



College of  
Physicians  
& Surgeons  
of Alberta

## Research Ethics Review Committee

# Check Lists for Submission of a Research Study for Review

### ATTENTION:

- \*\* Please separate all the information submitted into four complete packages and include a copy of the cover letter for each.
- \*\* Please be advised that effective September 1, 2008 the Research Ethics Review Committee (RERC) must receive all required documents before review of a study proposal commences. Required documents include the signed and dated Clinical Trial Agreement, Budget and any applicable signed and dated Service Provider Agreements.
- \*\* If you send an incomplete submission to RERC, Research Ethics staff will hold the information you provided and send you a letter outlining missing documents. If you submit all missing documents by the following month's submission deadline, the protocol will then go to RERC for review. If your submission is still incomplete after that deadline passes however, Research Ethics will return your documents to you.

### Full Protocol Review

Submissions for full protocol review must include the following:

- Review Fee
  - 5 Copies
- Entire Research Protocol
  - 4 Copies
  - Cover letter – signed by the investigator
  - Signed Application Form
  - Advertising, if applicable
  - Justification for the use of Placebo, if applicable
  - Informed Consent Form on the Investigator's letterhead
  - Health Information Act Requirements
  - Investigator's Brochure/Product Monograph
  - Any documents that involve subject interaction (e.g. questionnaires, newsletters, recruitment materials, advertisements, diaries, etc.)
- 2 Copies
  - Curriculum Vitae for the Investigator and Co-Investigator(s) (if applicable) including all past and present research experience
  - Signed and dated Declaration of Conflict of Interest for the Investigator and Co-Investigator(s)
  - Signed and dated Clinical Trial/Financial Agreement
  - Per-Item Per-Visit Budget
  - Signed and dated Service Provider Agreement(s), if applicable

## **Expedited Review**

Submissions for Expedited protocol review must include the following:

- Review Fee
- 3 Copies
- Cover letter – signed by the investigator
- Signed Application Form
- Curriculum Vitae for the Investigator and Co-Investigator(s) (if applicable) including all past and present research experience
- Signed and dated Declaration of Conflict of Interest for the Investigator and Co-Investigator(s)
- Advertising, if applicable
- Justification for the use of Placebo, if applicable
- Informed Consent Form on the Investigator's letterhead
- Health Information Act Requirements
- Investigator's Brochure/Product Monograph
- Entire Research Protocol
- Signed and dated Clinical Trial/Financial Agreement
- Per-Item Per-Visit Budget
- Signed and dated Service Provider Agreement(s), if applicable
- Any documents that involve subject interaction (e.g. questionnaires, newsletters, recruitment materials, advertisements, diaries, etc.)

## **Reciprocal Review**

Submissions for Reciprocal protocol review must include the following:

- Review Fee
- 3 Copies
- Cover letter – signed by the investigator
- Signed Application Form
- Curriculum Vitae for the Investigator and Co-Investigator(s) (if applicable) including all past and present research experience
- Signed and dated Declaration of Conflict of Interest for the Investigator and Co-Investigator(s)
- Advertising, if applicable
- Copy of the approval letter from the Research Ethics Board
- Copy of the approved Informed Consent Form from the Research Ethics Board
- Justification for the use of placebo, if applicable
- Informed Consent Form on the Investigator's letterhead – modified to the RERC's requirements
- Health Information Act Requirements
- Investigator's Brochure/Product Monograph
- Entire Research Protocol
- Signed and dated Clinical Trial/Financial Agreement
- Per-Item Per-Visit Budget
- Signed and dated Service Provider Agreement(s), if applicable
- Any documents that involve subject interaction (e.g. questionnaires, newsletters, recruitment materials, advertisements, diaries, etc.)

## **Multi-centre Studies**

### Adding a Qualified Investigator at Another Site

These submissions must include the following:

- Review Fee
- 1 Copy
- Cover letter – signed by the investigator
- Signed Application Form
- Curriculum Vitae for the Investigator and Co-Investigator(s) including all past and present research experience
- Signed and dated Declaration of Conflict of Interest for the Investigator and Co-Investigator(s)
- Approved version of the Informed Consent Form on the Investigator’s letterhead (please contact the Sponsor for the approved version)
- Advertising, if applicable
- Health Information Act Requirements
- Signed and dated Clinical Trial/Financial Agreement
- Per-Item Per-Visit Budget
- Signed and dated Service Provider Agreement(s), if applicable
- Any documents that involve subject interaction (e.g. questionnaires, newsletters, recruitment materials, advertisements, etc.)

## **Assessment Review**

These submissions must include the following:

- Review Fee
- 1 Copy
- 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, if available

## **Adding a Co-Investigator to an Approved Study**

These submissions must include the following:

- Application Form signed by the primary investigator and new co-investigator
- Informed Consent Form – please add line for the co-investigator information on the first page
- Current (for the present calendar year) Curriculum Vitae for the co-investigator which includes all past and present research experience. If the co-investigator does not have any research experience, confirm any training under the ICH Good Clinical Practice Guidelines and/or the Tri-Council Policy Statement. Confirmation of this training will be required before approval can be granted.
- Declaration of Conflict of Interest form signed by the Co-Investigator
- Subject Consent Form for the Disclosure of Health/Registration Information (if required)
- Advertising (if required)

### **Change of Address**

These submissions must include the following:

- Written acknowledgment of how subjects are being notified
- Written acknowledgment that applicable site information is being updated (e.g. informed consent form, consent to disclose health/registration information, advertising, clinical trial agreement, service provider agreements etc.)
- Updated HIA section 50 – what steps will be taken to ensure that confidentiality will be protected during the move and how subject information will be protected at the new site