

Post Approval Activity (PAA) "Nickname" required.

When creating a new Post-Approval Activity (PAA) in RISE, enter a "PAA nickname" to identify the *content* of the amendment or acknowledgment. The PAA nickname should be entered in the text box that appears on the opening page of the PAA (under the type of PAA to select). See screen shot below. The PAA nickname will facilitate audits, as well as the REB and yourself, by being able to view the nickname in the list of PAAs under the "Post Approval Activities (PAAs)" tab of a study. This will help to readily locate an item without needing to open each PAA to see what it contains.

The REB may return a PAA submission to you if an appropriate nickname is not provided.

The system will automatically identify whether it is an Amendment or Annual renewal or Request for Acknowledgment so you do not have to state this. The nickname should just identify what is in the Amendment or Request for Acknowledgment and differentiate between similar types. It is particularly important if you are reporting a protocol deviation, unanticipated event, or an updated Investigator Brochure, to identify this within the PAA nickname. see examples below.

Examples:

Protocol Deviation #1 – Drug Dosage Missed
Protocol Deviation #2 – Drug Dosage Decrease & Safety Letter Jan 1, 2009
IB Version #4 dated October 2009
IB Version #5 dated November 2010
Protocol Amendment #4 and Revised Consent
Protocol Amendment #5, Revised Consent and IB Version #6
Change of PI and Primary Contact
Six Monthly Safety Report

Screen Shot of opening page of the Post Approval Activity:

Post Approval Activities																	
*Select one of the following options to submit to the Research Ethics Board based on the guidelines listed on the right:																	
<table border="1"><thead><tr><th></th><th>Options</th></tr></thead><tbody><tr><td><input type="checkbox"/></td><td>Annual Renewal</td></tr><tr><td><input type="checkbox"/></td><td>Annual Renewal with Amendments to the Study (UBC BREB and UBC CREB studies only) <i>(The BCCA REB does not have this option)</i></td></tr><tr><td><input type="checkbox"/></td><td>Amendments to Study</td></tr><tr><td><input type="checkbox"/></td><td>Completion of Clinical Study</td></tr><tr><td><input type="checkbox"/></td><td>Completion of Behavioural Study</td></tr><tr><td><input type="checkbox"/></td><td>Request for Acknowledgement</td></tr><tr><td><input type="checkbox"/></td><td>Response to Request for Information (RFI)</td></tr></tbody></table>		Options	<input type="checkbox"/>	Annual Renewal	<input type="checkbox"/>	Annual Renewal with Amendments to the Study (UBC BREB and UBC CREB studies only) <i>(The BCCA REB does not have this option)</i>	<input type="checkbox"/>	Amendments to Study	<input type="checkbox"/>	Completion of Clinical Study	<input type="checkbox"/>	Completion of Behavioural Study	<input type="checkbox"/>	Request for Acknowledgement	<input type="checkbox"/>	Response to Request for Information (RFI)	<ul style="list-style-type: none">• Annual Renewals For Clinical studies click here for information on annual renewals. 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, safety letters, studies on hold, off hold, closed to accrual/enrollment, or miscellaneous information (PI, Sponsor or REB requires acknowledgement). Any other changes to an ongoing study must be submitted through an amendment.
	Options																
<input type="checkbox"/>	Annual Renewal																
<input type="checkbox"/>	Annual Renewal with Amendments to the Study (UBC BREB and UBC CREB studies only) <i>(The BCCA REB does not have this option)</i>																
<input type="checkbox"/>	Amendments to Study																
<input type="checkbox"/>	Completion of Clinical Study																
<input type="checkbox"/>	Completion of Behavioural Study																
<input type="checkbox"/>	Request for Acknowledgement																
<input type="checkbox"/>	Response to Request for Information (RFI)																
Nickname Enter a nickname for this PAA. What would you like this PAA to be known as to the Principal Investigator and study team? <i>(If you are notifying the REB of a protocol deviation or an unanticipated event, please include the words "protocol deviation" or "unanticipated event" as applicable in the nickname)</i>																	
<input type="text"/>	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.																

Continue to PAA Coversheet.