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Research Ethics

Explanations and pro-tips

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Overview

- Alberta - research ethics boards, reciprocity
- Application tips for success
  - administrative basics
  - ethics issues: recruitment, consent, HIA, minors, communities
- Questions

Research ethics in Alberta

- 3 REBs in Alberta authorized to review research using health information (that under HIA)

1. HREBA (3 committees)
2. University of Alberta (2 health panels)
3. University of Calgary (1 health REB)

- Conjoint Health Research Ethics Board (CHREB)
- U of C faculty staff or students from Medicine, Nursing or Kinesiology
- Other UC faculties and MRU for researchers accessing health info
- ~29 members, ~900 new studies annually, ~3400 open, active studies

Research ethics in Alberta

- Research Ethics Reciprocity Agreement (2013)
  -1 ethics review for multijurisdictional studies within AB
  -1 board for all cancer research (HREBA-CC)

- UC , UA, HREBA acknowledge each other's certifications (approvals),
  - "REB Exchange" now live

- Universities have *delegated* review of cancer protocols to HREBA CC

REB EXCHANGE

(Western) Reciprocity Agreement

- Effective November 2023, ethics approvals granted by UA, UBC and USK will be reciprocally acknowledged
- An IRISS application is still required, but the review is administrative only (no ethics review)
- REBX platform to be implemented on near horizon

Research Ethics Boards

- a committee of people with diverse expertise (e.g., law, medicine, research, ethics, data, lay community) who are knowledgeable in research ethics and responsible for ensuring the ethical acceptability of research involving humans in accordance with relevant policy and legislation

- research ethics review as peer review

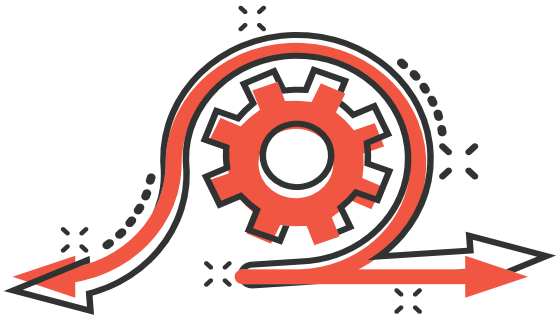
When is REB Review required?

- Required – generally, when humans, information about them/provided by them or their biosamples are used for research purposes (see TCPS Article 2.1)

- Exemptions – TCPS Articles 2.2, 2.3, 2.4
  - ublicly available info and either protected by law or no reasonable expectation of privacy
  - observations of people in public places (no interaction, no expectation of privacy, no identification)
  - secondary use of anonymous info

Research ethics review process

- Iterative
  - application submitted
  - administrative review
  - delegated (min risk) or full board (>min risk) review
  - Chair – final review
  - decision to PI
    - approve, or changes required



- CHREB metrics:
  - average time to approval – 53 days
    - 24 days with REB
    - 29 days with researchers

- 4-6 weeks for a well-completed application to be considered

REB and AHS

- Organizations are partners in health research
- REB approval is distinct from operational approval and data access
- AHS receives notice its resources are sought when you check “AHS” in your application (Impact and Operational Approvals page)
- AHS considers resource requirements (e.g., access to clinical areas, facilities, patients, staff, systems or data)
- AHS grants operational approvals and research agreements (DDAs)

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Common application trouble spots - and how to avoid them

Very basic stuff

- IRISS application
- Complete all required fields – the application is a project summary that communicates to the reviewer/Board/AHS how the study will be implemented
- Questions driven by regulatory standards
- *All questions preceded by a red asterisk (*) are required responses that map you to the application sections that are relevant to your study. All questions within the section to which you are mapped must be addressed.*

- www.ucalgary.ca/research/files/research/160617-checklist_chreb-certification_june-2016_0.pdf

Required supporting documents

- Researcher profile
  - TCPS/CITI certificates
  - CVs

- Application
  - Budget/budget on REB template
  - Protocol
  - External agency support
  - Dept. sign-off
  - University logo on documents
  - REB info on documents (footer)

More basic stuff

- Ensure that the application, protocol, consent, and budget contain consistent information relating to purpose, risk/benefits, number of study visits, number of procedures, sample size, etc.

- Ensure that you update the application in response to comments

IRISS – application

Data Management tips

- **Study Staff** page – all needing data access should be listed, AHS using information in IRISS to prepare the research agreements
- **Data Collection** page – specify all secondary data sources (both databases and charts), upload CRFs/data abstraction form
- **Data Identifiers** page – list identifiers, provide justification for why needed
- **Data storage, retention and disposal** page – Level 4 data must be kept on a secure institutional server (AHS or UC), not on individual computers

Ethics considerations - recruitment

Develop an ethical, practical recruitment plan

Think about

Voluntariness

- coercion?
- inducement?

Privacy

- who knows?
- who should know?

Ethics considerations - recruitment

- Problematic to approach people out of the blue, “cold call”

- Good approaches
  - Least invasive - opt in
  - Study introduced by “circle of care”
  - Consent for researcher to approach sought
  - Recruitment and consent then undertaken by researcher
  - Ideally researcher independent of care team

- Where the researcher is part of care team, strategies to mitigate influence include having alternate clinician obtain consent, allowing sufficient time to consider participation (not same day sign up), remaining blind to patient decision, emphasize voluntariness

Ethics and legal considerations - recruitment

Recruitment and the Health Information Act

- S. 34(1) Disclosure of individually identifying health information to be with consent
  - patient contact information cannot be given to researchers by clinicians without the consent of the patients
  - sometimes records need to be screened to identify eligible patients, researchers must request a waiver of consent for this access and will need permission from data custodian (e.g., AHS) to access

Ethics considerations – consent and minors

TCPS2 (2018)

- Consent is based on research decision-making capacity, not the age of majority
  - describe how this capacity will be assessed, use assent or consent as appropriate (IRISS – Informed Consent Determination page, CHREB guidance doc available)

45 CFR 46/21 CFR 56 (US)

- Consent based on age of majority, parental consent required (one or both parents, depending on risk, benefits)

Ethics considerations - recruitment

Minors and right to privacy

- confidentiality considerations relating to reproductive capacity, use of illicit substances

- initial recruitment conversation should be undertaken ahead of any research-related discussion with parents

- where minors decline, or are otherwise ineligible, discussion with parents does not proceed

Ethics considerations - consent

- Must be informed, voluntary and given by someone competent to make a research participation decision
- Ideally, prospective and given by participant but provision for alterations
  - surrogate consent (TCPS 3.9)
  - deferred consent (TCPS 3.8)
  - (re)gained capacity consent
- Context of consent, sensitivity
  - Respectful of time and space

Ethics considerations - consent

- Required content consistent across regulatory standards, CHREB consent templates assist researchers to ensure all content is included
- Reduce redundancy – take care not to duplicate information (i.e., REB and sponsor requirements)
- Readability
  - should be accessible to lay people, written at a grade 8-10 reading level (not a cut and paste of academic proposal)
  - readability index, proof-read and spell check before submitting (hemingwayapp.com)
  - ESL and translation

Health Information Act - consent

- Under HIA, identifiable health information can only be disclosed for a specific purpose (ie, research question), blanket or broad consent is not permitted

- Section 34 outlines required content
  (to whom, purpose, risks/benefits, can revoke)

- Blanket or broad consent can be sought for the use of de-identified data, build future use possibilities into consent at the outset

- With appropriate justifications, waivers can be granted

HIA Section 50

- Appropriate justifications
  - large study N
  - loss to follow up (transient population, passage of time)
  - high mortality rate
  - very small N (need all cases or research biased)
  - seeking consent might cause harm (distress, upset)
  - screening for eligibility

- Inappropriate justifications
  - data collected as part of normal medical record
  - does not impact patient care
  - patients won't know
  - "my patients"

Ethics considerations and distinct communities

- Core ethics principles cover respect for persons, concern for welfare and fairness
- Some people belong to cultural groups and communities where additional considerations are due, for example First Nations, Inuit and Metis communities (Chapter 9 TCPS)
- Researchers are responsible for ensuring research is respectful of community requirements – this includes engagement, a collaborative approach, research agreements, appropriate data ownership negotiations (e.g., OCAP)
- Indigenous Research Support Team (IRST) irst@ucalgary.ca

Summary

- The REB to which you should apply depends on your affiliation
- Application success depends on meeting both administrative and ethics standards
- Ethics standards are intended to protect participant welfare, foster public trust
- Getting it right can be challenging. Help is always available through the research ethics unit. Template consents, scripts, FAQs and other info is available on the CHREB website.
- Upfront consultation always welcome!

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Thank you for your attention!

Any questions?