

Request for Acknowledgement PAA – Clinical – SAMPLE FORM

Post Approval Activities

*** Select one of the following options to submit to the Research Ethics Board based on the guidelines listed on the right:**

Request for Acknowledgement

*** Nickname**

Enter a nickname for this PAA.

(If applicable to your PAA, include descriptive words such as "IB update" or "protocol deviation" or "unanticipated event" or "local SAE" in the nickname)

• Annual Renewals

For Clinical studies click [here](#) for information on annual renewals. Reminder: If this is an annual renewal of a for-profit (industry or pharmaceutical) sponsored study, an annual renewal fee is required. For more details about fee criteria, exemptions and methods of payment please consult the applicable REB administration or their web-site.

• Amendments to Study

Amendments are changes to an ongoing study. If you are changing any part of the study (e.g. co-investigators, title, agency, documentation) you must submit an amendment. Click [here](#) for more information on amending behavioural studies.

• Completion of Clinical Study

For Clinical studies click [here](#) for criteria on study completion.

• Request for Acknowledgement

Protocol deviations, unanticipated problems, new information, safety letters, local serious adverse events, studies on hold, off hold, closed to accrual/enrollment, or miscellaneous information (PI, Sponsor or REB requires acknowledgement). Click [here](#) for more information on Request for Acknowledgement criteria. Any other changes to an ongoing study must be submitted through an amendment.

Note: Investigator Brochures must be submitted as an amendment

Request for Acknowledgement Coversheet

The Request for Acknowledgement Coversheet (form) should be submitted in instances where the Investigator or the Sponsor requires an acknowledgement that the REB has received specific information.

Based on the guidelines on the right, enter details below with accurate information as this information will be returned "AS IS" to you in the REB Acknowledgement Certificate. Enter details into the application section.

Please Complete the Following Sections as Applicable

- **1.A.** For Safety letters, Study on/off hold, periodic safety update reports closed to enrollment, miscellaneous information, new information, and Unanticipated Problems that are not serious adverse events
- **1.B.** For Protocol Deviations
- **1.C.** For Unanticipated Problems that are Serious Adverse Events
- **1.D.** Attach documents
- **1.E** enter US information if applicable

1.A. Safety Letters, periodic safety update reports, Study on/off hold, closed to enrollment, miscellaneous information, new information, and unanticipated problems that are not serious adverse events(1C) or protocol deviations(1B).

Please include the following information:

- The status of the study (i.e. open or closed to enrolment or on-hold etc)
- Summary of the status of participants enrolled
- 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/study or other to be taken in response to the new information, unanticipated problem or new documentation. (*Revisions to study documentation require submission of an amendment to the REB. If an amendment has already been submitted, please indicate the PAA number)

Note: Attach documents in 1.D.

Note: Information entered below will appear "AS IS" on the REB Acknowledgement certificate.

- **Annual Renewals, Amendments and Completion of Study notices and Response to Request for Information (RFI) may not be submitted using this form.** If you are submitting one of these items, please go back and select the applicable form (PAA)
- **Investigator Brochures** should also not be submitted as a request for acknowledgement. Please submit these as an amendment.
- **Request for Acknowledgement** please click [here](#) for more information about Requests for Acknowledgement.
- **Safety letters, Dear Doctor letters, Line Listings, Unanticipated Problems that are not Serious Adverse Events (SAEs), Quarterly or Bi-Annual Periodic Safety Summary Reports, sponsor summaries of SAEs (e.g. CIOMS, SUSARs or other variations).**

Complete section 1.A. and attach all documents in 1.D.

Line listings that do not include a summary of the sponsor's interpretation of the pattern of SAEs, and a position statement on whether these warrant a change, do not qualify as a periodic safety update report and should not be submitted. If Line Listings are submitted without this summary, a reason for the submission must be included.

• **Studies temporarily closed or on hold/ study re-opened or off hold**

Enter the status of the study, effective date(s) and reason. Attach any supporting documents in 1.D.

• **Closed to accrual/enrollment**

Enter the status of the study, effective date closed to enrollment, reason, local accrual goal and the status of the subjects. Attach any supporting documents in 1.D.

• **Miscellaneous information**

PI, Sponsor or REB requires Request for acknowledgement.

• **Unanticipated Problems**

Notification of any incident, experience or outcome that could result in increased or different risks to the participants that were not anticipated/expected and/or that were not described in the original application other than an Unanticipated problem that is a Serious and Unexpected Adverse event (1C). This includes anything that could significantly impact the conduct of the study or alter the REB's approval or favourable opinion to continue the study.

- **New Information** that might adversely affect the safety or well-being of the study participants, the conduct of the trial or the participant's willingness to continue in a study, including new information or literature that has come out of other studies that could potentially have an impact on participants in this study.

1.B. PROTOCOL DEVIATIONS

If this is a notice to the REB concerning a Protocol deviation, please include the following:

- The status of the study (i.e. open or closed to enrolment or on-hold etc)
- Summary of the status of participants enrolled
- A description of the deviation that occurred with an explanation of the circumstances that led to the deviation and the resulting problem
- An explanation as to whether or not the deviation compromised the scientific integrity of the study
- An explanation of whether or not the deviation increased the risk or the possibility of risk for the research participant(s)
- If applicable, an explanation of whether and how participants affected by a protocol deviation will be informed
- A description of steps taken or that will be taken to correct/address the problem resulting from the deviation; and
- A plan for ensuring that similar deviation does not occur in the future.
- Confirm whether any previous protocol deviation(s) have occurred that have been previously reported to the REB. If so, please provide the PAA number.

Note: Attach documents in 1.D.

Note: Information entered below is to inform the REB, but will NOT appear on the acknowledgement certificate.

Protocol Deviations

For Clinical studies click [here](#) for information on protocol deviations.

1.C. UNANTICIPATED PROBLEMS that are SAE's

Please indicate the type of SAE you are submitting (refer to the guidelines on the right for criteria).

Non-Local [External] SAE (if this does not meet the criteria; a reason must be provided below as to why this is being submitted)
Please enter the following information:

- Justification of the assessment that the event described is both serious and unexpected
- Identification of all previous safety reports concerning similar adverse experiences
- Analysis of the significance of the current adverse experience in light of the previous reports **and**
- Outline of any proposed protocol changes, informed consent form changes or other corrective actions to be taken by the sponsor in response to the unanticipated problem.

Local SAE Please enter the following information:

- The status of the study (i.e. open or closed to enrolment or on-hold etc)
- Summary of the status of participants enrolled
- A detailed description of the local event (include the date, whether this is an initial or follow-up report, and whether the event reaction was mild, moderate or severe)
- An opinion expressed by the local investigator that the event is both serious and unexpected and a justification of that opinion
- An opinion expressed by the local investigator that the event is related or potentially related to the study drug/procedure/device and an explanation of that opinion

Criteria for Reporting:

Individual Local or non-local (external) Serious Adverse Events must meet the definition of an Unanticipated Problem (unexpected, related and involving greater risk - see definition) and must be reported within **Seven (7) days** of the occurrence of the event/ receipt of the notice of the reportable individual event.

Events that do not meet the above criteria are NOT acceptable as an individual report and instead must be reported to the REB in the form of a quarterly or six monthly **periodic safety update report** provided by the sponsor, which must include a meaningful interpretation of the events and a position statement as to whether these warrant a change (these reports should be submitted within **Fifteen (15) days** of receipt from the sponsor and be attached to 1.A above).

Click [here](#) for further information on reporting unanticipated events and [here](#) for UBC's policy on reporting unanticipated events.

<ul style="list-style-type: none"> • An opinion expressed by the local investigator regarding the implications of the SAE on the continuation of the study and any further actions that may be required such as changes to the study procedures, informed consent or protocol • A statement of the study team response to the event and the participant's outcome of the SAE <p>Note: Information entered below is to inform the REB, but will NOT appear on the acknowledgement certificate.</p>	
<p>1.D. DOCUMENTS</p> <p>Click "Add" to attach documents for this submission. The filenames you enter when attaching documents will appear "AS IS" on the REB Acknowledgement Certificate.</p> <p>Title</p>	<p>The REB cannot modify filename. The filename should include the information that you or your sponsor require, otherwise include an itemized list of the documents in the applicable section above.</p>
<p>1.E. Is this study US Federally Funded or Supported or regulated by the U.S. Food and Drug Administration?</p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p>If "Yes", please provide the U.S. Food and Drug Administration IND or IDE number below or explain why it is not available or not applicable.</p>	<p>The Office of Research Ethics is responsible for reporting all Unanticipated Problems to the Office For Human Research Protections or the U.S. Food and Drug Administration and in the latter case, the Investigational New Drug (IND) or the Investigational Device Exemption (IDE) numbers must be referenced in the report(s).</p>

You have reached the end of the Post Approval Activity (PAA) Coversheet. Please follow the steps below.

1) When you click "Continue", you will be brought to the PAA home page where **ONLY** the Principal Investigator or a Co-Investigator with full signing authority will be able to "Submit PAA" for review. For instructions on how to designate a Co-Investigator with signing authority select [here](#).

2) Click "Continue" to work on this PAA coversheet at a later time.

This post approval activity will be in "Pre Submission" state. To work on this again, click the "Edit PAA Coversheet" button on the left side of the PAA home page.

note: To update your own personal profile (appointments, email address, etc.), select the link to your name in the top right corner of your homepage.