REB EXCHANGE

Researcher Manual

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Brief REBX info

Introduction

REBX is a RISe feature that will connect human research ethics application platforms: RISe (UBC), IRISS (UCalgary), and ARISE (UAlberta) to facilitate the exchange of information and documents.

Websites

UBC website will have current status of study eligibility and which UBC REBs are onboarded.

REBX website for REBX system

Scenarios

Scenario 1 UBC is Board of Record (Lead site)

- UBC RISe application forms will remain the same.
- UBC PI goes through the usual process to obtain REB approval.
- After REB approval, UBC team can invite UCalgary or UAlberta as participating site.
- UBC documents will be shared with Alberta PI and Alberta REB via REBX.

Scenario 2 UBC is a Participating Site (pSite)

- UAlberta or UCalgary REB approves study then UBC is invited as participating site (pSite).
- UBC PI completes RISe Pages 1-4B or 4C and a truncated site-specific form.
- Alberta site's REB application and documents are shared with UBC via REBX.
- UBC Post-Approval Activity Coversheets remain the same.

*Frequently used acronyms/Terms

Acronym	Definition
REB	Research Ethics Board
REBX	REB eXchange feature
PAA	Post-Approval Activity (*Renewal, Amendment, Completion, or Request for Acknowledgement*)

Acronym/ Term	Definition
Primary Contact	Individual listed in RISe Application Box 1.2
pSite	participating site
UBC Study homepage	First screen shown after clicking on study application. Has flowchart and Study detail Dashboard/Table

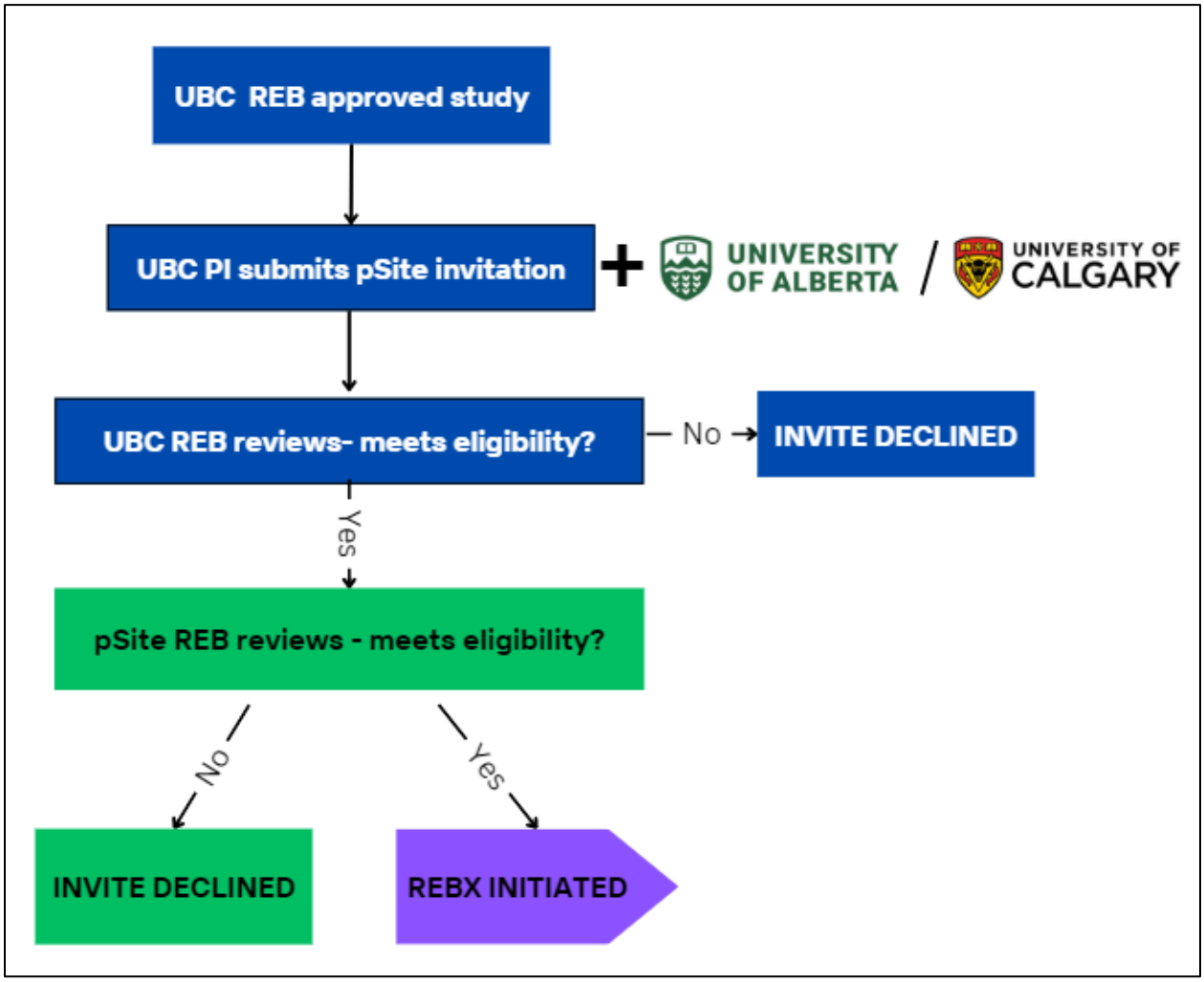
Full Glossary of terms can be found here

Scenario 1 UBC is Lead site

REBX Activation Process

UBC RISe Application forms will remain the same. REBX can only be initiated for REB Approved applications. UBC REB requirements will remain the same. New RISe menu buttons and new tabs will appear when REBX is initiated.

Add Participating Site (pSite) Overview



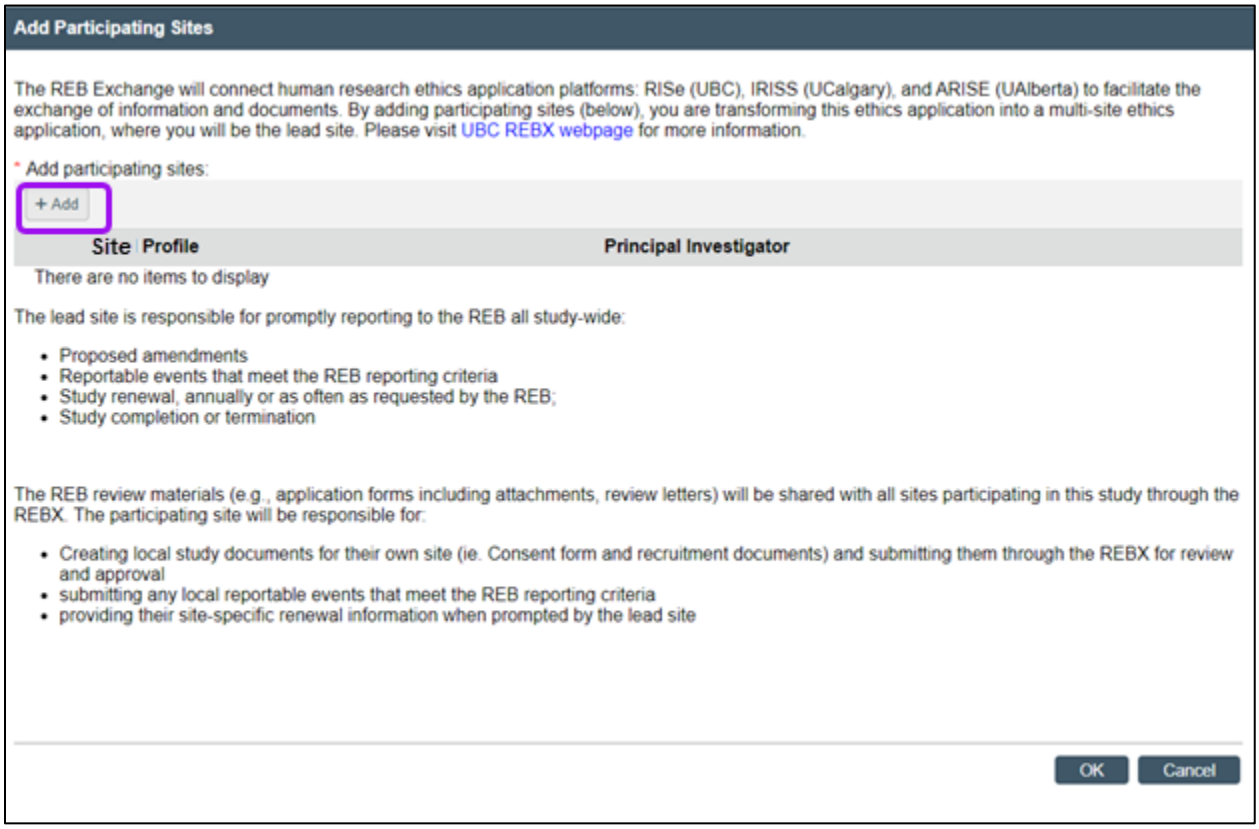
Note, that adding REBX sites is not done via an Amendment. Steps to add pSite, listed below.

How to invite pSite

Login to RISe and Select the approved ethics application. Anyone with online RISe access to the application can add REBX Participating sites. The following shows how to invite a pSite

- On the left-hand side of the menu bar, click

- A pop-up will appear. Click <+Add> to enter pSite details.



Pop-up below will show:

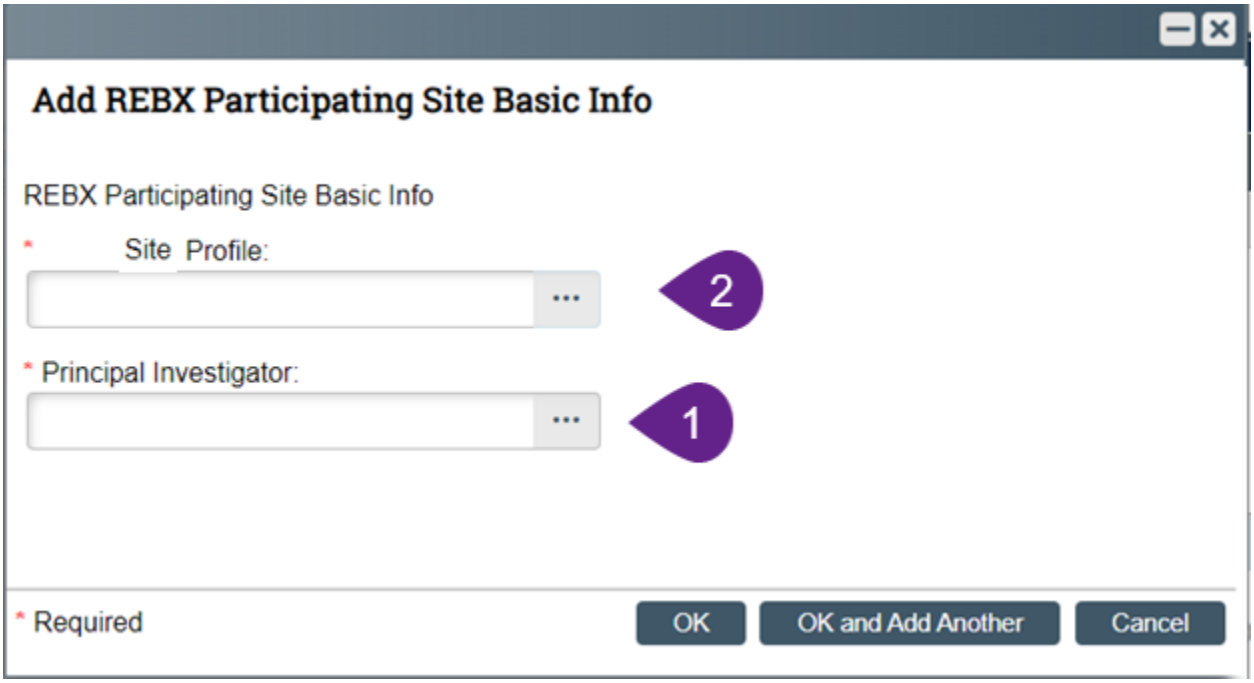
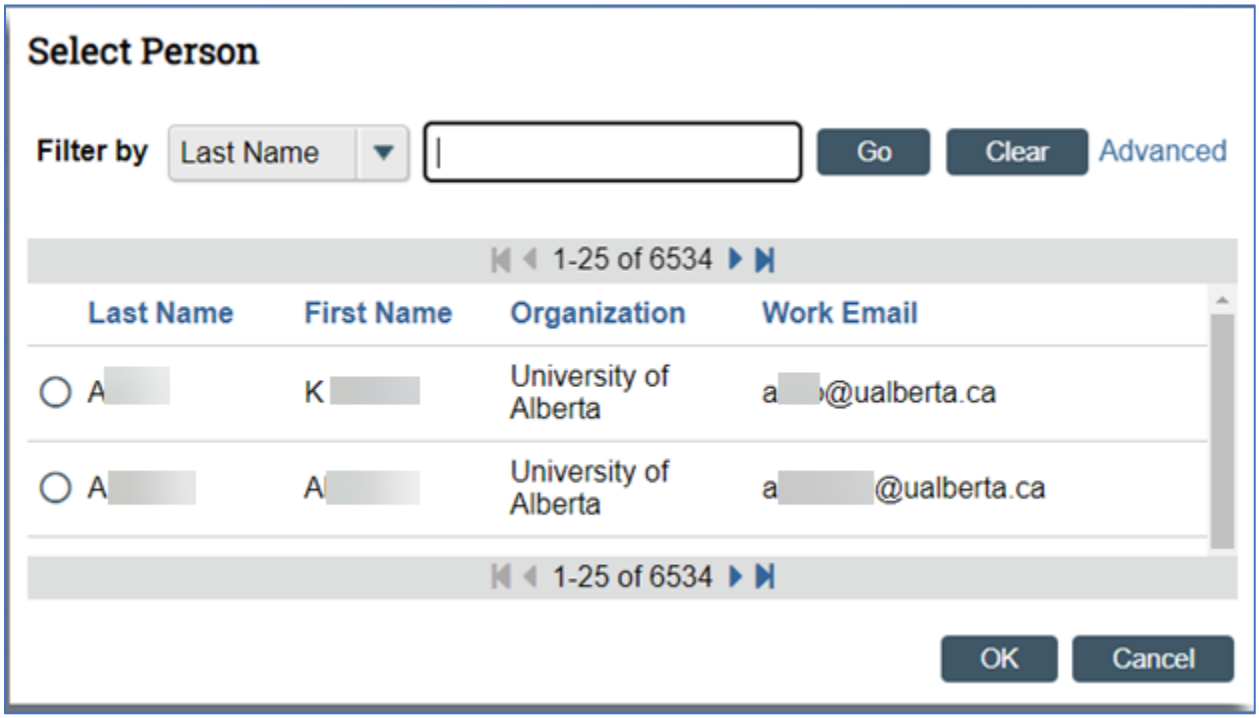


Figure 1

(1) Pop-up for Add Principal Investigator:

- Select or search Alberta PI list.

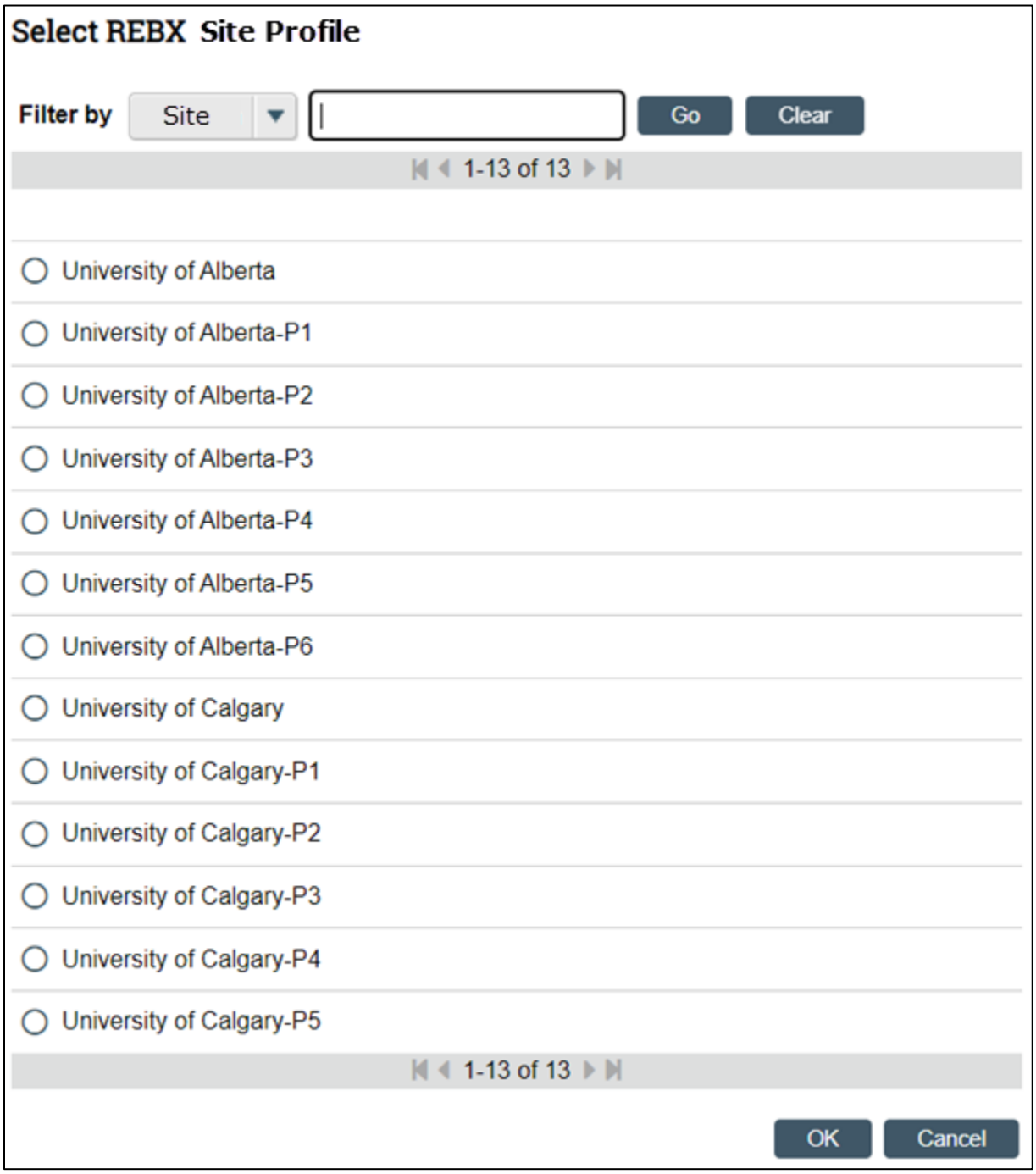


**Verify pSite PI email to ensure, correct individual selected

Click <OK>

This will bring you back to Figure 1

- Select **Site Profile** (2) A pop-up box will appear



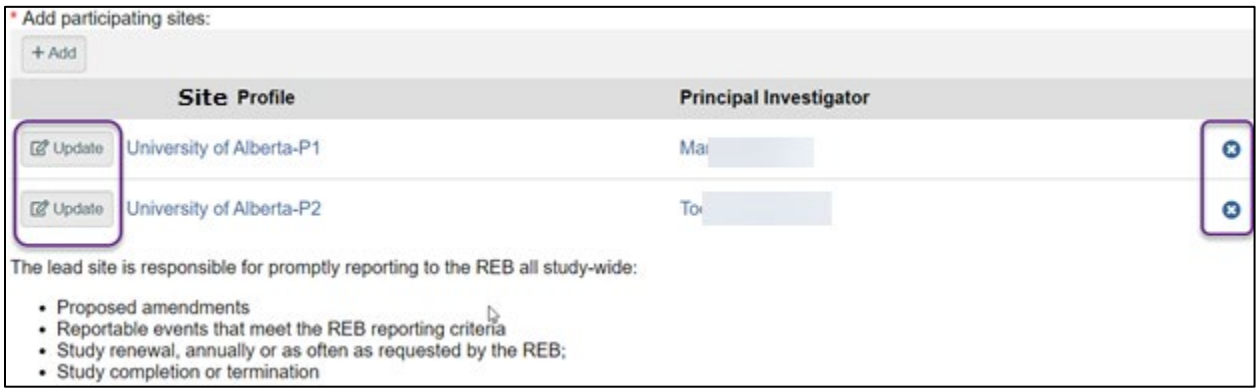
- Select site.
    - If you have pSites in both Universities, then you will need to repeat this "How to invite pSite" process per site.

- If you have multiple pSite PIs in a University, please select University-P1; University-P2; etc For instance, “University of Alberta-P1” PI: Mary Jones next site you add is “University of Alberta-P2” PI: Tommy Smith (see image below).

Multiple Institutions and PIs can be selected using the same “Add Participating Site” activity.

Note I: Before submitting the invitation, please review selected information and in case of error update or remove the selected information

Note II: Unique Site profile (e.g., University of Alberta-P1) can be added only once per study

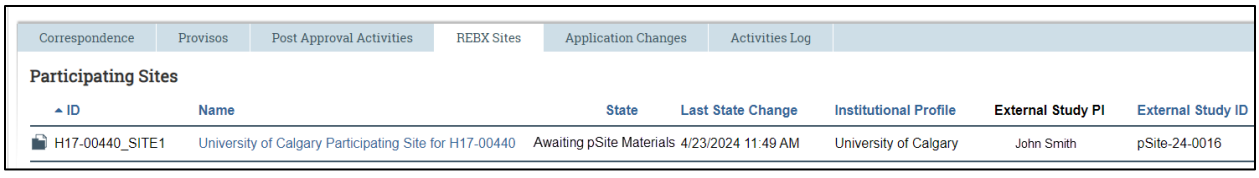


Invitation will be sent to UBC REB office for eligibility review. If study is eligible, it will route to pSite REB for eligibility review, and eligibility is confirmed again then pSite REB will download UBC approved application and documents.

New tab: REBX Sites

After pSite REB has accepted invitation, then a new tab will appear in your study Application Homepage.

Click this tab to see the pSites.



Each pSite will have their own row in this table.

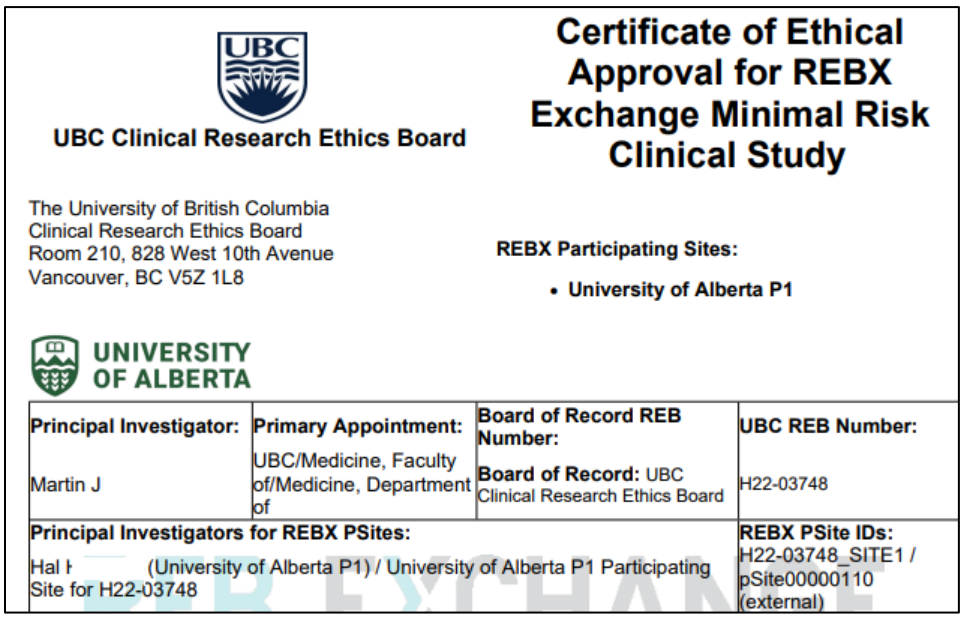
Click under column “Name” to access pSite details

After clicking this pSite application you can see the state is **Awaiting Site Materials**

This pSite is to submit local documents for pSite REB review. pSite REB will review pSite application, issue provisos and when ready, will notify UBC REB when they are ready for approval.

UBC REB will review the pSite application details and may issue provisos to the pSite if warranted.

When ready for approval, UBC REB will release the joint certificate of approval with the following info: pSite Intuitional logo, pSite PI name, pSite site name and pSite ethics application #. Certificate will have REB Exchange watermark. This certificate will be available in RISe and also emailed to UBC PI, UBC Primary contact listed in RISe and pSite PI and pSite Primary Contact.



UBC Clinical Research Ethics Board

Certificate of Ethical Approval for REBX Exchange Minimal Risk Clinical Study

The University of British Columbia
Clinical Research Ethics Board
Room 210, 828 West 10th Avenue
Vancouver, BC V5Z 1L8

REBX Participating Sites:

- **University of Alberta P1**

UNIVERSITY OF ALBERTA

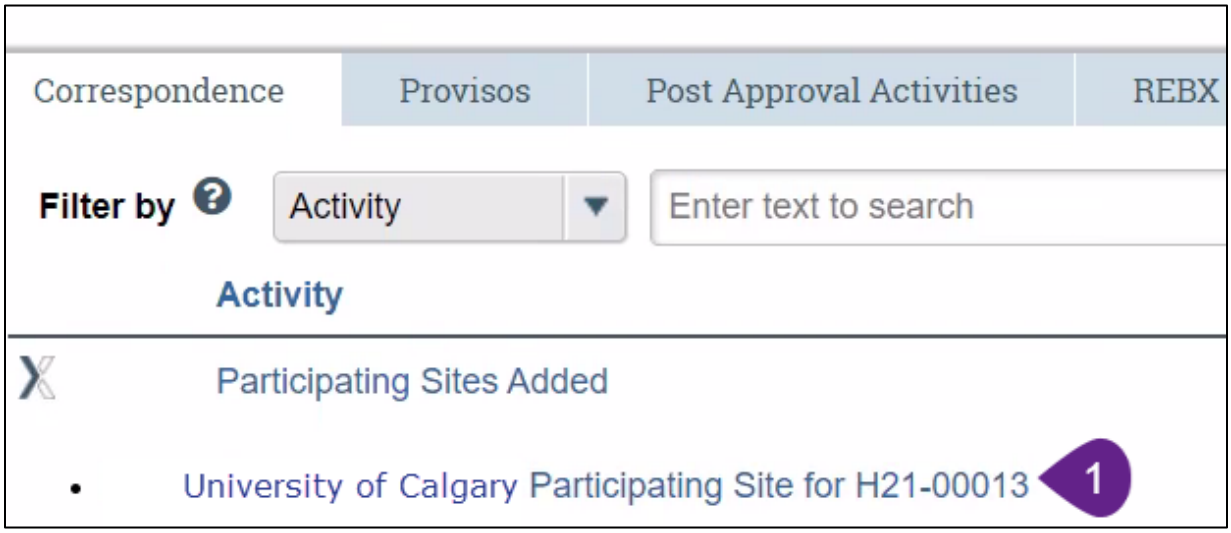
Principal Investigator:	**Primary Appointment:**	**Board of Record REB Number:**	**UBC REB Number:**
Martin J	UBC/Medicine, Faculty of/Medicine, Department of	**Board of Record:** UBC Clinical Research Ethics Board	H22-03748
Principal Investigators for REBX PSites: Hal I (University of Alberta P1) / University of Alberta P1 Participating Site for H22-03748			**REBX PSite IDs:** H22-03748_SITE1 / pSite00000110 (external)

Accessing pSite info and Application

Login to Rise, find UBC application in [**Human Ethics**] tab. After clicking on study, you enter Study homepage.

From Study homepage there are two ways to get to pSite home:

First method: In [**Correspondence tab**] for activity <X Participating Sites added> under this is a hyperlink that will bring you to this pSite's home.



Second method to access pSite house: From Study homepage, there is an **[REBX Sites]** tab. This tab is where UBC team can access each pSite info, Application and PAA.

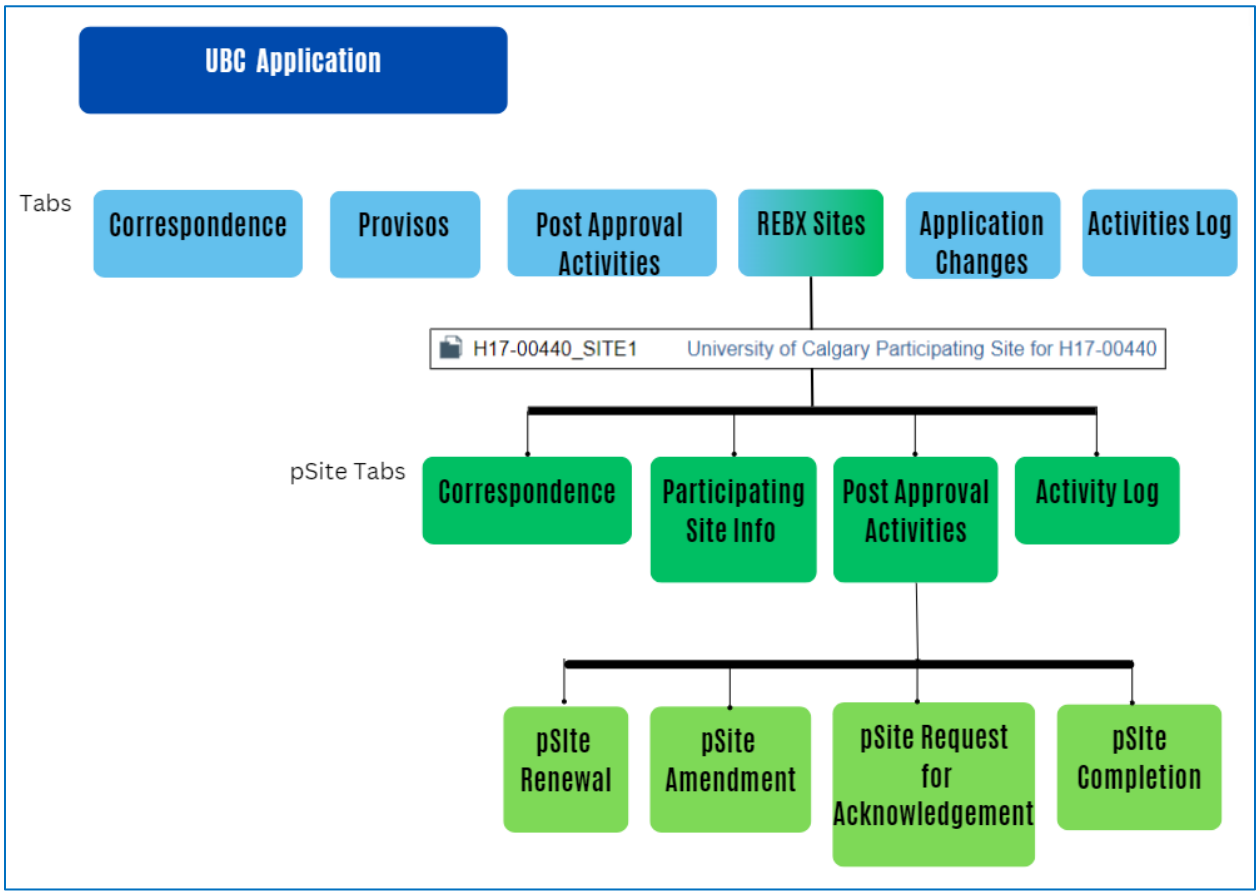


Figure 2

Blue tabs are your regular UBC file, with [REBX sites] tab as your path to access "pSite's house", which then branches to what is happening at that site (pSite application, PAAs).

UBC lead PI- Post Approval Activities (PAA)

Lead Site PI Responsibility
Submits global + local study amendments *e.g., Changes to study protocol, consent forms, materials.*
Submits study annual renewal *Lead site must ensure all pSite Renewal reports are submitted
Submits global + local site study reportable events/ Request for Acknowledgment: Eg. Global + local study privacy breaches, *safety updates, Clinical trial- Data Safety Monitoring Board/ Committee (DSMB/C) report.*
Submit study closure/ completion *After each pSIte has submitted their closure report to Lead Site REB.*

Key points:

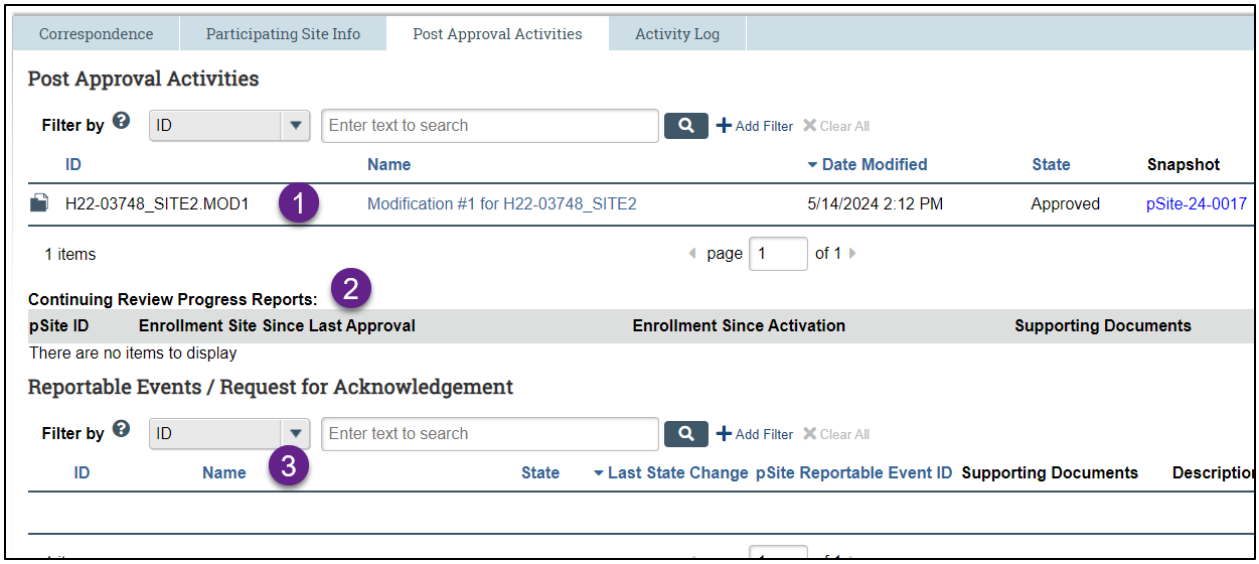
- UBC PI is responsible for **global** study amendments, renewals, request for acknowledgements, completions **+ local BC** amendments and request for acknowledgements.
- UBC study team will have access to pSite application, amendments, renewals, request for acknowledgements, completions and REB approval certificates.

UBC as lead- how to access pSite PAAs

See Figure 2 on how to navigate to pSite's house

Click on **[Post Approval Activities] tab**

This tab will show a table of the different type of PAAs



(1) Amendments section, listed as “Modification”

(2) pSite Annual renewal

(3) Request for Acknowledgment

<u>UBC as lead- Amendments</u>

Lead site is responsible to submit revisions for global Protocol + BC local study documents to lead REB for approval.

If Protocol update necessitates updates to local consent form documents (e.g. additional follow-up visit), ensure to remind **pSite they are still responsible for submitting their local revisions for pSite REB approval.**

<u>UBC as lead- Renewals</u>

UBC PI and primary contact will receive RISe expiry notifications as per usual. pSite teams will receive notifications as per their Ethics platform’s usual method. UBC PI to ensure that all pSite Renewal PAAs have been submitted or email pSite PI directly if pSite renewal not submitted in time.

To access pSite renewal info:

See Figure 2 on how to navigate to pSite’s house

Click on menu bar

to access enrollment #s.

This action can be run by PI and Study Team after the pSite study is approved by Lead site. Completed renewal form includes pSite data. If not completed, the form is empty.

Once all pSite reports collected, UBC PI submits renewal PAA to UBC REB outlining breakdown enrollment per site in **Clinical PAA Coversheet Box 3.4A/ Behavioural Coversheet box 1.2.3**. The expectation that UBC PI reports on BC sites. Information Alberta pSites can be added but this is not required.

Please note that if UBC submits renewal before all pSite renewal reports are submitted then the UBC REB will withhold approval until all have been submitted renewal reports. This is because approval by lead REB means approval for all sites and in order to be compliant, each site needs to submit a renewal report every 12 months at minimum. If your expiry is soon, and pSite report missing, please remind Alberta collaborators to submit asap. If pSite is non-compliant, UBC REB may choose to inactivate that pSite, at which point ethics approval is no longer valid at that pSite.

UBC REB will review as per delegated review or full board as per UBC REB requirements. After, UBC REB approves the renewal, a joint certificate of approval will be issued.

UBC as lead- Request for Acknowledgment

UBC PI responsible for global + local BC site request for acknowledgements to UBC REB such as Global privacy breaches + local BC privacy breaches. UBC REB has the option to send this info to other pSite REBs.

Note Alberta PAA of this type is named Reportable event.

UBC as lead-Completion

Once all pSites have submitted their pSite Completions forms then UBC study team can submit Study completion. When UBC REB approves, study will be inactivated for all.

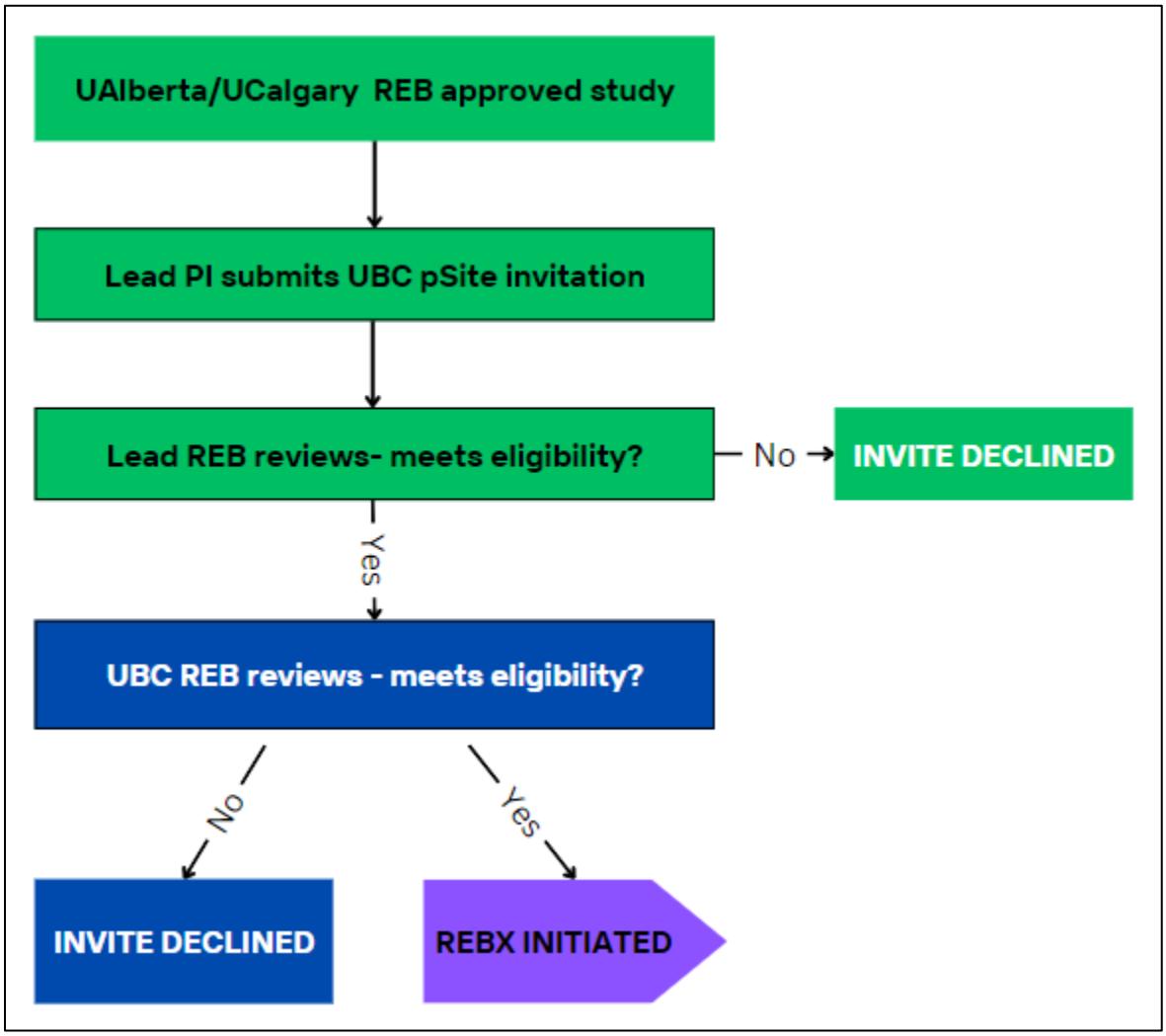
UBC cannot submit PAA Completion before pSite have submitted Completion. This is because once UBC Completion is approved, it will inactivate all sites including pSites.

If UBC PI needs to provide study sponsor with REB certificate that site has been closed before all the pSites, then this can be done via PAA-Request for Acknowledgement, including important info in Box 1A (Clinical) or just before Question 1A (Behavioural) so that will also copy over to REB Acknowledgement certificate.

Scenario 2: UBC is a Participating Site (pSite)

Process

Initial steps that occur prior to UBC PI seeing application in RISe:



If UBC REB or Lead Site declines the invitation, Lead Site PI/ UBC PI will be notified and REBX will not be initiated at the moment. Another invitation can be sent later if UBC REBX eligibility changes.

If UBC REB **accepts** the invitation then UBC pSite PI will receive an email notification that REBX has been initiated.

UBC PI action items:

- Please login to RISe
- You will find this new application in your [**My inbox]** tab in **Pre-submission state**
- Click on new application, if you choose not to participate, click <**Permanently Inactivate**> button in the left side menu.

OR

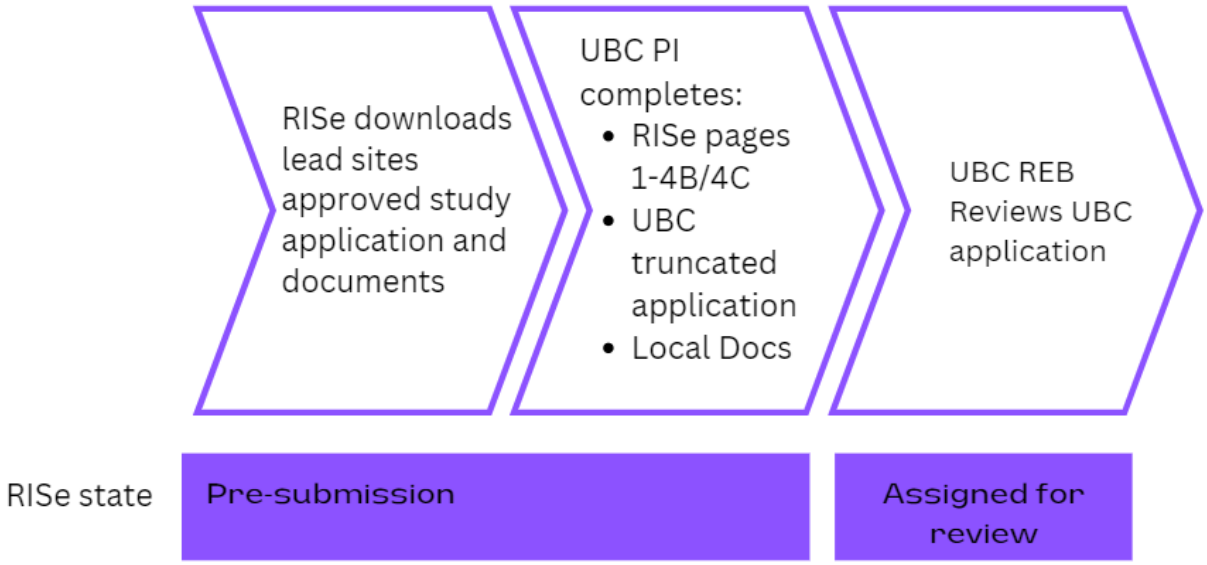
- If you accept invitation, click <**Edit application**> and complete application. If you would like your team to complete this, please add team member to Application Page 1, once saved, that individual will have access to application in RISe.

UBC as pSite- RISe Application Form Completion

As per Figure below, UBC PI will complete RISe pages 1- 4B /1-4C as per usual, then a truncated form, concise page 9, then regular RISe pages 10-11. You will also have access to the Alberta approved application and documents.

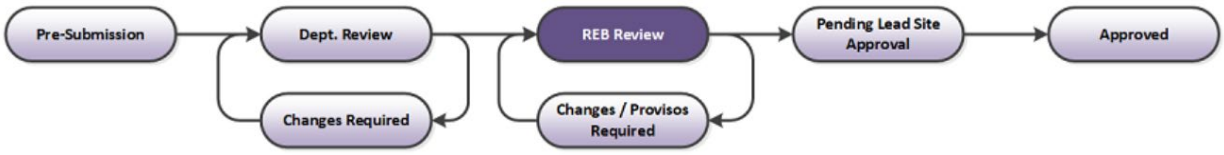
Local REB process/requirements will remain the same:

- When ready to submit application, it will still require Dept Head approval.
- Operational/Institutional approval are still required when applicable.

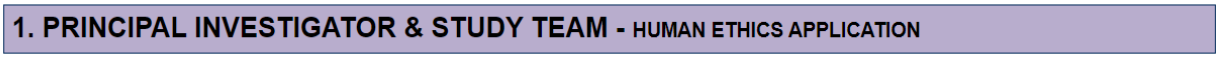


Purple look

When UBC is a pSite, RISe application will look visually different. Primary colour will be purple. Study application flow chart and state will be in Purple



Application form, page headings will be purple as well.

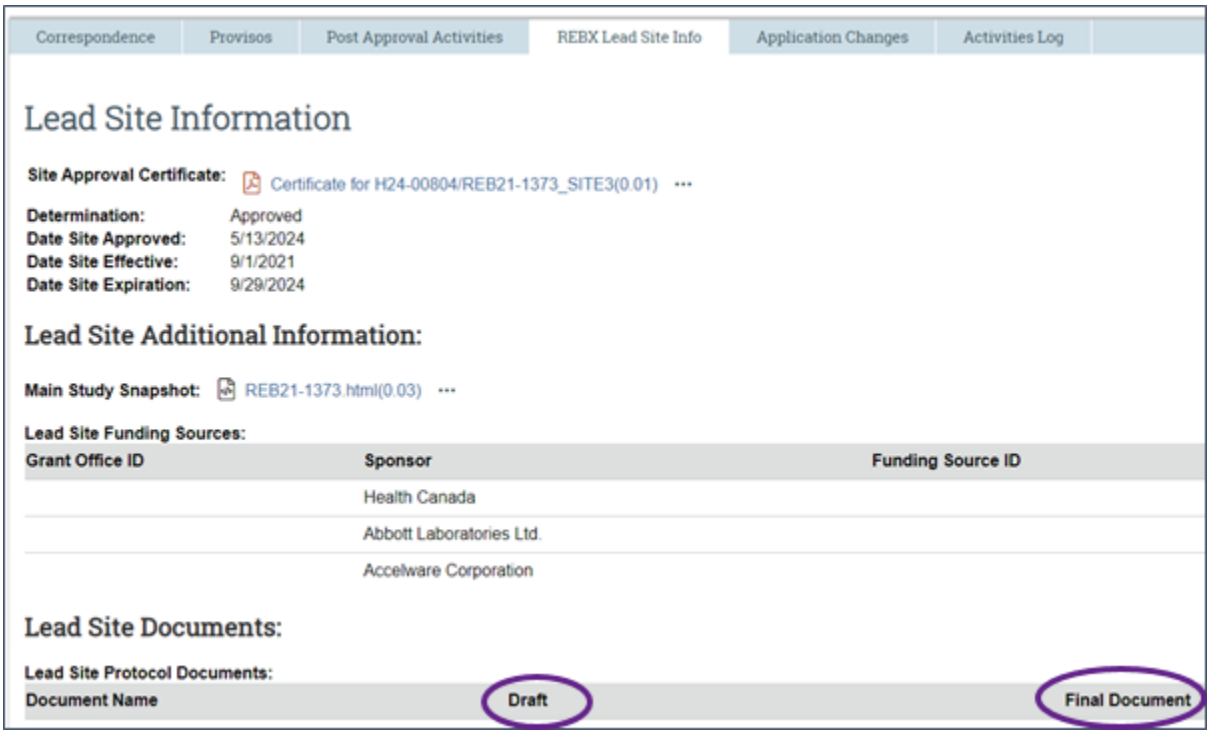


This will help UBC team identify that this is an REBX pSite application.

Tab: REBX Lead Site Info

Login to Rise, find UBC application in [**Human Ethics**] tab. After clicking on study, you enter Study homepage with a [**REBX Lead Site Info**] tab.

Click this tab to access lead site approved REB application form and documents. Use info here to complete the UBC ethics application. Info and documents found in this tab cannot be edited.



Since Lead site approved documents will be downloaded, UBC PI does not need to upload these documents in RISe Page 9 again.

Draft means it is still under REB review. **Final** means approved document and will be listed on Certificate of ethics approval.

UBC Behavioural applications:

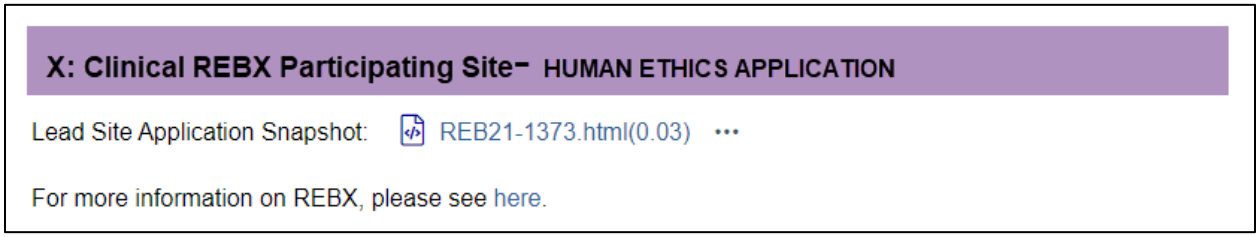
You will complete RISe applications Pages 1-4B as per usual then you will be asked to complete the REBX truncated form **Page R-REBX**. This form asks about local details such as local activities, recruitment, consenting and data storage.

UBC Clinical Applications:

You will complete RISe applications Pages 1-4C as per usual, then you will be asked to complete 1 of 4 possible truncated forms: REBX form **Page X** or Page A or Page M or Page C. Which truncated form depends on responses in from Page 4C. **Page X-REBX** asks about local details such as local activities, recruitment, consenting and data/biospecimen storage, regulatory questions.

Lead Site Application Snapshot

Lead site application snapshot can be found on top in **Page R** or **Page X**



This link with include lead site ethics application and list of approved documents. Please do not click links for documents but use documents found in **[Lead Site]** tab.

pSite Page 9 Documentation

Please **submit local documents only,** do not submit any duplicate documents that can be found in the **[REBX Lead Site Info]** tab.

If however, there are site-specific documents such as Site Protocol then please add to Box 9.7 for Behavioural application and Box 9.8A for Clinical.

All documents uploaded to Page 9 will be transferred via REBX to lead site.** **Exception-** For Clinical applications: Box 9.9 Reference documents: documents uploaded here will NOT be transferred to Lead site **nor** listed on Certificate of approval. Use this box to upload documents for REB review but you do not want to share with lead site (eg., Budget). Note, there is no need to upload Alberta documents in Box 9.9.

UBC pSite Study expiry date

Study expiry date will be synchronized with Lead site expiry. For the first approval period, this will always be less than the typical 1-year timeframe as lead site is approved first before pSite. After pSite renewal has been approved, then it will be the 1-year approval timeframe. See example below:

	Lead site approval	UBC pSite approval
Initial approval	Approved Feb 1, 2024 expiry Jan 31, 2025	UBC REB Approved- July 2, 2024 expiry Jan 31, 2025
Renewal	Jan 15, 2025 REB approval- expiry Jan 14, 2026	 Expiry Jan 14, 2026

UBC pSite Post-Approval Activities (PAA)

UBC PAA forms remain the same.

pSite PI Responsibility
Submits site-specific Amendments *e.g., Changes to local consent form, materials, local study team*
Submits pSite Annual Renewal
Submits pSite reportable events /Request for Acknowledgement *e.g, local privacy breaches, local protocol deviations, and local participant complaints, local Serious Adverse Events (SAE).*
Submit pSite closure / completion *Once research activities at site are complete and ethics approval is no longer required.*

UBC as pSite- Amendments

pSite PI is still responsible to submit any site-specific amendments, this includes amending RISe application content and UBC documents. For instance, global study Protocols amendments submitted by lead site only cover the submission of the updated Protocol, if Protocol update necessitates updates to local consent form or documents (e.g additional follow-up visit), **pSite PI is responsible for submitting local revisions for pSite REB approval.**

UBC as pSite- Renewal

UBC PI will receive email notification to submit a pSite renewal PAA. Complete the RISe PAA-renewal forms, submit in RISe and this will be sent to lead site directly via REBX. Once ready, lead site REB will approve the renewal, issue joint certificate of approval.

UBC as pSite- Request for Acknowledgment

pSite PI is still responsible to submit local events such as local privacy breaches, local participant complaints and local SAEs. Note Alberta PAA uses different terminology, it is named Reportable event.

UBC as pSite-Completion

UBC PI will submit pSite completion PAA to lead site via RISe. Once all pSites have submitted their pSite completion then lead site can submit Study completion. Once lead REB approves, all pSites will show study has been inactivated.

Summary table of Site PI responsibilities

Lead Site PI Responsibility	Participating Site (pSite) PI Responsibility
Submits lead site application (full) *Uploads study documents, specifies pSite*	**Submits pSite application (truncated)** *Truncated form and uploads site specific materials*
Submits global study amendments *e.g., Changes to study protocol, consent forms, materials.*	**Submits site-specific amendments** *e.g., Changes to local consent form, materials, local study team*
Submits study annual renewal *Lead site must collect all pSite Renewal reports	**Submits pSite annual renewal** *Prompted by lead site*
Submits global study reportable events/ Request for Acknowledgment: Eg. Global study privacy breaches, *safety updates, Clinical trial- Data Safety Monitoring Board/ Committee (DSMB/C) report*	**Submits pSite reportable events /Request for Acknowledgement** *e.g, local privacy breaches, local protocol deviations, and local participant complaints, local Serious Adverse Events (SAE).*
Submit study closure/ completion *After each pSIte has submitted their closure report.*	**Submit pSite closure / completion** *Once research activities at site are complete and ethics is no longer required.*

Glossary

Acronym	Meaning
DMSB	Data Monitoring and Safety Board
PAA	Post-approval activity (4 options as UBC, Renewal, Amendment, Request for Acknowledgement, Completion)
Page R	New REBX truncated form for Behavioural applications when UBC is a pSite
Page X	New REBX truncated form for Clinical applications when UBC is a pSite
PI	Principal Investigator
pSite	Participating Site
pSite house	Term used to describe- all pSite info, including application and PAAs see here for more info
REB	Research Ethics Board
REBX	REB eXchange, Plug-in feature to allow UBC RISe to exchange data with other ethics platforms
Reportable Event	Alberta's Post-approval activity- similiar to UBC's Request for Acknowledgment
SAE	Serious Adverse Event
Snapshot	Copy of the lead site's application form

Version History

Date	Event
1-Jun-2024	First draft
1-Sep-2025	Minor text revisions Additional text in sections: • UBC as lead- Renewals • UBC as lead-Completion

REB Exchange is an initiative funded by Alberta Innovates, University of Calgary, University of Alberta, University of British Columbia and Huron Consulting.