Clinical Renewal Coversheet

Post Approval Activities

Application Questions	Guidance Notes
* **1. Reason** **1.1.** Why is this renewal being requested, e.g. still recruiting or data collection is ongoing etc.? (Unless required by the sponsor, projects that no longer require interaction with participants or access to their data generally can be completed. Please click blue question mark)	Click here for more information pertaining to when a project qualifies for closure. Closures must be submitted as a Post Approval Activity (PAA) on RISe via Completion Option. If start date is changing, please revise the initial application accordingly.
1.2. If this research has not started, please explain why and indicate your plan for moving forward. If the project is on hold, please explain and indicate the anticipated start date.	

Grey Highlighted questions appear depending on previous answer(s).

* **2. Level of Review** Does this Annual Renewal qualify for Minimal Risk/Delegated Review? Click blue question mark for the criteria. ○Yes ○No	**Renewal:** Projects sponsored by the United States Department of Health and Human Services (DHHS) (e.g. NIH and its related Institutes, US Center for Disease Control, etc.) may require Full Board Review under 45 CFR 46.109 (e) and 45 CFR 46.110 (Code of Federal Regulations), unless they fall into one of the 9 categories recognized as eligible for expedited review. Generally, if a study is subject to these regulations, was initially reviewed by Full Board Review, the annual renewal must also be conducted by the Full Board unless the research meets the criteria outlined in category (8) or (9). For example, category (8) allows expedited review for research previously approved by the convened board as follows: "(a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; OR (b) Where no subjects have been enrolled and no additional risks have been identified; OR (c) Where the remaining research activities are limited to data analysis." Category 9 in turn allows for expedited review of research previously approved by the convened board, where that research is not conducted under an investigational new drug application or investigational device exemption, and where exemptions outlined in categories (2)-(8) do not apply, if the REB has determined and documented at a full board meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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Information on this Coversheet (e.g., enrollment numbers, dates of extracted charts/records/biospecimens, etc.) should match what is indicated in the main application. Otherwise, please explain below in Box 5.1. * **3. Participant Recruitment** **3.1.** Is participant consent obtained by researchers in this application? ○Yes ○No	Mark "Yes" if current application is consenting participants. Mark "No" if consent was obtained in a different application for eg, Consent obtained by Biobank team then data/samples are distributed to current application researchers.
3.2. Is this project currently recruiting, or will it be recruiting in the near future? ○Yes ○No	
3.3. How many participants are enrolled (signed consent) at BC sites covered by this Research Ethics Approval? If possible, breakdown the number per BC institution. a. Total enrolled since start : b. Enrollment Goal: c. Number of participants enrolled in the last 12 months: c.2. If there has been no BC participant enrolled in the last 12 months, please explain: Optional Components: d. In addition to the main study, does your application include optional components or consent forms (e.g., Optional Biobank, Optional MRI, etc)? ○Yes ○No d.2. **For optional components,** how many participants have enrolled at BC sites covered by this research ethics approval? Total enrolled since start, per component: (e.g Optional Biobank: 7; Optional MRI: 10)	Example: Box a: Total enrolled since start: 50 Box b. Enrollment goal: 75 Box c. Enrolled in last 12 months: 10 50 participants enrolled in the sites covered under this ethics approval of which 10 were recruited in the past 12 months. Total enrollment goals for sites under this application is 75. Box d. Mark "Yes" if you have a main study + optional components for which a participant can opt-in or sign a separate consent form.

Grey Highlighted questions appear depending on previous answer(s).

Application Questions	Guidance Notes
3.4. For multi-institutional project, how many participants are enrolled across all sites? a. Total enrolled worldwide : b. Enrollment Goal:	
3.5. How many participant withdrawals or screen failure have there been at BC sites covered by this Research Ethics Approval? If possible, breakdown the number per BC institution. Specify if the withdrawals have been reported previously to the REB or if this is the first time they have been reported.	Reference: ICH-GCP (E6) Guidance 4.3.4 states: Although a participant is not obliged to give his/her reason(s) for withdrawing prematurely from a trial, the investigator should make a reasonable effort to ascertain the reason(s), while fully respecting the participant's rights. Note: Participants must not be required to give their withdrawal notice in writing; verbal notice must be accepted.
3.6. To your knowledge, did any participant withdraw as a result of misconduct or complaints? If yes, please explain. [Add Document]	

Application Questions	Guidance Notes
4. Chart Reviews, Database Records and Sample Collection **4.1.** Complete section **only if** you are **not** required by the REB to consent individuals for the use of their data or biospecimen. How many charts/records and/or samples have you included in this research? a. Total included since start b. Targeted inclusion goal	Complete if you received a waiver of consent for secondary use of data (such as a chart review, Popdata, Health Data Platform BC) or biological materials (such as left over samples from diagnostic tests or surgeries) for part of or all of your project. If you are consenting participants for the use of their data or biospecimen, please fill out section 3 only.)
4.2. Confirm the date range of the charts/records being collected. Confirm the date range of Pathology or biobank samples being collected.	Dates of extracted charts/records/samples should match those indicated in the initial application (for e.g., Box 4.8B or Box M.4).
* **5. Progress report** **5.1.** Summary: Provide a brief summary on the progress of the project. If applicable, please also report on progress of optional components (e.g., Optional Biobank). Clarify if optional components are open to enrollment. For projects with multiple BC sites, please enter the enrollment status breakdown per site:	The summary of progress to date should include information on whether participants are still participating in the research project. Clinical trials: Indicate if the trial is open or closed to enrollment and the status of enrolled participants, i.e. if on study treatment or if all are now on long term follow up only. For projects open to enrolment, remarks about the ability to recruit participants are also appropriate, as is any information about the results from any interim analyses.

Application Questions	Guidance Notes
* **5.2.A.** Is your study a Health Canada / US FDA regulated trial or is funded by a for-profit entity? ○Yes ○No	

RISe programming: If 5.2A= "Yes", show 5.2B-5.2E		RISe programming: If 5.2A= "No",show 5.3
Please attach following reports if available: **5.2.B.** Summary newsletter: [Add Document] **5.2.C.** Monitoring report: [Add Document] **5.2.D.** Data Safety Monitoring Board: [Add Document] If you are conducting a clinical trial, a sponsor's summary report containing up-to-date information about the safety of participants is required. **5.2.E.** If there are no reports attached above, please explain why below and whether or not any monitoring or interim analysestook place. If so, indicate by whom and summarize the result: Textbox	OR	**5.3.** Please attach a summary report if available. [Add Document]

Box 5.3. and Box 5.2D If a Data safety monitoring board recommendation has been submitted to the REB within the last six months, quote the post-approval activity number (i.e. PAA A006).

If this is a National Cancer Institute of Canada Clinical Trials Group (NCIC CTG) or Canadian Cancer Society Research Institute (CCSRI) study, please attach a copy of the recent NCIC Clinical Trial Group Data Safety Monitoring Committee Report or provide an explanation as to why one is not available.

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5.4. Does your project include or contribute to a biobank or research registry? ○ Yes, Biobank (Biospecimen + Data) ○ Yes, Research Registry (Data only) ○ No **5.4.A** Is the BC team the biobank/registry custodian? ○Yes ○No **As custodian:** **5.4.A.1.** Please include a list of all projects linked to this biobank/registry, approved by BC REB **and** by other institutions. For BC projects, please list application # (for e.g., H25-01234) Textbox OR **As contributing site:** **5.4.A.A** Please list: -biospecimen type(s) -total number of participant's biospecimen shipped/awaiting transfer (E.g., Blood samples from 10 participants total shipped to Biobank custodian; blood samples from 5 participants awaiting transfer) Textbox Biobank: **5.4.A.2.** Please attach a report with the following information **OR** enter info below in textbox : -biospecimen type(s) -current number of biospecimen available in the collection (E.g., Blood samples- 120 vials available) Textbox [Add document]	**Box 5.4. Biobanks** (also known as biorepositories) are an organized collection of searchable human biological materials (biospecimens) stored for one or more specific or future unspecified research purposes. It may also include associated information about individuals from whom the biological materials were collected. **Registries** are repositories that collect and store information about humans specifically for use in subsequent research. The information may or may not include personally identifying information, clinical test results, x-rays, MRIs, information about race, age, or place of origin, etc., that is collected retrospectively or prospectively. **Box 5.4.A**. Custodianship- Responsibility for safe keeping of biospecimens and associated data and control of their use and eventual disposal in accordance with the terms of the consent given by the participant. Custodianship implies some rights to decide how the biospecimens are used and by whom, and also responsibility for safeguarding the interests of participants. **Box 5.4.A.1.** Projects linked to this biobank/registry include projects that have received samples from the biobank. Linked can also mean projects that share data/biospecimens with the biobank/registry. For eg, biobank recruits same participants as a study, that study shares its data with the biobank. Please note that UBC CREB expects that RISe application #s referenced in this box match what is listed in main application form boxes 4.3A and 4.3B.

Application Questions	Guidance Notes
* **6. Unanticipated Problems** **6.1.** Are there any outstanding actions that the REB, Data Safety Monitoring Board, and/or sponsor has requested that you take with regard to an unanticipated problem (including any serious and unexpected adverse event or Safety Letter)? If possible, breakdown the number of SAEs and Protocol Deviations per BC institution. ○Yes ○No	The Principal Investigator is responsible for summarizing outstanding issues related to unanticipated problems, including serious and unexpected adverse events either observed throughout the study period or submitted to the Principal Investigator by the sponsor for other sites in multi-centre trials. If an item has been submitted to the REB, quote the post-approval activity number (i.e. PAA A006).
6.2. Please explain outstanding actions.	
* **7. New Information** **7.1.** Provide the REB with any new information related to the project.	New information is any information that might adversely affect the safety or well-being of the research participants, the conduct of the trial or the participant's willingness to continue participation New information includes but is not limited to any relevant recent literature, interim findings, preliminary results of the study or of any other study (e.g. using the same drug), that has occurred or come to be known by the Investigator, since the last review.
8. Changes in Conflict of Interest Please provide details of any changes in relation to conflict of interest status of the Principal Investigator and/or other members of the research team.	

9. Lapsed Applications If ethics approval has expired, please provide the following information: a) Provide an explanation for the late renewal; b) Confirm that NO research activities took place during the time over which there was no valid ethical approval; c) Explain what strategies have been put in place so that this will not happen in the future.	**FAILURE TO COMPLY WITH REQUIREMENT FOR ANNUAL RENEWAL** Ideally, the REB office should receive the submission at least 4 weeks for minimal risk applications and 6 weeks for renewals that are Health Canada or US FDA regulated before the expiry date to allow enough time for review and approval. The RISe system sends out email reminders to the PI and Primary contact listed. Prior to the expiration date , either an Annual Renewal or a Completion Notification must be submitted to the REB using RISe. If either of these is not done, the REB may notify the investigator's Department Head or hold, suspend or terminate the project, in which case reactivation may require submission of a new application. **If applicable, funding may be at risk of not being released.** Any consent document signed during a period when there is no ethics approval is not valid. **Reminder: The PI may designate one or two co-investigators with signing authority for the study. For instructions contact your REB.**
10. Additional Comments:	All changes described above must be entered in the appropriate sections of the Application or the submission will be returned as incomplete. These changes can be made once you complete and exit this PAA coversheet.

This is the end of the Post Approval Activity (PAA) Coversheet.

1) Clicking "Continue" will bring you to the PAA homepage.

2) To work on this again, click the "Edit PAA Coversheet" button on the left side of the PAA homepage.

3) ONLY the Principal Investigator or a Co-Investigator with full signing authority will be able to "Submit PAA" from the PAA homepage for the initial submission.