

Common Challenges in Ethics Submissions

Suzanne Richardson, Pre/Post Review Manager, Clinical Research Ethics Board



Overview:

1. Institutional and national policies that outline & guide the UBC ethics process
2. UBC Research Ethics Boards (REBs)
3. Do you need ethics approval?
4. Ethics Review Process
5. Common Challenges
6. Subject Consent
7. Post-Approval Activities

1. UBC Policies that outline & guide the process

- UBC Policy 85 – Scholarly Integrity
- UBC Policy 89 – Research and Other Studies Involving Human Subjects
- UBC Policy 97 – Conflict of Interest and Conflict of Commitment

<http://universitycounsel.ubc.ca/policies/scholarly-activity/>

TCPS2

- Tri-Council Policy Statement (2nd Edition, 2010):

<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>

- TUTORIAL (Course on Research Ethics- CORE):

<http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/>

2. UBC Research Ethics Boards (REBs)

- Clinical REB
- Behavioural REB
- UBC Okanagan BREB (Behavioural studies only)
- Providence Health Care (PHC) REB
- BC Cancer Agency (BCCA) REB
- Children and Women's (C&W) REB

To which Board should you submit your application?

- REB should be chosen based on the following:
 - Principal Investigator's primary affiliation
 - Primary site where study is being conducted
- If study is being conducted at more than one UBC-affiliated institution (i.e. VGH and St. Paul's) use the above as a guide when choosing your REB
 - UBC REBs have a one board of record agreement

3. Do you need ethics approval?

- TCPS2 defines research as:
“An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation”
- Involves living human participants AND/OR
- Involves human biological materials, human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to material derived from living and deceased individuals.

Activities not requiring REB review

- Quality assurance & improvement studies, program evaluation & performance reviews, or testing within normal educational requirements when used *exclusively* for assessment, management or improvement purposes do not always require REB review
 - Checklist:
http://www.vchri.ca/i/pdf/Guidance_ResearchEthicsBoard_06Aug2010.pdf
 - Note a desire to publish does not necessarily mean that ethics is required
 - QA/QI data that you want to later use for research is considered secondary use of data and REB review is required
 - Refer to TCPS2 Article 2.5: <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/#toc02-1a>

Research Exempt from REB Review

- Research that relies exclusively on publicly available information
 - Legally accessible to public & appropriately protected by law
 - Publicly accessible information & no reasonable expectation of privacy
- Secondary use of **anonymous** information
 - Anonymous means data that has never had identifiable information associated with it.

4. Ethics Review Process

- All applications must be submitted online via RISE
- The CREB meets twice a month to review Full Board applications
- Minimal Risk applications are reviewed as they are submitted
- Do not expect to have your application approved the first time through. Provisos (changes requested by the REB) are typical, not the exception
- Use this process as an opportunity to improve the quality of your research

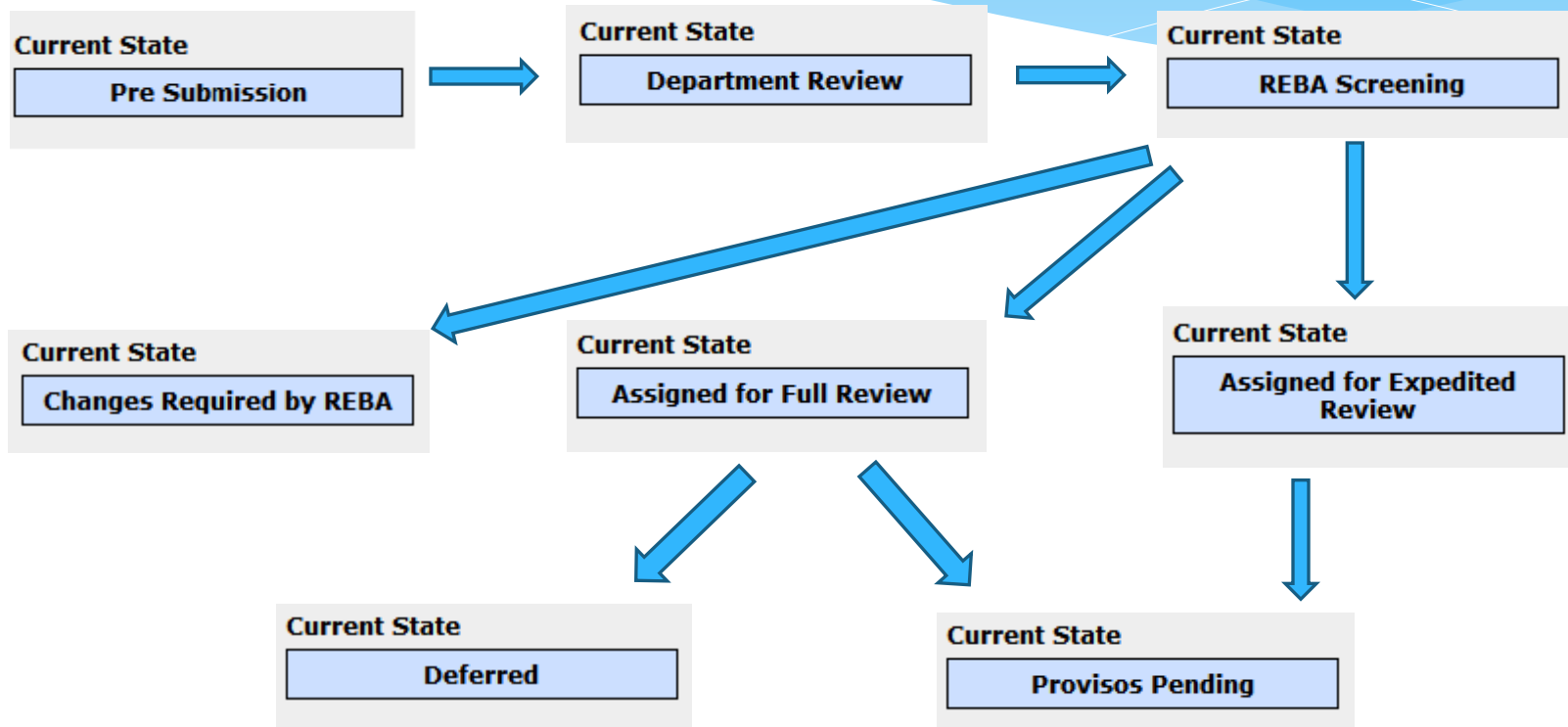
Researcher Information Services (RISe)

- Need a Campus-Wide Login (CWL) Account
<http://www.it.ubc.ca/cwl/homelink.shtml>
- Step by step directions for accessing RISe:
<http://www.rise.ubc.ca/content/how-logon-and-access-rise>

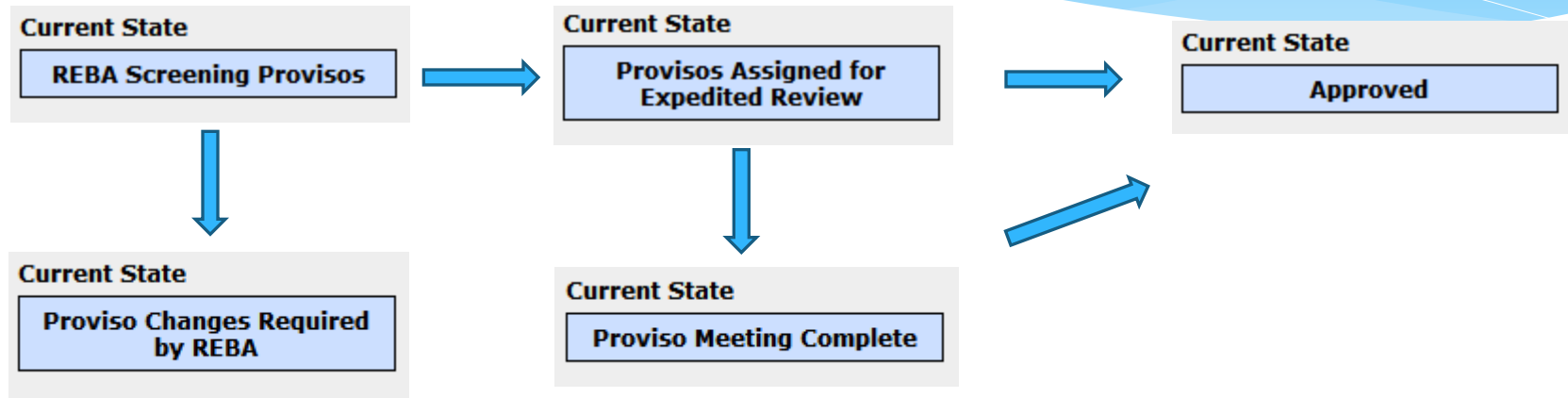
CREB Website Links

- CREB Guidance Notes and Templates:
<http://research.ubc.ca/ore/creb-forms-guidance-notes>
- CREB Meeting Dates and Deadlines:
<http://research.ubc.ca/ore/creb-meeting-dates-deadlines>
- CREB Advice & Things to Avoid:
<http://research.ubc.ca/ore/creb-advice-things-avoid>

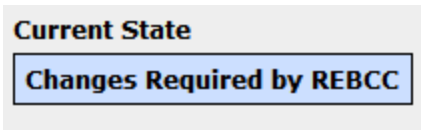
Various stages of the RISE application form



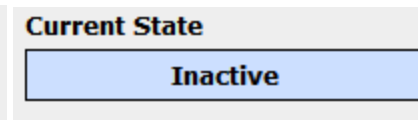
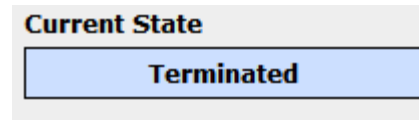
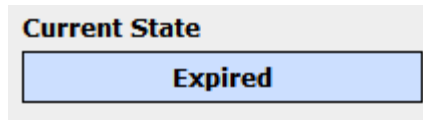
Various stages of the RISE application form cont'd



For PAAs:



No active ethics:



Types of Ethical Review

- **Minimal Risk**

- No greater risk than everyday life
- Examples include: studies using previously collected/existing clinical data and medical records, collection of non-invasive biological material, questionnaire studies, exercise studies (when participants are healthy), scans (EEG, EKG, MRI, ultrasound, x-rays, observational research, etc. See Guidance Note for Minimal Risk Studies:
<http://research.ubc.ca/ore/creb-forms-guidance-notes>

- **Full Board**

- There are situations where Minimal Risk studies need to be reviewed at Full Board, e.g. creation of a tissue bank, altered consent process, etc. Any Minimal Risk study can be referred to the Full Board if the reviewer feels it should be reviewed at the Full Board.
- Everything else

5. Common Challenges

- **Administrative**
 - Submit to appropriate REB and for appropriate level of review
 - Submit with enough time for your Department Head to sign off in order to meet the Full Board deadline
 - Ensure all fields in the application form are filled out as appropriate, and that this information matches what is written in the study documents
 - Ensure all documentation attached to page 9 opens properly, and that version numbers and dates match the application form
- **For proviso/deferral responses**
 - Ensure all amended documents have requested changes highlighted or tracked
 - Include a letter outlining each proviso and how they have been addressed

Common Challenges cont'd

- **Peer review (Box 4.4)**
 - All studies which are not minimal risk should have some form of peer review attached to Box 9.8 of the RISE application form
 - This can be internal OR external from an expert in the field who is at arms' length from the study
- **Recruitment (Box 5.4)**
 - Provide a detailed description of the recruitment methods
 - How will you avoid undue influence?
 - Justify exclusion of a particular group (e.g., based on sex, age, ethnicity, ability)
 - Clarify how you have access to the potential subjects' information in order to contact them for recruitment

Common Challenges cont'd

- **Potential Risks and Safeguards (Box 6.3)**
 - Quantify risks in percentages
 - List all potential risks (physical and emotional)
- **United States regulations (Box 7.12)**
 - Studies conducted by a U.S. government department and/or its agencies OR studies regulated by the FDA must follow:
 - [45 CFR Part 46](#) for all U.S. federal government department/agency funded research
 - [21CFR Part 50](#) and [21CFR Part 54](#) for trials regulated by the Food and Drug Administration

Common Challenges cont'd

- **Subject Identifiers and Confidentiality (Box 8.4)**
 - How will you ensure privacy and confidentiality of subject identities/data?
 - Justify any need to collect personal identifiers
- **Data retention (Box 8.6)**
 - As per UBC's [Policy #85](#) Original data for any given study must be retained in the unit of origin for *at least five years after the work is published or otherwise presented*

6. Subject Consent

“ The consent form is not meant to reassure the subject, quite the contrary, it is meant to raise every possible concern that might be relevant to the subject’s participation.”

Time (April 22, 2002)

- Consent is generally necessary in all situations where researchers prospectively gather data from individuals under a research protocol

Three Basic Elements:

Complete and Accurate

Readable

Voluntary

Use the UBC Clinical REBs Consent Form Template and Guide:

<http://research.ubc.ca/ore/creb-forms-guidance-notes>

*****CONSENT IS A PROCESS, NOT JUST A FORM*****

Requirement for Consent

- Need consent in all situations where researchers prospectively gather data from individuals under a research protocol
- Do not ethically require consent for
 - the use of data obtained from previously banked anonymized tissue that is NOT linked to other sources of data
 - retrospective chart or medical record reviews
 - provincially regulated databases/registries (e.g. Medical Services Plan, BC Centre for Disease Control)
 - disease specific registries with data collected from subjects who have already consented to its use for the sort of research being done
- If obtaining consent is impracticable, a researcher can propose a waiver of consent as long as all requirements under TCPS2 Article 3.7 are met: <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#toc03-1b>

7. After the Initial Approval: Post-Approval Activities

Your interaction with the CREB does not end with your Certificate of Approval!

- **Amendments**
 - Examples: changes to research team members, site additions/changes, changes to funding agency, new title, changes to study design/population/recruitment technique/experimental procedure, addition of new tests/open label extension phase/, emergency amendments and re-consent
- **Renewals:** annual review (4 weeks before expiry date – keep this in mind if your renewal will require Full Board review)
- **Protocol Deviations and Requests for Acknowledgement**
- **Notification of Study Closure**

Please contact us with any questions:

- Pia Ganz, Manager, CREB:
pia.ganz@ors.ubc.ca 604-875-4149
- Suzanne Richardson, pre/post review manager, CREB:
suzanne.richardson@ors.ubc.ca 604-875-4111 ext. 68919
- E. Sarah Bennett, pre/post review manager, CREB:
sarah.bennett@ors.ubc.ca 604-875-4111 ext. 68918
- Svitlana Franchuk, administrative assistant, CREB:
svitlana.franchuk@ors.ubc.ca 604-875-4111 ext. 68917