How to Submit a Human Post-Approval Activity (PAA) - Amendment

Prinz Apple | My Home | Logoff

Help

Page for Prinz Apple

My Roles

PI & Staff

Create:

🔵 Human Ethics

🐇 Animal Care

☣ Biosafety

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

Page for Prinz Apple

⚠ Open notifications

Welcome to your personal RISe Home Page.

Show/Hide Help

For help getting started, click on the links below to find answers to some frequently asked questions. To view your studies or declarations select the applicable tab below (Animal Care, Human Ethics, Conflict of Interest).

- To create a new application, click the appropriate button (Animal Care, Human Ethics or Conflict of Interest) from under the "I would like to create an application for...." heading on the left side of the screen.
- How do I create an amendment? (select Animal Care, Human Ethics)
- How do I create a renewal? (select Animal Care, Human Ethics)
- What do the different application states mean? (select Animal Care, Human Ethics, Conflict of Interest)
- How do I complete changes or provisos that have been requested? (select here)
- How do I update my personal profile? (select here)
  For more FAQs on Animal Care, Human ethics or Conflict of Interest select the applicable tab below.

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.

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

| 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).

New Applications

Filter by ❓ [ID ▾] [   ] [Go] [Clear] Advanced

	ID	Name	Type	Owner	State	▣ Last State Change
🔵	H15-00042	Clinical Study - December 18, 2015	Human Ethics	Apple, Prinz	Changes Required by REBA	08/01/2016 10:36
🔵	H16-00001	Abide	Human Ethics	Smith, Jane K.	Pre Submission	04/01/2016 11:36
🔵	H15-00039	nickname	Human Ethics	Apple, Prinz	Pre Submission	28/10/2015 10:52
🔵	H15-00038	v	Human Ethics	Apple, Prinz	Pre Submission	20/10/2015 14:05
🔵	H15-00020	552 Class Project	Human Ethics	Apple, Prinz	Pre Submission	22/09/2015 14:15
🔵	H15-00018	Group 4 Research Topic	Human Ethics	Apple, Prinz	Pre Submission	14/09/2015 11:57
🔵	H15-00017	_Human - Thu Aug 13 16:42:02 PDT 2015	Human Ethics	Apple, Prinz	Pre Submission	13/08/2015 16:42
🐇	A15-0002	SS	Animal Care	Apple, Prinz	Pre Submission	21/07/2015 13:06
🔵	H15-00016	clinical chart	Human Ethics	Apple, Prinz	Pre Submission	26/06/2015 11:41
🔵	H15-00015	New Title	Human Ethics	Apple, Prinz	Pre Submission	19/06/2015 13:13

PI and Staff

My Roles

PI & Staff

Create:

- Human Ethics
- Animal Care
- Biosafety

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

Page for Prinz Apple

⚠ Open notifications

Welcome to your personal RISe Home Page.

Show/Hide Help

For help getting started, click on the links below to find answers to some frequently asked questions. To view your studies or declarations select the applicable tab below (Animal Care, Human Ethics, Conflict of Interest).

- To create a new application, click the appropriate button (Animal Care, Human Ethics or Conflict of Interest) from under the "I would like to create an application for...." heading on the left side of the screen.
- How do I create an amendment? (select Animal Care, Human Ethics)
- How do I create a renewal? (select Animal Care, Human Ethics)
- What do the different application states mean? (select Animal Care, Human Ethics)
- How do I complete changes or provisos that have been requested? (select here)
- How do I update my personal profile? (select here)

For more FAQs on Animal Care, Human ethics or Conflict of Interest select the applicable tab below.

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.

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

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

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 see the details of the application or Post Approval Activity (PAA). Visit http://rise.ubc.ca/helpCenter /GN/RISe_FAQs.htm#Applications_Human for FAQs on Human Ethics.

Human Ethics Applications

Filter by ⓘ [ID ▼] [   ] [Go] [Clear] Advanced

ID	Name	Owner	State	☑ Last State Change	Minimal Risk	Expiration Date
H15-00042	Clinical Study - December 18, 2015	Apple, Prinz	Approved	08/01/2016 10:36	no	
H15-00041	Clinical Study - Dec. 2015	Apple, Prinz	REBA Screening	05/01/2016 16:12	no	
H16-00001	Abide	Smith, Jane K.	Pre Submission	04/01/2016 11:36	yes	
H15-00040	Copy of -- test	Apple, Prinz	Department Review	16/12/2015 15:37	yes	
H15-00032	study	Apple, Prinz	Department Review	04/11/2015 10:49	yes	
H15-00039	nickname	Apple, Prinz	Pre Submission	28/10/2015 10:52	yes	
H15-00029	text	Apple, Prinz	Department Review	20/10/2015 14:20	yes	
H15-00027	test	Apple, Prinz	Department Review	20/10/2015 14:19	yes	
H15-00028	Study	Apple, Prinz	Department Review	20/10/2015 14:18	yes	
H15-00030	test	Apple, Prinz	Department Review	20/10/2015 14:18	yes	

The University of British Columbia
a place of mind

UBC

Prinz Apple | My Home | Logoff

Help

Current State
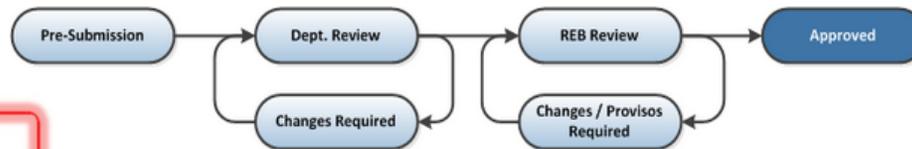
Approved

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

Pre-Submission → Dept. Review → REB Review → Approved

Changes Required

Changes / Provisos Required

Click to create a new PAA.

(H15-00042) Clinical Study - December 18, 2015

Principal		Approval Department:	Medicine, Department of
Primary		Department Approver:	Department Head
Type of Study:	Clinical	Review Board:	Clinical Research Ethics Board
Minimal Risk:	No	Co-Investigators with Signing Authority:	There are no items to display
Initial Approved Date:		Date Expires:	
Current Approval Certificate:		Version:	0 . 3
Type of Funding:	No Funding	US Affiliated Study:	No
Flag:	N/A		

| **Correspondence** | Provisos | Post Approval Activities | Application Changes |

Filter by Activity ▾ [   ] Go Clear Advanced

	Activity	Author	▼ Activity Date
REBA	Changes Required by REBA	Administrator, REB	08/01/2016 10:36
	✏ Changes are required		
Dept	Approved by Department	Head, Department	06/01/2016 09:40
	✏ Good job!		
PI&S	Submitted Changes to Department Approver	Apple, Prinz	06/01/2016 09:38
	✏ all done!		
Dept	Changes Required by Department	Head, Department	06/01/2016 09:36
	✏ Change it!		
PI	Submitted Application	Apple, Prinz	06/01/2016 09:33

<< Back   Save | | Print...   Continue >>

Post Approval Activities

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

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
○ Request for Acknowledgement
Clear

Choose "Amendments to Study" from the list.

Click "Continue" when done.

* **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 Amendment

Enter a nickname for the PAA.

Copyright © 2012 The University of British Columbia

<< Back   Save | | Print...   Continue >>

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

<< Back   Continue >>

Clinical Amendment Coversheet

Provide a summary of the changes to the Study (Application):

1) Complete this coversheet.
In the sections below provide information about this amendment for which you are requesting approval. This coversheet is to provide an overview of the amendment. The changes must be described in this coversheet and the changes must then be entered into the appropriate sections of the application.
2) Edit the application. If this is not done, the amendment will be returned as incomplete. (For example, if submitting an amended protocol, identify the document below and describe the changes, once you have completed the coversheet then edit the applicable sections of the application form.) This is to ensure that once approved, the application form will contain the current information for your study.
3) Submit the Amendment. When the above steps are completed the PI or one of the designated Co-investigators with Signing Authority must then submit the amendment. For **instructions on how to designate a Co-Investigator with signing authority** select here.

---

* 1.1 Proposed changes to study   Guidance Notes »

1.1. *Briefly describe the nature of the proposed change(s).*

* 1.2. *Please explain the reason for the proposed change(s).*

Briefly summarize (please do NOT cut and paste from the protocol).

1.1: Explain *'what'* the change(s) are, using the following categories:

a) Participant safety: changes to known risks, eligibility criteria, treatment, procedures, data monitoring etc. that affect participant safety.

b) Scientific Interpretability: changes to study objectives, endpoints, sample size, planned statistical analysis or interim analysis that affect the study design or scientific interpretability.

c) Administrative changes: changes in study personnel, project title, sponsor, start or end dates, specimen handling, or any other similar changes that do not affect safety or scientific interpretability.

1.2: Explain *'why'* each change was made. (For example, the previous PI has left the institution; interim data has resulted in a need to change the study objectives, etc.)

Ensure that the changes in the documents are identifiable by either using highlights or track changes.

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.

---

* 2. Changes in Principal Investigator   Guidance Notes »

Will the Principal Investigator (PI) be changed on the study?

○ Yes   ○ No   Clear

If "Yes", you must select here and complete the form with signatures then add the form below by clicking "Add".

Select "Add" to attach the signed letter for changing the Principal Investigator.

Add

Do not change the submitting PI's name on this application or you will not be able to continue to submit the application (the REB will do this when they approve this amendment). However, if the submitting PI will continue to require online access to this study, you must add them to the list of co-investigators in View 1.3 of the application.

Ensure that any study materials (e.g. consent or assent forms) are revised to reflect the new Principal Investigator. Attach the revised study documents to View 9 of the application and delete only the documents that are being replaced.

An updated Certificate of Approval will be issued to the newly designated Principal Investigator only.

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

1) Click "Continue" to enter the amendment changes in the application (this must be completed before the PAA can be submitted by the PI).

If this is not the initial completion of the coversheet, you will be taken directly to the PAA home page where you can edit the application or coversheet.

2) Submit the PAA for review.

When the application amendments have been completed, click "Save" then "Exit". 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.

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.

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

1. PRINCIPAL INVESTIGATOR & STUDY TEAM - HUMAN ETHICS APPLICATION

* 1.1. Principal Investigator

Please select the Principal Investigator (PI) for the study. Once you hit "Select", you can enter the PI's name, or enter the first few letters of his or her name and hit "Go". You can sort the returned list alphabetically by First name, Last name, or Organization by clicking the appropriate heading.

Prinz Apple   Select...   Clear

Primary Appointment: UBC (UBC)
Rank: Visiting Dignitary
Email: na

Enter Principal Investigator Primary Department and also the primary location of the PI's Institution:

GUIDANCE NOTES
A Principal Investigator (PI) either has a faculty appointment (Clinical Assistant Professor, Clinical Associate Professor, Clinical Professor, Assistant Professor, Associate Professor, Professor or BCCA Investigator) OR is deemed a PI by an affiliated institution or by a Dean.

The PI bears the overall responsibility for the conduct of the study and is required to act within the guidelines of the TCPS2.

Instructors who are applying for research ethics approval for class-based projects in courses they are teaching can be listed as a PI on their application. Please contact the REB manager if you are submitting a class project and require the capacity to list yourself as a PI on the application.

If you cannot find the PI's name in the list, have it added into the RISe system by emailing the following information to RISe Support: Full Name (Including Middle Initial), Department (or affiliation with the University), UBC Rank, Email Address, Phone Number and UBC employee number (if applicable). Once an account is created, new users will receive their researcher number via email.

1.2. Primary Contact

Provide the name of ONE primary contact person in addition to the PI who will receive ALL correspondence, certificates of approval and notifications from the REB for this study. This primary contact will have online access to read, amend, and track the application.

Prinz Apple   Select...   Clear

Primary Appointment: UBC (UBC)
Rank: Visiting Dignitary
Email: na

Selecting a primary contact is optional. If a primary contact is not selected, the PI will be the only person to receive all correspondence from the Research Ethics Board Administration (REBA). Graduate students preparing ethics applications for their dissertation projects should list themselves as the primary contact. The Primary Contact may also be listed in one of the categories below. Note that the PI may change the Primary Contact anytime without an amendment.

Study Team Members

Complete sections 1.3, 1.4 and 1.5 below to add Co-Investigators and additional study team members and to designate the type of online access you would like them to have.

To add Co-Investigators and additional study team members in questions 1.3 and 1.4:

1. Click "Add".
2. Enter the name, or enter the first few letters of the person's name and click "Go".
3. You can sort the returned list alphabetically by First name, Last name, or Organization by clicking the appropriate heading.

Please make sure you have added yourself as either the Principal Investigator, primary contact, co-investigator, or a study team member with online access in order to continue with the application.

If you cannot find your name or any of your study team members' names in the list, have them added or inform them to add themselves by emailing the following information to RISe Support(risesupport@ors.ubc.ca): Full Name (Including Middle Initial), Department (or affiliation with the University), UBC Rank, Email Address, Phone Number and UBC employee number (if

Page 1 of the Application

<< Back | Save | Exit | Hide/Show Errors | Print... | Jump To: | 1. Principal Investigator & Study Team - Human Ethics Application ▾ | Continue >>

Click "Save" between pages and before you "Exit" the application.

Use the Jump to: tool to navigate the pages of the application.

1. Principal Investigator & Study Team - Human Ethics Application
2. Study Dates and Funding Information - Human Ethics Application
3. Study Team - Human Ethics Application
4. Clinical Study Review Type
5. Summary of Study and Recruitment - Human Ethics Application for Clinical Study
6. Participant Information and Consent Process - Human Ethics Application for Clinical Study
7. Number of Participants and Drugs - Human Ethics Application For Clinical Study
8. Data Monitoring- Human Ethics Application For Clinical Study
9. Documentation - Human Ethics Application for Clinical Study
10. Fee for Service - Human Ethics Application for Clinical Study
12. Save Application - Human Ethics Application

1. PRINCIP

* 1.1. Principal I

Please select the Principal Investigator (PI) fo letters of his or her name and hit "Go". You clicking the appropriate heading.

Prinz Apple | Select... | Clear

Primary Appointment: UBC (UBC)
Rank: Visiting Dignitary
Email: na

Enter Principal Investigator Primary Departme

either has a faculty appointment r, Clinical Associate Professor, Clinical sor, Associate Professor, Professor or eemed a PI by an affiliated institution or

sponsibility for the conduct of the study n the guidelines of the TCPS2.

ng for research ethics approval for class-hey are teaching can be listed as a PI e contact the REB manager if you are and require the capacity to list yourself

name in the list, have it added into the e following information to RISe Support: e Initial), Department (or affiliation with Email Address, Phone Number and UBC able). Once an account is created, new users will receive their researcher number via email.

1.2. Primary Contact

Provide the name of ONE primary contact person in addition to the PI who will receive ALL correspondence, certificates of approval and notifications from the REB for this study. This primary contact will have online access to read, amend, and track the application.

Prinz Apple | Select... | Clear

Primary Appointment: UBC (UBC)
Rank: Visiting Dignitary
Email: na

Selecting a primary contact is optional. If a primary contact is not selected, the PI will be the only person to receive all correspondence from the Research Ethics Board Administration (REBA). Graduate students preparing ethics applications for their dissertation projects should list themselves as the primary contact. The Primary Contact may also be listed in one of the categories below. Note that the PI may change the Primary Contact anytime without an amendment.

Study Team Members

Complete sections 1.3, 1.4 and 1.5 below to add Co-Investigators and additional study team members and to designate the type of online access you would like them to have.

To add Co-Investigators and additional study team members in questions 1.3 and 1.4:

1. Click "Add".
2. Enter the name, or enter the first few letters of the person's name and click "Go".
3. You can sort the returned list alphabetically by First name, Last name, or Organization by clicking the appropriate heading.

Please make sure you have added yourself as either the Principal Investigator, primary contact, co-investigator, or a study team member with online access in order to continue with the application.

If you cannot find your name or any of your study members' names in the list, have them added or inform them to add themselves by emailing the following information to RISe Support(risesupport@ors.ubc.ca): Full Name (Including Middle Initial), Department (or affiliation with the University), UBC Rank, Email Address, Phone Number and UBC employee number (if

PAA Homepage

Help

... > ... > Kyle Woo - SFU Test > Clinical Trial PAA Amendment

Current State

| Pre Submission |

Edit PAA Coversheet

Edit Application

Activities

| PI | SUBMIT PAA |

| PI | Permanently Inactivate |

| PI&S | PI and Staff Comments |

Viewing/Printing

Application - Review/Print

PAA Coversheet - Review/Print

Application Changes

Study Homepage

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

🌐 **PAA** **(H14-00043-A003)** Clinical Trial PAA Amendment

Principal Investigator:	Apple , Prinz	**Primary Contact:**	Apple , Prinz
Type of Study:	Clinical	Review Board:	Clinical Research Ethics Board
Meeting Type:		Meeting Date:	
Activity Type:	Amendments to study	PAA Approval Certificate:	
Study State:	Approved	**Study Expiry Date:**	15 September 2016
Type of Funding:	No Funding	**US Affiliated Study:**	No
Flag:	N/A		

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** | 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 ▾ | [   ] | Go | Clear | Advanced

No data to display.

Clinical Amendment Coversheet

Edit the Amendment Coversheet and click "Continue" when done.

Provide a summary of the changes to the Study (Application):

1) Complete this coversheet.
In the sections below provide information about this amendment for which you are requesting approval. This coversheet is to provide an overview of the amendment. The changes must be described in this coversheet and the changes must then be entered into the appropriate sections of the application.
2) Edit the application. If this is not done, the amendment will be returned as incomplete. (For example, if submitting an amended protocol, identify the document below and describe the changes, once you have completed the coversheet then edit the applicable sections of the application form.) This is to ensure that once approved, the application form will contain the current information for your study.
3) Submit the Amendment. When the above steps are completed the PI or one of the designated Co-investigators with Signing Authority must then submit the amendment. For **instructions on how to designate a Co-Investigator with signing authority** select here.

---

* 1.1 Proposed changes to study

1.1. *Briefly describe the nature of the proposed change(s).*

Description of nature of proposed changes

* 1.2. *Please explain the reason for the proposed change(s).*

Description of reason for proposed changes

Briefly summarize (please do NOT cut and paste from the protocol).

1.1: Explain *'what'* the change(s) are, using the following categories:

a) Participant safety: changes to known risks, eligibility criteria, treatment, procedures, data monitoring etc. that affect participant safety.

b) Scientific Interpretability: changes to study objectives, endpoints, sample size, planned statistical analysis or interim analysis that affect the study design or scientific interpretability.

c) Administrative changes: changes in study personnel, project title, sponsor, start or end dates, specimen handling, or any other similar changes that do not affect safety or scientific interpretability.

1.2: Explain *'why'* each change was made. (For example, the previous PI has left the institution; interim data has resulted in a need to change the study objectives, etc.)

Ensure that the changes in the documents are identifiable by either using highlights or track changes.

---

* 2. Changes in Principal Investigator

Will the Principal Investigator (PI) be changed on the study?

○ Yes ⦿ No Clear

If "Yes", you must select here and complete the form with signatures then add the form below by clicking "Add".

Select "Add" to attach the signed letter for changing the Principal Investigator.

[Add]

Do not change the submitting PI's name on this application or you will not be able to continue to submit the application (the REB will do this when they approve this amendment). However, if the submitting PI will continue to require online access to this study, you must add them to the list of co-investigators in View 1.3 of the application.

Ensure that any study materials (e.g. consent or assent forms) are revised to reflect the new Principal Investigator. Attach the revised study documents to View 9 of the application and delete only the documents that are being replaced.

An updated Certificate of Approval will be issued to the newly designated Principal Investigator only.

Current State

Pre Submission

Edit PAA Coversheet

Edit Application

Activities

PI SUBMIT PAA

PI Permanently Inactivate

PI&S PI and Staff Comments

Viewing/Printing

Application - Review/Print

PAA Coversheet - Review/Print

Application Changes

Study Homepage

PAA(H14-00043-A003) Clinical Trial PAA Amendment

Principal Investigator:	Apple , Prinz	**Primary Contact:**	Apple , Prinz
Type of Study:	Clinical	**Review Board:**	Clinical Research Ethics Board
Meeting Type:		**Meeting Date:**	
Activity Type:	Amendments to Study	**PAA Approval Certificate:**	
Study State:	Approved	**Study Expiry Date:**	15 September 2016
Type of Funding:	No Funding	**US Affiliated Study:**	No
Flag:	N/A		

Click to continue making amendments to your study / application.

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 ▼] [   ] [Go] [Clear] Advanced

No data to display.

<< Back | Save | Exit | Hide/Show Errors | Print... | Jump To: 1. Principal Investigator & Study Team - Human Ethics Application ▾ | Continue >>

"Save" and "Exit" once changes are complete.

Use the Jump to: tool to navigate and make any additional amendments to the application.

1. Principal Investigator & Study Team - Human Ethics Application
2. Study Dates and Funding Information - Human Ethics Application
3. ~~Human Ethics Application~~
~~Review Type~~
5. Summary of Study and Recruitment - Human Ethics Application for Clinical Study
6. Participant Information and Consent Process - Human Ethics Application for Clinical Study
7. Number of Participants and Drugs - Human Ethics Application For Clinical Study
8. Data Monitoring- Human Ethics Application For Clinical Study
9. Documentation - Human Ethics Application for Clinical Study
10. Fee for Service - Human Ethics Application for Clinical Study
12. Save Application - Human Ethics Application

1. PRINCIPAL INV

* 1.1. Principal Investigator

Please select the Principal Investigator (PI) for
letters of his or her name and hit "Go". You
clicking the appropriate heading.

Prinz Apple [Select...] [Clear]

Primary Appointment: UBC (UBC)
Rank: Visiting Dignitary
Email: na

Enter Principal Investigator Primary Departme

...) either has a faculty appointment
r, Clinical Associate Professor, Clinical
sor, Associate Professor, Professor or
...eemed a PI by an affiliated institution or

...sponsibility for the conduct of the study
...n the guidelines of the TCPS2.

...ng for research ethics approval for class-
...hey are teaching can be listed as a PI
...e contact the REB manager if you are
...and require the capacity to list yourself

...name in the list, have it added into the
...e following information to RISe Support
...: Initial), Department (or affiliation with
...Email Address, Phone Number and UBC
...able). Once an account is created, new
users will receive their researcher number via email.

1.2. Primary Contact

Provide the name of ONE primary contact person in addition to the PI who will receive ALL correspondence, certificates of approval and notifications from the REB for this study. This primary contact will have online access to read, amend, and track the application.

Prinz Apple [Select...] [Clear]

Primary Appointment: UBC (UBC)
Rank: Visiting Dignitary
Email: na

Selecting a primary contact is optional. If a primary contact is not selected, the PI will be the only person to receive all correspondence from the Research Ethics Board Administration (REBA). Graduate students preparing ethics applications for their dissertation projects should list themselves as the primary contact. The Primary Contact may also be listed in one of the categories below. Note that the PI may change the Primary Contact anytime without an amendment.

Study Team Members

Complete sections 1.3, 1.4 and 1.5 below to add Co-Investigators and additional study team members and to designate the type of online access you would like them to have.

To add *Co-Investigators and additional study team members in questions 1.3 and 1.4:*

1. Click "Add".
2. Enter the name, or enter the first few letters of the person's name and click "Go".
3. You can sort the returned list alphabetically by First name, Last name, or Organization by clicking the appropriate heading.

Please make sure you have added yourself as either the Principal Investigator, primary contact, co-investigator, or a study team member with online access in order to continue with the application.

If you cannot find your name or any of your study team members' names in the list, have them added or inform them to add themselves by emailing the following information to RISe Support(risesupport@ors.ubc.ca): Full Name (Including Middle Initial), Department (or affiliation with the University), UBC Rank, Email Address, Phone Number and UBC employee number (if

UBC The University of British Columbia
a place of mind

Edit: Human Ethics - H13-00097-001

<< Back   Save | Exit | Hide/Show Errors | Print... | Jump To: 9. Documentation - Human Ethics Application for Clinical Study ▾   Continue >>

9. DOCUMENTATION - HUMAN ETHICS APPLICATION

Please attach the documentation for the study. The Research Ethics Office cannot change document names or dates.

INSTRUCTIONS

View the guidelines to the right of each section to see where the document should be attached. Documents will appear on the certificate of approval with the information that you enter when you attach the document. Please check that version dates, document names etc. are accurate and match those on the attached documents. Submit final versions only (i.e. not "drafts") except that blanks can be included for names and addresses in documents to be sent to specific individuals or organizations. Revisions required by the Board should be highlighted.

New Applications: Attach the documents to the applicable section (refer to guidelines on right)

Response to Proviso, Deferral, Changes Required by REBA, or Amendments:
If you are submitting a revised version of a document that is already attached, delete only the document that you are replacing and attach the revised version of the same document (Do NOT delete any of the other documents). You may add a new document but you must indicate in your response or PAA coversheet that you have added a new document for review.

9.1.A. Protocol

Examples of types of protocols are listed on the right. Click "Add" to enter the required information and attach the documents.

[Add]

Document Name
There are no items to display

Clinical Applications

- Clinical trial protocol
- Clinical research proposal
- Amendments to full protocols
- History or Summary of Changes to Amendments

NOTE: If this application is part of the streamlined review process outlined in question 4.6, UBC specific documents must be appended in Sections 9.1 – 9.7, as applicable.

> **Pay particular attention to the guidelines if you intend to replace documents or submit new ones.**

9.1.B.

Health Canada regulatory approval (receipt will be acknowledged)

[Add]

Document Name	Version	Date	Document
There are no items to display			

9.1.C.

FDA IND or IDE letters (receipt will be acknowledged)

[Add]

Document Name	Version	Date	Document
There are no items to display			

9.2. Consent Forms

Examples of types of consent forms are listed on the right. Click "Add" to enter the required information and attach the forms.

Attach all consent forms for the research, including the following:

- Participant consent form

Committees | **Studies** | **Help**

Current State

Pre Submission

Activities

- ☑ Edit PAA Coversheet
- ☑ Edit Application
- [PI] **Submit PAA**
- [PI] Permanently Inactivate
- [PI&S] PI and Staff Comments

Viewing/Printing

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

⊕^{PAA}(H13-00097-A002) Clinical Test PAA Amendment

Principal Investigator:	Apple , Prinz	**Primary Contact:**	
Type of Study:	Clinical	**Review Board:**	Clinical Research Ethics Board
Meeting Type:		**Meeting Date:**	
Activity Type:	Amendments to Study	**PAA Approval Certificate:**	
Study State:	Approved	**Study Expiry Date:**	October 30, 2014
Type of Funding:	Grant	**US Affiliated Study:**	No
Flag:	N/A		
CM Conflicts:	Prinz Apple		

Click to submit your PAA for review. Only the PI has this "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 ▼] [_____] [Go] [Clear] Advanced

No data to display.

Committees | **Studies** | **Help**

... > Studies > Clinical Test October 8, 2013 > Clinical Test PAA Amendment

Current State

> Pre Submission

Activities

- Edit PAA Coversheet
- Edit Application
- Submit PAA
- Permanently Inactivate
- PI and Staff Comments

Viewing/Printing

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

PAA (H13-00097-A002) Clinical Test PAA Amendment

Principal Investigator:	Apple , Prinz	**Primary Contact:**	Apple , Prinz
Type of Study:	Clinical	**Review Board:**	Clinical Research Ethics Board
Meeting Type:		**Meeting Date:**	
Activity Type:	Amendments to Study	**PAA Approval Certificate:**	
Study State:	Approved	**Study Expiry Date:**	October 30, 2014

Type of Funding:

Flag:

CM Conflicts:

Correspondence

This contains all
date and time it

Filter by

Execute "Submit PAA" on H13-00097-A002 - Windows Internet Explorer

http://test.rise.ubc.ca/sandbox/ResourceAdministration/Activity/form?ActivityType=com.webridge.entity.Entity[OID[99829148D474DB47B9A87

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

PAA (H13-00097-A002) Clinical Test PAA Amendment

Principal Investigator:	Apple , Prinz	**Primary Contact:**	Apple , Prinz
Type of Study:	Clinical	**Review Board:**	Clinical Research Ethics Board
Meeting Type:		**Meeting Date:**	
Activity Type:	Amendments to Study	**PAA Approval Certificate:**	
Study State:	Approved	**Study Expiry Date:**	October 30, 2014

Your PAA - Amendment has been submitted to the REB and will be screened by the REB Admin (REBA) prior to forwarding for REB review.

No

CM Conflicts: Prinz Apple

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 ⌄ | | Go | Clear | Advanced

	Activity	Author	⌄ Activity Date
PI	Submitted Post Approval Activity	Apple, Prinz	10/30/2013 3:29 PM PDT