**RESEARCH ETHICS BOARD (REB)**

**AMENDMENT REQUEST**

***INSTRUCTIONS FOR COMPLETION***

**N.B. ALL changes to research protocols or information/consent documents, advertisements, study instruments, etc. must have REB review and approval prior to implementation, except where necessary to eliminate immediate hazards to study participants.**

**Amendments must be submitted in such a way that:**

* The old wording is clearly identified (for example, **bolded ~~strikethrough~~ text**).
* The new wording is clearly identified (for example, *italicized* *grey-shaded* text).
* It is clear why each amendment has been made. (Rationale)
* The amendment can be evaluated in context. Supply a copy of the protocol with the affected pages flagged and the relevant sections outlined by hand.
* It is clear whether each amendment increases risk or discomfort for the participant in any way.

**Please submit:**

* One copy of a typed completed **Amendment Request Form** (attached) with original signature of the Locally Responsible Investigator.

* A cover letter (synopsis) from the Investigator is helpful, but not mandatory.
* **For changes to existing documents:**
	+ One copy of any amended document containing the proposed changes (eg. protocol, information sheet/consent form, drug or device brochure, advertisement, study instrument, questionnaire, etc.).
	+ A detailed explanation/justification for each change.
	+ If the information/consent forms or recruitment advertisements have been changed, provide two “clean” copies of amended document(s). One clean copy of the approved amended document(s) with the dated REB stamp will accompany the approval letter from the REB Chair.
* **For new documents:**
	+ One copy of any new document (eg. protocol, information sheet/consent form, drug or device brochure, advertisement, study instrument, questionnaire, etc.).
	+ An explanation / rationale for the newly added document(s) must be provided.

**Submit the Amendment Request form, together with supporting documentation to the Research Ethics Board Office, Niagara Health System.**

**Please send an electronic copy (in addition to the hard copy with original signatures) to:**

**nhsresearchethicsboard@niagarahealth.on.ca**

**Research Ethics Board – Amendment Request**

## *Complete the application in NO smaller than 11 point font; handwritten submissions are NOT acceptable*

**Press “F11” to take you to the next fill-in box and begin typing, double click on a “check box” and click “checked”**

**Please Refer To Appended Instructions Before Completing This Form.**

|  |  |
| --- | --- |
| **NHS****REB PROJECT #:** |  |
| **TITLE OF PROJECT/STUDY:** |  |
| **LOCAL PRINCIPAL INVESTIGATOR:** |  |
| **MAILING ADDRESS:** |  |
| **TELEPHONE # AND EXTENSION:** |  |
|  |  |  |
| 1. | Indicate the number, version number and date of the document(s) being amended:       |
|  |  |
| 2. | Proposed Changes Affect: (Please check ([x] ) if YES) |
|  | a) | **Protocol** |  |
|  |  | * Study objectives, statistical analysis, design or methods
 | [ ]  |
|  |  | * Study instruments, questionnaires, etc.
 | [ ]  |
|  |  | * Number of participants
 | [ ]  |
|  |  | * Participant recruitment methods
 | [ ]  |
|  |  | * Eligibility criteria (inclusion / exclusion criteria)
 | [ ]  |
|  |  | * Study end date
 | [ ]  |
|  |  | * Principal and/or Sub-Investigators:If PI is changing, include a letter signed by the outgoing PI and the incoming PI indicating they both agree to the change. Attach a revised consent form which reflects the change of Principal / Sub-Investigator(s).
 | [ ]  |
|  |  | * Health Canada Therapeutic Products Director (TPD) approval:If TPD approved the original protocol, then TPD approval is also required for this amendment. Attach a copy of TPD approval [ ]  Attached
 | [ ]  |
|  |  | * Other:
 | [ ]  |
|  | b) | **Consent Form** | [ ]  |
|  | c) | **Information Sheet** | [ ]  |
|  | d) | **Advertisement and Recruitment Material** | [ ]  |
|  | e) | **Administrative** | [ ]  |
|  |  | * Change in Name of Sponsor
 | [ ]  |
|  |  | * Change in Contact Information
 | [ ]  |
|  |  | * Other (Specify):
 | [ ]  |
|  | f) | **Other** (Specify):       | [ ]  |
|  |  |  |  |
| 3. | Will there be any increase in risk, discomfort or inconvenience to the participants? [ ]  Yes [ ]  NoIf **YES**, provide detailed explanation / justification. [ ]  AttachedIs the risk considered to be [ ]  Low [ ]  Moderate [ ]  High? |

|  |  |
| --- | --- |
|  |  |
| 4. | What follow up action do you propose for participants who are already enrolled in the study?[ ]  Inform study participants ASAP[ ]  Re-Consent participants with the revised consent / assent forms ([ ]  Attached)[ ]  Other (please describe):      [ ]  No action required |
|  |  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Name of Local Principal Investigator (please type or print**)  |  |  |
|  |  |  |
| **Signature of Local Principal Investigator** |  | **Date (mm/dd/yyyy)**  |