



TRI-HOSPITAL RESEARCH ETHICS BOARD (THREB)

**AMENDMENT TO RESEARCH**

**REQUEST FORM FOR APPROVAL OF AMENDMENT  
TO PROTOCOL, CONSENT FORM or ADMINISTRATIVE or PERSONNEL CHANGES**

- 1. THREB #
- 2. TITLE of Protocol
- 3. 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)

4. Does the consent form require modification due to these changes? ( ) Yes ( ) No  
If "Yes", is a modified form included? ( ) Yes ( ) No

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

6. 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.
- 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)** copy of a typed completed **Amendment Request Form** with original signature of the Locally Responsible Investigator.
- **Fourteen (14)** additional copies of the signed **Amendment Request Form**
- **Fifteen (15) copies** of each of the following:
  - **A cover letter** from the Investigator or sponsor summarizing the changes and rationale is most often very helpful. 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 copy of the amended protocol.  
**AND either**
    - **Fifteen (15)** copies of the amended protocol with tracked changes and rationale for each change,  
**Or**
    - **Fifteen (15)** 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 copy of the amended document, and
    - **Fifteen (15)** copies of the amended document with changes “tracked” as indicated above and with a detailed explanation/rationale for the changes.
  - **For new documents:**
    - **Fifteen (15)** 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) copy of and new or amended investigator’s brochure for drugs or devices.**

Mail completed materials to:

Karen Goerz, Administrative Coordinator  
 Tri-Hospital Research Ethics Board  
 Kaufman Building, Rm K615  
 Grand River Hospital  
 835 King Street West  
 Kitchener, ON N2G 1G3

<b>For Office Use Only</b>	<b>THREB # _____</b>
1. Amended protocol with changes and rationale indicated	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Required number of copies	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Changes tracked on revised consent form and other documents	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. Amendment Request Form signed by Local Responsible Investigator	<input type="checkbox"/> Yes <input type="checkbox"/> No
5. All documentation complete	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. Industry sponsored trial review fee received	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No