An Introduction to the UBC Ethics Review Process and the Clinical Research Ethics Board

E. Sarah Bennett, Pre/Post Review Manager, Clinical Research Ethics Board

Overview:

1. Institutional and national policies that outline & guide the UBC ethics process
2. Does my project require REB review?
3. UBC Research Ethics Boards (REBs)
4. Ethics Review Process
5. Application Overview & Guidance Notes
6. Consent Form

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/

TCPS2

Core Principles of the Tri-council Policy Statement (TCPS2) are based on Respect for Human Dignity:

* Respect for Persons
* Concern for Welfare
* Justice

**** Respect for Human Dignity****

2. Does my project require REB review?

1. Research: "An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation"
2. Involves living human participants: "those individuals whose data, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question" AND/OR
3. Involves human biological materials, human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to material derived from living and decreased individuals.
   - Human biological material includes "tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, skin, hair, nail clippings, urine, saliva, and other body fluids."

RESEARCH EXEMPT FROM REB REVIEW

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

ACTIVITIES NOT REQUIRING REB REVIEW

1. 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 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

3. UBC Research Ethics Boards

- Clinical REB
- Behavioural REB
- Providence Health (PHC) REB
- BC Cancer Agency (BCCA) REB
- Children and Women's (C&W) REB
- UBC – Okanagan (UBC-O) REB

To which Board should I submit my application?

BREB

- Human participant research that are behavioural or social scientific in nature or involve humanities research. They may involve patients or healthcare providers; however, they are not clinical and do not involve invasive procedures. They do involve:
  - Questionnaires, interviews and focus groups
  - Observation
  - Data linkage
  - Secondary use of data
  - Deception
  - Video and/or audio taping

CREB

- Clinical interventions involving the testing of drugs, medical devices, and rehabilitation exercise programs
- The analysis of clinical data obtained from medical records
- Studies of a clinical nature involving linkage of data from existing databases

Grey areas

- Clinical studies may also involve interviews & questionnaires
- If a study involves physically invasive procedures, it must be reviewed by CREB, regardless of other elements
- If study involves psychological measures, CREB may ask BREB for expert opinion
- Behavioural studies can include access to participant's medical records (with consent)

CREB or BREB?

Your project involves interviewing people who are recovering from injury about daily tasks that they feel they can no longer do. The research aims to explore how people feel about not being able to do something they used to do with ease. It will confirm injury diagnosis and time of injury by examining medical charts.

CREB or BREB?

Your project is comparing two different methods for rehabilitating certain movements in a Stroke population. Your participants will be randomized to receiving either an experimental protocol or the standard of care protocol.

4. Ethics Review Process

- All applications must be submitted via RISe
- The CREB meets twice a month to review Full Board applications (Minimal Risk/Delegated Review applications generally do not need to go to the Full Board and 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

5. Application Overview & Guidance Notes

- New applications for clinical ethical review cover the study team, funding, COIs, timelines, study overview, risks and benefits, regulatory requirements, e.g. Health Canada No Objection Letter (NOL) for drugs, confidentiality and data retention, and documentation.
- All documentation must be attached to page 9, e.g. Protocol, Informed Consent Forms, advertisement, letters, Investigator Brochures and Product Monographs, NOLs, questionnaires and surveys etc.

5. Application Overview & Guidance Notes (continued)

A) Types of Ethical Review

B) Application Processing

C) Guidance Notes & Templates

5.a) 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.b) WHAT HAPPENS ONCE MY APPLICATION IS SUBMITTED?

Application submitted by Principal Investigator

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Approved by Department Head

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Appears in Research Ethics Board Administrators' inbox :

Minimal risk studies ➔ Reviewed by an REB member

Full Board studies ➔ 2 primary reviewers ➔ reviewed at Board meeting

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Provisos - most common scenario

Deferred – provisos with responses to be reviewed by Full Board

Approved – Certificate of Approval issued (usually Minimal Risk applications)

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Approved – Certificate of Approval issued

5.c) Guidance Notes & Templates

- CREB guidance notes and templates are found at

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

6. The Consent Form

" 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

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