Conjoint Health Research Ethics Board (CHREB)
Research Services, University of Calgary
2500 University Drive N.W. Calgary, AB T2N 1N4
Ph: (403) 220-2297 | Email: chreb@ucalgary.ca

Checklists for submission of ethics applications to the CHREB

Before you submit, please review the relevant checklist(s) below:

(1) ALL STUDIES:

☐ **Completed ethics application in IRISS**: Well-completed applications facilitate both administrative and ethical review. Please ensure all sections of your application have been filled out and all questions within the sections addressed. Please also ensure all required documents have been uploaded. Incomplete applications cannot be sent for ethics review, leading to delays.

> **NOTE:** Review the user guides on the **IRISS webpage** to learn how to get started.

☐ **Identification of study team**: All research team members must be registered in IRISS before they can be selected on the "Study Identification" page of the application.

- Principal Investigators are responsible for the conduct of the proposed research, including supervision of their students (undergraduate and graduate), medical residents, and post-doctoral fellows.
- **Principal Investigator Curriculum Vitae (CV)**: A current (i.e., within last 3 years) version of the PI's CV must be uploaded to the PI's "Researcher profile." Please review the user guide on Researcher profiles for direction.
- **Human ethics training** is mandatory for all Principal Investigators. One of the following training certificates must be completed and uploaded into the PI's Researcher Profile:
  - TCPS2 CORE Tutorial (**https://tcps2core.ca/welcome**); or
  - CITI Human Subjects Research Course (Biomedical or Social Behavioural-Educational module, whichever is most relevant to the PI's discipline: **https://about.citiprogram.org/en/series/human-subjects-research-hsr/**)
- The PI is responsible for ensuring that the other study team members have adequate training.
- All student investigators, medical residents, and post-doctoral fellows should be listed under *Study Team* on the "Study Identification" page of the application.

☐ **Operational and Departmental approval(s)**: Please obtain all relevant authorizations from those areas (e.g., University Departments, community agencies, school boards) whose operations will be affected by the proposed research. Upload the signed form to the "Documentation" page in the application.

> **NOTE:** if asking external organizations to assist with recruitment, please upload indications of support for this research. This can be a signed letter, or copies of email correspondence. Depending on the level of involvement, the CHREB may require support documents to be in place before approval is granted.

☐ **Research protocol**: Describes the background, rationale, objective(s), methods, and analyses. Protocol length, scope and breadth may vary depending on the nature of the research, however all should convey the importance of the research question and detail methods to sufficiently address the research question. Include in-text references and a literature cited section. Ensure the protocol is uploaded as a separate document under the "Documentation" page in the application.

NOTE: The Northern Alberta Clinical Trials and Research Centre (NACTRC) **website** provides good templates for developing research protocols.

☐ **Recruitment materials, if applicable:** Provide a complete description of how participants will be approached for study participation within the application (who, when, where, how). All documentation used to attract participants must be uploaded to the "Documentation" page in the application. This includes study advertising and recruitment posters, letter(s) of initial contact, webpage scripts and newsletters.

NOTE: Ensure the Ethics ID number (i.e., REBXX-XXXX) is included in the footer of each document. Also ensure all recruitment materials include the following standard statement: *The University of Calgary Conjoint Health Research Ethics Board has approved this research study.* Please add the University of Calgary logo (**found here**) to all recruitment material, as well.

☐ **Informed consent forms (ICF) and assent forms, if applicable**: These must be on institutional letterhead or contain the organization's logo (e.g., University of Calgary; and Alberta Health Services, if applicable). Please use the relevant template to develop the consents/assents for your study. **Consent templates** are available on the CHREB website under 'Forms and Templates'. Upload the completed form(s) to the Consent/Assent sections of the "Documentation" page in the application.

NOTE: Standard consent forms should be written at a grade 8-10 reading level. Use the **hemingwayapp.com** editor for assistance in determining the reading level.

NOTE: The Board may approve a **waiver of consent** for access to personal health information for research. In such cases, the investigator must formally request a waiver of consent (on the "Informed Consent Determination" page) and must demonstrate to the satisfaction of the Board that (a) the research is of sufficient importance to justify a waiver of consent, (b) adequate safeguards are in place to protect the privacy of personal information collected in the research, and (c) obtaining consent for access to the personal health information is unreasonable, impractical, or not feasible. (**Health Information Act, Section 50**)

☐ **Data collection instruments, if applicable**: Upload all questionnaires, surveys, interview guides, case report forms, etc., to the "Documentation" page in the application.

☐ **Budget summary:**

NOTE: A detailed budget includes cost breakdown (example – costs per visit per participant, specific line-items, etc.). If your study does not include a cost per participant breakdown, please complete the CHREB budget summary template (see *Funded Studies Without Detailed Grant or Sponsor Budget*).

Studies With Detailed Grant or Sponsor Budget: Upload a copy of the budget summary used for the grant application or agreement with the industry sponsor.

Funded Studies Without Detailed Grant or Sponsor Budget: Complete and upload the **budget summary template** available on the CHREB website under 'Forms and Templates' to the "Documentation" page in the application.

Unfunded Studies: If your study is unfunded, please complete the **budget summary template** with an estimate of "in kind" hours (how many hours study members will contribute to the study) and an estimate of total costs predicted to be incurred during this study (and how these costs will be covered).

> **NOTE:** Ensure funding source is recorded on the "Funding Information" page of the application. Ethics applications will not be reviewed unless funding is confirmed or a confirmation regarding alternate sources of funding is provided. If you have a pending grant application, please confirm in the budget summary template that the research will be undertaken if the grant application is unsuccessful. If this confirmation cannot be provided, your study will not be reviewed.

☐ **Approval letters and/or certificates from other major Research Ethics Boards, if applicable**: It is the responsibility of the PI to ensure all approvals from other jurisdictions are obtained prior to the initiation of the research; ethics certificates from other centres may be requested at the discretion of the CHREB. See Section 3, below, for specific guidance under the Health Research Harmonization Initiative in Alberta.

☐ **Health Canada No Objection Letter (NOL) and/or Investigational Testing Authorization (ITA), if applicable**: Upload to Section 9.0 on the "Documentation" page of the application.

(2) Research Sponsored by Industry or For-Profit Organizations

Read **guidance on which studies meet the administration fee criteria**.

☐ **Identified funding as from Sponsor**: Ensure "Contract (e.g. Industry sponsored/ for-profit organization)" is selected on the "Funding information" page in the application (Question 3).

☐ **Payment details entered into IRISS:** The REB Service(s) Fee page will trigger when "Contract" is chosen as the type of funding. The fee is payable regardless of the outcome of the review or contract status (this includes withdrawing the application after review by the REB has commenced).

(3) Studies approved under the Health Research Ethics Harmonization Initiative in Alberta:

If the study has been approved by the University of Alberta Health Research Ethics Board (HREB), submit the study using the REB Exchange (REBX) platform (https://www.rebexchange.ca/). The REBX streamlines the ethics application process for multi-site health research in Alberta. The application will undergo an administrative review, as per the Health Research Ethics Harmonization Initiative in Alberta.

To be considered under Harmonization please ensure the following are submitted:

☐ **Operational and Departmental approval(s):** Please obtain all relevant authorizations from those areas (e.g., University Departments, community agencies, school boards) whose operations will be affected by the proposed research. Upload the signed form to the "Local Documentation" page in the REBX application. If asking external organizations to assist with recruitment, please upload indications of support for this research. This can be a signed letter, or copies of email correspondence.

☐ **Local informed consent (ICF) and assent forms, if applicable**: Ensure the form(s) are on the **local** investigator's

institutional letterhead or contain the organization's logo (e.g., University of Calgary; and Alberta Health Services, if applicable). Please use the relevant template to develop the consents/assents for your study. **Consent templates** are available on the CHREB website under 'Forms and Templates'. Upload the completed form(s) to the Consent/Assent sections of the "Documentation" page in the application.

FINAL TIPS

Update the application: When changes are requested, please ensure appropriate changes are made within the relevant section(s) of the application. This ensures your application reflects accurate and up-to-date information.

Be accurate: Study title and document names will appear on the ethics approval certificate, as you have entered them in your application. Please ensure spelling, version numbers and dates are correct.

Be consistent: Check for consistencies across the application and between the application and all supporting documents. This includes sample sizes, recruitment periods, and version numbers on informed consent forms. Inconsistencies impede understanding and may result in delays in your ethics review.

FOR MORE INFORMATION

CHREB: *For ethics review questions, concerns, requirements and timelines*

- Refer to the CHREB website, here: **https://research.ucalgary.ca/conduct-research/ethics-compliance/human-research-ethics/conjoint-health-research-ethics-board**
- Read our "Frequently Asked Questions"
- Review our "Resources & Guidelines"
- Refer to the ethics application helper text. The application form provides guidance and relevant links throughout, on the right-hand side.

  Contact us
  - Email: **chreb@ucalgary.ca**
  - Phone: (403) 220-2297

IRISS: *For assistance navigating the IRISS application or technical issues*

- Review IRISS Research Ethics Board (REB) User guides: **https://research.ucalgary.ca/conduct-research/additional-resources/iriss**

  Contact us:
  - Email: **iriss.support@ucalgary.ca**
  - Phone: (403) 210-9300