HREBA | Health Research Ethics Board of Alberta

Checklist for the **Initial Submission** of a Research Study

Please be advised all required documents must be included on your IRISS study submission before the study is sent for review. If the submission is found to be incomplete, administrative staff will inform you of the missing information/documents using the IRISS system.

Note: The protocol number, protocol title and document names as entered in IRISS are what will appear on the approval certificate.

Studies for Full Board Review: submissions must be received by the deadline set by the Committee in order to be reviewed at the next full board meeting.

Studies for Expedited Review: studies which are considered to be 'minimal risk' may be eligible for expedited review. You can submit minimal risk protocols for review at any time.

Studies for Reciprocal Review: studies that have been approved by another HIA-designated research ethics board in Alberta may be eligible for reciprocal review. These studies can be submitted for expedited review at any time.

All submissions must contain the following information, when applicable;

- ☐ **Fill out all sections of the IRISS application**. The more information you provide in the application, the less questions the reviewer will have post-review. To prevent unnecessary delays, ensure that the information provided in the application form is consistent with the information in the protocol.
- ☐ Study protocol/proposal developed by the Sponsor or the Investigator
- ☐ Investigator brochures/product monographs for *all* drugs involved in study
- ☐ All Informed Consent Forms and/or Assent Forms, if applicable. Note that a Pregnant Participant or Pregnant Partner Consent Form is not required to be submitted until a pregnancy occurs. All forms must be on investigators letterhead and follow the guidelines provided by the Committee to which you are applying.
- ☐ All recruitment materials i.e. initial contact, advertising, webpage scripts, retention items, newsletters, etc.
- ☐ Questionnaires, cover letters, surveys, tests, interview scripts, etc.
- ☐ Per-item, per-visit budget
- ☐ Health Canada No Objection Letter (NOL)*:* studies requiring an NOL can be reviewed without the document, but the NOL must be received before final approval is issued.

Other Documents

- ☐ Review fee payment 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. NW, Edmonton, AB., T5J 4A7, Attention HREBA.