HREBA | Health Research Ethics Board of Alberta Clinical Trials Committee

HREBA – Clinical Trials Committee
1500, 10104 - 103 Avenue NW
Edmonton, Alberta, T5J 4A7

Check lists 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 following month's submission deadline, the protocol will then go to CTC for review.

** The 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.

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
- ☐ Informed Consent Forms; must be on the investigators letterhead. Includes Standard, Genetic, HIA s34 Consent to Disclose Health Information Form, etc.
- ☐ Assent forms, if applicable
- ☐ Questionnaires, cover letters, surveys, tests, interview scripts, etc.
- ☐ 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
    - Curriculum Vitae for the Investigator/Co-Investigator(s). This document must be current and include all past and present research experience. If research experience is not included, please provide any ICH Good Clinical Practice Guidelines and/or the Tri-Council Policy Statement training certificates.
- ☐ Review Fee made out to *Alberta Innovates - Health Solutions. Pleas*e attach a photocopy of the cheque in the REB Service Fees section of the *Documentation Page* of your IRISS submission. Please mail the cheque to 1500, 10104 - 103 Ave. NW, Edmonton, AB., T5J 4A7, attention Clinical Trials Committee.

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Delegated Review

Expedited Review

You can submit Expedited protocols for delegated review at any time. 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
- ☐ Informed Consent Forms; must be on the investigators letterhead. Includes Standard, Genetic, HIA s34 Consent to Disclose Health Information Form, etc.
- ☐ Assent forms, if applicable
- ☐ Questionnaires, cover letters, surveys, tests, interview scripts, etc.
- ☐ 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
    - Curriculum Vitae for the Investigator/ Co-Investigator(s). These must be current and include all past and present research experience. If research experience is not included, please provide any ICH Good Clinical Practice Guidelines and/or the Tri-Council Policy Statement training certificates
- ☐ Review Fee made out to *Alberta Innovates - Health Solutions*. Please attach a photocopy of the cheque in the REB Service Fees section of the *Documentation Page* of your IRISS submission. Please mail the cheque to 1500 – 10104 103 Ave, Edmonton AB., T5J 4A7, attention Clinical Trials Committee.

Reciprocal Review

You can submit Reciprocal protocols for delegated review at any time. 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
- ☐ Informed consent forms; must be on the investigator's letterhead. Includes Standard, Genetic, HIA s34 Consent to Disclose Health Information Form, etc.
- ☐ Assent forms, if applicable
- ☐ Questionnaires, cover letters, surveys, tests, interview scripts, etc.
- ☐ Protocol
- ☐ Investigator brochures/product monographs for all drugs involved in study

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- ☐ 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 Informed Consent Form from the Research Ethics Board
    - Curriculum Vitae for the Investigator/Co-Investigator. This must be current and include all past and present research experience. If research experience is not included, please provide any ICH Good Clinical Practice Guidelines and/or the Tri-Council Policy Statement training certificates
- ☐ Review Fee (made out to 'Alberta Innovates - Health Solutions') – please attach a photocopy of the cheque in the REB Service Fees section of the Documentation Page of your IRISS submission. Please mail the cheque to 1500 – 10104 103 Ave, Edmonton AB., T5J 4A7, attention Clinical Trials Committee.

Multicentre Studies (Additional Investigators)

Adding a Qualified Investigator at another Site

You can prepare these submissions at any time. They 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
- ☐ Approved informed consent forms; please contact the sponsor for the approved version, must be on the investigators letterhead. Includes Standard, Genetic, HIA s34 Consent to Disclose Health Information Form, etc.
- ☐ Assent forms, if applicable
- ☐ Questionnaires, cover letters, surveys, tests, interview scripts, etc.
- ☐ 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 Informed Consent Form from the Research Ethics Board
    - Curriculum Vitae for the Investigator/Co-Investigator. This document must be current and include all past and present research experience. If research experience is not included, please provide any ICH Good Clinical Practice Guidelines and/or the Tri-Council Policy Statement training certificates

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- ☐ Review Fee (made out to 'Alberta Innovates - Health Solutions') – please attach a photocopy of the cheque in the REB Service Fees section of the Documentation Page of your IRISS submission. Please mail the cheque to 1500 – 10104 103 Ave, Edmonton AB T5J 4A7, attention Clinical Trials Committee.

Assessment Review

These submissions must include a paper copy of the following:

- ☐ Entire research protocol or a well detailed summary (i.e. please include information such as inclusion/exclusion criteria, is the study investigator driven, sponsor funded, chart review, # of subjects etc.)
- ☐ Health Information Act Requirements section 50 (1) (b) (iii) indicating adequate confidentiality safeguards are in place including administrative, technical and physical.
- ☐ Is Consent to Disclose Health/Registration required from subjects?
- ☐ Informed Consent Form
- ☐ Review Fee (made out to 'Alberta Innovates - Health Solutions')

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 items in the Documentation Page of your IRISS file:

- ☐ Informed consent form – please add line for co-investigator information
- ☐ Current (for the present calendar year) Curriculum Vitae for the Co-Investigator, which includes all past and present research experience
- ☐ Signed Declaration of Conflict of Interest form (indicating that there is no conflict of interest) for the Co-Investigator
- ☐ Patient Consent Form for the Disclosure of Health/Registration Information, if required
- ☐ Advertising, if required

Change of Address for Research Site

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

- ☐ Notification of how subjects participating in your current studies are being notified
- ☐ Acknowledgment that your site information is updated on study documents (i.e. informed 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 is subject information at the new research site is protected