**Please complete, sign and submit this form to the** **[Research Ethics Office](#TBRHSC:  Mail to:  Research Ethics Office, TBRHSC, 980 Oliver Road, Thunder Bay,  ON   P7B 6V4)**

If you require any assistance, please contact [TBR\_REO@tbh.net](mailto:TBR_REO@tbh.net)

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| **TBRHSC REB** #: |  | Current REB Expiry Date: |  |
| Principal Investigator: |  | | |
| Full Study Title: |  | | |
| Person Completing Form: |  | Submission Date: |  |

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| **PROPOSED CHANGES TO:**  ***(Check All That Apply Below)*** | |
| **Please do not attach the *same version* of the same document more than once.** | |
| **Protocol**  Research Question.  Study objectives, design or methodology.  Medication Dosage or Medical Procedure.  Data Management/Statistical analysis.  Eligibility Criteria (inclusion/exclusion criteria).  Level of Risk.  Study end date.  Number of participants globally.  Number of participants locally.  Change in Principal Investigator/Co-Investigator.  Administrative Changes | |  |  |  |  | | --- | --- | --- | --- | | **MANDATORY DOCUMENTATION** | | |  | | Clean  Version | Track-Changes  Version | Rationale for Changes | Other  Support  Documentation | |  |  |  |  |   *Please make sure the above mentioned mandatory versions are attached before submitting this form.*  ***Please note: Changes to protocol may warrant changes to the Informed Consent Form.*** |
| **Participation Information**  Consent Form.  Study instruments, questionnaires, etc.  Recruitment methods.  Information Sheet or Letter. | |  |  |  |  | | --- | --- | --- | --- | | **MANDATORY DOCUMENTATION** | | |  | | **Clean**  **Version** | **Track-Changes**  **Version** | **Rationale for Changes** | **Other**  **Support**  **Documentation** | |  |  |  |  |   *Please make sure the above mentioned mandatory versions are attached before submitting this form.* |
| **Other**  Product Monograph (REB approval required).  Investigator Brochure (REB approval required).  Change in Principal Investigator/Co-Investigator.  No Objection Letter/Investigational Testing Authorization. | |  |  |  |  | | --- | --- | --- | --- | | **MANDATORY DOCUMENTATION** | | |  | | **Clean**  **Version** | **Track-Changes**  **Version** | **Rationale for Changes** | **Other**  **Support**  **Documentation** | |  |  |  |  |   *Please make sure the above mentioned mandatory versions are attached before submitting this form.* |
| **Other (specify):** | |  |  |  |  | | --- | --- | --- | --- | | **MANDATORY DOCUMENTATION** | | |  | | **Clean**  **Version** | **Track-Changes**  **Version** | **Rationale for Changes** | **Other**  **Support**  **Documentation** | |  |  |  |  |   *Please make sure the above mentioned mandatory versions are attached before submitting this form.* |

| **List of Documentation for this application.** | | | |
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|  | | | |
| Document title | Title/Appendix Reference | version # | version date  *(month day, year)* |
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| **Actions Required when implemented:** | | **Yes** | **No** | | **Documentation attached** | | |
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| Will the changes impact the implementation of the project locally? Consult Clinical Research Services to ensure change is endorsed before submitting to REB | |  |  | |  | | |
| Will the changes impact recruitment of future participants (potential harms/benefits, increased risk, discomfort or inconvenience)? | |  |  | |  | | |
| Will the changes impact current participants (potential harms/benefits, increased risk, discomfort or inconvenience)? | |  |  | |  | | |
| What follow-up do you propose for participants who are already enrolled in the study? | |  | | | | | |
| Inform study participants | |  |  | When? | |  | |
| Re-consent all participants with revised consent/assent forms | |  |  | When? | |  | |
| Re-consent active participants with the revised consent/assent forms | |  |  | When? | |  | |
| No action required | |  |  |  | | | |
| Other: attach explanation | |  |  |  | | | |
|  | |  |  |  | | | |
| **NOTE: Significant changes to the originally approved research study may constitute a new research study application. Please consult the Research Ethics Office at** [**TBR\_REO@tbh.net**](mailto:TBR_REO@tbh.net) **if there is a change in the research question, recruitment strategy and/or level of risk.** | | | | | | | |
| Principal Investigator’s Signature:  ***(sign and send final hard copy after printing)*** |  | | | | | |
| Print Name: |  | | | | | |
| Date: [month day, year ] |  | | | | | |

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| **For Research Ethics Office Use Only** | | | |
|  | **FULL BOARD REVIEW & APPROVAL** |  | **DELEGATED APPROVAL** |
| The following amendment(s) have been reviewed and approved by the full board of the TBRHSC Research Ethics Board at the REB meeting dated \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.  The quorum for approval was free from conflict and did not involve any member that is associated with this project. | | The following amendment(s) have been reviewed and approved by the Chair of the Thunder Bay Regional Health Sciences Centre (TBRHSC) Research Ethics Board.  This approval will be reported at the next full REB meeting. | |
| The Thunder Bay Regional Health Sciences Centre Research Ethics Board is guided by the policies and ethical standards put forth by the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects as well as the ICH Good Clinical Practice (GCP) guidelines.  Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Chair, TBRHSC Research Ethics Board month day, year | | | |
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| **Comments from REB:** | | | |