

Request for Acknowledgement PAA – Behavioural – 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. What would you like this PAA to be known as to the Principal Investigator and study team?

(If you are notifying the REB of a protocol deviation or an unanticipated event or local serious adverse event please include the words "protocol deviation" or "unanticipated event" or "local SAE" as applicable 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. For Behavioural studies click [here](#) for more details on annual renewals.

• 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.

• Completion of Behavioural Study

The researcher will have no further contact with subjects for the purpose of data collection, follow up, or research. Click [here](#) for more information on completion criteria.

• 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.

• Response to Request for Information (RFI)

The Research Ethics Board has issued a Request for Information (RFI) regarding your research study and requires a response. Use this option to respond to the REB.

Note: Investigator Brochures must be submitted as an amendment

Request for Acknowledgement Coversheet

The Request for Acknowledgement Coversheet and 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.

- **1.A.** For miscellaneous information and unanticipated problems
- **1.B.** *Attach documents*

1. A. Miscellaneous Information, Unanticipated Events

Please include the following information:

- *The status of the study and summary of participants enrolled*
- *A description of the incident, experience or outcome if applicable*
- *A description of any changes to the study to be taken in response to the unanticipated problem. (*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.B.*

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)

- **Miscellaneous information**

PI, Sponsor or REB requires Request for acknowledgement click [here](#) for more information.

- **Unanticipated problem**

An unanticipated problem is any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected (in terms of nature, severity, or frequency)
- Related or possibly related to participation in the research;
- Suggests that the research places research participants or others at a greater risk of harm than was previously known or recognized.

For example, the theft of a laptop containing confidential information about participants would constitute an unanticipated problem; an outbreak war or insurrection in the area of the research might constitute an unanticipated problem.

1.B. DOCUMENTS

Click "Add" to attach documents for this submission. The filenames you enter when attaching documents will appear "AS IS" on the REB Acknowledgement Certificate.

Title

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.