|  |  |
| --- | --- |
| SHA Logo **Research Ethics Board**  Research Department  Phone: (306) 655-6822  E-mail: [ResearchEthics@saskhealthauthority.ca](mailto:ResearchEthics@saskhealthauthority.ca)  Website: <https://www.saskhealthauthority.ca/our-organization/our-direction/research/getting-started> |  |
|
|  |

## Application for Annual Reapproval or Study Closure

|  |  |
| --- | --- |
| Principal Investigator: |  |
| Address: |  |
| SHA Project #: |  |
| Project Title: |  |
| Protocol #: |  |
| Date of Initial Approval: | Click or tap to enter a date. |
| Date of Last Renewal: | Click or tap to enter a date. |
| **Approval Expires:** | Click or tap to enter a date. |

*Please note that* ***Parts 1-6*** *of this form must be filled out for* ***all*** *types of studies.*

***Missing responses will result in your application being returned without review****, which will delay your reapproval. It is the responsibility of the Principal Investigator to ensure that applications are received by the Research Ethics Board with sufficient time for review in order to prevent a lapse in approval.*

|  |
| --- |
| 1. Is this study exactly the same as the protocol approved by the Saskatchewan Health Authority Research Ethics Board?    Yes  No     **If no,** please explain the changes, noting that changes described in the summary might require an Amendment. |
| **2.** Is the consent form exactly the same as the last approved version? Yes  No  N/A  **If no,** attach clean and redlined copies of the consent form. Please note that all consent forms must be approved by the REB before being implemented. |
| 1. How many participants were initially planned and how many have been enrolled to date? For retrospective studies, please indicate the number of patients’ charts estimated to be required (in part a) and the number that have been reviewed to date (in part b).   **a)** What was the targeted number of participants for enrolment in this study?  **b)** How many participants have been enrolled?  **c)** Is enrolment ongoing? Yes  No   (For chart review studies, if data abstraction is ongoing, select “yes”.) |
| **4.** **a)** During the past year, have there been any aspects of this study which should be drawn to our attention (e.g., adverse events, major or unexpected toxicity, unexpected difficulty in recruitment, ambiguous aspects)?     Yes  No  **If yes,** have all SAEs, unanticipated problems, amendments, revisions to the informed consent form, and administrative letters been submitted to Saskatchewan Health Authority Research Ethics Board?   Yes  No    **b)** Has a Data Safety Monitoring Board (DSMB) report or a Periodic Safety Update Report been produced in the past 12 months?    Yes  No  N/A  **If yes,** all DSMB and/or Periodic Safety Update reports produced in the past 12 months must be submitted along with this application. |
| **5.** During the last year, have you become aware of any changes in information or knowledge which would affect the relevance of this protocol? Yes  No  **If yes,** please explain. |
| **6.** Is the study still open? Yes  No  **If yes,** please fill out the progress report/current study status below:   1. Progress Report/Current Study Status: Choose an item.  * How much longer do you expect this study to continue? * Provide a brief summary of the project progress (i.e. *What research activities have been completed? What research activities are currently in progress? What research activities remain outstanding?*): * If biological material are used, specify type:   **If no,** submit a summary of the final report.  Please note that studies may only be renewed up to five years from the initial date of approval (i.e., initial approval plus four annual reapprovals). After that time, a new application must be made to the REB. Exceptions may be made at the discretion of the Chair only for clinical trials with lengthy follow-up periods if participant recruitment and treatment with study drugs has ceased.  If this is your last eligible year for reapproval, please contact the Chair of the REB at (306)-766-5533 in order to inquire as to what will be needed for reapplication next year. |
| 1. Contact Person for All Correspondence (if different from Principal Investigator):   Name:  Address:  Phone:       Fax:  Email: |

|  |
| --- |
| **I am requesting a one year reapproval of this project:**  Date: Click or tap to enter a date. Signature of Principal Investigator:  **I do not require reapproval of this project:**  Date: Click or tap to enter a date. Signature of Principal Investigator: |

**Reminder:** Please acknowledge the Saskatchewan Health Authority in presentations and publications resulting from this study.

If you are closing this study, please submit a list of presentations and publications that have emerged from this research.

|  |
| --- |
| For Administrative Use Only:  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of SHA REB Chair \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ❑ Extend one year from current expiry date ❑ Extend one year from date of Chair’s signature  ❑ Approve until \_\_\_\_\_\_\_\_\_\_\_ (DD-MM-YY) ❑ Not approved ❑ Closed |