

## GUIDANCE NOTES FOR REQUEST FOR ACKNOWLEDGEMENT

- Article #1 When to Use the Request For Acknowledgement Form
- Article #2: REB Submission Requirements for Unanticipated Problems and New Information
- Article #3: Investigator Reporting Obligations to Others

### INTRODUCTION

The following notes are intended to assist researchers with completion and submission of a Request for Acknowledgment Form.

#### ARTICLE #1: WHEN TO USE THE REQUEST FOR ACKNOWLEDGEMENT FORM

The Request for Acknowledgement Form should be submitted in any instance where the Investigator or the Sponsor requires an acknowledgement that the REB has received specific information. These situations include, but are not limited to:

- Protocol Deviation [see BCCA REB webpages for [policy on reporting protocol deviations](#)]
- Safety letters (provided that they do not meet the criteria for an SAE)
- DSMB reports
- Summary Reports
- Unanticipated Problems
- New Information
- Studies on hold, off hold
- Studies closed to accrual/enrollment

**Note: The following must be submitted as an Amendment (not in Request for Acknowledgement):**

- **Updated Investigator Brochures and Product Monographs Effective Oct 30, 2009:** These must be submitted as a **Request for Amendment** in RISE (attach the document to Section 9 of the RISE application).
- [Health Canada NOL \(No Objection Letters\)](#)
- [Clinical Trial Agreement \(Legal Contract\)](#)
- **Changes of investigators or study team members** (including the primary contact for the study) must be submitted in RISE as an 'Amendment' to the study (not as a request for acknowledgement).
- **Completion of Study Notification** is a separate category in RISE. Once a study is completed the PI must submit a "Notification of Study Closure" using the RISE system.  
(See [Guidance Notes For Notification Of Study Closure](#))

#### 1.1. Definitions

**New Information:** Any new information that might adversely affect the safety or well being of the study participants, the conduct of the trial, or the subject's willingness to continue in a study.

New information includes but is not limited to any relevant recent literature, interim findings, and preliminary results of the study or of any other study (e.g. using the same drug).

**Protocol Deviation:** A one-time unintentional divergence from the approved research protocol or consent document(s) identified after the event occurred.

**Unanticipated Problems:** Unanticipated problems are generally considered to be any incident, experience or outcome related or possibly related to participation in the research, or any changes that are made to the study that could result in increased or different risks to the participants than were previously known or recognized, that were not anticipated/expected (in terms of nature, severity or frequency) or that were not described in the original application. Unanticipated problems include anything that could significantly impact the conduct of the study or alter the REBs approval or favourable opinion to continue the study.

Unanticipated problems include, but are not limited to:

- Serious unexpected adverse events / reactions (including adverse device events) which should be reported to the BCCA REB in accordance with the applicable procedures [see BCCA REB webpages for [AE/SAE reporting procedures](#)]
- A breach of confidentiality or privacy
- Problems with the investigator or study personnel
- Fire, flood or other natural disaster
- Incidents of continuing and serious noncompliance with the ICH-GCPs, REBs requirements or applicable laws and regulations
- Termination or suspension of the study by a regulatory authority
- Any complaint by a subject that includes a report of an unanticipated risk or which cannot be resolved by the research staff
- Protocol deviations that in the opinion of the investigator places one or more participants at increased risk, or affects the rights, safety, or welfare of research participants

## ARTICLE #2: REB REPORTING REQUIREMENTS FOR NEW INFORMATION AND UNANTICIPATED PROBLEMS

All Requests for Acknowledgement should be submitted **as soon as reasonably possible** after the Principal Investigator receives the relevant documentation or becomes aware of the new information or unanticipated problem.

The term as soon as reasonably possible means that timing of reporting will vary in accordance with the severity / seriousness of the information being reported. Unless, however, the event is a routine safety letter, DSMB, summary report or changes to the Investigator's Brochure that are minor and/or routine in nature, **all unanticipated problems and local serious adverse events must be reported within seven days** of the incident, occurrence, outcome, event or the Investigator's receipt of the new information. Please see the BCCA REB guidelines for reporting AE/SAEs for specific timeline information.

All Requests for Acknowledgement should contain:

- the status of the study
- the number and status of subjects (i.e., on treatment, on follow-up, etc.)
- a description of the incident, experience or outcome if applicable
- a summary of the new information if applicable

- 
- a description of any changes to the protocol or other corrective actions that have been taken or are proposed to be taken in response to the new information, unanticipated problem or new documentation.
  - If required changes have been completed on a previous or concurrent amendment provide the Post Approval Activity number
  - A Post Approval Activity Nickname (PAA) that identifies what type of Request for Acknowledgement is being submitted [see BCCA REB webpage for a [guidance note on using PAA Nicknames](#) ].
- 

### **ARTICLE #3: INVESTIGATOR REPORTING REQUIREMENTS TO OTHERS**

Investigators conducting studies that are funded or supported by the US Federal Government or that are regulated by the US Food & Drug Administration are required to report all unanticipated problems to the applicable regulatory authorities, and if applicable, the study sponsor.