**RESEARCH ETHICS BOARD – AMENDMENT FORM**

**INFORMATION & INSTRUCTION SHEET**

**BACKGROUND – WHY IS AN AMENDMENT REPORT REQUIRED?**

* As per TCPS2 6.16, any changes made to an approved research study must be submitted to the REB for review and approval. Changes may not be implemented until approval has been obtained.
* GCP section 4.5.2 states that changes from the approved protocol must not be implemented until they’ve been approved by the REB, unless the change must be implemented to eliminate a hazard or harm to the study participants.

**WILL SUBMITTING AN AMENDMENT SLOW DOWN MY STUDY?**

No. When you submit an amendment to the REB, your study will continue to recruit and progress under the current approved protocol. Upon receipt of the amendment approval, you will implement the changes.

**WHAT TYPE OF REVIEW WILL BY AMENDENT REQUIRE?**

The level of review required by the board is dependent on the types of changes being made. Often, changes are minor – clarifications, typos, grammatical issues etc. These changes can be reviewed in an expedited fashion and an approval letter will be issued.

Changes that are more significant may require a more focused review. This helps to ensure the safety of our participants, as well as a high level of ethical integrity.

**WHAT IF I DON’T SUBMIT AN AMENDMENT AND I IMPLEMENT THE CHANGES?**

Conducting study activities without approval is not permitted. All study activities must be reviewed by the REB and receive approval. If you choose to implement changes without approval, you are putting yourself and your study participants at risk. In the event of an audit or a regulatory inspection, implementing changes without REB approval is considered a critical finding. Your study could be halted or shut down, either temporarily or permanently. Critical findings of this nature can also impact other researchers within the institution.

**IMPORTANT REMINDER FOR HEALTH CANADA REGULATED TRIALS!**

If you are conducting a clinical trial that is regulated by Health Canada, amendments must also be submitted to the proper Directorate for review and approval. It is imperative that the REB and Health Canada have approved the same versions of the protocol. All changes that are communicated to Health Canada must also be reviewed and approved by the REB before they may be implemented.

***Please delete this page once you have completed the form. Do not submit this page with the form.***

**RESEARCH ETHICS BOARD – AMENDMENT FORM**

Please complete all of the following sections. Amendments must be submitted to the REB for review and approval ***prior*** *to implementing the changes in the study. Do not submit amended REB applications.*

|  |  |
| --- | --- |
| **REB NUMBER:** Click here to enter text.  **PRINCIPAL INVESTIGATOR:** Click here to enter text.  **PROTOCOL TITLE:** Click here to enter text. | **DATE:** Click here to enter a date.  **CURRENT PROTOCOL DATE :** Click here to enter a date.  **CURRENT PROTOCOL VERSION #:** Click here to enter text.  **CURRENT ICF VERSION #:** Click here to enter text. |

**AMENDMENTS FOR REVIEW & APPROVAL**

Changes have been made to the following: (*Please check all that apply)*

|  |  |  |  |
| --- | --- | --- | --- |
| **Major** | Study Objectives | **Minor** | Typographical or Grammatical |
| Study Design/Study Population | Change or addition of Co-Investigator/Staff.  \***Please include TCPS2 certificate(s).** |
| Informed Consent Form/Information Sheet | Extension of Current Study Timeline\* |
| Inclusion/Exclusion Criteria | Other, Specify: Click here to enter text. |
| Sample Size (number participants in study) |  |
| Change in Dosage or Procedure |  |

**\*Note: *If you are requesting that a current study be extended (e.g. expected date of completion is later than originally expected), please indicate:***

**Projected date of Study Completion:** Click here to enter a date.

**Are there sufficient funds/resources in place to extend the study?**  YES  NO

**DOCUMENTS INCLUDED IN THIS SUBMISSION FOR REVIEW *OR*  Not Applicable**

*Please check all that apply. Include the version dates and numbers of the updated documents. The REB requires both a tracked changes copy and a final clean copy.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Document for Review** | **Tracked Copy** | **Clean Copy** | **Version Date** |
| Study Protocol |  |  | Click here to enter a date. |
| Main Informed Consent/Information Form (ICF) |  |  | Click here to enter a date. |
| Optional Consent Form(s) |  |  | Click here to enter a date. |
| Recruitment Tools/Posters Etc. |  |  | Click here to enter a date. |
| Other: Click here to enter text. |  |  | Click here to enter a date. |
| Other: Click here to enter text. |  |  | Click here to enter a date. |
| Other: Click here to enter text. |  |  | Click here to enter a date. |

**RATIONALE FOR AMENDMENT**

*In the box below, please summarize the changes that have been made. Include the rationale for these changes and how the study will be impacted.*

**PLEASE COMPLETE THE FOLLOWING:**

1. **Is this study currently open to recruitment?**

Yes

No

N/A – (e.g. chart review) *\* If “N/A,” proceed to investigator signature*

1. **To date, have any participants been enrolled in this study?**

Yes

No *\*If “no,” proceed to investigator signature*

1. **Did the nature of these changes present any potential immediate hazard to current/past participants that needed to be communicated to them on an urgent basis prior to the submission of this amendment?**

Yes\* Explain: Click here to enter text.

No

1. **Do the changes noted in this application require that current participants be re-consented?**

Yes

No *\*If “no,” proceed to investigator signature*

1. **Please indicate which of the following will be used to re-consent participants:**

Updated/Revised Full Informed Consent Form

Not applicable

1. **For participants who are currently enrolled in this study and who are receiving active treatment/intervention, indicate how the re-consenting process be handled.**

|  |  |
| --- | --- |
|  | Not applicable |
|  | Participants will be contacted immediately, revised consent/consent update form will be provided, and signatures will be obtained. |
|  | Participants will be contacted by phone and updated information will be provided orally. This discussion will be documented in the participant record. The revised consent/update form will be provided at the next visit and signatures will be obtained. |
|  | The revised consent/update form will be provided at the next visit and signatures will be obtained. This will be documented in the participant record. |
|  | This is not relevant for current study participants on active treatment/intervention |
|  | Other, Specify: Click here to enter text. |

1. **For those participants who are currently in the follow-up stage of the study, who only have sporadic visits, how will the re-consenting process be handled?**

|  |  |
| --- | --- |
|  | Not applicable |
|  | Participants will be contacted by phone and updated information will be provided orally. This discussion will be documented in the participant record. The revised consent/update form will be provided at the next visit and signatures will be obtained. |
|  | The revised consent/update form will be provided at the next visit and signatures will be obtained. This will be updated in the participant record. |
|  | The revised ICF/update form will be mailed to the participant. Receipt will be confirmed at the next visit, and this will be documented in the participant record. |
|  | Other, Specify: Click here to enter text. |

1. **For participants who are in the follow-up phase of study and are only contacted by phone, what actions will be taken to ensure appropriate information about the changes has been communicated to the participant?**

|  |  |
| --- | --- |
|  | The revised ICF/update form will be mailed to the participant. This will be documented in the participant record, and receipt will be confirmed during the next phone call. |
|  | This is not applicable |
|  | Other, Specify: Click here to enter text. |

1. **If the study is currently closed to recruitment and follow-up but the new findings/information affect the long-term health of the participant, how will this be handled?**

|  |  |
| --- | --- |
|  | Not applicable, the new information does not impact the long-term health of participants |
|  | The full revised consent form will be sent by registered mail; a contact will be included so participants may request additional information. This will be documented in the medical record. |

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

*I confirm to the best of my knowledge that the information provided above is accurate and true.*

*I agree to conduct this trial as per the Tri-Council Policy Statement (TCPS-2), the ICH Good Clinical Practice Guidelines (GCP), and all other regulatory guidance that may be applicable to this study including the Health Canada Division 5 Food & Drug regulations, Natural Health Product regulations, Division 3 Radiopharmaceutical regulations and the Health Canada Medical Device regulations, as well as all institution specific policies and procedures.*

**Qualified/Principal Investigator Name (typed):** Click here to enter text.

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

**Qualified/Principal Investigator Signature** **Date of Signature:** Click here to enter a date.

***You must keep a copy of this completed form for your study file***