If your [insert details of relevant procedure from which biological material was originally obtained] were/was conducted external to the [insert name of primary recruiting institution], you will need to provide your consent for the request to transfer part of this biological material to [insert name of primary recruiting institution], together with related personal health information."*

Under the Consent Heading at the end of the consent form:

- *"This study has been explained to me and any questions I had have been answered. In the event that my [insert details of relevant procedure from which biological material was originally obtained] were/was conducted external to the [insert name of primary recruiting institution], I give my consent for the request to transfer to [insert name of primary recruiting institution] a part of this biological material considered necessary for the research purposes described, together with any related personal health information."*

- *"If your [insert details of relevant procedure from which biological material was originally obtained] were/was completed at another institution, signing this consent form means that you are consenting to the collection of your biological material, together with any related personal health information, from that institution."*

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SRERS Administration
Trillium Health Partners

Scope

At this time Trillium Health Partners is electing to use SRERS for the following studies:

- Studies using the Ontario Cancer Research Ethics Board (OCREB) as the REB of Record;
- studies related to COVID-19.

Reminder: Institutional Research Administration Requirements

Privacy Considerations
The Principal Investigator is responsible for ensuring the following requirements are met.

- Consent is the default requirement for research-related access to patients, their personal information and their personal health information

Access to Patients

- Consent for access to patients for research purposes (i.e. consent to contact) must come from a member within the patient's circle of care.
- Acceptable approaches to accomplishing this requirement include:
    - Having a member within the patients circle of care obtain consent to being contacted by a member of the study team; this arrangement must be formally established with the impacted Trillium Health Partners clinical program and documented through the Trillium Health Partners standard Institutional Research Administration Requirements (completed and signed Resource Impact Estimate form)
    - Having a member of the study team act as an agent of Trillium Health Partners in the capacity of a member from the patients circle of care – this approach must be done through formal legal delegation of authority. The manner in which this is accomplished depends on the nature of the study and the institutional affiliation of the study team member assuming the responsibility. If study personnel are non-Trillium Health Partners personnel, this agency relationship must be articulated in the study agreement among the respective parties
- Exceptions to this institutional requirement for consent must be approved by the Research Ethics Board of Record in the form of documented approval of a waiver of the consent requirement.

Access to Patient Personal Information and Personal Health Information

- Consent for access to patients personal information and/or personal health information is the default mandatory requirement; this includes access for the purposes of identifying potential participants and for screening for eligibility
- Consent for access to patient's personal information and/or personal health information must come from a member within the patient's circle of care.
- Acceptable approaches to accomplishing this requirement include:
    - Having a member within the patients circle of care obtain consent to being contacted by a member of the study team; this arrangement must be formally established with the impacted Trillium Health Partners clinical program and documented through the Trillium Health Partners standard Institutional Research Administration Requirements (completed and signed Resource Impact Estimate form)

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  - Having a member of the study team act as an agent of Trillium Health Partners in the capacity of a member from the patients circle of care – this approach must be done through formal legal delegation of authority. The manner in which this is accomplished depends on the nature of the study and the institutional affiliation of the study team member assuming the responsibility. If study personnel are non-Trillium Health Partners personnel, this agency relationship must be articulated in the study agreement among the respective parties
- Exceptions to this institutional requirement for consent must be approved by the Research Ethics Board of Record in the form of documented approval of a waiver of the consent requirement.

Access to Medical Records and Obtaining Consent

- Consent for access to patients personal information and/or personal health information is the default mandatory requirement; this includes access for the purposes of identifying potential participants and for screening for eligibility
- Consent for access to patient's personal information and/or personal health information must come from a member within the patient's circle of care.
- Acceptable approaches to accomplishing this requirement include:
  - Having a member within the patients circle of care obtain consent to being contacted by a member of the study team; this arrangement must be formally established with the impacted Trillium Health Partners clinical program and documented through the Trillium Health Partners standard Institutional Research Administration Requirements (completed and signed Resource Impact Estimate form)
  - Having a member of the study team act as an agent of Trillium Health Partners in the capacity of a member from the patients circle of care – this approach must be done through formal legal delegation of authority. The manner in which this is accomplished depends on the nature of the study and the institutional affiliation of the study team member assuming the responsibility. If study personnel are non-Trillium Health Partners personnel, this agency relationship must be articulated in the study agreement among the respective parties
- Exceptions to this institutional requirement for consent must be approved by the Research Ethics Board of Record in the form of documented approval of a waiver of the consent requirement.

Institutional Representative Sign-off Process and Requirements in CTO STREAM

1. Investigator or Study Team Representative sends an email to the Corporate Manager Research Operations & Project Management including the following:
   a. Notification of submission in CTO stream requiring Institutional Signoff;
   b. THP Principal Investigator's (and any Co-Investigators) GCP completion certificate; and
   c. Confirmation of the following (in the form of responses to the below listed attestation statements):
      i. The Principal Investigator and any co-investigator at THP are appropriately qualified to act as the Principal Investigator (or Co-Investigator, if applicable) for the conduct of the study at THP
      ii. The Principal Investigator has access to the resources necessary to conduct the study; and
      iii. The Principal Investigator (and Co-Investigator, if applicable) has completed any mandatory clinical research training (initial and/or refresher courses) required at THP, if applicable and, if a physician, has been appropriately credentialed

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2. Corporate Manager, Research Operations & Project Manager prepares execution Memo for SVP Science (Robert Reid) which includes above-listed materials (attestation and GCP completion certificates)
3. SVP Science signs off on application in CTO Stream

Institution-Specific Administrative Requirements and Authorizations

For all studies authorized for research ethics review and oversight through CTO SRERS Trillium Health Partners standard requirements for:

1. study feasibility assessment (Health Systems Review) and signoff,
2. resource impact assessment and signoff,
3. research agreements, and
4. institutional authorization

must be met before a study can commence after receiving approval through CTO SRERS. In addition, for all applications through CTO SRERS an email must be sent to the secondary Institution Representative notifying of the requirement for the Primary Institution Representative signature on the application form. This email must include confirmation of the following:

- that the Principal Investigator and any co-investigators at Trillium Health Partners are appropriately qualified to act as the Principal Investigator (or Co-Investigator, if applicable) for the conduct of this study Trillium Health Partners;
- that the Principal Investigator has access to the resources necessary to conduct the study; and
- that the Principal Investigator (and Co-Investigator, if applicable) has completed any mandatory clinical research training (initial and/or refresher courses) required at Trillium Health Partners, if applicable and, if a physician, has been appropriately credentialed

Documentation of up-to-date mandatory training must be included with the email sent to the Secondary Institution Representative if this information is not already on file with the Research Operations department at Trillium Health Partners.

1. Study Feasibility Assessment and Signoff

Before submitting the study for review through CTO SRERS the Trillium Health Partners site investigator or their delegate must notify and review their study application with appropriate Health System Chief(s) and Director (confirm with program administrative lead whether this authorization is to come from the Director or the Vice President). Confirmation of their endorsement of the study at Trillium Health Partners and recommendation for approval is documented through signing the Health Systems Review section of the Trillium Health Partners study feasibility package.

2. Resource Impact Assessment and Signoff

As a publicly funded healthcare organization, for all research conducted within and/or under the auspices of the organization, Trillium Health Partners requires that all study specific activities that are undertaken within the organization or utilizing resources of the organization, are covered through study funding. The "Resource Impact Estimate" Form (also known as Appendix A) of the current REB application forms at Trillium Health Partners) is the manner in which our organization documents the study specific impact to departments within the organization. In addition, this document captures what aspect of the support from the department are considered study specific (over and above standard of care – meaning if a patient and/or participant was not participating in the study the activity would not be occurring), and will be reimbursed to the department. The researcher/research team is responsible for completing this document (Appendix A), connecting with the department head (Administrative Director or their delegate), sharing the necessary information with them in

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relation to the study and the respective impact to their department, and obtaining their dated signature on the document which should reflect the arrangements that have been made (which services will be reimbursed to the hospital AND whether reimbursement is not required to the department).

It is the site investigator or their delegate's responsibility to review the study protocol, the respective study specific requirements and identify which activities are considered standard practice at Trillium Health Partners and which activities are specific to the study (i.e. only occurring as a results of the study).

Before submitting the study for review through CTO SRERS the Trillium Health Partners site investigator or their delegate must:

- Meet with the impacted Health system(s) team and services to discuss the application, facilitate understanding of the protocol and impact on the system or service, and obtain the system's or service's support for the study. In general, this review should include the following individuals:
  - Health Systems Chief or designate of the impacted service(s).
  - Health Systems Director/Manager or designate of the impacted service(s).
  - Clinical Educator if staff orientation to the protocol will be required.
  - Clinical pharmacist if the study is a clinical trial involving drugs, biologics or natural health products.
  - Biomedical Engineering if the study is a clinical trial involving a medical device
  - Information and Privacy if the study involves the use of non-THP technology (software, applications, tools etc): (i) for the collection, use and disclosure of confidential information and/or personal health information, and/or (ii) that interfaces with Trillium Health Partners Health Information Systems
  - Director, Health Records or designate.
  - Professional Practice Leader(s)
  - Any other impacted areas as required
- Confirm funding arrangements with the study funder/sponsor
- Ensure all impacts of the study are identified and that a mechanism is in place to support those impacts

The arrangements made with the impacted Trillium Health Partners programs/units/departments must be documented through completion and signoff on the Trillium Health Partners resource impact estimate form.

3. Research Agreements

All research studies that involve: (1) the collection and disclosure of Trillium staff and/or patient information, and/or (2) the participation of Trillium Staff and/or patients requires an agreement that at minimum provides provisions for the protection of staff and/or patient information and protection of staff and/or patients throughout the conduct of the study. Trillium must enter into an agreement for the research before it can participate in such a study. The review, negotiation and execution of all research agreements (including confidentiality agreements/confidential disclosure agreements and non-disclosure agreements) is managed through Trillium Health Partners Research Operations department. All new agreements should be submitted to the Research Operations Analyst that manages the clinical program or through the general department email account at: ResearchOperations@thp.ca.

4. Institutional Authorization

The following material must be submitted to the Research Operations department at ResearchOperations@thp.ca once final REB approval has been granted through CTO SRERS in order for an institutional authorization letter to be issued to the local investigator:

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- Copy of the Health Canada No Objection Letter/Investigational Testing Authorization/XX (as applicable)
- Completed and signed hospital resource impact estimate forms for all hospital units/departments involved and/or impacted by the conduct of the study
- Completed and signed study feasibility (Health Systems Review) form
- REB approved study consent forms
- REB approved protocol
- REB final approval letter

Once the submitted material have been processed by the Research Operations department an Institutional Authorization letter will be issued which will acknowledge:

- The existence of an executed research agreement
- The existence of an executed Board of Record Agreement
- Resource impact analysis evaluation and signoff, and
- External REB approval

confirming that the study is authorized to start at Trillium Health Partners.

The CTO Streamlined System provides a streamlined approach to research ethics review. Each participating site must ensure that all necessary institutional authorizations and contracts/agreements are in place prior to beginning the research.

CTO Stream

Collaborators:

The following collaborators must be given a role on all Provincial Initial Application (PIA) forms and Centre Initial Application (CIA) forms.

Email: Robert.reid@thp.ca
Role: Institution Representative

Email: Elliott-Marc.Shamy@thp.ca
Role: Institutional Admin

Email: Delilah.ofosu-barko@thp.ca
Role: Institution Representative

Email: Natasha.mistry@thp.ca
Role: Institutional Admin

Email: Omwattie.harricharran@thp.ca
Role: Institutional Admin

Email: Kylie.walcott@thp.ca
Role: Institutional Admin

Email: Stephanie.fazzari@thp.ca
Role: Institutional Admin

Email: sarah.tagliapietra@thp.ca
Role: Institutional Admin

This access is automatically granted when the Centre Initial Application is created. **When Trillium Health Partners is the Provincial Applicant site the research team should immediately create the CIA for Trillium Health Partners (right after creating the PIA)**. This will ensure that access is automatically granted as required above, otherwise the research team will need to manually add these roles to the PIA prior to submission.

Institution Representative in application forms

The Primary Institution Representative must be indicated as follows in the applications within CTO Stream:

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Title:	Ms.
First Name:	Delilah
Surname:	Ofosu-Barko
Organization:	Trillium Health Partners
Address:	100 Queensway West – 6th Floor Clinical and Administrative Building
City:	Mississauga
Province/State:	Ontario
Postcode/Zip:	L5B 1B8
Telephone:	905-848-7580 ext 1610
Fax:	905-804-7988
Email:	delilah.ofosu-barko@thp.ca

The Secondary Institution Representative field should be left blank.

Absence Coverage – Institutional Representative Signature
Should the Primary Institutional Representative be away, the Institutional Representative signature request may be sent to Susan Law, Director Research at susan.law@thp.ca instead.