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Trillium Health Partners Research Ethics Board

Research Consent Form Guidance Document

September 19, 2019

*This is a sample consent form only.*

*Sections should be modified to reflect the details of the individual research study.*

*For questions related to the information contained in this document, contact* *THPREB@thp.ca* *or 905-848-7580 ext. 1682*

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**Consent Form**

**Title of Study:**

**Investigator(s)**: Name and role

 Institution

 Contact Information

**Sponsor/Funder:**

**Conflict of Interest Statement**:

**Please note: The consent form for patient participants should be written at a 6-8th grade reading level.**

**Introduction**

* Identify that the individual is being asked to participate in a research study
* Inform the participant to read the consent form thoroughly so they know what is being asked of them
* Indicate that participation in research is voluntary
* Describe why the participant has being asked to participate
* Describe what the participant s is being asked to do.
* Provide a brief explanation of the issue being investigated (a condensed version of the background in your protocol)

**Purpose**

* Describe what the study hoping to achieve
* Explain the significance of the study
* Describe who will be impacted by the study findings?

**Procedures**

* Provide a brief explanation about how the study will be conducted and outline what the participant is being asked to do
* Describe where the study is taking place
* Outline the participant’s time commitment to this study, including number of study visits
* Describe how data will be collected (e.g., answers to survey questions, interview transcripts, blood samples, health record) how data will be used.

**Study Participants**

* Describe inclusion/exclusion criteria
* Describe number of local and total participants

**Potential Risks and Benefits**

* Describe the foreseeable and potential risks and benefits of the study to participants, participant groups, and society. Outline how risks will be mitigated?
	+ Describe any resources or supports that will be available
	+ Describe if participants can opt out of any parts of the study.
	+ Describe how participants may skip any questions that they do not feel comfortable answering
* Outline who will cover any liability.
* A statement should be included about not waiving their legal rights, i.e. “In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions of their legal and professional responsibilities.
* Discuss the potential for material incidental findings and management plan
	+ Participant preference to receive material incidental findings (consent for disclosure of findings)
	+ When possible, identify what type of material incidental findings may be possible in the context of the research
	+ Explain material incidental findings in the consent form
	+ What findings may or may not be disclosed
	+ Describe likelihood of material incidental findings in the context of the research
	+ Who will be informed (patient, family physician, etc.)

**Confidentiality**

* Describe plan for storing data:(where, protections in place (e.g., encryption, de-identification, anonymized), who will have access
* Describe data retention plan
* Describe what data will be shared and how (e.g., presentations, publications)
* Explain if data may be used for the purposes other than the study

**Withdrawal from Study**

* Describe if, when and how the participant can withdraw from the study
* Describe what happens to any data collected prior to withdrawal.
* Explain consequences of withdrawal.

**Compensation**

* Describe participant compensation
* Describe any costs to participation

**Contact Information:**

* Explain that the research study has been approved by THP REB (and other REBs, if applicable)
* “If you have any questions about this study, please feel free to contact…@XXX-XXX-XXXX or email @.... If you have any concerns about your rights as a participant in this research study, you can call the Trillium Health Partners Research Ethics Board, 905-848-7580, x 1682.”

-- Signature Page --

On this page, include what the participant is consenting to by signing the page. Should include, at a minimum, the following statements:

**Statement of Consent:**

I understand the nature of research being conducted and what is expected of me.

I understand that my participation is voluntary; I understand that I can withdraw from the study at any time.

I have had the opportunity to have all my questions answered.

I agree to participate in the research study.

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Printed name of participant Signature of participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date

**(Only include this section if it is applicable to your study) If consent has been translated or the consent has been given by the Substitute Decision Maker (SDM), sign below:**

**SDM Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**SDM name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Translator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Translator name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

I have explained to the participant the purpose of the study and I have answered all their questions.

I will provide a copy of the signed consent form to the participant.

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Printed name of person who explained consent Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date