

**Biomedical Study Renewal Form**

**\*Note, if your study is complete please fill out the study closure form rather than this form.**

**Please type in your responses, print, and then send the original signed copy to our office or email to** **research.ethics@uregina.ca**

**Double click on boxes to check.**

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| **1. Title:** |
| **2. Bio #:**  | **3: Protocol #:**  |
| **4: Expiry Date:**  | **5: Clinical Trial Registration Number (If applicable):**  |
| **6. Contact Information:** |
|  | **Name:** | **Department:** | **Phone Number, Email, Fax Number** **(Provide only if different from previously submitted information):** |
| **Principal Investigator:** |  |  |  |
| **Contact Person:** |  |  |  |
| **7. Sponsor/Funding Agency:** |
| **8. Indicate whether delegated or full board review is required for this renewal.** **[ ]  Delegated Review (Please indicate which of the following apply)** **[ ]  Research involves no more than minimal risk** **[ ]  No research subjects have been enrolled in the study** **[ ]  Research remains open only for the long term follow up of participants** **[ ]  Remaining research is limited to data analysis****[ ]  Full Board Review:****[ ]  Regulatory/Sponsor requirement [e.g. US Federal Agency (e.g. NIH) or some sponsoring organization (e.g. NCIC, COG)]****[ ]  Other (please indicate):**  |
| **9. Did the initial protocol require a “No Objection Letter” (NOL) from Health Canada?** **[ ]  Yes** **[ ]  No****If Yes, please submit a copy of the original “NOL” if not already submitted.** **[ ]  Already submitted** **[ ]  Attached to renewal**  |
| **10. Location where research will be conducted (if different from previously submitted information):** |
| **11. Does this research involve another institution?** **[ ]  Yes** **[ ]  No** |
| **12. Is there interim analysis by a data safety monitoring board (DMSB) or some monitoring committee?** **[ ]  Yes** **[ ]  No****Has there been a report from a DMSB or safety monitoring committee in the last year?** **[ ]  Yes** **[ ]  No****If Yes, what was the outcome?** **[ ]  Continue study as planned** **[ ]  Modifications were suggested****[ ]  Close study temporarily** **[ ]  Close study permanently** |
| **13. Have there been any changes to the study (study design, changes in recruitment material, procedures, consent process,) that have not already been reviewed and approved by the Bio-REB?** **[ ]  Yes** **[ ]  No****If Yes, please submit an amendment.** |
| **14. Please indicate which version of the consent form(s) is(are) currently being used (date and/or version number).** |
| **15. Have there been any changes in research personnel, such as principal investigator, sub-investigators, Clinical Research Assistants, residents or students?** **[ ]  Yes** **[ ]  No****If Yes, please list the former/new personnel and position.** |
| **16. What is the current status of the study? (Please mark all that apply)****[ ]  Recruitment has not yet started.** **[ ]  Research participants are currently being recruited.****[ ]  Recruitment is closed.****[ ]  Recruitment is closed and data collection involving participants is on-going.**  **What was the original number of participants to be recruited? \_\_\_\_\_\_\_** **How many participants have been screened? \_\_\_\_\_\_\_** **How many participants were enrolled? \_\_\_\_\_\_\_** **How many research participants are currently in the study and receiving treatment? ­­­­­ \_\_\_\_\_\_\_\_** **Is there a significant change in anticipated enrollment? Is yes, please explain.** **[ ]  Yes** **[ ]  No****[ ]  The data collection is complete except for long-term follow-up of participants.** **How many participants are currently not receiving treatment but still in the follow-up stage of the study? \_\_\_\_\_\_\_\_****[ ]  The data collection is complete, remaining research activities are limited to data analysis only.****[ ]  The study is closed (Please complete the Biomedical REB Study Closure Form)** |
| **17. How many research participants have been withdrawn from or discontinued the study? \_\_\_\_\_\_\_\_** **Please provide a reason for each withdrawal (if known):****[ ]  Need for Other Treatment, number \_\_\_\_\_** **[ ]  Withdrawn Consent/Dropped Out, number: \_\_\_\_\_\_** **[ ]  Serious Adverse Event, number: ­­\_\_\_\_\_\_** **[ ]  Other, number \_\_\_\_\_ (Specify reason, if known)** |
| **18. Since receiving original ethics approval, have any ethical concerns arisen?** **[ ]  Yes** **[ ]  No****If Yes, please describe concerns in detail.** |
| **19. Have there been any serious adverse or unexpected events at this site?** **[ ]  No serious adverse events** **[ ]  Expected serious adverse events only** **[ ]  Unexpected serious adverse events (Please attach a Serious Adverse Event Report for any unreported unexpected serious adverse events.)** |
| **20. Were there major protocol deviations: [ ]  Yes [ ]  No****Please attach a Protocol Deviation Report form for any unreported major protocol deviations.** |
| **21. Have any findings, new information or study modifications changed the risk level of this study for current and future participants?** **[ ] Yes** **[ ]  No** **If Yes, explain the changes made, how participants will be notified and whether or not participants will be re-consented or refer to approved or submitted protocol amendment.** |
| **23. Provide a brief summary of study progress.**  |
| **24. Indicate the expected closure date of this study.** |

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**Signature of Principal Investigator Date**

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***Signature of Student Investigator Date***