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| INTEGRATED POST-APPROVAL APPLICATION FORM FOR AMENDMENTS, RENEWALS, CLOSE-OUTS, ACKNOWLEDGEMENTS OF PREVIOUSLY APPROVED RESEARCH **Email Completed Form to:**  [REB@fraserhealth.ca](mailto:REB@fraserhealth.ca) | | | | | | |
| **FHREB No.** | | **Principal Investigator** | | **Surname** | | **First Initial** |
| **Study Title:** | | | | | | |
| **Current Study Funder:** | | | | | | |
| **Current Main Contact**  The FHREB response will be returned to this contact. | | | **Surname** | | **First Name** | |
| **Email Address** | | | |
| **Submission Authorization**  An electronic (i.e. scanned) or digital signature will be taken as evidence that the Fraser Health PI/delegate has reviewed and approved the information included in this submission. The site must retain a written Delegation of Authority Log if the latter. | | | **Principal Investigator or Delegate Signature** | | | |
| **Date YYYY MM DD** | | | |
| **Is this an Amendment? Yes**  **For Amendments:** Any changes to the study and/or study documents, including the title, consent form, protocol, etc., must be submitted as an amendment and approved BEFORE implementation. Please note that Investigator’s Brochures for regulated clinical trials may be submitted as an amendment only IF there are accompanying changes to the study protocol and consent form(s).  **Instructions:** Please complete [**Amendment**](#Amendment) **pages 2 - 3.** Refer to [Guidance Notes for Amendments](https://www.fraserhealth.ca/media/20170721-guidance-notes-for-amendments.pdf) | | | | | | |
| **Is this a Renewal? Yes**  **For Renewals:** Ongoing studies MUST be renewed prior to the expiry date of the initial ethics approval certificate or subsequent renewal (typically one year from previous approval). This includes studies where any data collection (including tissue and secondary data collection) is ongoing, including clinical trials with research participants on follow up only or regulated clinical trials that have not been formally closed out by the study sponsor.  **Instructions:** Please complete [**Renewal**](#Renewal) **pages 4 - 6.** Refer to [Guidance Notes for Renewals](https://www.fraserhealth.ca/media/20171108_FHGN_Renewal.pdf) | | | | | | |
| **Is this a Close-out? Yes**  **For Close-outs:** Studies that have completed ALL study-related procedures may be closed if the study principal investigator is confident that ALL data collection is complete. Note that regulated clinical trials must be closed by the sponsor before a submission can be made to the FHREB.  **Instructions:** Please complete [**Closeout**](#Closeout) **pages 7 - 8**. Refer to [Guidance Notes for Close-outs](https://www.fraserhealth.ca/media/20170721-guidance-note-for-closure.pdf) | | | | | | |
| **Is this an Acknowledgement? Yes**  **For Acknowledgements:**  These include submission of Investigator’s Brochures that do not require changes to the protocol or consent form(s) AFTER initial approval by the FHREB, NON-LOCAL Serious Adverse Events for regulated Clinical Trials, Data Safety Monitoring Board letters, other safety updates, administrative letters, other new information that does not require an amendment. Please complete [**Acknowledgement**](#Acknowledgement) **page 9.** | | | | | | |
| **For Information on Submission of** [**LOCAL Serious and Unexpected Adverse Events**](https://www.fraserhealth.ca/health-professionals/research-and-evaluation/find-resources/forms-guidance-notes-templates/forms-guidance-notes-templates) **for clinical trials,** [**Protocol Deviations**](https://www.fraserhealth.ca/media/20170601-protocol-deviation-guidance.pdf)**, or** [**Change of Principal Investigator**](https://www.fraserhealth.ca/media/20170721-guidance-notes-for-amendments.pdf)**.** | | | | | | |

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| **A.** **FOR AMENDMENTS OF PREVIOUSLY APPROVED RESEARCH: COMPLETE PAGES 2 and 3.**  Requests for amendments may receive Delegated Review by the FHREB if the changes are minor, do not materially affect the assessment of the study’s risks and benefits and do not substantially change the specific aims/design of the study. Delegated Review is conducted by a designated FHREB member or the FHREB Co-ordinator as delegated by the FHREB. The delegated reviewer has the authority to refer any amendment submission to the Full Board for review, if deemed necessary and would notify the principal investigator.  **The exception to Delegated Review for regulated clinical trials is described below.** |
| **FOR ALL REGULATED CLINICAL TRIALS:** HEALTH CANADA AND/OR THE UNITED STATES FOOD AND DRUG ADMINISTRATION REQUIRE **FULL BOARD REVIEW** OF THE FOLLOWING CHANGES TO AN APPROVED STUDY. IF APPLICABLE, TICK OFF ALL THAT APPLY. IF NOT APPLICABLE, THE SUBMISSION WILL RECEIVE DELEGATED REVIEW.  Addition of genetic testing, new genetic tests or tissue banking where genetic testing may or will be performed;  Addition of an open-label extension phase following a randomized trial;  Significant changes to the study intervention or design that requires a new or revised Letter of No Objection from Health Canada;  Emergency Amendments that arise because of participant safety concerns and that are therefore submitted after  implementation, and;  Significant changes to the protocol that may affect participant safety and may include (but are not limited to):  Change in drug dosing/duration of exposure,  Decrease in monitoring,  Change in recruitment technique that may affect confidentiality or the perception of coercion,  Change in experimental procedure or study population. |
| **1. DOCUMENTS SUBMITTED FOR APPROVAL OF THE AMENDMENT**   1. Please list ALL submitted documents. Ensure that all changes made to submitted documents are highlighted using tracked changes or shading. Note that this does not apply to industry sponsored protocols; however a list of the protocol changes must accompany the revised protocol. A VERSION DATE MUST BE ON ALL SUBMITTED DOCUMENTS OR THE APPLICATION WILL BE CONSIDERED INCOMPLETE AND RETURNED. If more room is required to list all amended documents, please submit a separate page.  |  |  | | --- | --- | | **New Documents** | **Revised Documents** | |  |  |  1. Does the amendment require revision to the presently approved consent form? **Yes**   **No** 2. Will already enrolled participants be formally re-consented using the revised consent form? **Yes**   **No**   If No, please explain how participants will be informed as applicable. |
| **2. Proposed Changes to Study**   1. Will the study changes affect participant safety (e.g. changes to known risks, eligibility criteria, treatment, procedures, monitoring)? **Yes**  **No** If No, proceed to 2b.   **If Yes**, describe the changes and how they affect participant safety.  Explain why these changes are necessary. |
| b. Will the study changes affect scientific interpretability (e.g. changes to study objectives, clinical endpoints if applicable, sample size, planned statistical or qualitative analyses)? **Yes**  **No** If No, proceed to 2c.  **If Yes**, describe the changes and how they affect scientific interpretability.  Explain why these changes are necessary. |
| c. Are there any administrative changes that do not affect the safety or scientific interpretability (e.g. title, study personnel, sponsor or funding source)? **Yes**   **No**  **If Yes**, describe the changes.  Explain why these changes are necessary. |

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| 1. **FOR RENEWALS OF PREVIOUSLY APPROVED RESEARCH COMPLETE PAGES 4 - 6.** | |
| **For Delegated Review:** Requests for renewal of previously approved research may receive Delegated Review by the FHREB when the following apply:   * the research is minimal risk * the research is more than minimal risk but wherein:   + the remaining research-attributable risk is minimal, e.g. no new interventions to current participants and no enrolment of additional participants   + there are no significant changes to the research   + there is no increase in risk to or other ethical implications for the participants since the most recent FHREB Full Board review   + FHREB Chair deems delegated review is appropriate.   Delegated Review is conducted by a designated FHREB member or the FHREB coordinator as delegated by the FHREB. The delegated reviewer has the authority to refer any renewal submission to the Full Board for review, if deemed necessary and would notify the principal investigator.  **For Full Board Review:** Clinical trials that are regulated by the United States Food and Drug Administration or funded by United States federal government departments and agencies may require Full Board Approval. Please refer to Guidance Notes for Renewals for further information at <http://research.fraserhealth.ca/approvals_%26_ethics/forms-and-guidance-notes/>  **Please indicate if Full Board Review is required: Yes**  **No**  If No, the renewal application will receive Delegated Review. | |
| **1. REQUIRED INFORMATION FOR APPROVAL OF THE RENEWAL**  **a.** Current protocol version number and date:  **b.** Is this study continuing to recruit and enrol participants?  **Yes**  **No**  **c.** **If Yes**, Please list the version # and dates below of the most recently FHREB approved consent form(s) and **attach to the submission**.    The consent form(s) will be reviewed to ensure that all the current FHREB standard requirements are met. If revisions are required, a Modifications Required/Deferral Memo will be issued. The revised consent form will then have to be submitted to the FHREB Coordinator before the annual renewal can be approved by the FHREB.  **d.** **If No**, the previously approved consent form does NOT need to be submitted. Are the study participants on follow up only? **Yes**   **No**  **e. If No,** and study participants are not on follow up, please estimate when the study will be closed**.** | |
| 1. Total # of participants enrolled in the study to date (including number of individual records accessed for secondary data studies). |  |
| **3.** Total # of participants enrolled since the most recent renewal.  **\*For industry-sponsored study:** please ensure overhead fees have been paid |  |
| **4.** Please identify where participants have been recruited from. | |
| 1. Total # of participant withdrawals since initial or subsequent renewal certificate of ethical approval.   Please include a summary of the reason for the withdrawals, if known: |  |
| 1. Total # of participant complaints since initial or subsequent renewal certificate of ethical approval.   Please include a summary of the reason for the complaints: |  |
| 1. Provide a brief summary of the progress of the study. Include information on whether the recruitment of participants has gone according to plan and any other details about whether the study implementation is meeting its timelines. | |
| 1. Special attention should be directed towards any local serious and unexpected adverse events (SAEs) that occurred during clinical trials or any unforeseen harms that arose during other types of research. Describe any local SAEs/unforeseen harms that have been observed, provide an opinion on whether they were study-related, whether they affect the ethics of continuing the study, and whether they necessitate any changes to the informed consent process. **Note that it is not sufficient to state that SAEs have been previously submitted for review to the FHREB.**   **FOR REGULATED CLINICAL TRIALS ONLY:** Please indicate whether there are any outstanding SAE reports that have not yet been sent back from the FHREB office. | |
| 1. Is there any new information, e.g. incidental findings, changes in regulatory approvals or changes in scientific knowledge that might affect the ethical basis or risk of the research design?  **Yes**  **No**   **If Yes,** please describe. | |
| 1. **CLINICAL TRIALS ONLY:** Have any Data Safety Monitoring Board (DSMB) reports been submitted?   **Yes**  **No**  **If, Yes,** list the DSMB reports submitted to date and their corresponding recommendations. | |
| 1. Have there been any amendments to this study since the date of the Certificate of Initial Ethical Approval or since the date of the Certificate of Annual Renewal, whichever is the later?   **Yes**   **No**  **If Yes,** Please list and summarize these amendments. Note that the summary should be a brief note that clearly describes what was previously amended. Please check this summary against the actual documentation to ensure that all of these amendments have all been submitted to the FHREB for approval. | |
| 1. For **ABOVE-MINIMAL RISK** studies: Has the Principal Investigator completed the Tri-Council Policy Statement Core Tutorial?   **Yes**   **No**  Please list the date of completion and attach a copy of the certificate if it has not been previously provided to the FHREB:    Please note that the FHREB requires that all Principal Investigators conducting above minimal risk research studies must complete the Tri-Council Policy Statement 2 tutorial at <http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/> before the first annual renewal. | |

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| FOR RESEARCH STUDY CLOSE-OUT, COMPLETE PAGES 7 - 8. | | | |
| **1.**  Date of Initial Approval **YYYY MM DD**        Type of Initial Approval  Delegated Review  Full FHREB Review | | | |
| **2.**  Date of Completion **YYYY MM DD**        (Last date of data collection from participant or secondary sources of data)  **For Regulated Clinical Trials Only:** Date of Site Close-out Visit**:** **YYYY MM DD** | | | |
| **3.** # of participants enrolled or individual secondary sources of data collected since either the initial or subsequent renewal certificate of ethical approval (i.e. in the most recent study year period). | | | |
| **4.** Total # of participants enrolled or individual secondary sources of data collected. | | | |
| **5. FOR RESEARCH INVOLVING DIRECT ENROLMENT OF HUMAN PARTICIPANTS ONLY:**  **a**. Date first participant enrolled **YYYY MM DD**        **b.** Date last participant enrolled **YYYY MM DD** | | | |
| **c.** Total # of Local and Unexpected Serious Adverse Events (SAEs) or research harm events |  | **d.** Total # of Local Deaths |  |
| **e. FOR REGULATED CLINICAL TRIALS ONLY:**  Total # of Non-Local SAEs |  | **f. FOR REGULATED CLINICAL TRIALS ONLY:** Total # of participants lost to follow-up |  |
| **g.** Total # of participants who withdrew consent | | | |
| **6.** Please describe where all research related documents will be stored (i.e. specify location). | | | |
| **7.** Please describe where electronic data will be stored (i.e. specify location on computer) and specify safeguards for protection (e.g. password/encrypted) | | | |
| **8.** Please indicate the storage period for your study:  If regulated clinical trials, storage is for 25 years  If for all other study types, storage is for 5 years | | | |
| **9.** Summarize the implementation of the study below. | | | |
| ***The Principal Investigator’s signature on Page 1 attests that all contact with study participants and/or collection of data/tissue from secondary sources has ceased.*** | | | |

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| **OVERHEAD COLLECTION FOR INDUSTRY SPONSORED RESEARCH ONLY**  **PLEASE PROVIDE THE SPONSOR’S PAYMENT LEDGER**  **(i.e. spread sheet that lists all participant visits to closure)**  **Submitted for Review  Submission pending**  Any reimbursements or adjustments required because of participant drop-out for any reason including failure to reach optimum visit schedule based on study criteria before study completion, can be noted below; however a separate request for reimbursement for payment must be received in writing at or after the time that the close-out report is submitted. Researchers will be reimbursed for any balance owing to them upon review of the sponsor’s payment ledger. |

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| **Knowledge Transfer: Submission of Research Results/Impacts**  Once study results are analyzed and interpreted, submit all final documents to our department. Final documents include, but are not limited to: publications, presentations, abstracts, lay summaries, conferences proceedings, clinical practice guidelines or operation guidelines.  **Action:** Please indicate below if you give your permission for submitted material(s) to be uploaded to the [**Fraser Health Research Study Database**](https://www.fraserhealth.ca/health-professionals/research-and-evaluation/how-we-can-help/research-study-database/). Our team will work with you to create a Fraser Health Research Abstract or Summary Document to promote and share your work.  **Yes Permission is Granted  No Permission is Granted** |

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| D. FOR REQUEST FOR ACKNOWLEDGEMENT |
| **INSTRUCTIONS: Please attach and indicate the type of submission.**  Non-local Serious Adverse Event Report; Date(s) of Report:  Periodic Safety Update Report; Date:  Administrative Letters/Sponsor Correspondence; Date  Other (please explain)    **Click for information on submission of** [**LOCAL Serious and Unexpected Adverse Events**](https://www.fraserhealth.ca/health-professionals/research-and-evaluation/find-resources/forms-guidance-notes-templates/forms-guidance-notes-templates) **for clinical trials,** [**Protocol Deviations**](https://www.fraserhealth.ca/media/20170601-protocol-deviation-guidance.pdf)**, or** [**Change of Principal Investigator**](https://www.fraserhealth.ca/media/20170721-guidance-notes-for-amendments.pdf)**.** |
| **1.** Please provide additional information if required. |