**Page X- REBx Truncated Form-Clinical**

\*\*\*Note pages 1-4C from RISe will still be asked of researchers.
Grey highlighted questions to show/hide depending on previous answer.



 Lead Site Application Snapshot: html added

 For more information on REBX, please see [here](https://researchethics.ubc.ca/about-human-research-ethics/how-obtain-ethics-approval/reb-exchange-rebx).

| **New Questions** | **Guidance notes to be added to** Guidance Notes |
| --- | --- |
| **X.1.** Provide a brief description of activities the BC researchers listed in this application will be involved in.  | Please specify which aspects of the study the UBC researchers will be involved in. For example, if they are only involved in data analysis, please state this. If UBC researchers will be involved in all aspects of the study, such as recruitment, data collection, and analysis, please indicate this. |
| **X.1.1.** If local activities differ from the lead site, please describe the differences. |  |
| **X.2.** How many local participants do you expect to enroll? |  |
| **X.3.** Provide a detailed description of local recruitment methods. Include: Guidance Notes1. How will prospective participants be identified?
2. By what means will recruitment be done (e.g., Posters, in-person, ,etc.)?
3. Who will contact prospective participants?
4. If you have more than 1 BC site, indicate if there are site-specific recruitment methods.
 | Privacy legislation in BC states that organizations cannot provide contact information for clients without their consent, unless permission is obtained from the Provincial Privacy Commissioner or through other approved health authority channels.Click [here](https://researchethics.ubc.ca/clinical-research-ethics/creb-guidance-notes/ubc-clinical-research-ethics-general-guidance-notes#GN10) for information on recruitment.Please ensure the same sites are listed on page 4.A of the application.If you intend to use REACH BC as a recruitment tool, please attach recruitment posting and scripts to box 9.5. Templates available from REACH BC. |
| **X.4.** Consent Guidance NotesPlease specify for local participants: a) who will explain the consent formb) who will consent participantsc) details of where consent will be obtained and under what circumstancesd) the relationship between the person obtaining consent and the participant. | Refer to [TCPS 2 Article 3.2](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html#2) for more information about the consent process.Click [here](https://researchethics.ubc.ca/clinical-research-ethics/creb-guidance-notes/ubc-clinical-research-ethics-general-guidance-notes#GN13) for information on the consent process. |
| **X.5.** Will participants have the capacity to give fully informed consent on their own behalf? (Yes/No) Guidance NotesX.5.A. Provide details of the nature of the incapacity (e.g., young age, mental health or physical condition). [Textbox]X.5.B. If a participant does not have the capacity to give fully informed consent, who will consent on their behalf? [Textbox]X.5.C. If a participant does not have the capacity to give fully informed consent, will they be able to give assent to participate? (Yes/ No)X.5.D. Please explain how assent will be sought. Please be sure to attach copies of the assent form to page 9. [Textbox] | Refer to [TCPS2 Chapter 3](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html#c), Section C for more information on decision-making capacity. Click [here](https://researchethics.ubc.ca/clinical-research-ethics/creb-guidance-notes/ubc-clinical-research-ethics-general-guidance-notes#GN15) for information on individuals who lack the capacity either temporarily or permanently to consent for themselves.Please note that not having attained the legal age of majority in BC (19 years) does not necessarily mean that the participants are unable to provide their own consent. |
| **X.5.1A.** If your research involves participants who may lack the capacity to consent, please specify:a) Whether and how the capacity to consent will be assessed and documented. b) The qualifications and role of the individual(s) responsible for making this assessment.Ensure appropriate documentation (scripts, checklists) are attached to Page 9.  | X5.1.A (b) If capacity to consent is determined by the clinical care team please indicate as such. If capacity to consent is determined by research staff indicate experience/training of the individuals. |
| **X.6.** Does your research involve First Nations, Inuit or Métis Peoples of Canada or other Indigenous communities? (Yes/No) Guidance Notes**X.6.A**. Please note that additional provisos will be issued regarding research conducted on biological material and or data originating from Indigenous peoples or distinct communities. [Textbox] | Click here for TCPS 2 [Chapter 9](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter9-chapitre9.html) on Research Involving the First Nations, Inuit and Metis Peoples of Canada. While Chapter 9 is designed for Indigenous research, the guiding principles can also be applied for distinct communities (e.g., the Deaf community). See TCPS 2 [Article 2.11](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter2-chapitre2.html#11) Research Involving Communities. |
| **X.7.** Data retention and destruction Please describe for BC sites Guidance Notes: a) describe how and where the data will be storedb) what will happen to the data at the end of the studyc) how long the study data will be retainedd) when and how the data will be destroyede) what plans are there for future use of the data; and f) who will have access to the data in the future and for what purpose. | Please include the following information: Final disposition/storage of all research-related study documents.According to [UBC Policy SC6](https://universitycounsel.ubc.ca/policies/scholarly-integrity-policy/) on Scholarly Integrity, data must be retained for at least 5 years after publication within a UBC facility, but may be retained for a longer period provided they are stored securely. There is no explicit requirement for destruction of data at the end of this period.Responsibility for security of data rests with the Principal Investigator.In some cases, data are of such value that they should not be destroyed (e.g., oral history interviews). In these cases, please describe your plans to preserve this material. The consent process should outline these plans and describe how and when it may be appropriate for others to have access to this information.**For Clinical trials:** [Effective February 11, 2022](https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices.html) Health Canada has reduced the period for keeping clinical trial records for drugs and natural health products from 25 years to 15 years. Note: The REB requires at a minimum an annual report for multi-year projects, and an end-of-study report for all studies at study completion. A completion of study notice must be submitted via RISe. |
| **X.8.** Will data be transferred between sites? (Yes/No) **X.8.1.** Please describe: a) the type of data to be transferredb) who the data will be transferred toc) where the data will be transferred (list institution &country); and d) how the data will be sent. |  If information will be sent outside of the local site, please indicate the type of information to be transferred and in what form it will be in when transferred.[TCPS 2, Chapter 5,](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter5-chapitre5.html#a) identifies 5 different categories of data collected from research participants, each with different implications for the privacy of participants. When sending data off site, the data should be coded. Justification for sending directly identifying information or indirectly identifying information off site must be provided and approved by the REB before data is transferred.* **Directly identifying information** - the information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).
* **Indirectly identifying information** - the information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic).
* **Coded information** - direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the Principal Investigator retains a list that links the participants' code names with their actual name so data can be re-linked if necessary).
* **Anonymized information** - the information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.
* **Anonymous information** - the information never had identifiers associated with it (e.g. anonymous surveys) and risk of identification of individuals is low or very low.
 |
| **X.8.2**. Will there be a data/material transfer agreement? (Yes/No) Guidance Notes | Material/ Data transfer agreements may be required by the institution receiving or sending biospecimen/data. Please verify with theinstitutions. Completed agreements can be attached after initial approval via anamendment. Note that if this changes in the future, an amendment must besubmitted before biospecimen/data are transferred. |
| **X.9.** Will researchers access BC medical or health records? (Yes/No)---X.9.1.A. Please list source [Textbox]X.9.1.B. Describe how permission to access the medical records/data and to collect and use these records/data for research purposes will be obtained. Guidance Notes [Textbox] | **X.9.1.B**: Please ensure that the access and use of the charts/records or data from an existing registry or database is permitted under privacy law and that the organization or department with custody and control of the information is aware of this use and access and has either approved it or explain the status of that approval. Note that data, such as medical records, under the custody of health authorities require Institutional/Operational approval. |
| **X.10.** Will BC researchers collect or analyze biospecimens? (Yes/No) |  |
| **X.10.1.** Will biospecimens be transferred between sites? (Yes/No) Guidance Notes**X.10.1.A**. Please describe:a) the type of biospecimens to be transferred b) who the biospecimens will be transferred to c) where the biospecimens will be transferred d) how the biospecimens will be sent and e) confirm that only de-identified biospecimens will be transferred. | Please indicate the type of biospecimens/data to be transferred and in what form it will be in when transferred. Material Data transfer agreements may be required by the institution receiving or sending biospecimen/data. Please verify with the institutions. Completed agreements can be attached after initial approval via an amendment. Note that if this changes in the future an amendment must be submitted before biospecimen/data are transferred. |
| **X.10.2.** For each study component use headings (eg, “Main study”, “Sub-study”) then for each group, describe for biospecimens: a) what will happen to the study biospecimens at the end of the study; b) how long the study biospecimens will be retained; c) where, when and how the biospecimens will be destroyed d) what plans are there for future use of the biospecimens, including who will have access to the biospecimens in the future and for what purpose. e) IF samples are transferred to another site, please respond to the above sub-question regarding transferred samples. | Please complete if your study involves the handling of biospecimens (e.g. blood samples) |
| **X.11.** Health Canada Is this study a clinical trial of a drug, device, or natural health product or uses positron-emitting radiopharmaceuticals requiring Health Canada regulatory approval (Yes/No) Guidance Notes**X.11.1.** Please check all that apply :* Clinical trial pursuant to the provisions of Part C, Division 5, of the Food and Drugs Act.
* Clinical trial of a Natural Health Product pursuant to the Natural Health Product Regulations.
* Investigational testing of a class II, III or IV medical device pursuant to the Medical Device Regulations.
* Requires the submission of a clinical trial application pursuant to the Guidance Policy on the use of positron-emitting radiopharmaceuticals (PER) in basic research.
 | The sponsor is an individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial. For unfunded/investigator-initiated studies, the sponsor could be the principal/qualified investigator. The sponsor is usually responsible for applying for regulatory approval from the appropriate Health Canada Directorate. Refer to Section 5 of the GCP Guidelines by clicking [here](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/international-conference-harmonisation/efficacy/good-clinical-practice-consolidated-guideline-topic.html) for a full description of the duties and responsibilities of the sponsor. Click [here](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents.html) for information on regulatory approvals and registration. |
| **X.12.** US RegulationsIs there a requirement for this research to comply with United States regulations for research ethics? OR if this study is being funded by an NIH or DHHS grant, please mark "Yes"(Yes/No) Guidance Notes----**X.12.1** A) Please indicate whether or not an FDA Investigational New Drug (IND) number (drug studies) or an FDA Investigational Device Exemption (IDE) is required for the research. B) Enter the applicable number below Guidance Notes[Textbox] | Mark "yes" if this study is: a) conducted or funded by the US Department of Health and Human Services (DHHS) (see link below), or b) is required to comply with either the U.S. FDA or any other U.S. regulations. The PI is responsible for ensuring that the study complies with the applicable U.S. regulations. Click [here](https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html) for a listing of the DHHS operating and staff divisions.-----The Office of Research Ethics is responsible for reporting Unanticipated Problems to the DHHS Office For Human Research Protections (OHRP) or the U.S. FDA. In the latter case, the IND or IDE number must be referenced in the report(s). If a U.S. FDA IND or IDE number is applicable, the Ethical Certificate of Approval will not be released until a valid number is entered in Box 7.12B and if available, appropriate documentation is attached to Box 9.1.C.Please note for REBX, only Box X.12.1 applies.  |

Page 9 Documentation **New Concise REBx Page 9:**

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| --- | --- |
| **Box** | **Guidance notes** Guidance Notes |
|  **9.2.** Consent form | Attach all Localconsent forms for the research, including the following:* Participant consent form
* Normal/Control participant consent form
* Biobanking consent form
* Substitute decision maker consent form
* Other consent forms

Click [here](https://researchethics.ubc.ca/clinical-research-ethics/creb-forms-templates) for the BC Common Clinical Informed Consent Form Template.Refer to the appropriate REBs' website for other consent form templates  [Children's and Women's Research Ethics Board](http://www.phsa.ca/researcher/ethics-approvals/research-ethics-approval/ubc-childrens-and-womens-research-ethics-board) [Providence Health Care Research Ethics Board](https://www.providenceresearch.ca/en/research-ethics).For BC Cancer Studies, please see website for template [here](http://www.bccancer.bc.ca/our-research/ethics-oversight/researchethics/consent-templates)\* June 2024 - Please note for REBX, BC Cancer and Children’s and Women’s sites have not yet been onboarded. |
| **9.3.** Assent forms  | Attach all assent forms for the research, including the following:* Young child assent form
* Adolescent assent form
* Adult assent form
* Biobanking assent form
* Other assent forms
 |
| **9.5.** Recruitment documents (Ads, Posters, letters of initial contact, etc). | This includes any type of communication (e.g. flyer, email recruitment message, Internet posting, radio/television script, poster, newspaper ad) that is directed to potential participants for the purpose of recruitment. The purpose of this documentation is to ensure that the recruitment measures are appropriate and do not cause undue influence on potential participants.Click [here](http://www.phsa.ca/researcher/ethics-approvals/research-ethics-approval/ubc-childrens-and-womens-research-ethics-board) for **UBC C&W Research Ethics Board** policies regarding participant handouts and advertisements.\* June 2024 - Please note for REBX, Children’s and Women’s sites have not yet been onboarded. |
| **9.8A.** Data Collection forms and Other Documents | Examples of other types of documents:* Data collection sheet
* Clinical Trial Agreement
* Other associated documents not attached above
* CIHR Stem Cell oversight approval letter
* Transcript of Audio Visual item
* Website content
* Peer review report

If applicable, please attach a transcript (the document must include a version date) of any video or audio file. |
| **9.9.** Reference Documents - These documents will NOT be listed in the Certificate of approvalPlease attach reference documents here. For e.g., Consent forms or Ethics certificates from non-BC sites. For Alberta documents and more info, click blue question mark for info. | REBs at times, request reference documents during the review process to inform their decisions.  These documents however, are not being approved by the BC REB.  Such as: * Consent forms from non-BC sites
* Certificate of Ethics approval-from non BC sites
* Material transfer agreement.
* Purchase agreement

For REBX, Alberta documents do not need to be uploaded here as this will be downloaded by RISe. \*Documents attached in this box will NOT be listed in the BC Certificate of ethics  approval. |