



a place of mind

THE UNIVERSITY OF BRITISH COLUMBIA

# **How to Submit a Human Post-Approval Activity (PAA) – Renewals, Acknowledgements, and Completions**



Help

My Home for Prinz Apple

PI and Staff

My Roles

PI & Staff

I would like to create a new application for ...

- Conflict of Interest
- Human Ethics
- Animal Care
- Biosafety

I would like to ...

Send Feedback

Committees

Name

- Animal Care Committee
- BC Cancer Agency Research Ethics Board
- Biosafety Committee
- Children's and Women's Research Ethics Board
- Clinical Research Ethics Board
- Conflict of Interest Committee
- Providence Health Care Research Ethics Board
- UBC Behavioural Research Ethics Board
- UBC Okanagan Behavioural Research Ethics Board

## My Home for Prinz Apple

Welcome to your personal RISE Home Page.

To view your ethics studies or declarations select the applicable grey tab below (Animal Care, Human Ethics, Conflict of Interest). Click [here](#) for FAQs.

- My Inbox
- Conflict of Interest
- Human Ethics**
- Animal Care
- Biosafety
- Inactive
- Reports/Tutorials

Your 'Inbox' is a folder for receiving items that require your attention. Once each item is addressed, it will leave your 'Inbox' and be filed under one of the other applicable tabs. Click on the name of the study to see details of the application or Post Approval Activity (PAA).

Click on the Human Ethics tab to view all your Human Ethics applications.

### New Applications

ID	Name	Type	Owner	State	Last State Change
C13-00004-R004	COI / COC Declaration	COI	Apple, Prinz	Pre Submission	10/24/2013 4:18 PM
H13-00098	mnhJKHOHL	Human Ethics	Apple, Prinz	Pre Submission	10/23/2013 3:27 PM
H13-00097	Clinical Test October 8, 2013	Human Ethics	Apple, Prinz	Pre Submission	10/10/2013 11:02 AM
B13-0004	test	Biosafety	Apple, Prinz	Pre Submission	10/3/2013 12:03 PM
H13-00096	RISe Tutorial	Human Ethics	Apple, Prinz	Pre Submission	9/27/2013 4:28 PM
H13-00095	holita	Human Ethics	Smith, Jane K.	Pre Submission	9/19/2013 4:33 PM
H13-00094	x	Human Ethics	Apple, Prinz	Pre Submission	9/3/2013 2:43 PM
H13-00093	x	Human Ethics	Apple, Prinz	Pre Submission	9/3/2013 2:41 PM
H13-00092	Fibrosis	Human Ethics	Apple, Prinz	Pre Submission	9/3/2013 11:16 AM
H13-00091	abcd	Human Ethics	Apple, Prinz	Pre Submission	9/3/2013 11:16 AM

### Post Approval Activities (In Progress)

ID	Name	Type	Owner	State	Last State Change	PAA Type
H12-00050-A001	Additional activities	Human-Post Approval Activities	Apple, Prinz	Pre Submission	3/20/2013 12:02 PM	Annual Renewal with Amendments
H11-00001-A006	Snezana - test	Human-Post Approval Activities	Apple, Prinz	Pre Submission	1/16/2013 2:23 PM	Amendments to Study



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This folder contains all of your Human Ethics applications as well as Post Approval Activities (i.e. amendments, renewals, requests for acknowledgements) that are approved or pending review. Click on the name of the study to go to the details of the study or on Post Approval Activity (PAA). Click [here](#) for FAQs on Human Ethics.

Click on the Name of the study for which you would like to submit a PAA.

### Human Ethics Applications

ID	Name	Owner	State	Last State Change	Minimal Risk	Expiration Date
H13-00097	Clinical Test October 8, 2013	Apple, Prinz	Approved	10/30/2013 9:36 AM	yes	
H13-00098	mnhJKHOHL	Apple, Prinz	Pre Submission	10/23/2013 3:27 PM		
H13-00086	Test September 3, 2013	Apple, Prinz	Department Review	10/4/2013 3:45 PM	yes	
H13-00089	Test - September 3, 2013	Apple, Prinz	Department Review	10/4/2013 11:35 AM	yes	
H13-00096	RISe Tutorial	Apple, Prinz	Pre Submission	9/27/2013 4:28 PM	no	
H13-00095	holita	Smith, Jane K.	Pre Submission	9/19/2013 4:33 PM	yes	
H13-00094	x	Apple, Prinz	Pre Submission	9/3/2013 2:43 PM	yes	
H13-00093	x	Apple, Prinz	Pre Submission	9/3/2013 2:41 PM		
H13-00087	Test - September 3, 2013	Apple, Prinz	Department Review	9/3/2013 11:59 AM	yes	
H13-00088	heart study	Apple, Prinz	Department Review	9/3/2013 11:58 AM	yes	

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### Post Approval Activities (In Progress)

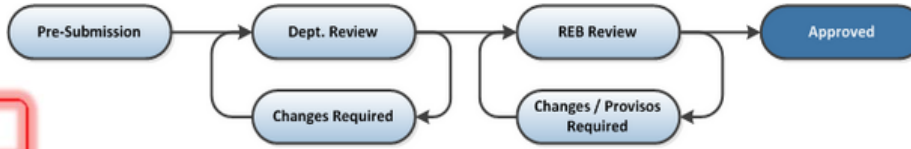
ID	Name	Owner	State	Last State Change	Option	Minimal Risk
H12-00011-A002	Test	Apple, Prinz	REBA Screening	7/24/2013 9:58 AM	Amendments to Study	no
H12-00050-A001	Additional activities	Apple, Prinz	Pre Submission	3/20/2013 12:02 PM	Annual Renewal with Amendments	yes
H11-00001-A006	Snezana - test	Apple, Prinz	Pre Submission	1/16/2013 2:23 PM	Amendments to Study	no
H11-00001-A003	test	Apple, Prinz	REBA Screening	3/6/2012 3:58 PM	Annual Renewal	yes

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Current State

Approved



Create:

**PAA** New Post Approval Activity

Activities

- PI&S PI and Staff Comments
- PI Designate Signing Authority
- PI Change Primary Contact
- PI&S Copy Application

Viewing/Printing

- Application - Full
- Application - Review/Print

Return to My Home

(H12-00004) Massive Transfusion in Liver Transplantation

Principal Investigator:	Jane K. Smith	Approval Department:	Medicine, Department of
Primary Contact:	Jane K. Smith	Department Approver:	Department Head
Type of Study:	Clinical	Review Board:	Clinical Research Ethics Board
Minimal Risk:	Yes	Co-Investigators with Signing Authority:	There are no items to display
Initial Approved Date:	29 September 2014	Date Expires:	29 September 2015
Current Approval Certificate:	<a href="#">View</a>	Version:	1 . 0
Type of Funding:	Grant	US Affiliated Study:	No
Flag:	N/A		
CM Conflicts:	Prinz Apple		

Click to create a new PAA.

Correspondence Provisos Post Approval Activities Application Changes

Filter by	Activity	Author	Activity Date
REBA	Approved	Administrator, REB	29/09/2014 16:08
	<a href="#">See Approval Certificate</a>		
	<a href="#">Approval Comments</a>		
Dept	Approved by Department	Head, Department	29/09/2014 16:06
	<a href="#">go Dr. Apple</a>		
PI	Submitted Application	Apple, Prinz	29/09/2014 16:04



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Save | | Print...

Continue >>

Choose the appropriate activity from the list.

### Post Approval Activities

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

Options

- Annual Renewal
- Annual Renewal with Amendments to the Study (UBC BREB, UBC CREB and C&W REB studies only)
- Amendments to Study
- Completion of Clinical Study
- Completion of Behavioural Study
- Request for Acknowledgement
- Response to Request for Information (RFI)

[Clear](#)

\*

#### 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)

Clinical Test PAA Renewal

Enter a nickname for the PAA.

- 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

Click "Continue" when done.

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Save | | Print...

Continue >>



<< Back

Complete all applicable questions and summarize the year's progress.  
Click "Continue" when done.

Continue >>

### Clinical Annual Renewal Coversheet

#### \* 1. Reason

1.1. Why is this renewal being requested, e.g. still recruiting or data collection is ongoing etc.? (Note that unless required by the study sponsor, studies that no longer require interaction with participants or access to their data generally no longer need research ethics approval. See guidance on the right.)

1.2. If this research has not started please explain why and indicate your plan for moving forward. If the study is on hold, please explain and indicate the anticipated start date.

Click [here](#) for more information pertaining to when a study qualifies for closure. Study closures must be submitted as a Post Approval Activity (PAA) on RISE.

If study start date is changing, please revise the initial application accordingly.

#### \* 2. Level of Review

Does this Annual Renewal qualify for Minimal Risk/Delegated Review criteria.

Yes  No [Clear](#)

Refer to the guidance notes in the boxes to the right for detailed explanations of the questions, instructions on how to fill out the form and useful links to documents.

All studies qualify for delegated review at annual renewal **UNLESS** they are required to comply with U.S. regulations (see below) or full board review is required by the sponsor, or the REB Chair or delegate has requested renewals be reviewed at the full board.

**Studies that must comply with U.S. regulations** must be submitted for full board review unless they meet the following criteria for minimal risk/delegated review:

- The research is (i) permanently closed to the enrollment of new participants; and (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow up of participants; **OR**
- Where no participants have been enrolled and no additional risks have been identified; **OR**
- Where the remaining research activities are limited to only the analysis of already collected data.

For Full Guidelines click [here](#).

#### \* 3. Participant Recruitment

3.1. Does this study involve direct interaction with human participants? (If no, skip to question 4, **Participant Data: Chart Review and Sample Collection**. If yes, you must answer all of the questions in this section.)

Yes  No [Clear](#)

#### 3.5. WITHDRAWALS

Reference: ICH-GCP (E6) Guidance 4.3.4 states: Although a participant is not obliged to give his/her reason(s) for withdrawing prematurely from a trial, the investigator should make a reasonable effort to ascertain the reason(s), while fully respecting the participant's rights.



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Save | Exit | Hide/Show Errors | Print... | Jump To: End of PAA Coversheet - PAA ▾

Continue >>

**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.*

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: End of PAA Coversheet - PAA ▾

Continue >>

**Click "Continue" to save and close the PAA Coversheet. You will automatically be taken to the PAA Homepage.**



A PAA number is appended to the original Study ID number.

Current State

Pre Submission

Edit PAA Coversheet

Activities

- SUBMIT PAA
- Permanently Inactivate
- PI and Staff Comments

Viewing/Printing

- Application - Full
- Application - Review/Print
- PAA Coversheet - Review/Print
- Study Homepage

PAA(H12-00004-A004) Clinical Test PAA Renewal

Principal Investigator:	Apple, Prinz	Primary Contact:	Smith, Jane K.
Type of Study:		Primary Contact:	Clinical Research Ethics Board
Meeting Type:		Meeting Date:	
Activity Type:	Annual Renewal	PAA Approval Certificate:	
Study State:	Approved	Study Expiry Date:	29 September 2015
Type of Funding:	Grant	US Affiliated Study:	No
Flag:	N/A		
CM Conflicts:	Prinz Apple		

To track the status of your PAA through the approval process, refer to the "Current State" box.

As the state of your PAA is "Pre Submission", your PAA Coversheet is still open for any edits you may want to make.

Correspondence  
This contains all the correspondence and activities completed on the PAA before approval. The title bar shows each activity that was completed, who completed it, and the date and time it was completed.

Filter by Activity [dropdown] [Go] [Clear] [Advanced]

No data to display.





Current State

Pre Submission

Edit PAA Coversheet

Activities

PI SUBMIT PAA

PI Permanently Inactivate

PI&S PI and Staff Comments

Viewing/Printing

Application - Full

Application - Review/Print

PAA Coversheet - Review/Print

Study Homepage

**PAA(H12-00004-A004) Clinical Test PAA Renewal**

<b>Principal Investigator:</b>	Apple , Prinz	<b>Primary Contact:</b>	Smith , Jane K.
<b>Type of Study:</b>	Clinical	<b>Review Board:</b>	Clinical Research Ethics Board
<b>Meeting Type:</b>		<b>Meeting Date:</b>	
<b>Activity Type:</b>	Annual Renewal	<b>PAA Approval Certificate:</b>	
<b>Study State:</b>	Approved	<b>Study Expiry Date:</b>	29 September 2015
<b>Type of Funding:</b>	Grant	<b>US Affiliated Study:</b>	No
<b>Flag:</b>	No		
<b>CM Conflicts:</b>	Prinz Apple		

Click to submit your PAA for review. Only the PI has the "Submit PAA" activity.

Correspondence

Provisos

This contains all the correspondence and activities completed on the PAA before approval. The title bar shows each activity that was completed, who completed it, and the date and time it was completed.

Filter by Activity [dropdown] [Go] [Clear] [Advanced]

No data to display.



Current State

Pre Submission

Edit PAA Coversheet

Activities

SUBMIT PAA

Permanently Inactivate

PI and Staff Comments

Viewing/Printing

Application - Full

Application - Review/Print

PAA Coversheet - Review/Print

Study Homepage

PAA(H12-00004-A004) Clinical Test PAA Renewal

Principal Investigator:

Apple, Prinz

Primary Contact:

Smith, Jane K.

Type of Study:

Meeting Type:

Activity Type:

Study State:

Type of Funding:

Flag:

CM Conflicts:

Correspondence

Provisos

This contains all the correspondence it was completed.

Filter by Activity

Execute "Submit PAA" on H12-00004-A004 - Mozilla Firefox

sandbox.rise.ubc.ca/sandbox/ResourceAdministration/Activity/form?ActivityType=com.webridge.entity.Entity[OID[99829148D47]

Submit PAA

Declaration:

**I agree to abide by the Tri-Council Policy for Ethical Conduct for Research Involving Human Subjects.**

Agreeing to the declaration above by clicking "OK" to submit is equivalent to your signature.

Click "OK" to submit the post approval activity to the Research Ethics Board for review. If you are not ready for submission, click "Cancel".

Click "OK" to send your PAA for review.

OK Cancel



Current State

REBA Screening

Activities

PI Permanently Inactivate

PI&S PI and Staff Comments

Viewing/Printing

- Application - Full
- Application - Review/Print
- PAA Coversheet - Full
- PAA Coversheet - Review/Print
- Study Homepage

**PAA (H12-00004-A004) Clinical Test PAA Renewal**

<b>Principal Investigator:</b>	Apple, Prinz	<b>Primary Contact:</b>	Smith, Jane K.
<b>Type of Study:</b>	Clinical	<b>Review Board:</b>	Clinical Research Ethics Board
<b>Meeting Type:</b>		<b>Meeting Date:</b>	
<b>Activity Type:</b>	Annual Renewal	<b>PAA Approval Certificate:</b>	
<b>Study State:</b>	Approved	<b>Study Expiry Date:</b>	29 September 2015
<b>Type of PAA:</b>		<b>Flag:</b>	No
<b>CM Conflicts:</b>	Prinz Apple		

**Your Annual Renewal PAA has been submitted to the REB, and will be screened by the REB Admin (REBA) prior to forwarding for REB review.**

Correspondence

Provisos

This contains all the correspondence and activities completed on the PAA before approval. The title bar shows each activity that was completed, who completed it, and the date and time it was completed.

Filter by	Activity	Author	Activity Date
PI	Submitted Post Approval Activity	Apple, Prinz	18/12/2015 15:29