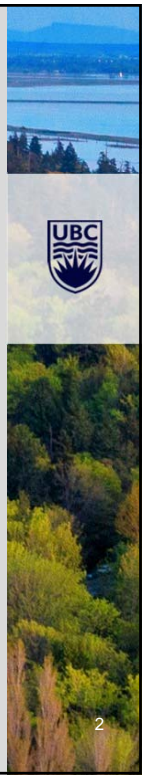
VCHRI RESEARCH CHALLENGE- OBTAINING ETHICS APPROVAL

Elmira Chan, UBC Clinical research ethics board

AREAS THAT WILL BE COVERED

- RISe application
- Required documentation
- Consent Form
- Approval process
- Post-approval process



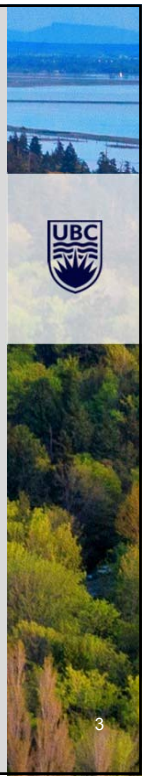
UBC RISe Application Process for VCH clinicians

- PIs that are NOT affiliated with UBC

1. Log on to RISe, click your name on the top right corner to access your profile. Principal Investigator's profile must add VCHRI in Question 3. Hit Apply.

2.Application Box 11.2B, please download the Declaration form and obtain the signature of your VCH manager. Attach to section.

3. Select VCHRI as the Dept for approval when submitting application. Note- this is different from the VCH operational approval (obtained separately if required).

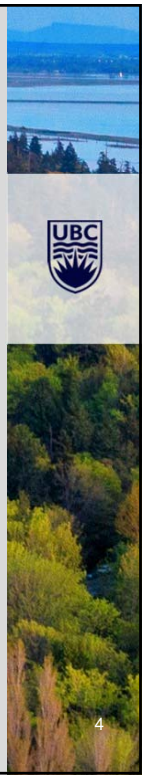


UBC RISe Application

Login to UBC RISe

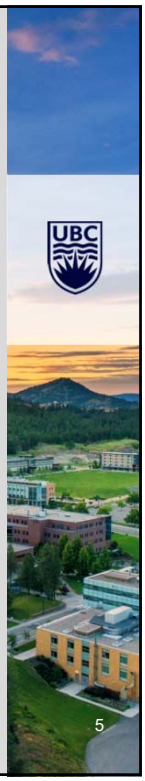
https://www.rise.ubc.ca/

Let's go through an application together



SUBMISSION TIPS

- Attach any documents that will be seen by the participant (ads, letters, consent form) or any data collection forms (questionnaires)
- Standardized assessments – Replace “Name” with “Study ID”. Replace “DOB” with “Age” (if possible).
- Application is **consistent** (application content matches consent form, protocols, ads)



CONSENT FORMS TIPS

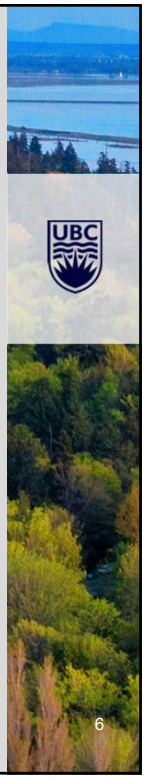
- BC Common Clinical Consent Template

http://bit.ly/common-clinical-informed-consent-template

  - This template is an all-in-one and very patient centric. Edit to be applicable to your study.

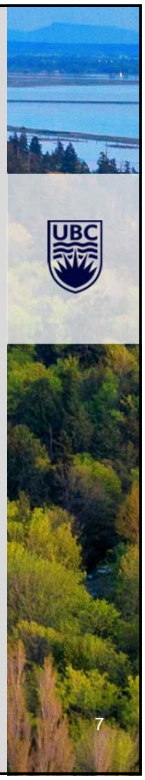
- For other templates (assent forms, optional consent)

https://ethics.research.ubc.ca/clinical-research-ethics/creb-forms-templates



CONSENT FORMS TIPS

- Reading level appropriate for target audience
  - Participants from the general population (Grade 7 reading level, define technical terms or acronyms at first use) Max 3 acronyms.
    - Bad Eg. (The CoA for this study was issued by BoR.)??
  - Appropriate amount of information for informed consent. Average length for minimal risk (7-11 pgs)
  - If possible, have the consent form read by someone from your target audience.



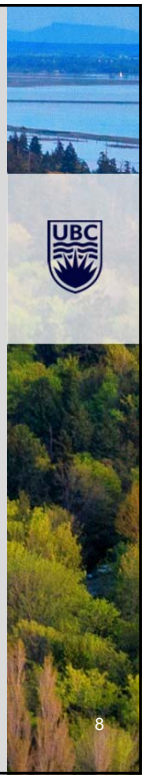
CONSENT FORMS TIPS

All Clinical studies should have the following template sections in the Consent Form:

- Section 16. Confidentiality section
- Section 17. Waiver of rights
- Section 20. UBC complaint line
- Signature, Page 31

EDIT template required wording to be applicable.

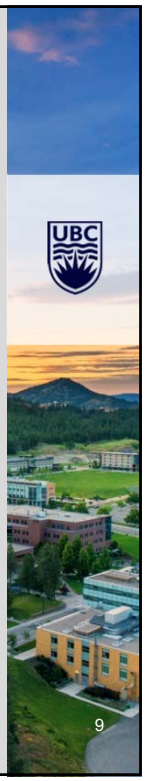
(e.g., Remove “Health Canada”)



SUBMISSION TIPS-RECRUITMENT

- BC privacy laws- Personal information should not be used to contact individuals for research participation unless there has been PRIOR consent to do so.
    - Clinician vs Researcher

- One method of recruitment is the VCH letter of initial contact found https://www.vchri.ca/forms this can be used to mailout to patients.



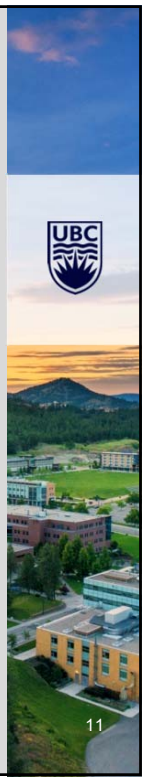
SUBMISSION TIPS-RECRUITMENT

- Recruitment of patients- can be approached by someone who is within their circle of care to advise patients about the study and ask if the he/she would like to find out more. With permission, patients may be referred to study staff.

- Communications with participants- transmit using a UBC-hosted email address or Institutional emails (e.g. VCH). (**NO** third party- gmail, Hotmail, Outlook).

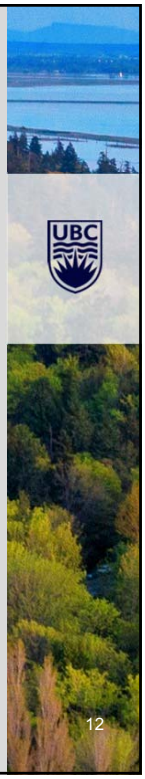
DATA STORAGE

- UBC policy - study data must be kept for **at least 5 years** after it has been published or presented.
- Digital data - stored on an **encrypted**, password protected computer or secure hospital network.
- NO to the 3rd party cloud (Dropbox, OneDrive). VCH has secure FTP, UBC workspace.
- Hardcopies- de-identified, stored in locked cabinets kept separate from consent forms.



MINIMAL RISK- TURNAROUND

Minimal Risk	Timeframe
	Reviewed as they come into queue
Provisos-issued	Average 1-2 weeks
Team responds to provisos	Dependent on researchers
Response from REB	1-2 weeks
Approval	Approx 1 month after Dept approval



FULL BOARD- TURNAROUND

Reviewed at Full board	Timeframe
	See REB websites for Deadlines and meeting dates
After the meeting	Provisos- issued after it is collated (a few business days after meeting).
Team responds to provisos	Dependent on researchers
Team submit response to REB	Response from REB 1-2 weeks
Approval	CREB turnaround approx. 4-6 wks

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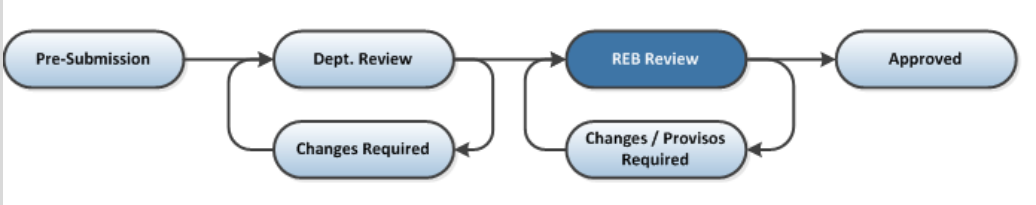
RISE APPLICATION

- RISe study homepage will have a flow chart



- lifecycle of the application.
- Only the PI can submit the new application. Allow time for Dept. Head review.
- The REB will receive the application when it is in “REB Review” stage.

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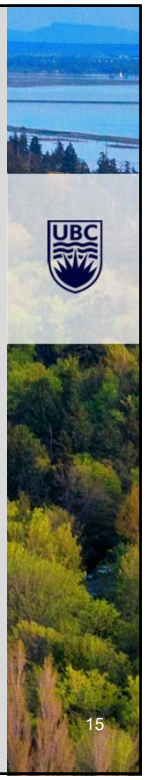
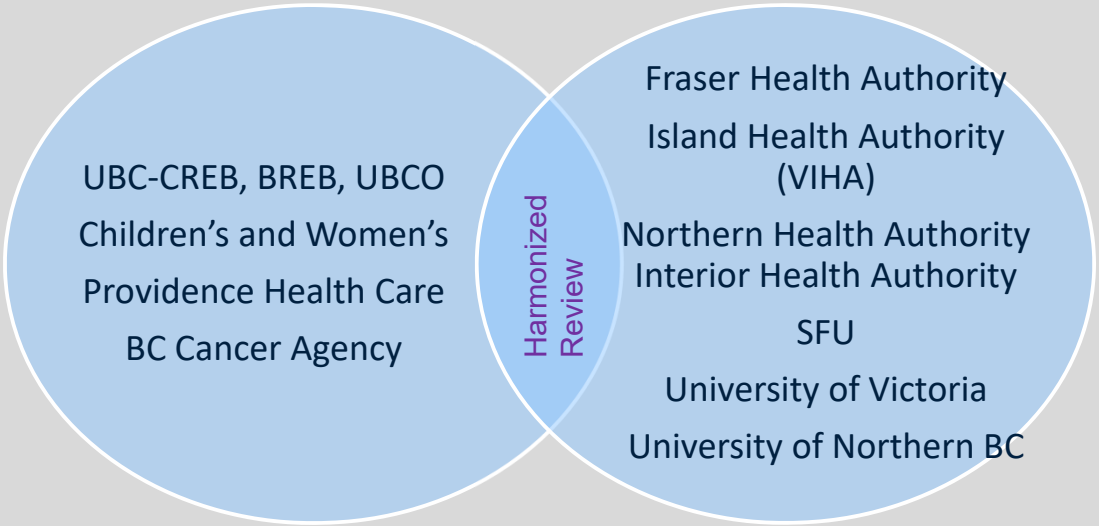
RISE APPLICATION

State	Meaning
Pre submission	Working document
Department review	Awaiting Dept Head approval
Screening	REB staff is checking application for completeness
Assigned for expedited review	Undergoing minimal risk review
Assigned for full review	Undergoing full board review
Provisos Pending	Provisos have been issued
Changes required	Can occur any time when application needs updating
Expired	Approval has lapsed- Submit a renewal



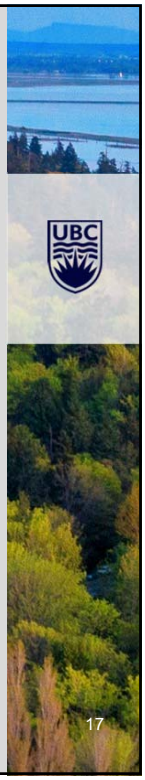
BC HARMONIZATION INITIATIVE



If your study requires harmonized review then review times will be longer

PROVISO RESPONSE

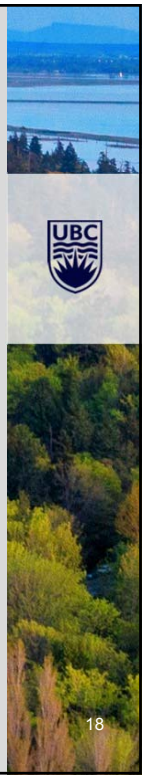
1. Provisos are points of clarification or discussion points between the REB and research team.
2. If the proviso says “Clarify” or “Justify” please explain your responses.
3. If the proviso is related to a document, please make sure to amend the document where it is applicable.
4. Study team members can submit the proviso responses to the REB



PROVISO RESPONSE

Instructions:

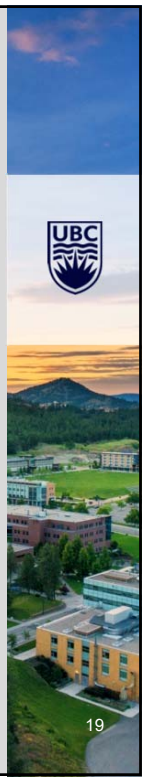
1. Look under the "Provisos" tab for the list of provisos.
2. Copy provisos into a Word Document and provide a response to each proviso underneath. Attach this document to RISe
3. Any modified documentation (i.e. consent forms, protocol etc.) all changes must be **tracked (eg** ~~Typo)~~ **/highlighted Within** the document.
4. Replace the previous version of the modified document in Page 9 with the new modified version, leaving only the most current version.



GOT ETHICS APPROVAL NOW WHAT?

- Obtain Operational/institutional approval of the sites.
- Notify the REB with any changes via Post-approval activities (renewal, amendment, acknowledgment)
- UBC RISe Tutorials include how to submit Post-approval activities

https://www.rise.ubc.ca/guidance-notes-and-tutorials/user-tutorials

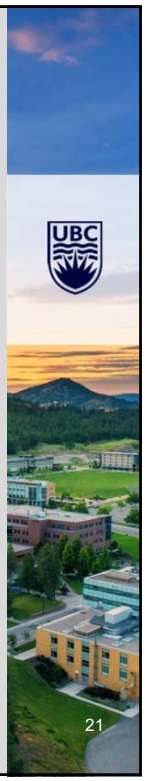


OPERATIONAL/INSTITUTIONAL APPROVAL

- VCHRI https://www.vchri.ca/forms Contact person: wylo.kayle@vch.ca
- PHC http://www.providenceresearch.ca/research-ethics/institutional-approvals Contact person: alex.trethewey@ubc.ca
- BCCHR http://www.phsa.ca/researcher/ethics-approvals/institutional-approvals Contact: cwreb@bcchr.ubc.ca
- Contact the appropriate site to determine operational approval requirements

POST APPROVAL ACTIVITIES DEFINED

- Renewal – Annual progress report on the study
- Amendment – any changes to the application. This will unlock the application for editing.
- Renewal with amendment- combination of the above. Not always available for all boards.
- Completion – The study is complete, no more data collection or interaction with participants.
- Acknowledgement- Notification to the REB of any adverse events or protocol deviations



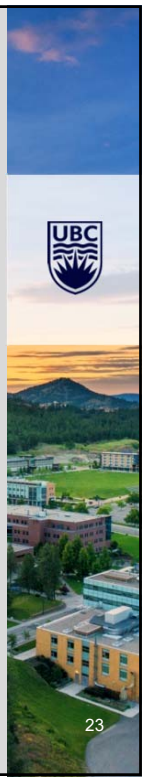
POST APPROVAL ACTIVITIES APPROXIMATE TURNAROUND

- Renewal – 1-2 business days
- Amendment – 1-2 days to 1 week for simple changes
- Renewal with amendment- 1 week
- Completion – 1 week
- Acknowledgement- 1 week

It may be possible to have provisos issued. Turnaround for approval would depend on this.

UBC CREB CONTACTS

- Pia Ganz, Manager, Clinical 604-875-4149 pia.ganz@ors.ubc.ca
- Elmira Chan, Pre/post Review Manager 604-875-4111 ext. 68918 elmira.chan@ors.ubc.ca
- Anita Lillquist, Ethics Review Coordinator 604-875-875-4167 anita.lillquist@ors.ubc.ca
- Svitlana Franchuk, Administrative assistant 604-875-4111 ext. 68917 svitlana.franchuk@ors.ubc.ca



UBC BREB CONTACTS

- Jean Ruiz, Senior Research Ethics Analyst – Behavioural 604-827-5310 jean.ruiz@ors.ubc.ca
- Alanna Dyck, Review Coordinator 604-827-5112 (maternity leave replacement) maria.valente@ors.ubc.ca
- Wendy Bond, Research Ethics Coordinator 604-822-4581 wendy.bond@ors.ubc.ca
- Nadia Rad, Senior Administrative Coordinator 604-827-5114 nadia.rad@ors.ubc.ca


QUESTIONS?