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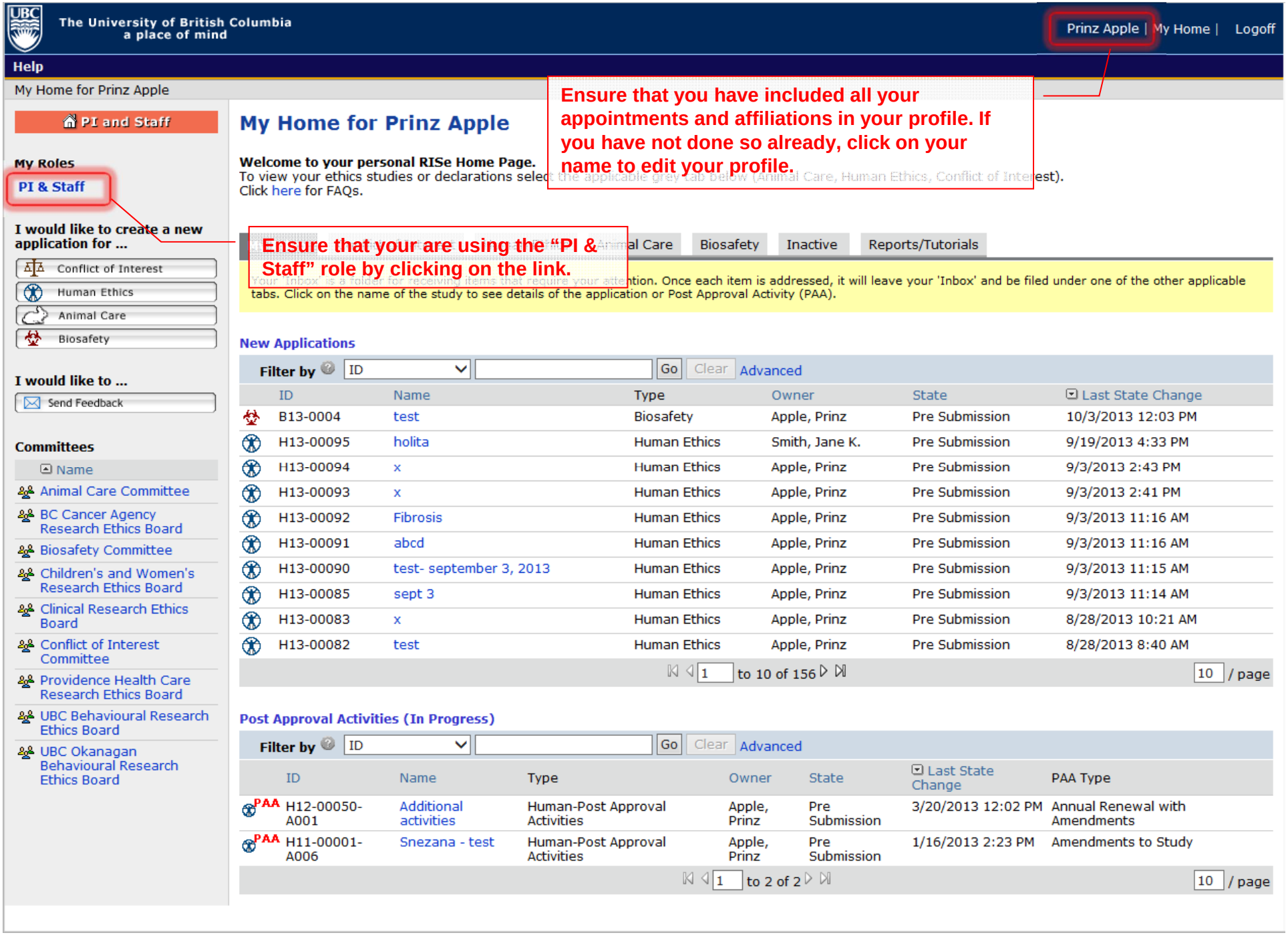
How to Submit a New Human Ethics UBC Clinical Application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Prinz Apple | My Home | Logoff
Help
My Home for Prinz Apple
PI and Staff
My Roles
PI & Staff
I would like to create a new application for ...
Conflict of Interest
Human Ethics
Animal Care
Biosafety
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.
Ensure that you have included all your appointments and affiliations in your profile. If you have not done so already, click on your name to edit your profile.
Ensure that your are using the "PI & Staff" role by clicking on the link.
Biosafety
Inactive
Reports/Tutorials
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
B13-0004 test Biosafety Apple, Prinz Pre Submission 10/3/2013 12:03 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
H13-00090 test- september 3, 2013 Human Ethics Apple, Prinz Pre Submission 9/3/2013 11:15 AM
H13-00085 sept 3 Human Ethics Apple, Prinz Pre Submission 9/3/2013 11:14 AM
H13-00083 x Human Ethics Apple, Prinz Pre Submission 8/28/2013 10:21 AM
H13-00082 test Human Ethics Apple, Prinz Pre Submission 8/28/2013 8:40 AM
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Post Approval Activities (In Progress)
Filter by ID Go Clear Advanced
ID Name Type Owner State Last State Change PAA Type
PAA H12-00050-A001 Additional activities Human-Post Approval Activities Apple, Prinz Pre Submission 3/20/2013 12:02 PM Annual Renewal with Amendments
PAA 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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Help

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PI and Staff

My Roles

PI & Staff

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

- Conflict of Interest
- Human Ethics
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I would like to ...

- Send Feedback

Committees

Name
Animal Care Committee
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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 to create a new Human Ethics application for a brand new study.

New Applications

Filter by ID Go Clear Advanced

ID	Name	Type	Owner	State	Last State Change
B13-0004	test	Biosafety	Apple, Prinz	Pre Submission	10/3/2013 12:03 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
H13-00090	test- september 3, 2013	Human Ethics	Apple, Prinz	Pre Submission	9/3/2013 11:15 AM
H13-00085	sept 3	Human Ethics	Apple, Prinz	Pre Submission	9/3/2013 11:14 AM
H13-00083	x	Human Ethics	Apple, Prinz	Pre Submission	8/28/2013 10:21 AM
H13-00082	test	Human Ethics	Apple, Prinz	Pre Submission	8/28/2013 8:40 AM

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Post Approval Activities (In Progress)

Filter by ID Go Clear Advanced

ID	Name	Type	Owner	State	Last State Change	PAA Type
PAA H12-00050-A001	Additional activities	Human-Post Approval Activities	Apple, Prinz	Pre Submission	3/20/2013 12:02 PM	Annual Renewal with Amendments
PAA 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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Page 1 of the Application

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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.

Select...

Enter Principal Investigator Primary Department and also the primary [illegible] of the PI's institution

Begin by selecting the Principal Investigator. If you have previously held a PI role, this field may automatically be populated with your name.

Guidance Notes are located in the boxes to the right of the application form. They include detailed explanations of the questions, instructions on how to fill out the form and useful links to documents and contacts.

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. [illegible] track the application.

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.
4. Select the boxes beside ALL applicable names and click "OK".

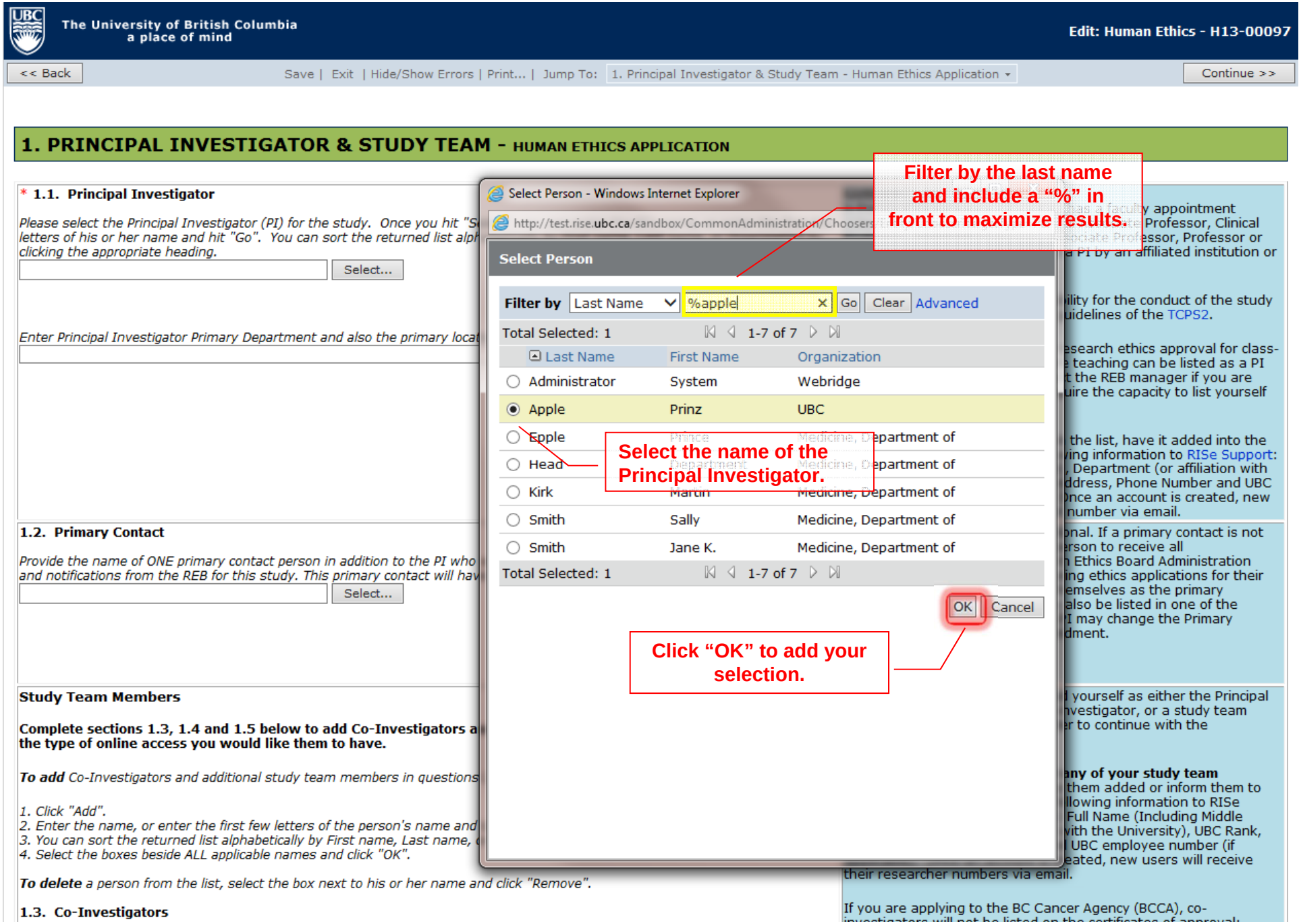
To delete *a person from the list, select the box next to his or her name and click "Remove".*

1.3. Co-Investigators

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 applicable). Once an account is created, new users will receive their researcher numbers via email.

If you are applying to the BC Cancer Agency (BCCA), co-[illegible]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Edit: Human Ethics - H13-00097
<< Back
Save | Exit | Hide/Show Errors | Print... | Jump To: 1. Principal Investigator & Study Team - Human Ethics Application
Continue >>
1. PRINCIPAL INVESTIGATOR & STUDY TEAM - HUMAN ETHICS APPLICATION
* 1.1. Principal Investigator
Please select the Principal Investigator (PI) for the study. Once you hit "S
letters of his or her name and hit "Go". You can sort the returned list alph
clicking the appropriate heading.
Select...
Enter Principal Investigator Primary Department and also the primary locat
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and notifications from the REB for this study. This primary contact will hav
Select...
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the type of online access you would like them to have.
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1. Click "Add".
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3. You can sort the returned list alphabetically by First name, Last name,
4. Select the boxes beside ALL applicable names and click "OK".
To delete a person from the list, select the box next to his or her name and click "Remove".
1.3. Co-Investigators
Select Person - Windows Internet Explorer
http://test.rise.ubc.ca/sandbox/CommonAdministration/Choosers
Select Person
Filter by Last Name %apple Go Clear Advanced
Total Selected: 1 1-7 of 7
Last Name First Name Organization
Administrator System Webridge
Apple Prinz UBC
Epple Prince Medicine, Department of
Head Department Medicine, Department of
Kirk Martin Medicine, Department of
Smith Sally Medicine, Department of
Smith Jane K. Medicine, Department of
Total Selected: 1 1-7 of 7
OK Cancel
Filter by the last name and include a "%" in front to maximize results.
Select the name of the Principal Investigator.
Click "OK" to add your selection.
their researcher numbers via email.
If you are applying to the BC Cancer Agency (BCCA), co-

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Make it a habit to hit "Save" before you "Continue" to the next page.

1. PRINCIPAL INVESTIGATOR & STUDY TEAM - HUMAN ETHICS APPLICATION

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Prinz Apple Select... Clear

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

Enter Principal Investigator

Some questions are marked with a red asterisk. This indicates that the question is a required field. If you leave these questions unanswered, you will not be allowed to proceed to the next page of the application.

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.

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Select...

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If you are applying to the BC Cancer Agency (BCCA), co-investigators will not be listed on the certificates of approval;

2. STUDY DATES & FUNDING INFORMATION - HUMAN ETHICS APPLICATION

Project Period

* **2.1.A.**

*Please choose **ONE** of the following:*

- *You plan to start collecting data immediately after obtaining ethics and any other required approvals (the start date on the ethics certificate will reflect the approval date),*

☐

OR

- *You plan to start data collection at a later date i.e., 2 months or more after approvals are obtained. Click the calendar icon below to select the dates (Internet Explorer) or enter the dates manually using the format yyyy-mm-dd.*

Estimated start date:

* **2.1. B.**

Estimated end date:

In multi-phase projects, include the period that involves research with human participants.

Whenever you encounter questions that require you to input a date, please use the calendar icon to select your dates as it will ensure the proper formatting of your entry.

Source of Funds

* **2.2.A. Types of Funds**

Please select the applicable box(es) below to indicate the type(s) of funding you are receiving to conduct this research. ***You must then complete section 2.3 and/or section 2.4 for the name of the source of the funds to be listed on the certificate of approval.***

	Type(s) of Funding
☐	Grant
☐	No Funding
☐	Grant-in-aid
☐	For-Profit Sponsor (Industry or Pharmaceutical)
☐	Internal Funds
☐	Other (Enter details in 2.3 or 2.4 as appropriate)

"Source of Funds" refers to the funder, sponsor, grantor, or agency (government, industry, and non-profit) that is providing the funds needed to undertake the project. Note that you should not indicate that your study is "For Profit" if a sponsor is only collaborating and not funding the study, e.g., they are providing the study drug or laboratory space only.

2.2.B. *For Industry Sponsored studies, please provide a sponsor contact.*

2. STUDY DATES & FUNDING INFORMATION - HUMAN ETHICS APPLICATION

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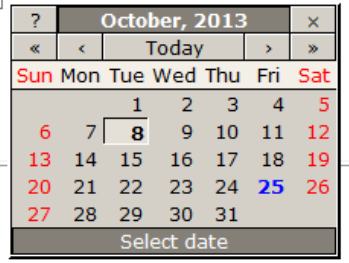
Estimated start date:
October 8, 2013



* **2.1. B.**

Estimated end date:

Source of Funds

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Type(s) of Funding
☐ Grant
☐ No Funding
☐ Grant-in-aid
☐ For-Profit Sponsor (Industry or Pharmaceutical)
☐ Internal Funds
☐ Other (Enter details in 2.3 or 2.4 as appropriate)

2.2.B. *For Industry Sponsored studies, please provide a sponsor contact.*

Add

UBC Number	Title	Funding PI	Sponsor

2.4. Research Funding Application/Award Associated with the Study not listed in question 2.3.

Please click "Add" to enter the details for the research funding application/award associated with this study that is not listed in question 2.3. When you press "Add" you can do a search for your funding award by doing a search in the "Sponsor" box - over 7000 options are listed

Add

Title	Sponsor
There are no items to display	

U.S. Funding

* **2.5.A.** *Is this a DHHS grant? (To view a list of DHHS funding agencies click on "add" in 2.5.B below)*

◯ Yes ◯ No Clear

2.5.B. *If yes, please select the appropriate DHHS funding agency from the selection box, and attach the grant to box 9.8. of the application.*

Add

DHHS Sponsor List
There are no items to display

Attach DHHS Grant Application for each sponsor listed above

Add

Title
There are no items to display

The **Department of Health and Human Services**, DHHS (US Federal Agencies), requires the Research Ethics Board to review the actual grant application to compare it to the protocol being approved, to ensure that they are the same. Your certificate of approval will not be released until this documentation is attached.

* **2.6. Conflict of Interest**

Do any of the following statements apply to the Principal Investigator, Co-Investigators and/or their partners/immediate family members?

- *Receive personal benefits in connection with this study over and above the direct cost of conducting this study. For example, being paid by the funder for consulting. (Reminder: receiving a "finders fee" for each participant enrolled is not allowed).*
- *Have a non-financial relationship with the sponsor (such as unpaid consultant, advisor, board member or other non-financial interest).*
- *Have direct financial involvement with the sponsor (source of funds) via ownership of stock, stock options, or membership on a Board.*
- *Hold patent rights or intellectual property rights linked in any way to this study or its sponsor (source of funds).*

◯ Yes ◯ No Clear

If you select "Yes", you will be taken to View 3 to enter Conflict of Interest information. If you select "No", you will be brought to View 4 to enter Study details.

The REB needs to be satisfied that participants are informed of conflict of interest matters in the consent process. Note that "immediate family members" includes partners and children (whether living in the household or not). The REB does not require that the investigator identify holdings in managed mutual funds to be declared in the conflict of interest statements. If you answer yes to this question you will be asked to provide more detail on view 3 of the application.

To save information on each view as you are working, especially if you are working on the view for a long period of time, select the "Save" button located at the top or bottom of the view in the blue bar. Your work on each view will automatically be saved once you hit the "Continue" button.

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4. STUDY TYPE - HUMAN ETHICS APPLICATION

*** 4.1. UBC Research Ethics Board**

Indicate which UBC Research Ethics Board you are applying to and the type of study you are applying for:

Research Ethics Boards
○ BC Cancer Agency Research Ethics Board - Clinical
○ BC Cancer Agency Research Ethics Board - Behavioural
○ Children's and Women's Research Ethics Board - Clinical
○ Children's and Women's Research Ethics Board - Behavioural
○ Providence Health Care Research Ethics Board - Clinical
○ Providence Health Care Research Ethics Board - Behavioural
○ UBC Okanagan Behavioural Research Ethics Board
○ UBC Behavioural Research Ethics Board
○ UBC Clinical Research Ethics Board

Clear

UBC's REBs have signed a one board of record agreement. Studies taking place at multiple UBC sites require review and approval by only one UBC-Affiliated REB. Choice of Board should be determined by the PI's primary appointment and/or the main location of the research.

Clinical projects are those involving surgery, the administration of drugs, medical imaging or other diagnostic techniques, biopsies, the taking of blood or other specimens, the review of clinical medical records, and any invasive procedure. A clinical research project that also includes questionnaires or interviews should be submitted to a Clinical Research Ethics Board.

Behavioural projects are those that are behavioural or social scientific in nature or involve humanities research. They may involve the study of patients or healthcare providers; however, they are not clinical and do not involve invasive procedures. They do include research involving interviews, observations, and the administration of questionnaires or tests.

Select the appropriate ethics board by clicking the radio button to the left.

*** 4.2. Institutions and Sites for Study**

Enter the locations for the institutions and sites where the research will be carried out under this Research Ethics Board approval (including specimens processed by pathology, special radiological procedures, specimens obtained in the operating room, or tissue requested from pathology).

If your research will not be carried out at an institutional site, please check the "N/A" box. Otherwise click "Add" and enter the appropriate letter to see the locations for the institutions and sites where the research will be carried out under this Research Ethics Board approval: B for BC Cancer Agency; C for Children's and Women's Health Centre of BC; P for Providence Health Care U for UBC Campus V for Vancouver Coastal Health

You will encounter questions where you must click "Add" to select an item from an established list.

N/A: ☐

4.2.A. Institutions and Sites for Study

Add

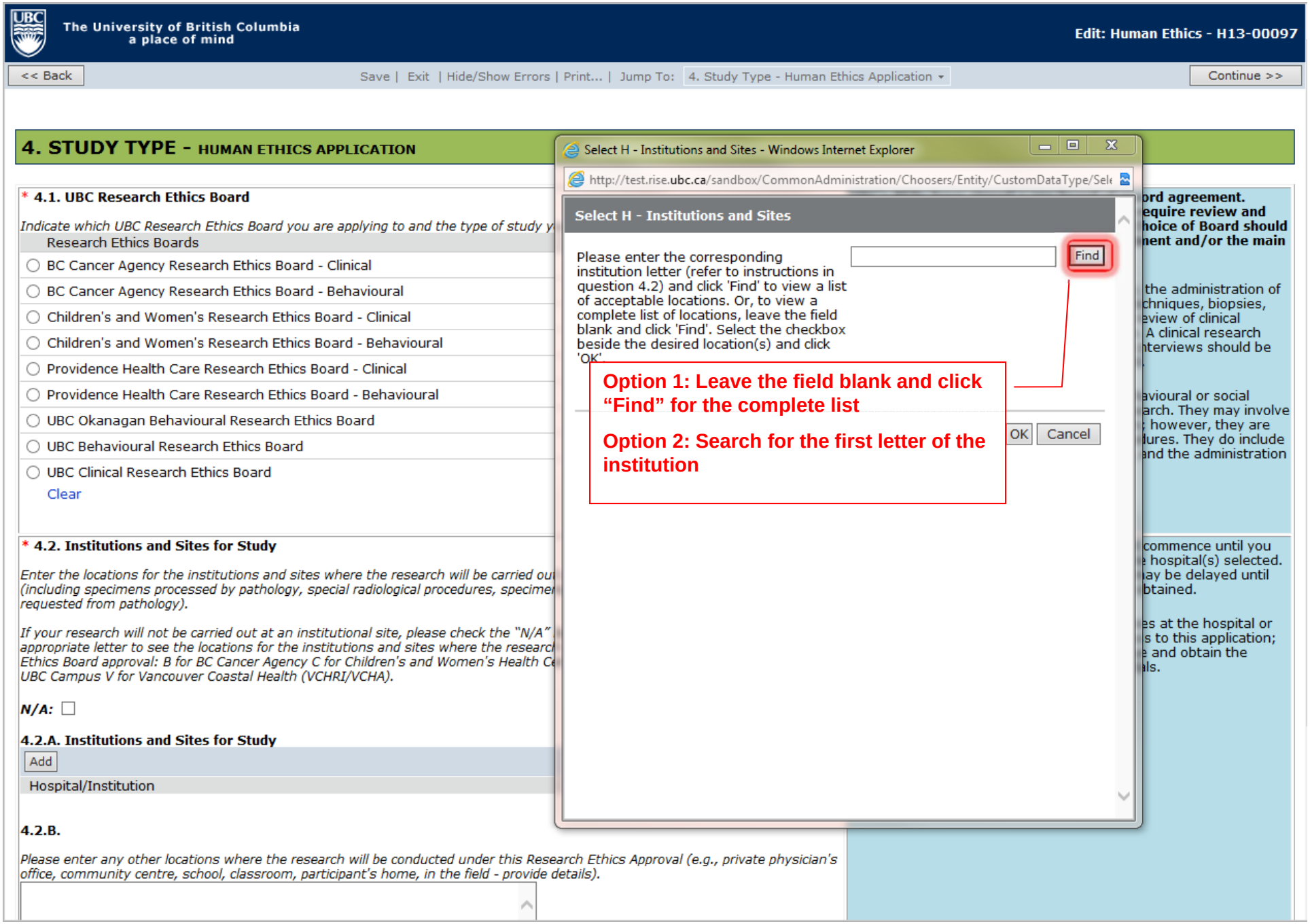
Hospital/Institution	Site

Research at UBC's affiliated hospitals cannot commence until you receive local site / resource approval from the hospital(s) selected. Issuing of the certificate of ethical approval may be delayed until site approval from the hospital(s) has been obtained.

The Hospital Administrator for facilities/services at the hospital or centre selected will be granted viewing access to this application; however, it is the PI's responsibility to pursue and obtain the necessary approvals from the various hospitals.

4.2.B.

Please enter any other locations where the research will be conducted under this Research Ethics Approval (e.g., private physician's office, community centre, school, classroom, participant's home, in the field - provide details).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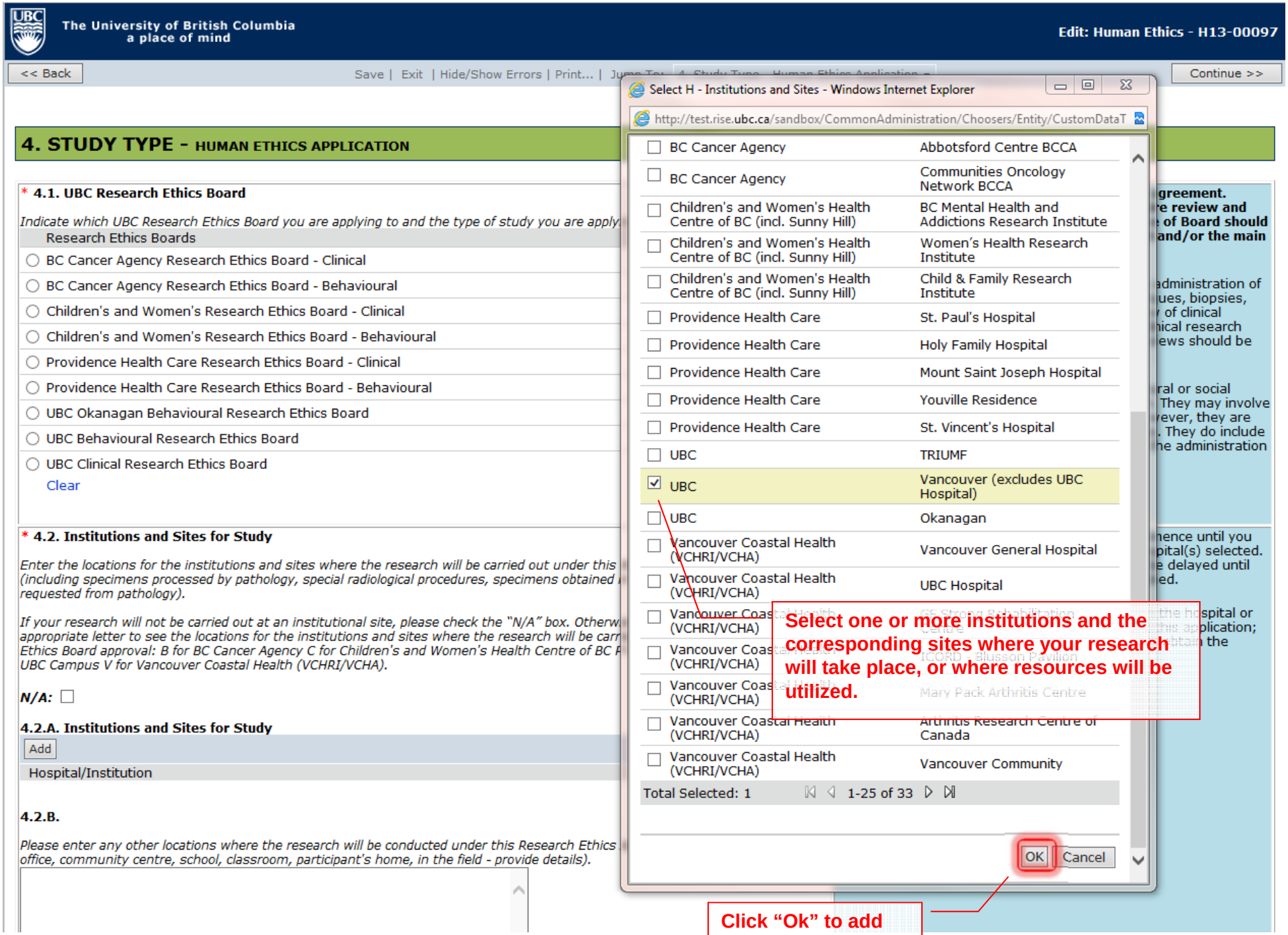
4. STUDY TYPE - HUMAN ETHICS APPLICATION
* 4.1. UBC Research Ethics Board
Indicate which UBC Research Ethics Board you are applying to and the type of study y
Research Ethics Boards
BC Cancer Agency Research Ethics Board - Clinical
BC Cancer Agency Research Ethics Board - Behavioural
Children's and Women's Research Ethics Board - Clinical
Children's and Women's Research Ethics Board - Behavioural
Providence Health Care Research Ethics Board - Clinical
Providence Health Care Research Ethics Board - Behavioural
UBC Okanagan Behavioural Research Ethics Board
UBC Behavioural Research Ethics Board
UBC Clinical Research Ethics Board
Clear
* 4.2. Institutions and Sites for Study
Enter the locations for the institutions and sites where the research will be carried ou
(including specimens processed by pathology, special radiological procedures, specime
requested from pathology).
If your research will not be carried out at an institutional site, please check the "N/A"
appropriate letter to see the locations for the institutions and sites where the researc
Ethics Board approval: B for BC Cancer Agency C for Children's and Women's Health C
UBC Campus V for Vancouver Coastal Health (VCHRI/VCHA).
N/A:
4.2.A. Institutions and Sites for Study
Add
Hospital/Institution
4.2.B.
Please enter any other locations where the research will be conducted under this Research Ethics Approval (e.g., private physician's office, community centre, school, classroom, participant's home, in the field - provide details).
Select H - Institutions and Sites - Windows Internet Explorer
http://test.rise.ubc.ca/sandbox/CommonAdministration/Choosers/Entity/CustomDataType/Sele
Select H - Institutions and Sites
Please enter the corresponding institution letter (refer to instructions in question 4.2) and click 'Find' to view a list of acceptable locations. Or, to view a complete list of locations, leave the field blank and click 'Find'. Select the checkbox beside the desired location(s) and click 'OK'.
Find
OK
Cancel
Option 1: Leave the field blank and click "Find" for the complete list
Option 2: Search for the first letter of the institution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Save | Exit | Hide/Show Errors | Print... |
Continue >>
4. STUDY TYPE - HUMAN ETHICS APPLICATION
* 4.1. UBC Research Ethics Board
Indicate which UBC Research Ethics Board you are applying to and the type of study you are apply
Research Ethics Boards
BC Cancer Agency Research Ethics Board - Clinical
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Children's and Women's Research Ethics Board - Clinical
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Providence Health Care Research Ethics Board - Behavioural
UBC Okanagan Behavioural Research Ethics Board
UBC Behavioural Research Ethics Board
UBC Clinical Research Ethics Board
Clear
* 4.2. Institutions and Sites for Study
Enter the locations for the institutions and sites where the research will be carried out under this
(including specimens processed by pathology, special radiological procedures, specimens obtained
requested from pathology).
If your research will not be carried out at an institutional site, please check the "N/A" box. Otherw
appropriate letter to see the locations for the institutions and sites where the research will be carr
Ethics Board approval: B for BC Cancer Agency C for Children's and Women's Health Centre of BC
UBC Campus V for Vancouver Coastal Health (VCHRI/VCHA).
N/A:
4.2.A. Institutions and Sites for Study
Add
Hospital/Institution
4.2.B.
Please enter any other locations where the research will be conducted under this Research Ethics
office, community centre, school, classroom, participant's home, in the field - provide details).
Select H - Institutions and Sites - Windows Internet Explorer
http://test.rise.ubc.ca/sandbox/CommonAdministration/Choosers/Entity/CustomDataT
BC Cancer Agency | Abbotsford Centre BCCA
BC Cancer Agency | Communities Oncology Network BCCA
Children's and Women's Health Centre of BC (incl. Sunny Hill) | BC Mental Health and Addictions Research Institute
Children's and Women's Health Centre of BC (incl. Sunny Hill) | Women's Health Research Institute
Children's and Women's Health Centre of BC (incl. Sunny Hill) | Child & Family Research Institute
Providence Health Care | St. Paul's Hospital
Providence Health Care | Holy Family Hospital
Providence Health Care | Mount Saint Joseph Hospital
Providence Health Care | Youville Residence
Providence Health Care | St. Vincent's Hospital
UBC | TRIUMF
UBC | Vancouver (excludes UBC Hospital)
UBC | Okanagan
Vancouver Coastal Health (VCHRI/VCHA) | Vancouver General Hospital
Vancouver Coastal Health (VCHRI/VCHA) | UBC Hospital
Vancouver Coastal Health (VCHRI/VCHA) | Arthritis Research Centre of Canada
Vancouver Coastal Health (VCHRI/VCHA) | Vancouver Community
Total Selected: 1
1-25 of 33
OK
Cancel
Select one or more institutions and the corresponding sites where your research will take place, or where resources will be utilized.
Click "Ok" to add your selection.

The University of British Columbia
a place of mind

Edit: Human Ethics - H13-00097

<< Back | Save | Exit | Hide/Show Errors | Print... | Jump To: 4. Study Type - Human Ethics Application | Continue >>

4. STUDY TYPE - HUMAN ETHICS APPLICATION

*** 4.1. UBC Research Ethics Board**

Indicate which UBC Research Ethics Board you are applying to and the type of study you are applying for:

Research Ethics Boards

- ○ BC Cancer Agency Research Ethics Board - Clinical
- ○ BC Cancer Agency Research Ethics Board - Behavioural
- ○ Children's and Women's Research Ethics Board - Clinical
- ○ Children's and Women's Research Ethics Board - Behavioural
- ○ Providence Health Care Research Ethics Board - Clinical
- ○ Providence Health Care Research Ethics Board - Behavioural
- ○ UBC Okanagan Behavioural Research Ethics Board
- ○ UBC Behavioural Research Ethics Board
- ○ UBC Clinical Research Ethics Board

Clear

UBC's REBs have signed a one board of record agreement. Studies taking place at multiple UBC sites require review and approval by only one UBC-Affiliated REB. Choice of Board should be determined by the PI's primary appointment and/or the main location of the research.

Clinical projects are those involving surgery, the administration of drugs, medical imaging or other diagnostic techniques, biopsies, the taking of blood or other specimens, the review of clinical medical records, and any invasive procedure. A clinical research project that also includes questionnaires or interviews should be submitted to a Clinical Research Ethics Board.

Behavioural projects are those that are behavioural or social scientific in nature or involve humanities research. They may involve the study of patients or healthcare providers; however, they are not clinical and do not involve invasive procedures. They do include research involving interviews, observations, and the administration of questionnaires or tests.

*** 4.2. Institutions and Sites for Study**

Enter the locations for the institutions and sites where the research will be carried out under this Research Ethics Board approval (including specimens processed by pathology, special radiological procedures, specimens obtained in the operating room, or tissue requested from pathology).

If your research will not be carried out at an institutional site, please check the "N/A" box. Otherwise click "Add" and enter the appropriate letter to see the locations for the institutions and sites where the research will be carried out under this Research Ethics Board approval: B for BC Cancer Agency C for Children's and Women's Health Centre of BC P for Providence Health Care U for UBC Campus V for Vancouver Coastal Health (VCHRI/VCHA).

N/A: ☐

4.2.A. Institutions and Sites for Study

Add

	Hospital/Institution	Site	
View	UBC	Vancouver (excludes UBC Hospital)	Remove

The selected institutions and sites will be listed.

4.2.B.

Please enter any other locations where the research will be conducted under this Research Ethics Approval (e.g., private physician's office, community centre, school classroom, participant's home, in the field - provide details).

Research at UBC's affiliated hospitals cannot commence until you receive local site / resource approval from the hospital(s) selected. Issuing of the certificate of ethical approval may be delayed until site approval from the hospital(s) has been obtained.

The Hospital Administrator for facilities/services at the hospital or centre selected will be granted viewing access to this application; however, it is the PI's responsibility to pursue and obtain the necessary approvals from the various hospitals.

4*. CLINICAL STUDY REVIEW TYPE - HUMAN ETHICS APPLICATION

View 4* collects application details.

4.3. Relationship with other proposals

4.3.A.

If this proposal is closely linked to any other proposal previously/simultaneously submitted, enter the Research Ethics Board number of that proposal.

4.3.B.

If applicable, please describe the relationship between this proposal and the previously/simultaneously submitted proposal listed above.

4.3.C.

Have you received any information or are you aware of any rejection of this study by any Research Ethics Board? If yes, please provide known details and attach any available relevant documentation in question 9.7.

○ Yes ○ No Clear

Indicate whether the study is an extension or a sub-study of a primary study or if the study is utilizing samples or data collected under a previous study.

A sub-study is a concurrent study on a sub-sample/population of the original study sample/population.

Click here for further information on **sub-studies and extension studies**.

If a study has been rejected by another UBC-affiliated REB, it may not be re-submitted to any other UBC-affiliated REB.

If the study is a clinical trial, Health Canada must be notified of the rejection/disapproval of the study.

* **4.4. Level of Risk**

After reviewing the minimal risk guidance notes and the criteria for minimal risk, does this study qualify for minimal risk review? Note that all studies which do not fall into the minimal risk category will undergo full board review.

○ Yes ○ No Clear

Click here for information on minimal risk.

* **Peer Review**

If this research proposal has received any independent scientific/methodological peer review, please include the names of committees or individuals involved in the review. State whether the peer review process is ongoing or completed. All above minimal risk studies generally require a peer review.

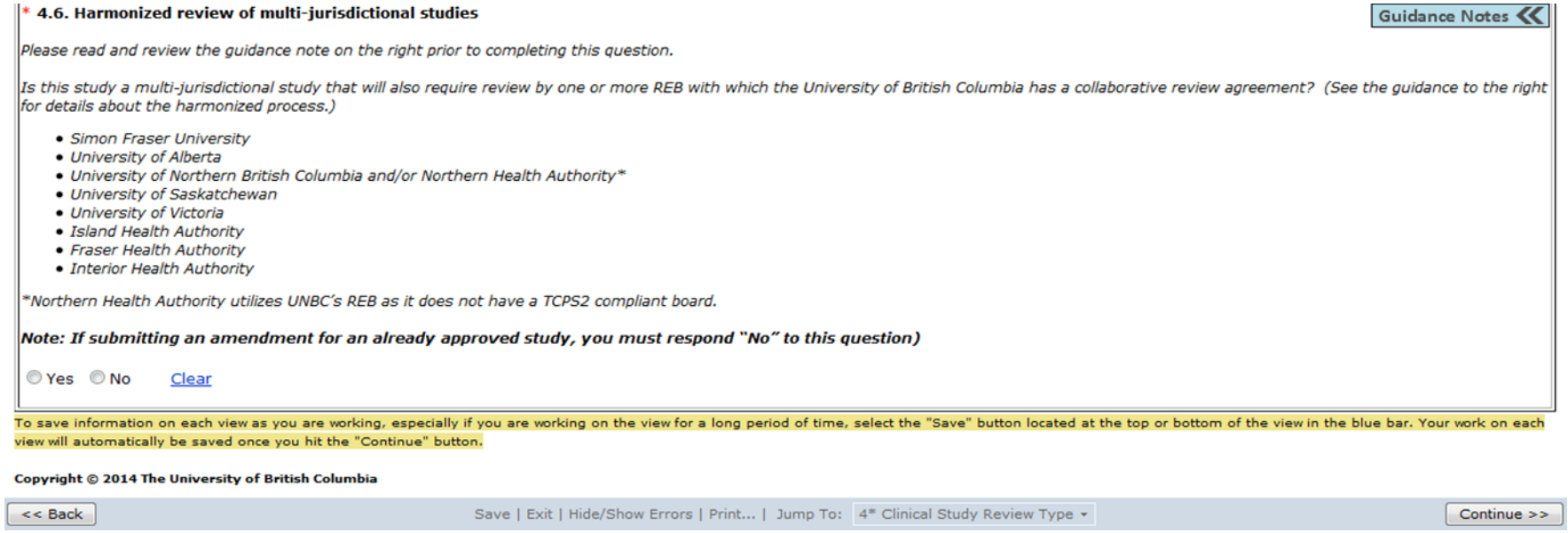
4.5.A.

External peer review details:

Article 2.7 of the TCPS2 stipulates that the REB must review the ethical implications of the methods and design of a research project. Peer review is required by all UBC- affiliated REBs for research projects that pose more than minimal risk to participants.

Enter peer review information in this box and attach any relevant documentation to box 9.8 of the RISe application. If your study is not minimal risk, **do NOT leave this box blank or state "not applicable." Your application will be sent back to you, if appropriate information is not provided. If a peer review has not been conducted, please explain why this is the case.**

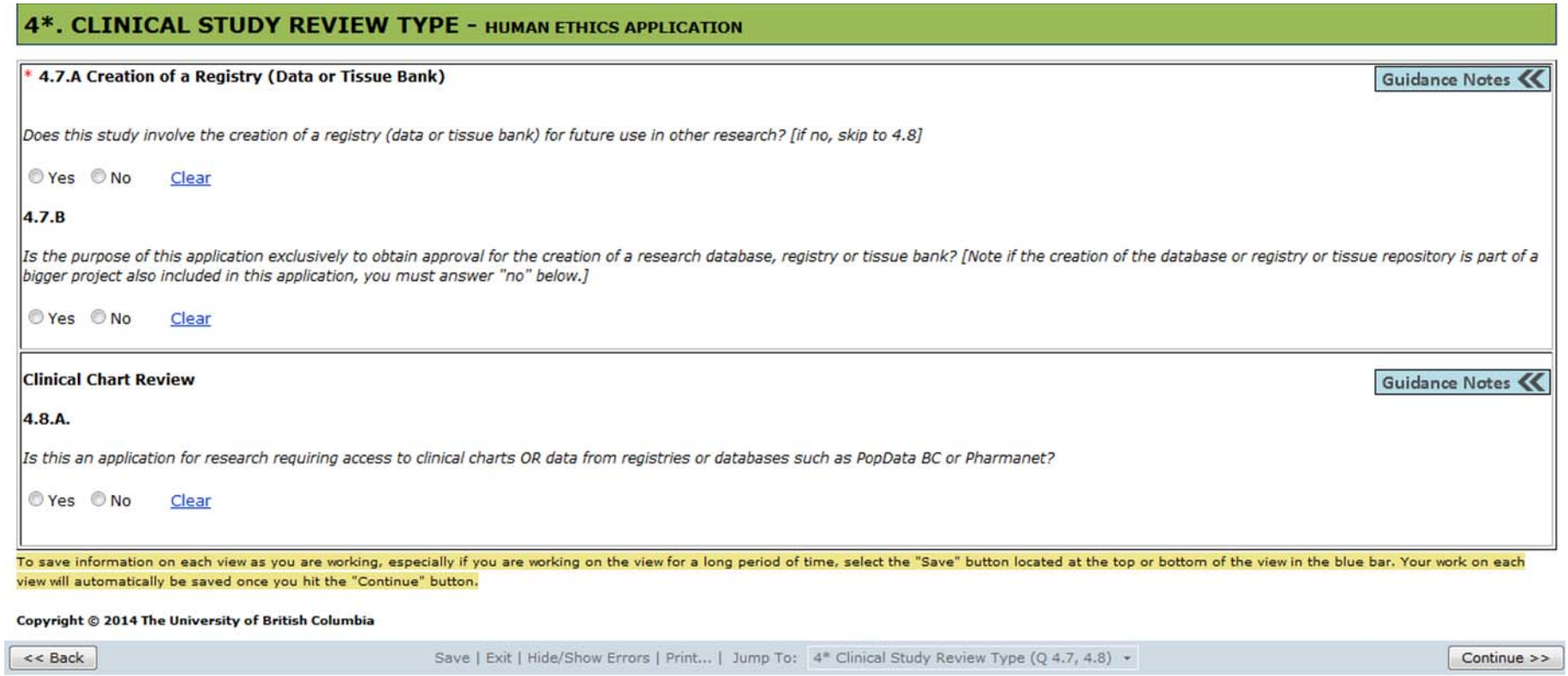
Regardless of the circumstances of the research, the REB may



Depending on answers chosen in section 4.6, you will be asked to fill the appropriate view after clicking "Continue".

***Selecting "No" under section 4.6 will route you to section 4* (Clinical Study Review Type).**

***Selecting "Yes" under section 4.6 will route you to section E (Harmonized Review of Multi-Jurisdictional Studies).**



Depending on your answers chosen in section 4.7.A, 4.7.B and 4.8.A you will be asked to fill the appropriate view after clicking "Continue".

Selecting "Yes" under section will close access to section 4.7.A and route you to section C (Creation of a Research Database, Registry or Biorepository) when you click "Continue".

4*. CLINICAL STUDY REVIEW TYPE - HUMAN ETHICS APPLICATION

* **4.7.A Creation of a Registry (Data or Tissue Bank)** Guidance Notes

Does this study involve the creation of a registry (data or tissue bank) for future use in other research? [if no, skip to 4.8]

○ Yes ◉ No Clear

4.7.B

Is the purpose of this application exclusively to obtain approval for the creation of a research database, registry or tissue bank? [Note if the creation of the database or registry or tissue repository is part of a bigger project also included in this application, you must answer "no" below.]

◉ Yes ○ No Clear

Clinical Chart Review Guidance Notes

4.8.A.

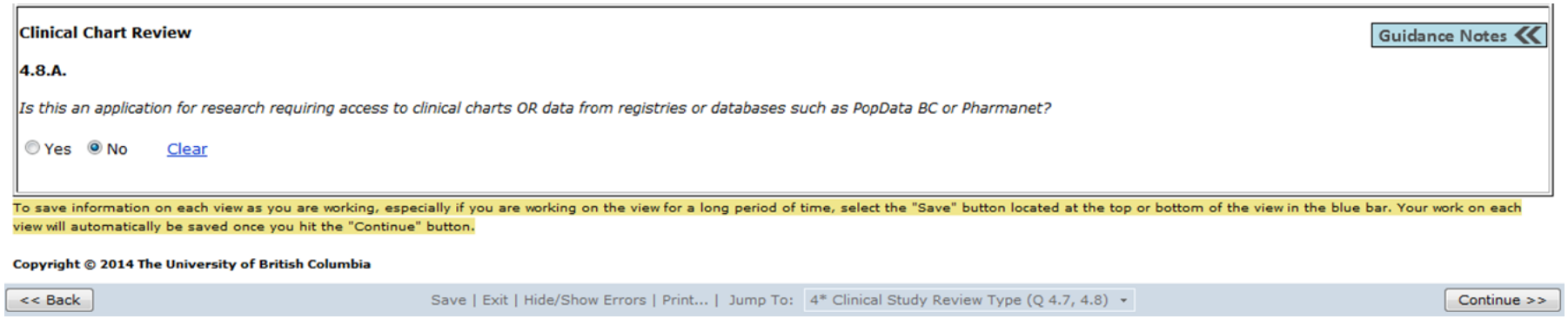
Is this an application for research requiring access to clinical charts OR data from registries or databases such as PopData BC or Pharmanet?

○ Yes ○ No Clear

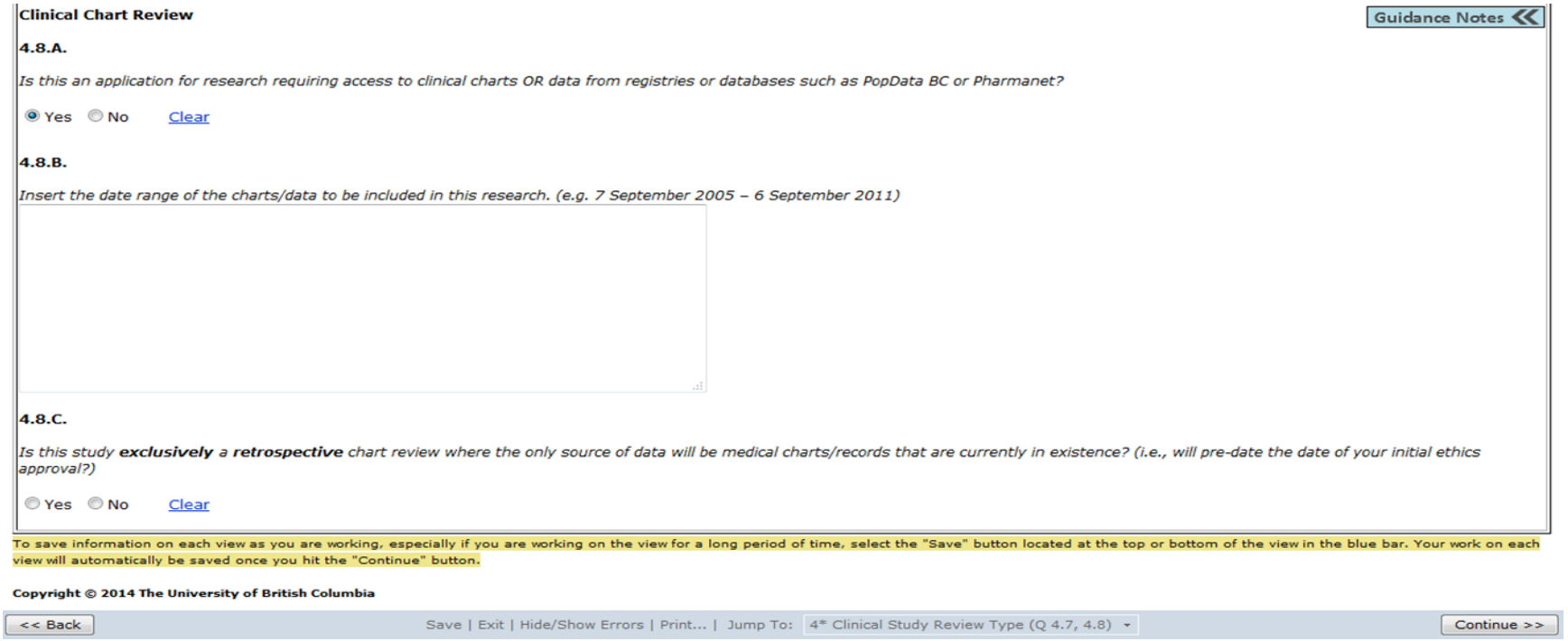
To save information on each view as you are working, especially if you are working on the view for a long period of time, select the "Save" button located at the top or bottom of the view in the blue bar. Your work on each view will automatically be saved once you hit the "Continue" button.

<< Back | Save | Exit | Hide/Show Errors | Print... | Jump To: 4* Clinical Study Review Type (Q 4.7, 4.8) | Continue >>

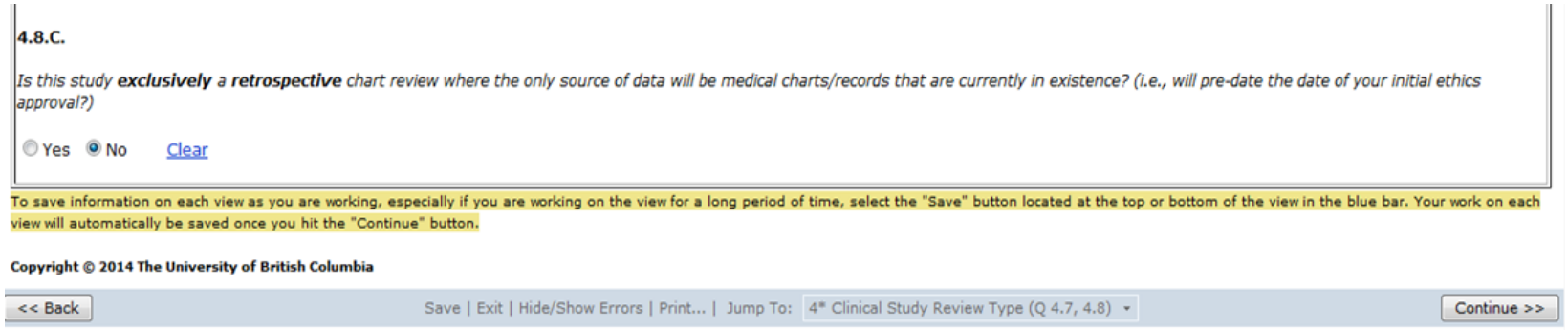
Selecting "No" under section 4.7.A will open section 4.8.A.



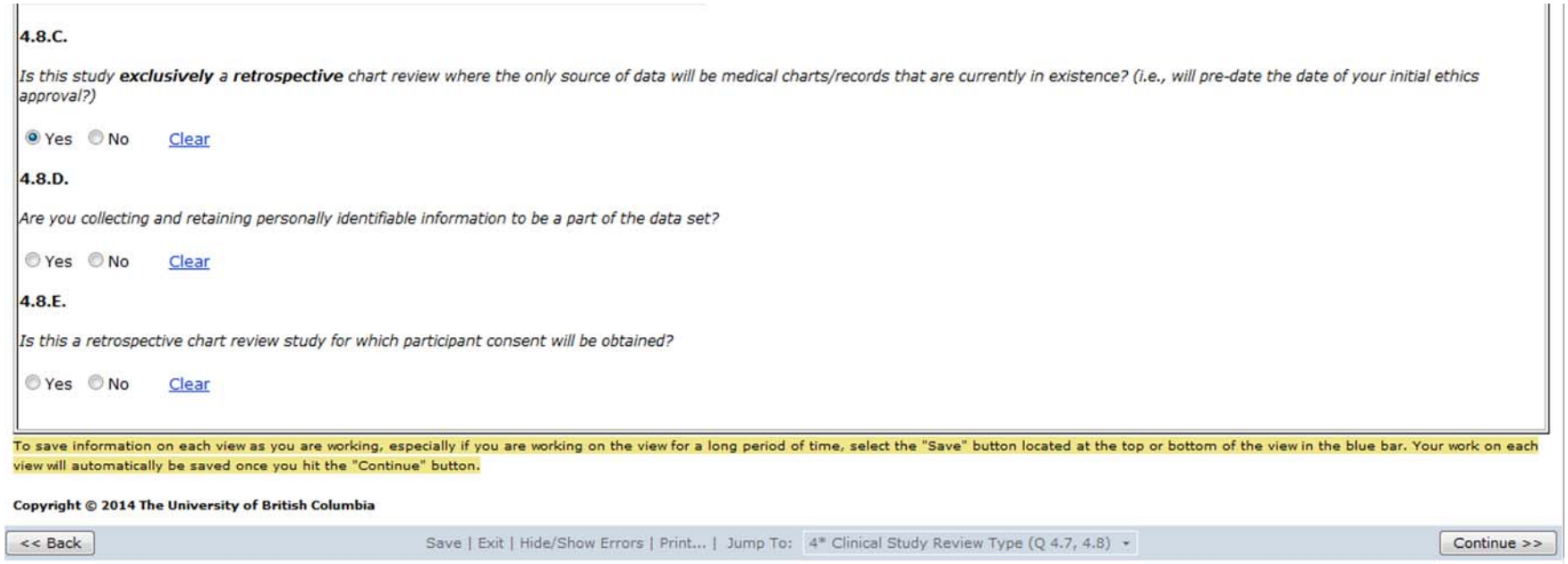
Selecting "No" under section 4.8.A and clicking on "Continue" will route you to section 5 (Summary of Study and Recruitment)



Selecting "Yes" under section 4.8.A will open up Sections 4.8.B and 4.8.C



Selecting "No" under section 4.8.C and clicking "Continue" will route you to section 5 (Summary of Study and Recruitment)



Selecting "Yes" under section 4.8.C will open up sections 4.8.D and 4.8.E.

***Selecting "Yes" under section 4.8.E will route you to section 5 (Summary of Study and Recruitment)**

***Selecting "No" under section 4.8.E will route you to section A (Retrospective Clinical Chart Reviews)**

E. Harmonized Review of Multi-Jurisdictional Studies - HUMAN ETHICS APPLICATION

* **E.1.** *Which of the following REBs are also required to review and approve this study?*

Guidance Notes

Please check all that apply.

Check the institution below
☐ Simon Fraser University
☐ University of Alberta
☐ University of Northern British Columbia and/or Northern Health Authority*
☐ University of Saskatchewan
☐ University of Victoria
☐ Island Health Authority
☐ Fraser Health Authority
☐ Interior Health Authority

***Selecting "Yes" under section 4.6 will route you to section E (Harmonized Review of Multi-Jurisdictional Studies).**

**If the study involves Northern Health Authority, please select UNBC as Northern Health Authority does not have a TCPS2 compliant board.*

* **E.2.** *Have any of the following REBs already reviewed and approved this study?*

Guidance Notes

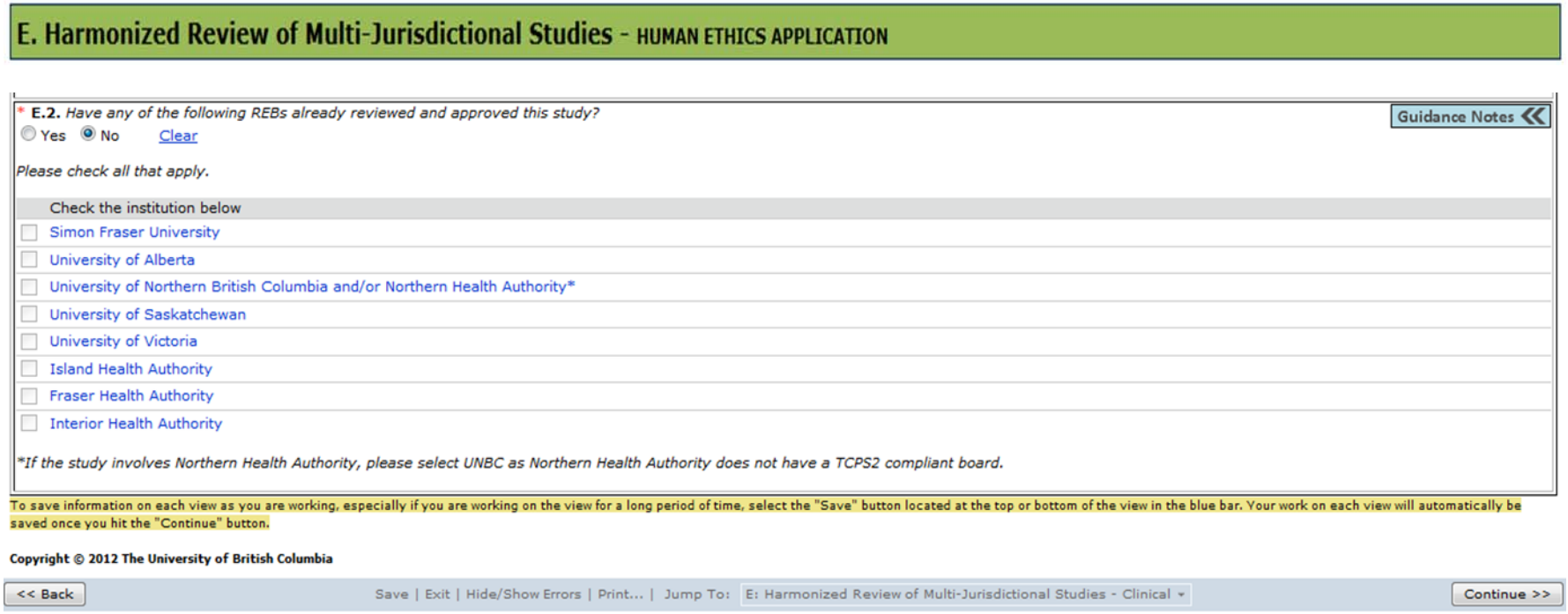
○ Yes ○ No Clear

Please check all that apply.

Check the institution below
☐ Simon Fraser University
☐ University of Alberta
☐ University of Northern British Columbia and/or Northern Health Authority*
☐ University of Saskatchewan
☐ University of Victoria
☐ Island Health Authority
☐ Fraser Health Authority
☐ Interior Health Authority

**If the study involves Northern Health Authority, please select UNBC as Northern Health Authority does not have a TCPS2 compliant board.*

To save information on each view as you are working, especially if you are working on the view for a long period of time, select the "Save" button located at the top or bottom of the view in the blue bar. Your work on each view will automatically be saved once you hit the "Continue" button.



Selecting "No" under section E.2 and clicking on "Continue" will route you to section 4* (Clinical Study Review Type)

E. Harmonized Review of Multi-Jurisdictional Studies - HUMAN ETHICS APPLICATION

* **E.2.** *Have any of the following REBs already reviewed and approved this study?* Guidance Notes

(•) Yes ( ) No Clear

Please check all that apply.

Check the institution below
☐ Simon Fraser University
☐ University of Alberta
☐ University of Northern British Columbia and/or Northern Health Authority*
☐ University of Saskatchewan
☐ University of Victoria
☐ Island Health Authority
☐ Fraser Health Authority
☐ Interior Health Authority

**If the study involves Northern Health Authority, please select UNBC as Northern Health Authority does not have a TCPS2 compliant board.*

* **E.3. Local Recruitment** Guidance Notes

Provide a detailed description of the method of recruitment for the local (UBC) sites. For example, describe who will contact prospective participants and by what means this will be done. Ensure that any letters of initial contact and other recruitment materials are amended to meet local requirements and attached to this submission on Page 9.

dfae

* **E.4. Local Consent Process** Guidance Notes

Specify who will explain the consent form and consent participants for the local (UBC) sites. Include details of where the consent will be obtained and under what circumstances.

dfae

* **E.5. Disposition of Local (UBC) Study Data** Guidance Notes

E.5.A.

Describe what will happen to the data at the end of the study (including how long the study data will be retained, when and how the data will be destroyed), and what plans there are for future use of the data, including who will have access to the data in the future and for what purpose

Selecting "Yes" under section E.2 will open up sections E.3, E.4, E.5.A and E.5.B and when you click on "Continue, you will be routed to section 9 (Documentation)

C. Creation of a Research Database, Registry or Biorepository - HUMAN ETHICS APPLICATION

Please note that all required fields are marked with a red asterisk and need to be filled out before being able to proceed onto the next page. Please make sure to save your work before continuing onto the next page in an effort to make sure your work is not lost. You can do so by clicking on the **"Save"** link at the top or the bottom of this page.

Selecting "Yes" under section 4.7.A will route you to section C (Creation of a Research Database, Registry or Biorepository) when you click "Continue".

* **C.1.** *What is the scope and purpose of the database, registry or biorepository?* Guidance Notes

fsgr s__

* **C.2.** *What are the anticipated public and scientific benefits of the database, registry or biorepository?* Guidance Notes

fsgr

C.3. *Over what period of time will data be collected?* Guidance Notes

sfgrs

C.4.A. Sources Guidance Notes

A. Retrospective Clinical Chart Reviews - HUMAN ETHICS APPLICATION

Please note that all required fields are marked with a red asterisk and need to be filled out before being able to proceed onto the next page. Please make sure to save your work before continuing onto the next page in an effort to make sure your work is not lost. You can do so by clicking on the **"Save"** link at the top or the bottom of this page.

* **A.1** *Summarize the research proposal*

Guidance Notes

***Selecting "No" under section 4.8.E will route you to section A**

(Retrospective Clinical Chart Reviews)

* **A.2** *Describe how permission to access the medical records and to collect and use these records will be obtained.*

Guidance Notes

A.3 *Briefly describe the type of data that you intend to collect (e.g., disease, diagnosis, outcome, demographic, aggregate, personal-level). Please attach a data collection/ data extraction form to Question 9.8A of the application for review.*

Guidance Notes

A.4 *Number of Records/Patient Charts*

Guidance Notes

5. SUMMARY OF STUDY AND RECRUITMENT - HUMAN ETHICS APPLICATION

Please note that all required fields are marked with a red asterisk and need to be filled out before being able to proceed onto the next page. Please make sure to save your work before continuing onto the next page in an effort to make sure your work is not lost. You can do so by clicking on the **"Save"** link at the top or the bottom of this page.

View 5 collects details about the study.

* **5.1. Study Summary**

5.1.A

Provide a short summary of the project written in lay language suitable for non-scientific REB members. DO NOT exceed 1000 words and do not cut and paste directly from the study protocol.

* **5.1.B**

Summarize the research proposal:

For 5.1.B: Summarize the research proposal using the following headings: 1) **Purpose** 2) **Hypothesis** 3) **Justification** 4) **Objectives** 5) **Research Method** 6) **Statistical Analysis**

In the description of **purpose**, include the following:
- Name of the investigational drug(s) used in this study
- Name of any marketed drug(s) used outside of its approved indication
- Name and description of any positron-emitting radiopharmaceuticals to be used
- Name and description of any new investigational device(s) to be used
- Name and description of any marketed device to be used in an experimental mode

In the description of **justification** include the following:
- A description of the standard treatment
- A description of alternative treatments (other than standard treatments)
- Justification of the use of placebo, if applicable

In the description of **statistical analysis** include the following:
- A summary of the primary and secondary end-points
- Statistical analysis planned
- Planned sample size

Click here for further information on the **research proposal summary**.

A copy of the research protocol/proposal must be attached to box 9.1 of the application

5.2. Inclusion Criteria

Inclusion Criteria. Describe the participants being selected for this study, and list the criteria for their inclusion. For research involving human pluripotent stem cells, provide a detailed description of the stem cells being used in the research.

Please enter the inclusion criteria as an itemized list.

Click here for information on **inclusion criteria for participants**.
Click here for **criteria for expedited review of pluripotent stem cell research**.

5.3. Exclusion Criteria

Exclusion Criteria. Describe which potential participants will be excluded from participation, and list the criteria for their exclusion.

Provide all exclusion criteria as described in the protocol/proposal. Otherwise, indicate how these criteria differ from those in the protocol/proposal.

As the TCPS2 cautions against research that excludes particular

6. PARTICIPANT INFORMATION AND CONSENT PROCESS - HUMAN ETHICS APPLICATION

* **6.1. Time to Participate** *How much time will a participant be asked to dedicate to the proje* //	Include how many minutes/hours over how many weeks/months the participant will be asked to dedicate to the project. Ensure that you also include this information in the consent form. The amount of time stated in the application must be consistent with ALL other study documents, e.g., recruitment letters or posters, protocol, and consent forms.
6.2. Time to Participate – Normal/Control Participants *If applicable, how much time will a normal/control volunteer be asked to dedicate to the project?*	Include how many minutes/hours over how many weeks/months the participant will be asked to dedicate to the project. This must be consistent with the information noted in the consent document. Please refer to Box 5.5 for a definition of a control group. If the proposal does not involve a control group, enter "N/A".
6.3. Risks/Harms *Describe what is known about the risks (harms) of the proposed research.*	Include any information about discomfort or incapacity that the participants are likely to endure as a result of the experimental procedure, along with the details of any known side effects which may result from the experimental treatment. Quantify risks using percentages where possible. Click here for information on **risks (harms)**.
6.4. Benefits *Describe any potential benefits to the participant that could arise from his or her participation in the proposed research.*	Specify the benefits to the participant. If there are no benefits, state this explicitly. If any specific therapeutic benefits cannot be assured, but may be hoped for by the participant, state explicitly that the participant may or may not benefit from participation in the study.
6.5. Reimbursement	As per the TCPS2 (Article 3.1), incentives offered to participants should not be so large or attractive as to encourage reckless

View 6 collects information about study participation.

7. NUMBER OF PARTICIPANTS AND REGULATORY APPROVALS/REGISTRATION FOR CLINICAL STUDY - HUMAN ETHICS APPLICATION

View 7 collects information about regulatory approvals and the number of participants.

7.1. Multi-Centre Studies

7.1.A.

Is this a multi-centre study (involves centres outside of those ap

○ Yes ○ No Clear

If known, please list the other sites below:

7.1.B.

Is this study being submitted for ethical approval to any other BC or Canadian Research Ethics Board?

○ Yes

○ No

○ Unknown

Clear

If yes, please provide the name of the REB(s) and if available, contact information:

These questions will assist the REB to consider coordination of their review with the other research sites.

Please note that this is not the same as question 4.6 which is specifically directed to studies involving other Institutions with which UBC has a collaborative review or reciprocity agreement.

7.2. Number of Participants

7.2.A.

How many participants (including controls) will be enrolled in the entire study? (i.e. the entire study, world-wide)

7.2.B.

How many participants (including controls) will be enrolled at institutions covered by this Research Ethics Approval? (i.e. only at the institutions covered by this approval)

Of these, how many are controls?

Controls are people acting in a control capacity including normal participants.

8. SECURITY OF DATA, CONFIDENTIALITY OF PERSONAL INFORMATION, and DATA MONITORING FOR CLINICAL STUDY - HUMAN ETHICS APPLICATION

8.1. Unblinding in an Emergency

Describe the provisions made to break the code of a double-blind study in an emergency situation, and indicate who has the code.

Click here for information on **unblinding in the event of an emergency.**

View 8 collects data security, monitoring and confidentiality details.

8.2. Data Monitoring Procedures

Describe data monitoring procedures while research is ongoing. Include details of planned interim analyses, Data and Safety Monitoring Board, or other monitoring systems.

For clinical trials, the researcher is responsible for providing the REB with an acceptable plan for monitoring the safety of participants, including a plan for the tabulation, analysis and reporting of safety data, and the sharing of other new information in a form that permits REBs to interpret and respond appropriately (TCPS2, 11.7).

* **8.3. Study Stoppage**

Describe the circumstances under which the study could be stopped early. Should this occur, describe what provisions would be put in place to ensure that the participants are fully informed of the reasons for stopping the study.

* **8.4. Personal Identifiers**

8.4.A.

Describe how the identity of the participants will be protected both during and after the research study, including how the participants will be identified on data collection forms.

Unique Study Code: UBC REBs require the use of a unique study code not derived from or related to the information about the individual, i.e., name, SIN, PHN, hospital number, DOB, address, or unique characteristic.

Click here for information on the **protection of participant identity.**

View 9 collects documentation for the study.

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.

Attach documents into the body of your application by clicking "Add".

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	Version	Date	Document
There are no items to display			

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			

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.

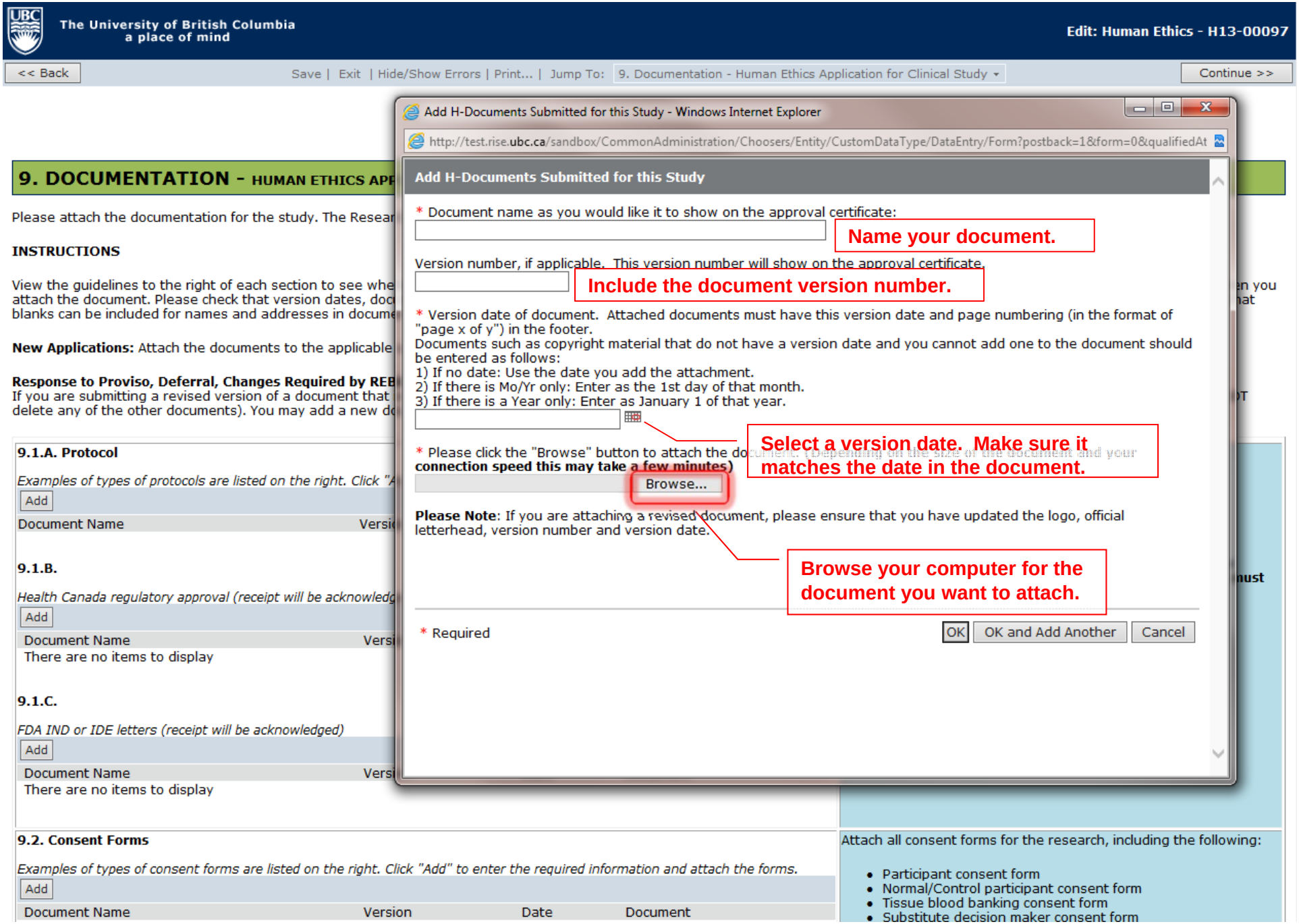
9.2. Consent Forms

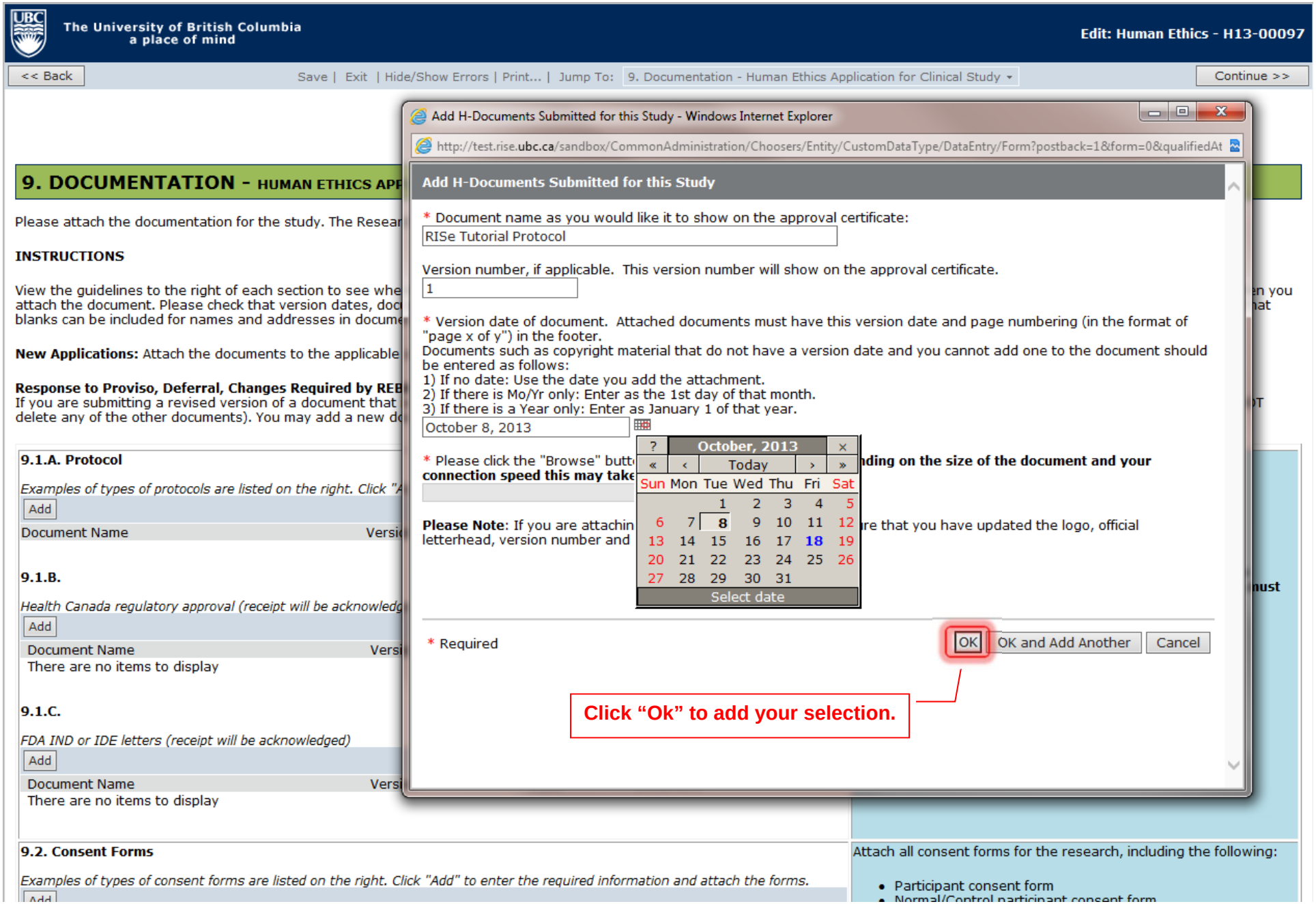
Examples of types of consent forms are listed on the right. Click "Add" to enter the required information and attach the forms.

Add

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

- Participant consent form
- Normal/Control participant consent form
- Tissue blood banking consent form


The University of British Columbia
a place of mind
Edit: Human Ethics - H13-00097
<< Back
Save | Exit | Hide/Show Errors | Print... | Jump To: 9. Documentation - Human Ethics Application for Clinical Study
Continue >>
9. DOCUMENTATION - HUMAN ETHICS APP
Please attach the documentation for the study. The Resear
INSTRUCTIONS
View the guidelines to the right of each section to see whe
attach the document. Please check that version dates, doc
blanks can be included for names and addresses in docume
New Applications: Attach the documents to the applicable
Response to Proviso, Deferral, Changes Required by REB
If you are submitting a revised version of a document that
delete any of the other documents). You may add a new do
9.1.A. Protocol
Examples of types of protocols are listed on the right. Click "A
Add
Document Name
Versi
9.1.B.
Health Canada regulatory approval (receipt will be acknowledg
Add
Document Name
Versi
There are no items to display
9.1.C.
FDA IND or IDE letters (receipt will be acknowledged)
Add
Document Name
Versi
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.
Add
Document Name
Version
Date
Document
Attach all consent forms for the research, including the following:
Participant consent form
Normal/Control participant consent form
Tissue blood banking consent form
Substitute decision maker consent form
Add H-Documents Submitted for this Study - Windows Internet Explorer
http://test.rise.ubc.ca/sandbox/CommonAdministration/Choosers/Entity/CustomDataType/DataEntry/Form?postback=1&form=0&qualifiedAt
Add H-Documents Submitted for this Study
* Document name as you would like it to show on the approval certificate:
Name your document.
Version number, if applicable. This version number will show on the approval certificate.
Include the document version number.
* Version date of document. Attached documents must have this version date and page numbering (in the format of "page x of y") in the footer.
Documents such as copyright material that do not have a version date and you cannot add one to the document should be entered as follows:
1) If no date: Use the date you add the attachment.
2) If there is Mo/Yr only: Enter as the 1st day of that month.
3) If there is a Year only: Enter as January 1 of that year.
Select a version date. Make sure it matches the date in the document.
* Please click the "Browse" button to attach the document. Depending on the size of the document and your connection speed this may take a few minutes)
Browse...
Please Note: If you are attaching a revised document, please ensure that you have updated the logo, official letterhead, version number and version date.
Browse your computer for the document you want to attach.
* Required
OK
OK and Add Another
Cancel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Edit: Human Ethics - H13-00097
<< Back
Save | Exit | Hide/Show Errors | Print... | Jump To: 9. Documentation - Human Ethics Application for Clinical Study
Continue >>
9. DOCUMENTATION - HUMAN ETHICS APP
Please attach the documentation for the study. The Resear
INSTRUCTIONS
View the guidelines to the right of each section to see whe
attach the document. Please check that version dates, doc
blanks can be included for names and addresses in docume
New Applications: Attach the documents to the applicable
Response to Proviso, Deferral, Changes Required by REB
If you are submitting a revised version of a document that
delete any of the other documents). You may add a new d
9.1.A. Protocol
Examples of types of protocols are listed on the right. Click "A
Add
Document Name
Versi
9.1.B.
Health Canada regulatory approval (receipt will be acknowledg
Add
Document Name
Versi
There are no items to display
9.1.C.
FDA IND or IDE letters (receipt will be acknowledged)
Add
Document Name
Versi
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.
Add
Attach all consent forms for the research, including the following:
Participant consent form
Add H-Documents Submitted for this Study - Windows Internet Explorer
http://test.rise.ubc.ca/sandbox/CommonAdministration/Choosers/Entity/CustomDataType/DataEntry/Form?postback=1&form=0&qualifiedAt
Add H-Documents Submitted for this Study
* Document name as you would like it to show on the approval certificate:
RISe Tutorial Protocol
Version number, if applicable. This version number will show on the approval certificate.
1
* Version date of document. Attached documents must have this version date and page numbering (in the format of "page x of y") in the footer.
Documents such as copyright material that do not have a version date and you cannot add one to the document should be entered as follows:
1) If no date: Use the date you add the attachment.
2) If there is Mo/Yr only: Enter as the 1st day of that month.
3) If there is a Year only: Enter as January 1 of that year.
October 8, 2013
October, 2013
Today
Sun Mon Tue Wed Thu Fri Sat
1 2 3 4 5
6 7 8 9 10 11 12
13 14 15 16 17 18 19
20 21 22 23 24 25 26
27 28 29 30 31
Select date
* Please click the "Browse" butt
nding on the size of the document and your
connection speed this may take
Please Note: If you are attachin
re that you have updated the logo, official
letterhead, version number and
* Required
OK
OK and Add Another
Cancel
Click “Ok” to add your selection.

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	Version	Date	Document	
RISe Tutorial Protocol	1	October 8, 2013	[View]	Delete

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			

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.

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:

10. FEE FOR SERVICE FOR CLINICAL STUDY - HUMAN ETHICS APPLICATION

Industry For-Profit Sponsors

Guidance Notes

Send the $3000.00 fee to the Clinical Research Ethics Board (CREB) OR enter details below stating that the fee will be sent and by when. It is the investigator's responsibility to communicate this requirement to the sponsor and collect the payment prior to CREB submission if possible.

* *Please indicate which of the following methods of payment will be used for this application.*

Method of Payment
(•) N/A (Not funded by an Industry For-Profit Sponsors)
( ) A cheque made payable to "University of British Columbia", sent to: UBC Clinical Research Ethics Office Room 210, Research Pavilion 828 West 10th Avenue Vancouver, BC V5Z 1L8
( ) A Journal Voucher crediting: a. Speedchart (EDJM) b. Account: 477500 c. Fund: F0000 d. Dept. ID: 354000 e. Project Grant: 35F40100 *Make sure to debit your Project Grant using Account 5512 [No Title] n the cheque is received from the funder, please process as a cost recovery by using the same Project Grant and Account on the Cash Receipt form. * Make sure the Journal Voucher is signed by an authorized signatory.

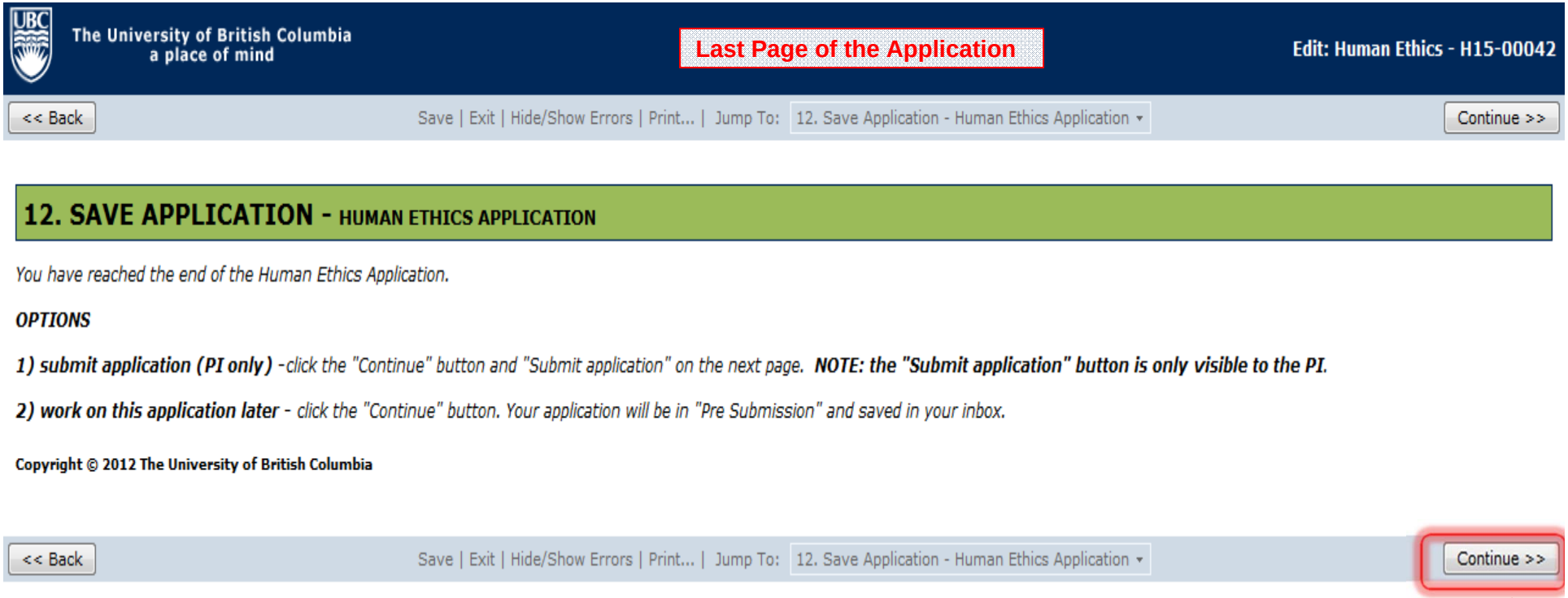
Clear

Select one of the methods of payment. Methods of payment may be different than shown here for the REB where you submit your application.

OR

Enter information stating when the fee will be sent:

To save information on each view as you are working, especially if you are working on the view for a long period of time, select the "Save" button located at the top or bottom of the view in the blue bar. Your work on each view will automatically be saved once you hit the "Continue" button.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Last Page of the Application
Edit: Human Ethics - H15-00042
<< Back
Save | Exit | Hide/Show Errors | Print... | Jump To: 12. Save Application - Human Ethics Application
Continue >>
12. SAVE APPLICATION - HUMAN ETHICS APPLICATION
You have reached the end of the Human Ethics Application.
OPTIONS
1) submit application (PI only) -click the "Continue" button and "Submit application" on the next page. NOTE: the "Submit application" button is only visible to the PI.
2) work on this application later - click the "Continue" button. Your application will be in "Pre Submission" and saved in your inbox.
Copyright © 2012 The University of British Columbia
<< Back
Save | Exit | Hide/Show Errors | Print... | Jump To: 12. Save Application - Human Ethics Application
Continue >>
Hit “Continue” to save and close the application – You will automatically be taken to the Study Homepage.

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Committees | Studies | Reports | Help

... > Studies > Clinical Study - December 18, 2015

Current State

Pre Submission

Edit Application

Activities

PI SUBMIT APPLICATION

PI&S PI and Staff Comments

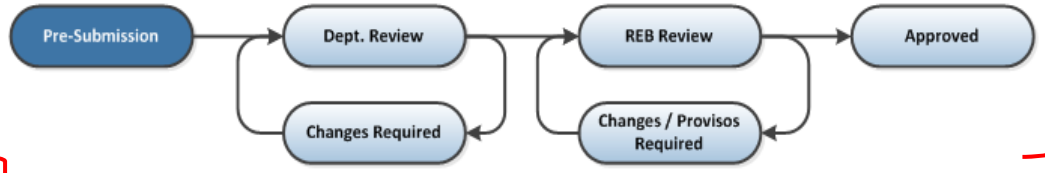
PI&S Permanently Inactivate

PI&S Copy Application

Viewing/Printing

Application - Review/Print

Return to My Home



To track the status of your application through the approval process, refer to the application state diagram

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

A system-generated Study ID Number and study nickname

Principal Investigator (PI):	Prinz Apple	**Approval Departm**	
Primary Contact:		**Department Appro**	
Typ		**Review Board:**	Clinical Research Ethics Board
Minimal Risk:	No	**Version:**	0 . 0
Meeting Type:		**Meeting Date:**	
Type of Funding:	No Funding	**US Affiliated Study:**	No
Flag:	N/A		

Activities that you may perform.

CM Con

As the state of your application is "Pre Submission", your application is still open for any edits you may want to make – click on the "Edit Application" button to go back into the application.

Correspondence | Provisos | Application Changes

This contains all the correspondence and activities completed on the application before the initial 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.

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Committees | Studies | Reports | Help

... > Studies > Clinical Study - December 18, 2015

Current State

Pre Submission

Edit Application

Activities

PI SUBMIT APPLICATION

PI&S PI and Staff Comments

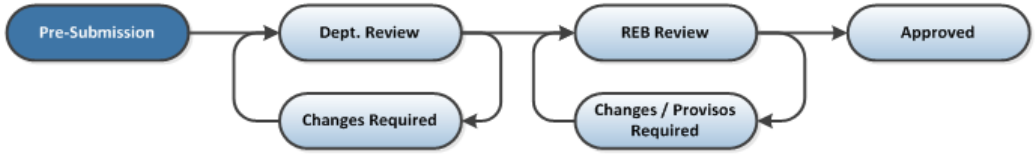
PI&S Permanently Inactivate

PI&S Copy Application

Viewing/Printing

Application - Review/Print

Return to My Home



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

Principal Investigator (PI):	Prinz Apple	**Approval Department:**	
Primary Contact:		**Department Approver:**	
Type of Study:	Clinical	**Review Board:**	Clinical Research Ethics Board
Minimal Risk:	No	**Version:**	0 . 0
Meeting Type:		**Meeting Date:**	
Type of Funding:	No Funding	**US Affiliated Study:**	No
Flag:	N/A		
CM Conflicts:	Prinz Apple		

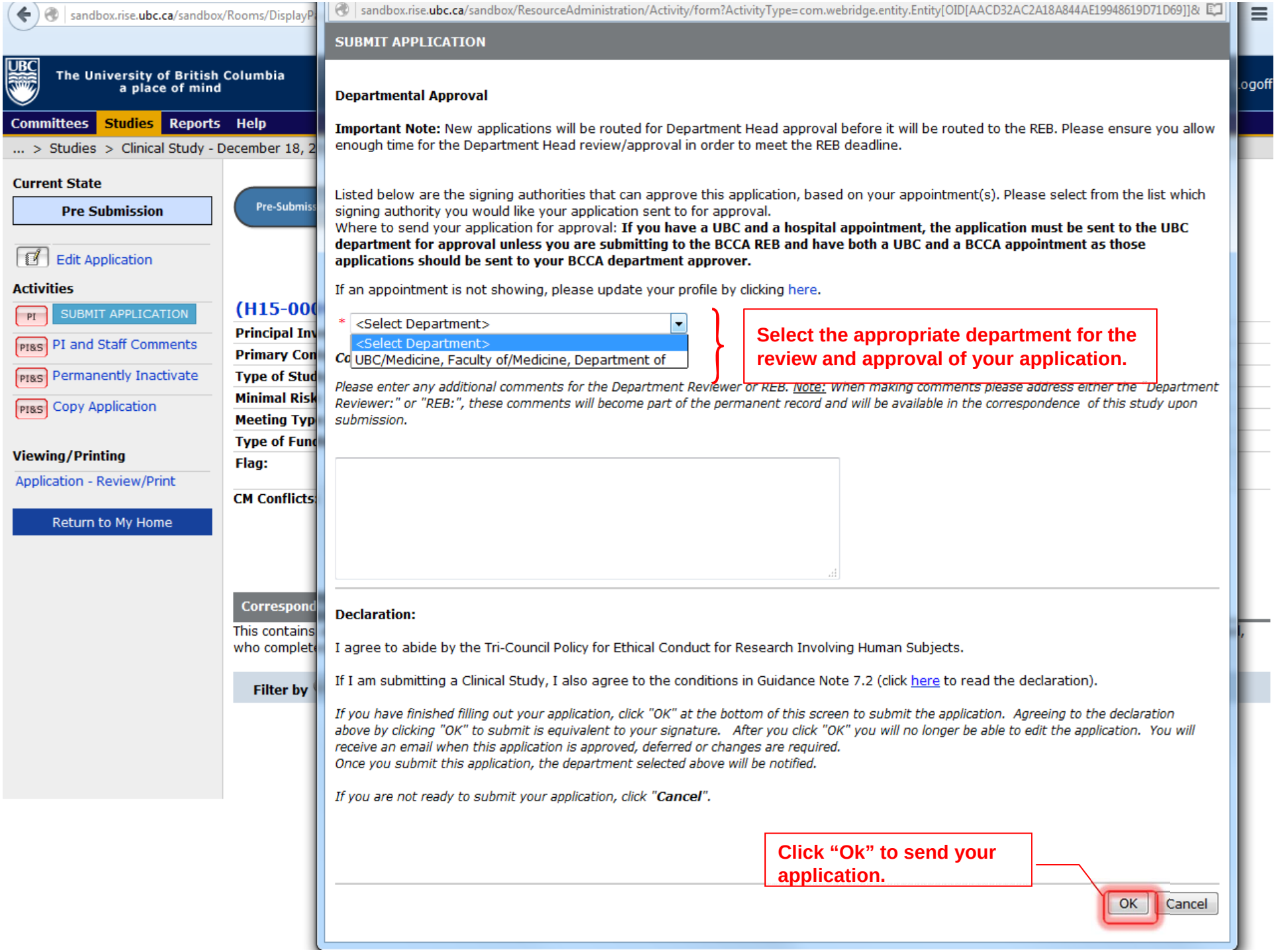
Click to submit your new application for review.

Correspondence | Provisos | Application Changes

This contains all the correspondence and activities completed on the application before the initial 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.


sandbox.rise.ubc.ca/sandbox/Rooms/DisplayP
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Studies
Reports
Help
... > Studies > Clinical Study - December 18, 2
Current State
Pre Submission
Edit Application
Activities
SUBMIT APPLICATION
PI and Staff Comments
Permanently Inactivate
Copy Application
Viewing/Printing
Application - Review/Print
Return to My Home
Pre-Submiss
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Type of Fund
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Correspond
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who complet
Filter by
sandbox.rise.ubc.ca/sandbox/ResourceAdministration/Activity/form?ActivityType=com.webridge.entity.Entity[OID[AACD32AC2A18A844AE19948619D71D69]]&
SUBMIT APPLICATION
Departmental Approval
Important Note: New applications will be routed for Department Head approval before it will be routed to the REB. Please ensure you allow enough time for the Department Head review/approval in order to meet the REB deadline.
Listed below are the signing authorities that can approve this application, based on your appointment(s). Please select from the list which signing authority you would like your application sent to for approval.
Where to send your application for approval: If you have a UBC and a hospital appointment, the application must be sent to the UBC department for approval unless you are submitting to the BCCA REB and have both a UBC and a BCCA appointment as those applications should be sent to your BCCA department approver.
If an appointment is not showing, please update your profile by clicking here.
<Select Department>
<Select Department>
UBC/Medicine, Faculty of/Medicine, Department of
Select the appropriate department for the review and approval of your application.
Please enter any additional comments for the Department Reviewer or REB. Note: When making comments please address either the "Department Reviewer:" or "REB:", these comments will become part of the permanent record and will be available in the correspondence of this study upon submission.
Declaration:
I agree to abide by the Tri-Council Policy for Ethical Conduct for Research Involving Human Subjects.
If I am submitting a Clinical Study, I also agree to the conditions in Guidance Note 7.2 (click here to read the declaration).
If you have finished filling out your application, click "OK" at the bottom of this screen to submit the application. Agreeing to the declaration above by clicking "OK" to submit is equivalent to your signature. After you click "OK" you will no longer be able to edit the application. You will receive an email when this application is approved, deferred or changes are required.
Once you submit this application, the department selected above will be notified.
If you are not ready to submit your application, click "Cancel".
Click “Ok” to send your application.
OK
Cancel

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Committees | Studies | Reports | Help

... > Studies > Clinical Study - December 18, 2015

Current State

Department Review

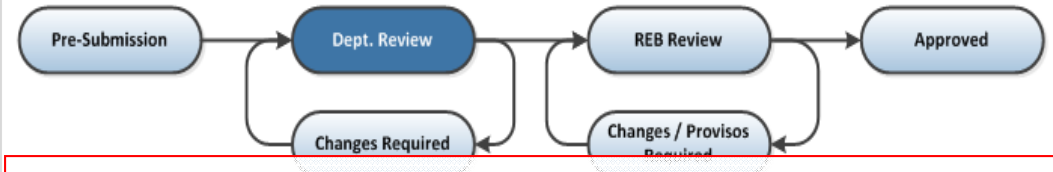
Activities

- PI&S PI and Staff Comments
- PI Permanently Inactivate
- PI&S Copy Application

Viewing/Printing

- Application - Full
- Application - Review/Print

Return to My Home



Notice the state of your application is now "Department Review" and your application is awaiting approval from the head of your department. If you notice a delay, please contact your Department Head. The REB will not receive the application until it is approved by your Department Head.

Primary Contact:		**Department Approver:**	
Type of Study:	Clinical	**Review Board:**	Clinical Research Ethics Board
Minimal Risk:	No	**Version:**	0 . 1
Meeting Type:		**Meeting Date:**	
Type of Funding:	No Funding	**US Affiliated Study:**	No
Flag:	N/A		
CM Conflicts:	Prinz Apple		

All your activities and comments can be viewed under the Correspondence tab.

Correspondence | Provisos | Application Changes

This contains all the correspondence and activities completed on the application before the initial 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 Application	Apple, Prinz	18/12/2015 11:51

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Prinz Apple | My Home | Projects | Logoff

Committees | Studies | Reports | Help

... > Studies > Kyle Test - SFU Test 2

Current State

REBA Screening

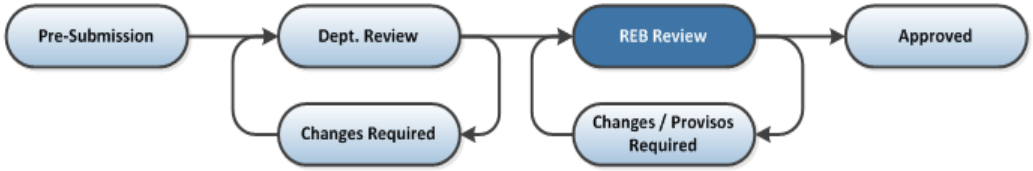
Activities

- PI&S PI and Staff Comments
- PI Permanently Inactivate
- PI&S Copy Application

Viewing/Printing

- Application - Full
- Application - Review/Print

Return to My Home



(H14-00046) Kyle Test - SFU Test 2

Once the REB has received the application, it will be in the "REBA Screening" state. At this point, the application will be screened by the REB Admin (REBA) prior to forwarding for REB review.

P			aculty of
P			t Head
T		Review Board:	BC Cancer Agency Research Ethics Board
Minimal Risk:	Yes	**Version:**	0.1
Meeting Type:		**Meeting Date:**	
Type of Funding:	Grant-in-aid, Grant, For-Profit Sponsor (Industry or Pharmaceutical), Internal Funds	**US Affiliated Study:**	No

CM Conflicts:

Correspondence | Provisos | Application Changes

This contains all the correspondence and activities completed on the application before the initial 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
Dept	Approved by Department	Head, Department	29/07/2014 14:31
	asdf		
PI	Submitted Application	Apple, Prinz	21/05/2014 14:45