

**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**](mailto:research.ethics@uregina.ca)

**Double click on boxes to check.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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***