HREBA | Health Research Ethics Board of Alberta Clinical Trials Committee

HREBA – Clinical Trials Committee
1500, 10104 - 103 Avenue NW
Edmonton, Alberta, T5J 0H8

Checklists for Submission of a Research Study

ATTENTION:

** Please be advised all required documents must be included on your IRISS protocol submission before review of a study proposal commences.

** If you send an incomplete submission to Clinical Trials Committee (CTC), the administrative staff will inform you of the missing information/documents through IRISS. If you submit all missing information/documents by the next day, the file can go for review for that month's meeting. If the requested information is not submitted by the next day, but before the following month's submission deadline, the protocol will then go to next month's CTC meeting for review.

** The full protocol title and document names as entered in IRISS are what will appear on the approval certificate.

** Information on HIA section 50 (how subject information is kept safe), declaration of conflict of interest, and justification of placebo are now found in the IRISS application form questions and do not require a separate document.

** Please note the new fee process. Alberta Innovates will now invoice your for each study submitted. Once you receive the invoice, review fee payments must be made out to Alberta Innovates.

Full Protocol Review

Submissions for full protocol review are due before 4:00pm on the deadline day and must include the following:

- ☐ Fill out all the IRISS application questions. The more information you provide in the application questions, the less questions the reviewer will have.
- ☐ Recruitment materials: this includes advertising, webpage scripts, retention items, newsletters, etc.
- ☐ Letter of Initial Contact, if applicable
- ☐ Participant Information and Consent Forms; must be on the investigator's letterhead. This includes Standard, Genetic, HIA s34 Consent to Disclose Health Information Form, etc. Please upload the initial consent forms with continuous line numbers for easy reference by going to Page Layout/line numbers/continuous.
- ☐ Assent forms, if applicable
- ☐ Questionnaires, cover letters, surveys, tests, interview scripts, etc. Anything that is given to the participant should be uploaded into this section on the documentation page of your IRISS application.
- ☐ Protocol
- ☐ Investigator brochures/product monographs for *all* drugs involved in study
- ☐ Health Canada No Objection Letter
- ☐ Other Documents
    - Clinical Trial Agreement (signed by all parties)
    - Per-item per-visit budget
    - Service provider agreements

HREBA | Health Research Ethics Board of Alberta
Clinical Trials Committee

HREBA – Clinical Trials Committee
1500, 10104 - 103 Avenue NW
Edmonton, Alberta, T5J 0H8

Delegated Review

Minimal Risk Protocol Review

You can submit minimal risk protocols for delegated review at any time; there is no submission deadline. These submissions must include the following:

- ☐ Fill out all the IRISS Application questions. The more information you provide in the application questions, the less questions the reviewer will have.
- ☐ Recruitment Materials: this includes advertising, webpage scripts, retention items, newsletters, etc.
- ☐ Letter of Initial Contact if applicable
- ☐ Participant Information and Consent Forms; must be on the investigators letterhead. This includes Standard, Genetic, HIA s34 Consent to Disclose Health Information Form, etc. Please upload the initial consent forms with continuous line numbers for easy reference by going to Page Layout/Line Numbers/ Continuous.
- ☐ Assent forms, if applicable
- ☐ Questionnaires, cover letters, surveys, tests, interview scripts, etc. Anything that is given to the participant should be uploaded into this section on the documentation page of your IRISS application.
- ☐ Protocol
- ☐ Investigator brochures/product monographs for *all* drugs involved in study
- ☐ Health Canada No Objection Letter
- ☐ Other Documents
    - Clinical Trial Agreement (signed by all parties)
    - Per-item per-visit budget
    - Service Provider Agreements

Multicentre Studies (Additional Investigators) - Adding a Qualified Investigator at another Site

If the protocol is previously approved by the CTC for another research site in Alberta, you can submit your study as an Additional Investigator Review. These previously approved protocols can be submitted for delegated review at any time; there is no submission deadline. These submissions must include the following:

- ☐ Only fill out the following IRISS Application sections. The more information you provide in the application questions, the less questions the reviewer will have.
    a. Study Staff, Funding, Location
    b. Participant Information, Recruitment, and Informed Consent
    c. Data Privacy and Confidentiality
    d. Documentation – upload all documents requiring CTC approval

  For all other sections, because the information has already been reviewed and approved by the CTC for the lead site, please type "Reviewed and Approved for (insert approved CTC file number here)"
- ☐ Recruitment materials: this includes advertising, webpage scripts, retention items, newsletters, etc.
- ☐ Letter of Initial Contact, if applicable
- ☐ Approved Participant Information and Consent Forms; please contact the sponsor for the approved version, must be on the investigators letterhead. This includes Standard, Genetic, HIA s34 Consent to Disclose Health Information Form, etc. Please upload the initial consent forms with continuous line numbers for easy reference by going to Page Layout/Line Numbers/ Continuous.

HREBA – Clinical Trials Committee
1500, 10104 - 103 Avenue NW
Edmonton, Alberta, T5J 0H8

- ☐ Assent forms, if applicable
- ☐ Questionnaires, cover letters, surveys, tests, interview scripts, etc. Anything that is given to the participant should be uploaded into this section on the documentation page of your IRISS application.
- ☐ Protocol
- ☐ Investigator brochures/product monographs for all drugs involved in study
- ☐ Health Canada No Objection Letter
- ☐ Other Documents
    - Clinical Trial Agreement (signed by all parties)
    - Per-item per-visit budget
    - Service provider agreements

Reciprocal Review

If the protocol is approved by the University of Alberta or University of Calgary research ethics board, you can submit your study as a Reciprocal Review. These previously approved protocols can be submitted for delegated review at any time; there is no submission deadline. These submissions must include the following:

- ☐ Fill out all the IRISS Application questions. The more information you provide in the application questions, the less questions the reviewer will have.
- ☐ Recruitment materials: this includes advertising, webpage scripts, retention items, newsletters, etc.
- ☐ Letter of Initial Contact, if applicable
- ☐ Participant Information and Consent Forms; must be on the investigator's letterhead. This includes Standard, Genetic, HIA s34 Consent to Disclose Health Information Form, etc. Please upload the initial consent forms with continuous line numbers for easy reference by going to Page Layout/Line Numbers/ Continuous.
- ☐ Assent forms, if applicable
- ☐ Questionnaires, cover letters, surveys, tests, interview scripts, etc. Anything that is given to the participant should be uploaded into this section on the documentation page of your IRISS application.
- ☐ Protocol
- ☐ Investigator brochures/product monographs for *all* drugs involved in study
- ☐ Health Canada *No Objection Letter*
- ☐ Other Documents
    - Clinical Trial Agreement (signed by all parties)
    - Per-item per-visit budget
    - Service provider agreements
    - Copy of the approval letter from the Research Ethics Board
    - Copy of the approved Consent Form from the other Research Ethics Board

HREBA – Clinical Trials Committee
1500, 10104 - 103 Avenue NW
Edmonton, Alberta, T5J 0H8

Adding a Co-Investigator to an Approved Study

Create a Modification in your IRISS protocol file, add the co-investigator to the application form and attach the following revised items in the Documentation Page of your IRISS file:

- ☐ Participant information and consent form – please add line for co-investigator information
- ☐ Please confirm the Conflict of Interest page in the IRISS application reflects the co-investigator's situation as well.
- ☐ Patient Consent Form for the Disclosure of Health/Registration Information, if required
- ☐ Advertising, if required

Change of Address for Research Site

For REC paper files: provide written notification of the following

- ☐ New address and contact numbers
- ☐ How subjects participating in your current studies are being notified
- ☐ Updated study documents (i.e. participant information and consent form, consent to disclose, advertising, clinical trial agreement, service provider agreements etc.)
- ☐ Update to the Health Information Act section 50 requirements for your new site – what steps are taken to ensure subject confidentiality will be protected during the move and how subject information at the new research site is protected

For IRISS files: Create a Modification in your IRISS protocol file, update the research site address/contact numbers and include the following items:

- ☐ Notification of how subjects participating in your current studies are being notified (include in the modification summary)
- ☐ Updated study documents (i.e. participant information and consent form, consent to disclose, advertising, clinical trial agreement, service provider agreements etc.)
- ☐ Update to the Health Information Act section 50 requirements for your new site – what steps are taken to ensure subject confidentiality will be protected during the move and how subject information at the new research site is protected. Please update the Data Privacy and Confidentiality section in the IRISS application describing the administrative, technological and physical safeguards to keep the subject's information safe at your new site.