



## **Alberta Cancer Research Ethics Committee Guidelines**

The Alberta Health Services (AHS) Alberta Cancer Research Ethics Committee (ACREC) provides scientific and ethical review of projects involving human subjects and/or submitted by cancer researchers throughout the province of Alberta.

To reduce duplication of process, both on the part of the researchers and the members/administrative staff of the ACREC, a single review process for research will exist. The process requires communication between north and south researchers, research teams, Clinical Research Unit staff, and the ACREC administrative staff.

The following procedures have been implemented in order to efficiently conduct cancer research in the province of Alberta, from initial review through to study completion. The procedures apply to research conducted at one or more sites.

**\*\*All ACREC documents described in the procedures below can be found on the external website at:**

**<http://www.cancerboard.ab.ca/Research/ResearchOversight/Ethics/>**

**This includes application forms, renewal forms, guidance documents, etc.\*\***

### **TABLE OF CONTENTS**

1. Initial Review of a Study
  - 1.1 Full Board Review
  - 1.2 Expedited Review
  - 1.3 Approval and Renewal Dates
2. Amendments
  - 2.1 Protocol Amendments from Sponsor
  - 2.2 Addition of a Participating Site to an ACREC Approved Study
3. Protocol Deviations and Waivers
  - 3.1 Reporting Deviations and Waivers
4. Serious Adverse Event Reporting
  - 4.1 Non-Local Serious Adverse Events
  - 4.2 Local Adverse Events

5. Annual Renewal Reporting
  - 5.1 Continuing Review
  - 5.2 Study Completion
  - 5.3 Expired Studies
6. Compassionate Access
7. Consent Form Requirements
  - 7.1 Requirements for Informed Consent
  - 7.2 Listing Investigators in the Consent Form
  - 7.3 Person Obtaining Consent
  - 7.4 Witness Signature
  - 7.5 Use of a Translator
  - 7.6 Banking for Future Research
  - 7.7 Optional Research
8. Clinical Trial Registration
9. Research Ethics Board Attestation Forms
10. ACREC Signing Authority

## **1. Initial Review of a Study**

### **1.1 Full Committee Review**

- 1.1.1 For each study to be conducted at more than one site, the following must be designated:
  - One Principal Investigator at the Lead Site (Lead PI)
  - One Principal Investigator for each Participating Site (Participating PI)
  - Co-Investigator(s) at each site (Co-Investigator)
  - Clinical Research Coordinator at Lead Site (Lead CRC)
  - Clinical Research Coordinator at Participating Site (Participating CRC)
  - Research Nurse at Lead Site (Lead RN)
  - Research Nurse at Participating Site (Participating RN)

Please Note: The Principal Investigator at each site (Lead and Participating) is considered the Qualified Investigator at that site as per Health Canada Regulations.

If a study is to be offered at more than one site, it is expected that sites will work in a collaborative manner, thereby increasing efficiencies and eliminating duplication of efforts wherever possible.

The Lead PI assumes responsibility for the coordination of the study and obtaining/meeting all regulatory requirements for the Lead Site and any Participating Site. If the study is conducted at **one site only**, that site will be considered the Lead Site and all regulatory requirements will be the responsibility of the PI at that site.

- 1.1.2 The Lead PI or qualified designee for a research study will prepare the application and all applicable documents for submission to the ACREC. If the application forms are completed by a qualified designee, the PI will be responsible for fully reviewing the documents prior to signing them off. Application forms with **full instructions** can be found on the external website listed on page 1 of this document.

Documents to be included with a submission are, at a minimum, those outlined in Section 3.1.2 GCP/ICH Guidelines (revised April 1, 2008):

- Protocol
- Investigator's Brochure
- Consent Forms
- Patient Diaries/Questionnaires
- Recruitment materials
- Health Canada No Objection Letter
- Etc.

- 1.1.3 Upon receipt of a completed application, a Research Ethics Coordinator (EC) will assign one file number to the study for all sites participating in the study.

- 1.1.4 The study will undergo review by the full committee at the next meeting of the ACREC.

- 1.1.5 After an initial positive ACREC review, a Pending Approval letter detailing all requested changes to the submitted documents and scientific and ethical concerns will be sent to the following:

- Lead PI
- Lead Clinical Research Coordinator (CRC)
- Lead Clinical Research Unit (CRU)

- 1.1.6 All requested changes and responses to ACREC concerns are submitted to Research Administration. Changes can be reviewed by an EC (if only changes were the ACREC requested changes to the consent form or study documents). The ACREC Chair will review any additional consent form changes requested by the Sponsor or responses to scientific and ethical concerns.

- 1.1.7 After a final positive review, the Final Approval letter will be released as a .pdf file via email to the following:

- Lead PI
- Lead CRC
- Lead CRU
- Lead Pharmacy

- Participating PI(s)
- Participating CRC(s)
- Participating CRU(s)
- Participating Pharmacy

The original approval letter and required copies will be sent via intra-hospital mail to the following:

- Lead PI (original letter)
- Participating PI (copy)
- Office of the Information and Privacy Commissioner (OIPC) (copy)

1.1.8 It is the responsibility of the Lead PI to ensure that all approved documents (protocol, IB, consent forms, diaries, etc.) are provided to the PIs at each of the Participating Sites.

1.1.9 The addition of a Participating Site to a study that has already received ACREC approval must be made by the Lead PI by way of an amendment to the study (see Section 2.2).

## **1.2 Expedited Review**

Research studies that deal solely with chart reviews, image reviews and basic laboratory studies are generally considered to be research of minimal risk to study subjects and are usually eligible for expedited review. The application for Research of Minimal Risk is based on Article 3.2 of the Tri-Council Policy Statement and is designed to provide consistent information to the ACREC.

- 1.2.1 The application form can be found on the external website listed on page 1 of this document and can be submitted for review at any time.
- 1.2.2 Such studies are reviewed and approved by the Chair of the ACREC and do not require full committee review and approval.
- 1.2.3 Approval is granted for a one year term from the date of the initial review.
- 1.2.4 A list of all studies that receive expedited approval is provided to each ACREC member for the next ACREC full committee meeting. ACREC members may request a copy of the application documents. If an ACREC member has concerns over a study, the study may be temporarily suspended until issues are resolved.

Expedited review is performed at the discretion of the Chair. The Chair is not able to disapprove a study that is submitted for expedited review. The study must be put forward for review at the next Full Committee ACREC meeting if the Chair has concerns or objections.

Research studies that may be eligible for expedited review may include the following:

- i) Drugs which have received Health Canada Approval (Investigational New Drug application is not required).
- ii) Medical devices which have been approved for marketing and are being used according to the approved labeling.
- iii) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from consenting adults. A consent form is to be prepared to outline the study, including risks and benefits, and to obtain consent even if blood is collected as an extra sample taken at the same time as blood draws for standard care.
- iv) Prospective collection of biological specimens for research purposes by noninvasive means [for example, nail clippings, saliva (stimulated and/or unstimulated), mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings, etc.].
- v) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.
- vi) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). This includes chart reviews and tissues that have previously been banked (i.e. accessing samples from the Canadian Breast Cancer Foundation Research Tumor Bank).
- vii) Collection of data from voice, video, digital, or image recordings made for research purposes.
- viii) Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

### 1.3 Approval and Renewal Dates

- 1.3.1 **Final Approval Date:** the final approval date of a study that has been reviewed (either full committee or expedited review) is the date that all conditions for final approval have been met and approved by the ACREC Chair or designate (for example: consent form revisions or responses to scientific concerns have been submitted and approved by the ACREC Chair or designate).
- 1.3.2 **Annual Renewal Date** (or Anniversary Date as per certain sponsors): the annual renewal date is the date by which a request for renewal must be submitted, reviewed and approved as per the ACREC Annual Renewal Reporting Guidelines found on the external website listed on page 1 of this document.

- Studies receiving Full Committee review: the annual renewal date is one year from the date of the meeting at which the study was reviewed
- Studies receiving expedited review: the annual renewal date is one year from the date of initial review.

## **2. Amendments**

### **2.1 Protocol Amendments from Sponsor**

2.1.1 The Lead PI of the study must submit all revised study documents that require ACREC approval to Research Administration. This may include, but is not limited to the following:

- protocol amendments
- revised consent forms
- Revised study documents (Investigator's Brochures, subject diaries, recruitment materials, etc)
- Health Canada's Letter of No Objection (if applicable)

2.1.2 Once reviewed, an amendment approval letter will be issued to the following:

- Lead PI
- Lead CRC
- Lead CRU
- Lead Pharmacy
- Participating PI
- Participating CRC
- Participating CRU
- Participating Pharmacy

2.1.3 It is the responsibility of the Lead PI to ensure that the Participating Site(s) PI receives all of the approved document(s).

### **2.2 Addition of a Participating Site to an ACREC Approved Study**

2.2.1 If an AHS research site is interested in conducting a study that has already been approved by the ACREC, the PI at the Lead Site must submit the addition of the site(s) as an amendment to the study. All required GCP/ICH documentation for the additional site is to be submitted by the Lead PI. Information from the original study application should be used, which will be amended to include the additional site specific information as well as the required signatures from the site requesting approval to participate.

2.2.2 Approval will be sent to the Lead PI and the PI at the Participating site.

2.2.3 Scientific and ethical approval for the study at the Participating Site is effective as of the date of the ACREC approval letter. The renewal date for the additional site entering the study will be the same date as that for the Lead Site.

- 2.2.4 Prior to study commencement at the additional site, it is the responsibility of the Lead PI and the Participating PI to ensure that all other institutional requirements are in place e.g. departmental services assessments, amendments to the financial contract amendments or sub-contracts with the sponsor, etc.

### **3. Protocol Deviations and Waivers**

Local study protocol deviations must be submitted to Research Administration using the Protocol Deviation Reporting Form found on the external website. Investigators must review all local protocol deviations and assess their significance to the health and safety of subjects and to the integrity of the study.

Where in the opinion of the investigator a local protocol deviation constitutes or may constitute a safety risk to the subjects in the protocol or compromises the integrity of the study, the deviations are to be reported by the investigator in a timely fashion to the ACREC using the Protocol Deviation Reporting Form or a form specified by the sponsor of the study and agreed upon between the ACREC and the investigator.

#### **3.1 Reporting Protocol Deviations and Waivers**

- 3.1.1 The Investigator at the site where the deviation occurs must complete a Protocol Deviation Form which can be found on the external website.
- 3.1.2 The Form is to be submitted to the ACREC within 72 hours of becoming aware of the deviation.
- 3.1.3 Protocol deviation forms will be reviewed by the ACREC Chair.
- 3.1.4 Acknowledgement of the protocol deviation will be sent back to the following:
- PI at the site where the deviation occurred
  - CRC at the site where the deviation occurred
  - CRU at the site where the deviation occurred
- 3.1.5 Any follow up action requested by the ACREC Chair must be addressed by the Investigator at the originating site.
- 3.1.6 Requests for Protocol Waivers that have been approved by the sponsor must be submitted to the ACREC for acknowledgement. Documentation of the sponsor's approval must accompany the submission to the ACREC.

### **4. Serious Adverse Event Reporting**

Definitions and guidelines for Serious Adverse Event (SAE) reporting are found on the external website listed on Page 1 of this document.

#### **4.1 Non-Local (Sponsor Generated) Serious Adverse Events**

4.1.1 The Lead PI is responsible for submitting all sponsor generated serious adverse events and/or safety reports using the ACREC Non-Local Serious Adverse Event Reporting Form found on the external website.

4.1.2 The following must be submitted for ACREC acknowledgement of Non-Local SAEs:

- Original signed Non-Local SAE Reporting Form
- One (1) copy of the Non-Local SAE Reporting Form for each Participating Site
- One (1) additional copy

For example, if in addition to the Lead Site there are two (2) Participating Sites, the original signed form and three(3) copies are required.

4.1.3 Once acknowledged by the ACREC, the original signed and dated form will be sent to the Lead PI, one (1) copy will be sent to the PI at each Participating Site, and one (1) copy will remain in the ACREC study file.

4.1.4 The PI at each Participating Site must then sign the form to acknowledge the receipt and review of the Non-Local SAEs. There is a signature line included on the form for the Participating Site PI.

Please note: the Participating Site PI can sign the form after ACREC acknowledgement.

## **4.2 Local Serious Adverse Events**

4.2.1 The investigator at the site where the SAE occurs is responsible for submitting the completed report to the ACREC using the ACREC Local Serious Adverse Event Reporting Form.

4.2.2 The following must be submitted for acknowledgment by the ACREC Chair for Local SAEs:

- Original signed Local SAE Reporting Form from site where SAE occurred
- One (1) copy of the Local SAE Reporting Form
- One (1) set of all SAE supporting documentation

4.2.3 Local SAEs will be reviewed by the ACREC Chair and reported to the Committee at the next meeting of the ACREC.

4.2.4 Following review, the original signed and dated form will be sent back to the site from which the SAE originated and one (1) copy of the form and supporting documentation will remain in the ACREC study file.

## **5. Annual Renewal Reporting**

Guidelines for Annual Renewal Reporting are found on the external website listed on Page 1 of this document. Requests for annual renewal must be reviewed by the ACREC within 30 days of the study annual renewal (anniversary) date. The annual renewal date will be retained. If the request for annual renewal is reviewed more than 30 days in advance of the annual renewal date, the annual renewal date will be changed to

reflect the date that the request was reviewed. If a request for annual renewal is received after the annual renewal date, the request will be handled according to Section 5.3 below.

## **5.1 Continuing Review**

- 5.1.1 Annual renewal memos will be generated by an EC and distributed to the Lead PI 3 months in advance of the renewal date.
- 5.1.2 It is the responsibility of the Lead PI to prepare and submit annual renewal forms to the ACREC, providing information from the Lead Site and Participating Site(s).
- 5.1.3 Requests for annual renewal should be submitted to the ACREC at least 2 months prior to date of study expiration (date provided in the previous ACREC renewal approval letter).
- 5.1.4 Requests for annual renewal will be reviewed and approved either by the ACREC Chair (expedited review) or by the full committee ACREC as outlined in the Annual Renewal Reporting Guidelines posted on the external website listed on Page 1 of this document.
- 5.1.6 The annual approval letter will be generated by an EC and forwarded via email as a .pdf file to the following:
  - Lead PI
  - Lead CRC
  - Lead CRU
  - Lead Pharmacy
  - Participating PI
  - Participating CRC
  - Participating CRU
  - Participating Pharmacy

The original annual approval letter and required copies will be sent via intra-hospital mail to the following:

- Lead PI (original)
- Participating PI (copy)
- OIPC (copy)

One (1) copy of the annual approval letter will be attached to the annual renewal form and filed in the ACREC study file.

## **5.2 Study Completion**

- 5.2.1 It is the responsibility of the Lead PI to inform the ACREC when a study is completed/terminated/withdrawn/abandoned.
- 5.2.2 For industry sponsored studies, the Lead PI must submit an ACREC Study Completion Form and corresponding documentation from the sponsor

- regarding the closure (if the closure is for all sites). The Study Completion Form can be found on the external website listed on page 1 of this document.
- 5.2.3 Should the Sponsor of a study being conducted at multiple sites decide to close out only certain sites, it is the responsibility of the PI at the site involved to submit a Study Completion Form to the ACREC for review. The end date for this site will be updated in the ACREC files independent of the Lead or other sites. The Lead PI (if closed site is a Participating Site will be informed by the ACREC of the closure).
- 5.2.4 For investigator initiated studies, the ACREC Study Completion Form must be submitted with relevant information.
- 5.2.5 Study Completion Forms will undergo expedited review unless Full Committee review is requested by the ACREC Chair.
- 5.2.6 Acknowledgement of study completion will be sent to:
- Lead PI
  - Lead CRC
  - Lead CRU
  - Lead Pharmacy
  - Participating PI
  - Participating CRC
  - Participating CRU
  - Participating Pharmacy
  - OIPC
  - Copy for ACREC files (to be filed with the Study Completion Form)

### **5.3 Expired Studies**

#### 5.3.1 General Information

- (i) A study for which a request for annual renewal is not received prior to its annual renewal date will be considered terminated by the ACREC.
- (ii) An EC will issue a Notification of Study Closure together with a Return Form to the Lead PI and Notification of Study Closure only to the Participating Site PI.
- (iii) Study activity must cease immediately at all sites. If subjects are receiving protocol mandated treatment, intervention or other study procedures, a written request must be submitted immediately to the ACREC Chair for approval for these activities to continue pending study reactivation.
- (iv) Until approval for the request has been granted by the ACREC, subjects must not receive protocol mandated treatment, intervention or other study procedures.
- (v) The Return Form is to be submitted to Research Administration by the Lead PI to inform the ACREC of the intention to either close the study completely or re-activate the study.

#### 5.3.2 Study Completion

If the Lead PI has no intention of continuing or re-activating an expired study at the Lead Site or any of the Participating Sites, a Study Completion Form must be submitted to the ACREC as per Section 5.2 above.

### 5.3.3 Study Re-Activation

- (i) If the Lead PI intends to continue the study at the Lead Site or any of the Participating Sites, a Study Reactivation Form from the external website, listed on page 1 of this document, must be completed and submitted to ACREC with the most recently approved study documents. Instructions for re-submission are on the form. The study will be included on the agenda for the next Full Committee ACREC meeting and reviewed as per Section 1.1.
- (ii) The Lead PI must submit a request as per section 5.3.1 to continue treating subjects during the time from expiry to re-review at the full committee ACREC meeting.

## 6. Compassionate Access

In cases of urgent special need under provisions characterized as Compassionate Access, where it would otherwise not be reasonable for the matter to be handled as a routine application, the ACREC Chair or the Deputy Chair (or Acting Chair in the absence of both Chair and Deputy Chair) may call upon at least two other members of the Committee and review the application. The special consideration group may collectively undertake a special review of the application in proportional measure to the urgency of the case and decide accordingly. Such review must include consideration of scientific and ethical matters. The circumstances, details and decision of the special consideration group shall be reported to the full committee at the next committee meeting.

- 6.1 The PI must submit a request for compassionate access together with the Special Access approval from Health Canada.
- 6.2 The request will be assigned a file number and reviewed as described above.
- 6.3 After a positive review, an approval letter for the request for compassionate access will be issued via email as a .pdf file to the following:
  - PI
  - CRC
  - CRU
  - Pharmacy

The original approval letter will be sent via intra-hospital mail to the PI.

It is important to note that a request for compassionate access is patient specific. Approval does not cover all patients who may require access. A separate request for compassionate access must be submitted for each case.

## **7. Consent Form Requirements**

### **7.1 Requirements for Informed Consent**

The ACREC consent form template includes all the required elements for informed consent in compliance with ICH Good Clinical Practice (GCP). It is to be used in conjunction with the sponsor-provided sample consent to ensure all study specific information is also included. For additional information on informed consent form elements, an Informed Consent Form Required Elements checklist can be found on the external website listed on Page 1 of this document.

### **7.2 Listing Investigators in the Consent Form**

The consent form document must include the contact information for the Lead PI and the Participating Site PI(s). It is not necessary to include the full list of Co-Investigators at each site in the consent form. It is acceptable to the ACREC for a list of contact information to be provided to subjects on study, separate of the main consent form document. This may be in the form of an ACREC approved "Information Sheet" that is distributed together with the consent form(s).

### **7.3 Person Obtaining Consent**

The person obtaining consent may be the Principal Investigator [Lead or Participating Site(s)]. The Principal Investigator at each site may delegate a study team member(s) who has sufficient knowledge of the study and the process of informed consent (Good Clinical Practice Section 4.8) to obtain informed consent. Study team members who are delegated to obtain consent will be required to be listed on the study delegation log.

### **7.4 Witness Signature**

As per GCP Section 4.8.9, an impartial witness should be present during the informed consent discussion if the subject or subject's legally authorized representative is not able to read or if the consent process must be conducted in another language (translator). The ACREC consent form template makes allowances for these situations.

### **7.5 Use of a Translator**

Potential research participants who are not proficient in the language used by the researchers should not be disqualified from the opportunity to participate in potential research. The consent process may be conducted with the use of a translator who is

competent in the language used by the researchers and the participant, and that translator must be an impartial witness (for example, someone not involved in the research study or related to the participant). Refer to Tri-Council Policy Statement Article 2.1(b) and GCP Section 4.8.9.

## **7.6 Banking for Future Research**

The ACREC banking consent form template is intended to be used only for the optional collection and storage of samples (blood, tumour tissue, urine, saliva, etc.) for research in the future. A banking consent form outlining the required samples and the intent to store samples is required. The banking consent form must clearly state that choosing not to participate in the banking of samples for future research will not affect the subject's opportunity to participate in the main study.

If banking of samples collected as part of the main study is mandatory for participation in the main study, this should be included in the main consent form and not submitted as a separate banking for future research consent form..

Where samples required for research are described/outlined in the protocol as part of the data that will be used in the final study report (not stored for future research) (i.e. pharmacogenetics, pharmacodynamics, pharmacokinetics, biomarker research, etc.) the banking for future research consent form is not to be used. Where analysis is a mandatory component of a research study, it is to be included in the main consent form as described above. Please see section 7.7 below if the analysis is an optional component of the study.

## **7.7 Optional Research**

Optional research refers to protocol procedures/research that does not affect subject participation in the main research study (i.e. a sub-study). The information related to the optional research should therefore not be included in the main consent form. A separate consent form outlining the optional research procedures/research must be provided to subjects and clearly state that choosing not to participate in the optional research will not affect participation in the main study.

As optional research is a separate study from the main study, the consent form template may be used to outline the optional research study, procedures, requirements for participation, etc.

## **8. Clinical Trial Registration**

The **International Committee of Medical Journal Editors (ICMJE)** released a statement in September 2004 and an update in the June 15, 2005 edition of JAMA regarding upcoming changes to publication policies for clinical trials.

The position of the ICMJE is that all clinical trials involving intervention research must be registered in a publicly accessible searchable domain to allow for and encourage awareness and transparency. Failure to register an applicable trial will prevent it from ever being published in any journal that belongs to the ICMJE. This includes major journals such as JAMA, NEJM, CMAJ, Lancet and others. Although there are journals not part of this consortium, JCO for example, one can only foresee the same regulation coming from them in the future.

---

**Initial 2005 International Committee of Medical Journal Editors definition of research requiring registration:**

“any research project that prospectively assigns human subjects to intervention or comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome”

This initial definition excluded Phase I studies and research that was not intended to change clinical practice.

**2007 ICMJE Definition Update:**

“any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes”

Health related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes).

Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration.

The ICMJE member journals will start to implement the expanded definition of clinically directive trials for all trials that begin enrollment on or after 1 July 2008.

**For information regarding Clinical Trial Registration, please refer to the following:**

**<http://www.icmje.org/#aboutur>**

**<http://www.icmje.org/faq.pdf>**

---

There may be trials whose goal is to investigate biology of disease or provide preliminary data that may lead to larger, clinically directive trials. In the event that such a trial was not registered, it would be up to the editor of the journal as to whether

or not such research would be acceptable for publication. Researchers would have to provide a compelling argument as to why the decision was made not to register.

For research which is industry sponsored (or cooperative group), the sponsor of the study will usually register the trial. The Registration Number and registry name must be provided to the ACREC (refer to Section 17 of the ACREC Application Form).

For Investigator Initiated Research, the Protocol Registration System Form (PRS) must be completed by the Lead PI and submitted to the Clinical Research Unit at the Lead Site. Further information can be obtained from Clinical Research Manager (CCI) at (780) 432-8909 or the Clinical Research Manager (TBCC) at (403) 521-3388.

## **9. Research Ethics Board Attestation Forms**

As of January 17, 2008, approval letters from the ACREC include the ACREC certification statement and the required ACREC contact information. As such, the submission of REBA forms is not required.

## **10. ACREC Signing Authority**

- 10.1 If the Chair is a PI or Co-Investigator, the Deputy Chair will sign any correspondence related to these studies. Should the Deputy Chair be unavailable for an extended amount of time (usually greater than one week), the Acting Deputy Chair will sign correspondence.
- 10.2 If changes to a consent form or other documentation are administrative in nature, an EC may approve these changes without sending them to the ACREC Chair (Deputy/Acting Deputy Chair) for review. Such changes include typos, change of name in the consent form, changes to header and footer, pagination corrections, printing of consent form on new facility letterhead, etc. These changes have no effect on patient safety and can be approved within Research Administration by the EC.
- 10.3 The receipt of standard documentation from the Sponsor such as Investigator Brochures, Product Monographs, medication diaries, validated questionnaires, etc. may be acknowledged by the EC. These documents will be sent to the Chair if the updated version results in changes to subject safety, the consent form or the treatment plan of the subjects on study.
- 10.4 The receipt of Non-Local Serious Adverse Events (SAE) will be acknowledged by the EC except where changes to the consent form are required as a result of the report. The Chair will acknowledge Non-Local SAE reports for which consent form changes are required and also all Local SAE reports as per the SAE Reporting guidelines found at:  
<http://www.cancerboard.ab.ca/Research/ResearchOversight/Ethics/>