#  Logo for Cambridge Memorial Hospital Logo for Grand River Hospital

# TRI-HOSPITAL RESEARCH ETHICS BOARD (THREB)

## AMENDMENT TO RESEARCH

### REQUEST FORM FOR APPROVAL OF AMENDMENT

#### TO PROTOCOL, CONSENT FORM or ADMINISTRATIVE or PERSONNEL CHANGES

All submissions must be typed, excepting check marks and signature. (**Handwritten submissions will not be accepted**.)

1. THREB #

2. INVESTIGATOR

3. TITLE of Protocol

4. The following over-all evaluation of the amendment is given by the locally responsible investigator:

**[ ] Minor** (no increase of risk or burden on research subject and no implication for hospital resources; includes changes that are only administrative)

**[ ] Moderate** (some substantive changes in protocol that require explanation to patient/subject)

**[ ] Major** (may alter originally proposed study outcomes, including statistical power, risks or benefits)

5. Do changes involve increased risk, burden or discomfort for participants? **( ) Yes ( ) No**

6.Does the consent form require modification due to these changes? **( ) Yes ( ) No**

If "Yes", is a modified form included? **( ) Yes ( ) No**

7. Provide a **brief summary or overview** of the changes, either in the space below or in a

cover letter.

8. ATTACH A **DETAILED DESCRIPTION** OF CHANGES.

THESE SHOULD BE **FORMATTED AS DESCRIBED** ON THE FOLLOWING PAGE.

**Name of Local Responsible Investigator:**

 **(Print or Type Name)**

**Signature of Local Responsible Investigator:**

**Date:**

**Amendments must be submitted in such a way that the THREB members can easily see:**

**1. the old wording;**

**2. the new wording;**

**3. the rationale or justification for each change.**

For Consent Forms especially, the following should be the norm. Exceptions must be justified.

* The **old wording** is clearly identified and printable in black & white (for example**, ~~bolded strikethrough~~ text).**
* The **new wording** is clearly identified and printable in black & white (for example**, *italicized* *grey-shaded* text).**
* It is clear why each amendment has been made (the **rationale** is given).
* It is clear whether each amendment increases **risk or discomfort** for the participant in any way.

**Please submit:**

* **One (1)** hard copy of a typed completed **Amendment Request Form** with **original signature** of the Locally Responsible Investigator, and **five (5)** additional hard copies of the form.
* **An electronic copy, if possible, of each of the documents below, sent to** laurie.dietrich@grhosp.on.ca
* **Five (5) hard copies (collated)** with each of the following:
	+ **A cover letter** from the Investigator or sponsor summarizing the changes and rationale. Moreover, for changes in lengthy protocols, a summary with old wording, new wording, and rationale or detailed explanation for each change can be substituted for a full protocol with tracked changes and rationale as indicated below.
	+ **For changes to existing protocols:**
		- **One (1)** clean hard copy of the amended protocol.

**AND either**

* + - **Five (5)** hard copies of the amended protocol with tracked changes and rationale for each change,

**Or**

* + - **Five (5)** hard copies of the summary with old wording, new wording and rationale for each change.
	+ **For changes to existing information sheet/consent form, advertisement, study instrument, questionnaire, etc :**
		- **One (1)** clean hard copy of the amended document and
		- **Five (5)** copies of the amended document with changes “tracked” as indicated above and with a detailed explanation/rationale for the changes.
	+ **For new documents:**
		- **Five (5)** copies of any new document (e.g. protocol, information sheet/consent form, drug or device brochure, advertisement, study instrument, questionnaire, etc.) including a rationale for adding the new document.
* **One (1) hard copy of and new or amended investigator’s brochure for drugs or devices (electronic version not needed).**

Mail completed materials to: Laurie Dietrich, Administrative Coordinator

 Tri-Hospital Research Ethics Board

 Grand River Hospital, Kaufman Building, Rm K415

 835 King Street West

 Kitchener, ON. N2G 1G3

|  |
| --- |
| For Office Use Only THREB #\_\_\_\_\_\_\_\_\_\_\_\_1. Amended protocol with changes and rationale indicated 🞏 Yes 🞏 No 2. Required number of copies 🞏 Yes 🞏 No3. Changes tracked on revised consent form and other documents 🞏 Yes 🞏 No4. Amendment Request Form signed by Local Responsible Investigator 🞏 Yes 🞏 No5. Industry sponsored trial review fee received 🞏 N/A 🞏 Yes 🞏 No  |