



## UBC REBx Truncated Form- Behavioural


\*\*\*Note pages 1-4B from RISE will still be asked of researchers.




Grey highlighted questions to show/hide depending on previous answer.





### REBX Participating Site - HUMAN ETHICS APPLICATION

Lead Site Application Snapshot: < html>



For more information on REBx, please see [here](#).

New Questions	Guidance notes 
<b>R.1.</b> 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.
<b>R.1.1.</b> If local activities differ from the lead site, please describe the differences.	
<b>R.2.</b> How many local participants do you expect to enroll?	


New Questions	Guidance notes 
<p><b>R.3.</b> Provide a detailed description of local recruitment methods. Include: </p> <ol style="list-style-type: none"> <li>How will prospective participants be identified?</li> <li>By what means will recruitment be done (e.g., Posters, in-person, etc.)?</li> <li>Who will contact prospective participants?</li> <li>If recruitment will occur in person, what sites will be used (e.g. doctor's office, community site, hospital clinic, etc.)?</li> <li>If you have more than 1 BC site, indicate if there are site-specific recruitment methods.</li> </ol>	<p>If you intend to use REACH BC as a recruitment tool, please attach the study information to Box 9.4. This will be either the REACH BC "Add a Research Study" PDF form or the "study posting preview" generated on REACH BC. Include "REACH BC" in the title of the document. If any substantial changes are made to your study description as a result of ethics review (e.g. participant inclusion criteria, research focus), the updated REACH BC study description must be re-uploaded to your ethics application before it will be approved. You will need to submit your certificate of ethics approval (which will record the addition or inclusion of REACH BC) before your study will be posted to the site.</p>
<p><b>R.4.</b> Consent </p> <p>Please specify for local participants:</p> <ol style="list-style-type: none"> <li>who will explain the consent form</li> <li>who will consent participants</li> <li>details of where consent will be obtained and under what circumstances</li> <li>the relationship between the person obtaining consent and the participant.</li> </ol>	<p><a href="#">Article 3.12</a> of TCPS 2 states that "Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent" (see also <a href="#">Article 10.2</a>).</p> <p>Ethics boards recognize that written consent may not be appropriate for certain types of research. Researchers wishing to obtain oral consent should describe the alternative means of obtaining and documenting consent. A script of the oral consent process should be appended to Box 9.2.</p>


New Questions	Guidance notes 
<p><b>R.5.</b> Will participants have the capacity to give fully informed consent on their own behalf? (Yes/No) </p> <p>a. Provide details of the nature of the incapacity (e.g., young age, mental health or physical condition). [Textbox]</p> <p>b. If a participant does not have the capacity to give fully informed consent, who will consent on their behalf? [Textbox]</p> <p>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</p> <p>d. Please explain how assent will be sought. Please be sure to attach copies of the assent form to page 9. [Textbox]</p>	<p>Click <a href="#">here</a> for information on individuals who lack the capacity either temporarily or permanently to consent for themselves.</p> <p>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.</p>
<p><b>R5.1.A.</b> If your research involves participants who may lack the capacity to consent, please specify:</p> <p>a) Whether and how the capacity to consent will be assessed and documented.</p> <p>b) The qualifications and role of the individual(s) responsible for making this assessment.</p> <p>Ensure appropriate documentation (scripts, checklists) are attached to Page 9 </p>	<p>R5.1.A(b)</p> <p>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.</p>
<p><b>R.6.</b> Does your research involve First Nations, Inuit or Métis Peoples of Canada or other Indigenous communities? (Yes/No) </p> <p>Please note that additional provisos will be issued regarding research conducted on data originating from Indigenous peoples or distinct communities. [Textbox]</p>	<p>Click <a href="#">here</a> for TCPS 2 Chapter 9 on Research Involving the First Nations, Inuit and Metis Peoples of Canada</p>

New Questions	Guidance notes ?
<p>R.7. Data retention and destruction Please describe for BC sites ?:</p> <p>a) how and where the data will be stored</p> <p>b) what will happen to the data at the end of the study</p> <p>c) how long the study data will be retained</p> <p>d) when and how the data will be destroyed</p> <p>e) what plans are there for future use of the data; and</p> <p>f) who will have access to the data in the future and for what purpose.</p>	<p>Please specify data retention and destruction methods for all data types to ensure confidentiality (e.g., tapes should be demagnetized, paper copies shredded).</p> <p>According to <a href="#">UBC Policy SC6</a> 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.</p> <p>Responsibility for security of data rests with the Principal Investigator.</p> <p>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.</p>
<p>R.8. Will data be transferred between sites? (Yes/No)</p> <p>R.8.1 Please describe:</p> <p>a) the type of data to be transferred</p> <p>b) who the data will be transferred to</p> <p>c) where the data will be transferred (list institution &amp; country); and</p> <p>d) how the data will be sent.</p>	

New Questions	Guidance notes 
R.8.2 Will there be a data transfer agreement? (Yes/No) 	Data transfer agreements may be required by the institution receiving or sending 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 data are transferred.

## Page 9 Concise Page 9

Box	Guidance notes 
9.2 Documentation of Consent	<ul style="list-style-type: none"> <li>Participant consent form</li> <li>Parent/guardian consent form</li> <li>Other consent forms</li> <li>Description of process for obtaining consent (e.g. oral consent script)</li> <li>Click <a href="#">here</a> for more guidelines on behavioural informed consent forms</li> </ul>
9.3 Documentation of Assent	<ul style="list-style-type: none"> <li>Participant assent form</li> <li>Other assent forms (e.g. oral assent script)</li> <li>Click <a href="#">here</a> for more information on assent for the Vancouver &amp; Okanagan UBC BREBs</li> <li>Click here for UBC C&amp;W Research Ethics Board <a href="#">assent template</a> and <a href="#">adolescent assent template</a></li> </ul> <p>* June 2024 - Please note for REBX, Children's and Women's sites have not yet been onboarded.</p>
9.5 Advertisements to Recruit Participants (Ads, Posters, letters of initial contact, etc).	<p><b>Advertisement to Recruit Participants</b> This includes any type of communication (e.g. flyer, radio/television script, poster, newspaper ad, internet message) that</p>

Box	Guidance notes 
	<p>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 not coercive.</p> <p>Click <a href="#">here</a> for <b>UBC C&amp;W Research Ethics Board</b> policies on participant handouts and advertisements.</p> <p>* June 2024 - Please note for REBX, Children's and Women's sites have not yet been onboarded.</p>
9.7. Other Documents	<p>If applicable, please attach a transcript (the document must include a version date) of any CD, tape or audio file and send the hard copy to the office of Board of Record.</p> <p>Other documents regularly required include the following:</p> <ul style="list-style-type: none"> <li>• Deception form and written or verbal debriefing. Please click <a href="#">here</a> to complete the form, then save and attach it to question 9.7</li> <li>• Evidence of Agency approvals from other institutions</li> </ul> <p>If this is an application using the streamlined process as indicated in Question 4.6, please append <b>ALL</b> relevant documentation from the other approving REB, including the application form, all correspondence from and to the approving REB, the proposal approved, the certificate of approval, the other REB approved informed consents, etc.</p>