Submitting an application to the CHREB

Tips & Tricks

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IRISS Application

1.0 * Select the appropriate Research Ethics Board:
CHREB

- Focus on describing the research activities (not standard of care or pre-research activities).

- Identify what data you will collect and where it will come from (retrospective or collected through the research intervention)

Getting Started – Study Staff

Study Identification

1.0 * Abbreviated Study Title (or acronym): *(100 characters)*
Test Protocol

2.0 * Full Study Title:
test

3.0 * Principal Investigator:

A person will only appear in the drop-down menus under Questions 4.0, 5.0, and 6.0 if they have an active IRISS account and their account is configured for the selected REB. *TIP: if you are having difficulty finding someone – use %last name to filter all users with that last name. If the user does not appear it means they do not have an IRISS account, or their account is not configured for the selected REB. Iriss.support@ucalgary.ca can assist you with the next steps. For UCalgary applicants, only institutional email addresses (ex: @ucalgary.ca, @ahs.ca) should be used for research purposes.*

4.0 Co-Investigators:

Profile	Last	First	Department	E-Mail	Phone	Account Status

There are no items to display

Students, Medical Residents, Post Doctoral Fellow Co-Investigators:

Profile	Last	First	E-Mail	Phone	Status	Account Status

There are no items to display

5.0 Study staff, Study Coordinator(s), Research Assistant(s) or Research Nurse:

Profile	Last	First	E-Mail	Phone	Status	Account Status

- Institutional Email Addresses
- Students need to be listed
- CV for the PI

Study Objectives and Design

This page is meant to briefly describe the study's rationale, objectives, and the methods used to address the research question. Please spell out all acronyms.

1.0 **Anticipated date that research will begin:**

2.0 **Anticipated date that research will end:**

3.0 **Anticipated date that interaction with participants will begin:**

4.0 **Anticipated date that interaction with participants will end:**

5.0 * **Briefly** describe the **(1)** Background & Rationale, **(2)** Research Question & Objectives and **(3)** Methods: *(maximum of 750 words)* .
Be sure the description is understandable for readers without specialized content expertise. Citations and references are not required.

6.0 Describe procedures, treatment, or activities that are above or in addition to standard practices:
Provide as many details as necessary to enable consideration of risks to participants.
Note: Cutting and pasting descriptions from grant proposals, thesis proposals, protocols, etc. is normally not sufficient to properly complete this section.

- Summary
- No references
- Participant perspective
- Research Methods

Risks Assessment

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.

1.0 **Potential Physical Risks and Discomforts**

* Participants might feel physical fatigue
* Participants might feel physical stress, e.g. cardiovascular stress tests.
* Participants might sustain injury, infection, and intervention side-effects or complications.

Potential Psychological, Emotional, Social and other Risks and Discomforts

* Participants might feel psychologically or emotionally stressed, demeaned, embarrassed, worried, anxious, scared or distressed
* Participants might feel psychological or mental fatigue, e.g. intense concentration required.
* Participants might experience cultural or social risk, e.g. loss of privacy or status or damage to reputation.
* Participants might be exposed to economic or legal risk, e.g. non-anonymized workplace surveys.

2.0 * Will the risks be greater than those encountered by the participants in everyday life?

3.0 * Provide details of the risks and discomforts associated with the research, in addition to

- Risks should be outlined and match what is told to participants in the consent form.

- How you collect data can introduce risk depending on the topic
  - e.g., One-on-one Interviews vs. Focus Groups

Benefits Analysis

1.0 * Describe potential, direct benefits of the proposed study to the participants. If there are no benefits, state this explicitly:

2.0 * Describe the scientific, scholarly or societal benefits of the proposed research:

3.0 * Benefits/Risks Analysis: Describe the relationship of benefits to risks of participation in the research:

- Benefits should be stated conservatively
- Participant incentives and reimbursements are not a direct benefit of research

Recruit Potential Participants

1.0 How will potential participants be identified and/or recruited? Describe how participants will be invited to take part in the study, if applicable:

2.0 How will people obtain details about the research in order to make a decision about participating? (*select all that apply*)

- [x] Potential participants will contact researchers
- [x] Researchers will contact potential participants
- [x] Contact will be made through a third party or intermediary (including snowball sampling)

3.0 Provide the locations where the participants will be recruited:

4.0 Will potential participants be recruited through pre-existing relationships with researchers?

◯ Yes ◯ No

5.0 Will the study involve any of the following? *(select all that apply)*

- Describe all recruitment methods including how the uploaded documents/materials will be used.
- Describe who will make the first approach to potential participants for research.
  - circle of care approach
  - Undue influence
- External organization support

Indigenous Peoples

1.0 If you will be obtaining approval from Elders, formal leaders, knowledge keepers, or other community representatives, provide details:

2.0 If leaders of the community will be involved in the identification of potential participants, provide details:

3.0 Provide details if:
- property or private information belonging to the community as a whole is studied or used;
- the research is designed to analyze or describe characteristics of the community; or
- individuals are selected to speak on behalf of, or otherwise represent the community

4.0 * Provide information on how informed and prior consent, Ownership, Control, Access and Possession (OCAP) of data and/or related community expectations will be addressed:
test

5.0 Provide information on how final results of the study will be shared with the participating community?

6.0 Describe how you have engaged the community:

7.0 Is there a formal research agreement with the community?
(●) Yes ( ) No

7.1 Provide details about the agreement or why an agreement is not in place, not required, etc.:

- Chapter 9 of the TCPS2 further outlines considerations for conducing indigenous research or research concerning indigenous communities.

Waivers of Consent

Informed Consent Determination

1.0 * What type of consent will you be seeking? *(select all that apply)*

- [ ] Consent from an adult with decision making capacity
- [ ] Consent from a minor with decision making capacity
- [ ] Third party consent (e.g., surrogate consent, surrogate consent with regained capacity consent, parental consent)
- [x] Waiver of consent
- [ ] Deferred consent
- [x] Not applicable (e.g. secondary data analysis of anonymized data)

Waiver of consent (HIA)

- Chart reviews (paper and EMRs)
- AHS health databases

TCPS2 waiver of consent

- Research data use

Informed Consent Determination

1.0 * What type of consent will you be seeking? *(select all that apply)*
Consent from an adult with decision making capacity
Consent from a minor with decision making capacity
Third party consent (e.g., surrogate consent, surrogate consent with regained capacity consent, parental consent)
Deferred consent

Describe how you will assess decision-making capacity in your participants who are minors:
***

2.0 How is consent to be indicated and documented? (*select all that apply*):
Signed consent form

3.0 Authorized Representative, Third Party Consent, Assent

3.1 Explain why the participant is unable to give informed consent (e.g. young age, mental or physical condition, etc.):

3.2 Will the participant who does not have capacity to give full informed consent be asked to give assent?
○ Yes ● **No**

3.3 In cases where participants (re)gains capacity to give informed consent during the study, how will they be asked to provide consent on their own behalf?

4.0 What assistance will be provided to participants, or those consenting on their behalf, who may require additional accommodation?
test

5.0 * When a participant wishes to end participation in the research or certain aspects of the research, describe what will occur:
test

6.0 Describe the circumstances and limitations of data withdrawal from the study, and provide a deadline after which participants cannot withdraw their data. If data cannot be withdrawn provide a justification:
test

7.0 Will this study involve any group(s) where non-participants are present?
● **Yes** ○ No

The right consent form for the right participant

- Participant Consent? Surrogate Consent? Regained Capacity?

Deferred Consent

- Justified under TCPS2 3.7A or 3.8

Mature Minors

- How will capacity be assessed?
- Not allowed in studies that have US FDA oversight.

Data withdrawal options - allowed or not allowed?

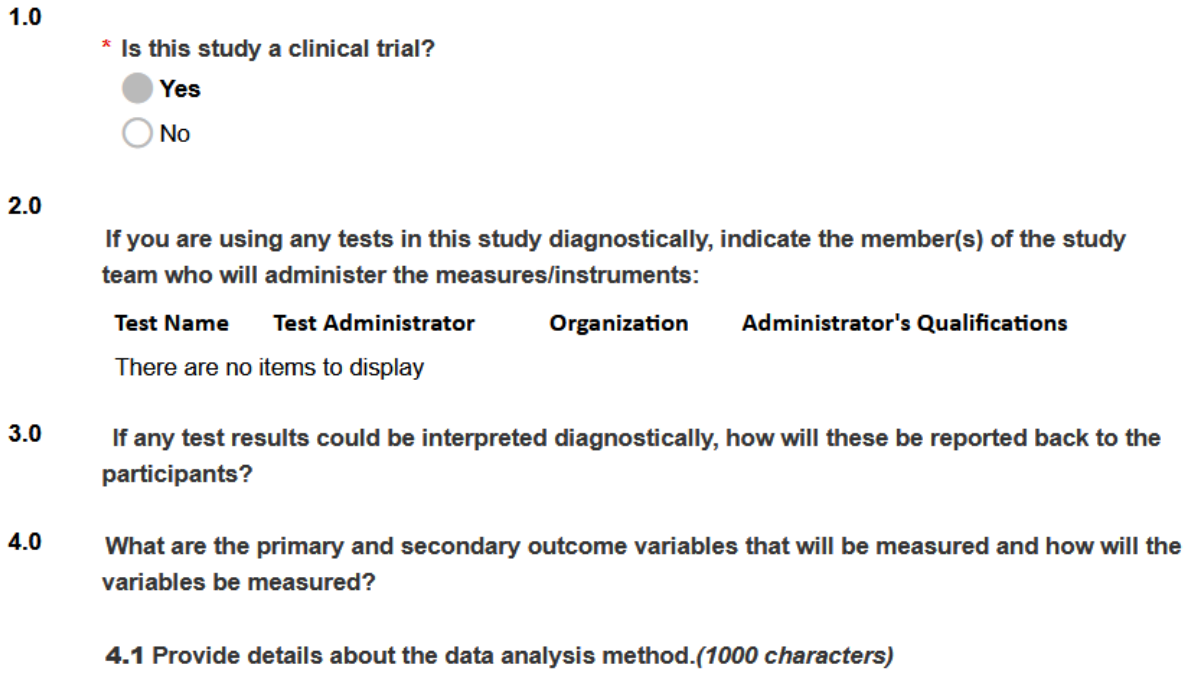
- Justification for retaining data
- Timeline for allowing data withdrawal

Research Methods and Procedures

- [x] Use of deception or partial disclosure (not including double-blind procedures)
- [x] Interviews (in-person, telephone, email, videoconferencing, chat rooms, etc.)
- [x] Focus groups (including electronic/online focus groups)
- [x] Surveys and questionnaires (including internet surveys and questionnaires)
- [x] Behavioral tasks
- [x] Community-based research
- [x] Participatory action research (participants are collaborators or co-researchers)
- [x] Observational research (including internet-based observations)
- [x] Sound or image (other than audio- or video-recordings of interviews; e.g., video recording of a dance performance; audio recording of pronunciations)
- [x] Materials created by participants (e.g., artwork, writing samples, journals, software, etc.)
- [x] Use of Psychology Research Participation System (RPS - requires separate registration with RPS)

- [x] Food, nutrition, and nutraceuticals
- [x] Drugs and natural health products
- [x] Biologics and/or vaccines
- [x] Medical devices
- [x] Health and biological specimen collection (including use of previously collected specimens)
- [ ] Chart reviews
- [x] Registries and databases (including biobanks)
- [x] Radiation/diagnostic Imaging; any test or procedure that may involve exposure to radiation (including screening chest x-ray, MRI)
- [x] Non-medical electro-mechanical devices
- [x] Stem cell research (attach SCOC Approval in Documentation section "Other")
- [x] None of the above

Research Methods and Procedures



1.0

* Is this study a clinical trial?

- (●) Yes
- ( ) No

2.0

If you are using any tests in this study diagnostically, indicate the member(s) of the study team who will administer the measures/instruments:

Test Name	Test Administrator	Organization	Administrator's Qualifications
There are no items to display			

3.0 If any test results could be interpreted diagnostically, how will these be reported back to the participants?

4.0 What are the primary and secondary outcome variables that will be measured and how will the variables be measured?

4.1 Provide details about the data analysis method.*(1000 characters)*

Clinical Trial (Yes, or No?)

If **Yes**:

- *Clinical Trial* and *Data Safety and Monitoring for Clinical Trials* pages

- Register the study in a publicly accessible registry before recruitment of the first trial participant.

- Health Canada documents

(if applicable)

Data Identifiers

1.0

* **Personal Identifiers:** will you be collecting – at any time of the study, including recruitment of participants – any of the following *(check all that apply)*:

- [ ] Surname and first name
- [ ] Initials
- [ ] Address
- [ ] Full Postal Code
- [ ] First 3 digits of postal code
- [ ] Telephone Number
- [ ] Fax Number
- [ ] Email Address
- [ ] Full Face Photograph or other recording
- [ ] Student ID Number
- [ ] Employee ID Number
- [ ] Full Date of Birth
- [ ] Year of Birth
- [ ] Age at time of data collection
- [ ] Vehicle Identifiers
- [ ] Professional Certificate/License Number
- [x] Other

- List the identifiers that study team members will collect at any point in the study.
- For large databases, list the identifiers that the data custodian will collect and/or use.

Data Identifiers

3.0 If identifying information will be removed at some point, when and how will this be done?

4.0 * Specify what **identifiable** information will be **RETAINED** once data collection is complete, and explain why retention is necessary. Include the retention of master lists that link participant identifiers with de-identified data:
test

5.0 If applicable, describe your plans to link the data in this study with data associated with other studies (e.g. within a data repository) or with data belonging to another organization:

- Describe if a master list will be maintained by the study team.
- Data you collect can be Anonymous or Anonymized
  - E.g., a survey can be anonymous whereas an interview can be anonymized

Required Documents

1.0 Recruitment Materials:

- Even if the document comes directly from a sponsor or another lead site, if the document will be used locally, please add the UofC logo & “This study has been approved by the University of Calgary Conjoint Health Research Ethics Board (REBXX-XXXX).”
- These details can be added on as a sticker.

5.0 Questionnaires, Cover Letters, Surveys, Tests, Interview Scripts, etc.

6.0 Other Non-Consent Participant Materials:

Required Documents

7.0 Protocol, Proposal

- or **Grant submission**
- Must include background and references.

12.0 Other Documents

- Department Approval form
- If multi-site, the approval documents from other REBs

13.0 Budget

- CHREB or Sponsor template

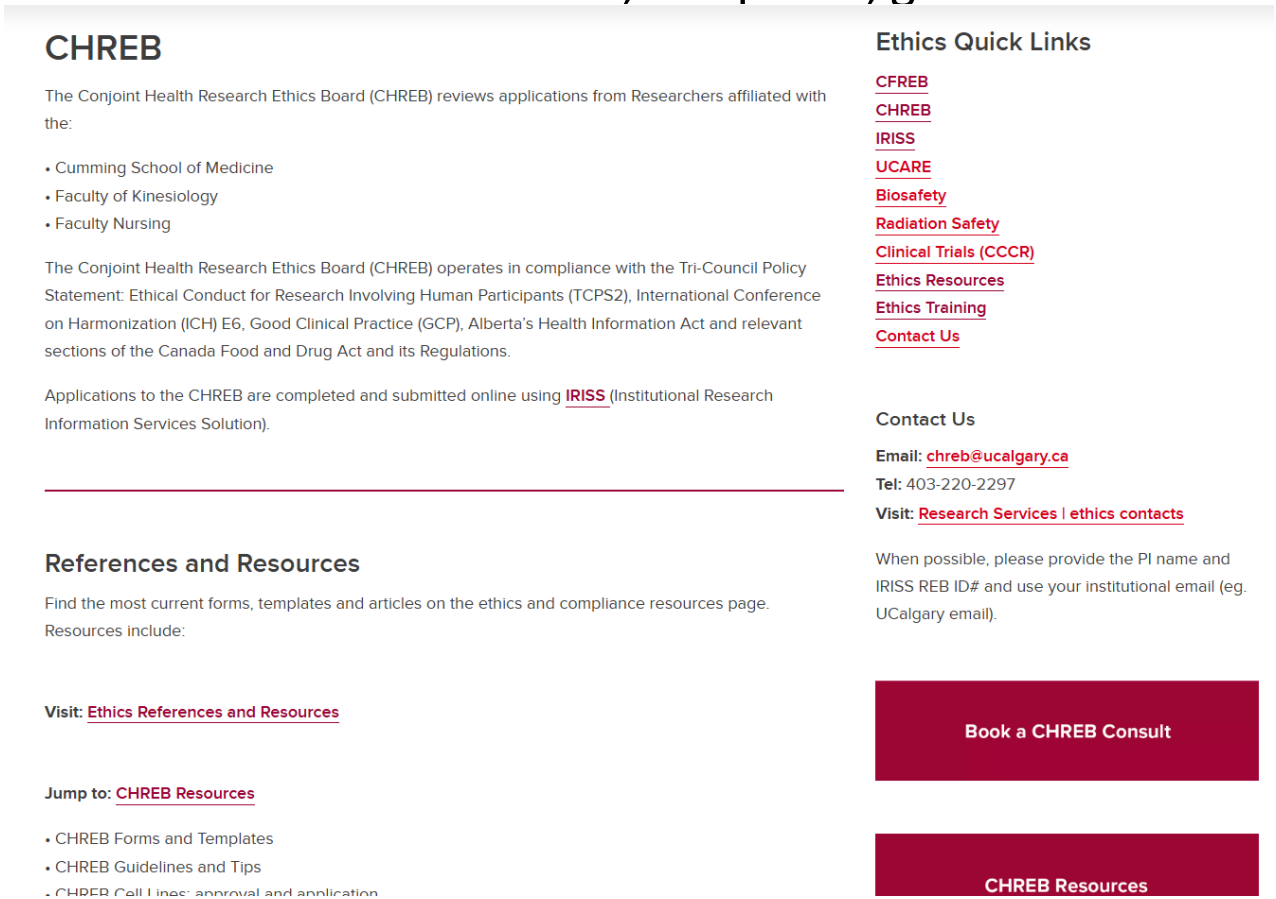
Required Documents

3.0 Informed Consent / Information Document(s)

- Reading Level
- Use the CHREB template(s).
- Data withdrawal allowances and deadlines
- Incidental findings
- Future use of data for other research purposes.
- If a clinical trial with an investigational health product, need to discuss post-trial access
- Third party consent (parental or surrogate/SDM) needs to be separate from main consent.

How We Can Help

The CHREB website is a resource for forms, templates, guidance documents and FAQs.



CHREB

The Conjoint Health Research Ethics Board (CHREB) reviews applications from Researchers affiliated with the:

- Cumming School of Medicine
- Faculty of Kinesiology
- Faculty Nursing

The Conjoint Health Research Ethics Board (CHREB) operates in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Participants (TCPS2), International Conference on Harmonization (ICH) E6, Good Clinical Practice (GCP), Alberta's Health Information Act and relevant sections of the Canada Food and Drug Act and its Regulations.

Applications to the CHREB are completed and submitted online using IRISS (Institutional Research Information Services Solution).

References and Resources

Find the most current forms, templates and articles on the ethics and compliance resources page. Resources include:

Visit: Ethics References and Resources

Jump to: CHREB Resources

- CHREB Forms and Templates
- CHREB Guidelines and Tips
- CHREB Cell Lines: approval and application

Ethics Quick Links

CFREB
CHREB
IRISS
UCARE
Biosafety
Radiation Safety
Clinical Trials (CCCR)
Ethics Resources
Ethics Training
Contact Us

Contact Us

Email: chreb@ucalgary.ca
Tel: 403-220-2297
Visit: Research Services | ethics contacts

When possible, please provide the PI name and IRISS REB ID# and use your institutional email (eg. UCalgary email).

Book a CHREB Consult

CHREB Resources

https://research.ucalgary.ca/research-services/ethics-compliance/chreb

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