Research Ethics Board Review

Requirements for CHREB approvals

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Learning Objectives

- Practical session on how to submit an ethics application online using the IRISS platform
- Overview of the process/requirements for obtaining approval to conduct research using AHS resources



IRISS: the platform

IRISS

IRISS is Alberta's highest volume ethics and animal care system with **OVER 24,000 USERS** and has capacity to **scale exponentially.**

Notable:

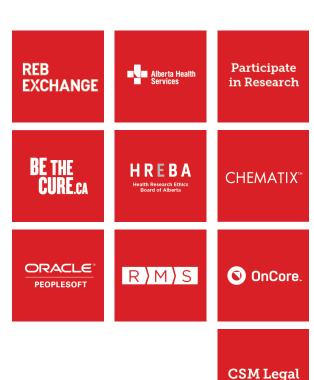
- REB x 3 (CHREB, CFREB, HREBA)
- ACC (3 committees)
- Supports 196 board members (6 boards across REB and ACC)
- Supports 23 staff (REB and ACC)



IRISS: integrations

Current Integrations:

- **REB Exchange -** multi-site human ethics
- AHS operational approvals
- Participate in Research + Be the Cure recruitment
- HREBA Health Research Ethics Board of Alberta
- **CSM Legal Agreements** replaced SharePoint submissions
- **Biosafety** certifications
- **Peoplesoft** credential validation, project accounting
- **RMS** grant management
- OnCore clinical trial management





IRISS Registration

The same login process for REB, ACC, CSM Legal, and AHS

2. Get a UCalgary IT account

An IT account provides you a secure way of identifying yourself to a variety of online and on-campus services available at the University of Calgary.

It is a unique digital identity that follows the naming convention of firstname.lastname.

To Register for a UCalgary IT account:

- 1. Get an active UCID number (Follow the steps above if you do not have a UCID.)
- 2. Register for an IT account

3. Register for an IRISS account

IRISS is accessible through the University of Calgary's CAS (Central Authorization System) portal.

To get an IRISS account:

- 1. Register for an active IT account
- 2. Log into the UCalgary' CAS system using your IT username and password
- 3. Register for an IRISS account
- **1.** Once approved, log-in to IRISS through the main CAS portal above.

Please – do NOT register for more than one IRISS account. Register for IRISS with UCalgary.

If you need access to HREBA.CC, HREBA.CTC or HREBA.CHC; simply email iriss.support@ucalgary.ca and it will be added to your account.

Duplicate accounts will be closed.



Questions?

- REB application/process questions
 - How to answer the application questions
 - What information does the REB require with the submission
 - What documentation is required?
 - Contact <u>chreb@uclagary.ca</u>
- Technical Support
 - How to access IRISS
 - How to use IRISS (REB, ACC, REBX, AHS)
 - Navigation Assistance
 - Contact <u>iriss.support@ucalgary.ca</u>



Administrative Requirements

IRISS Researcher Profile

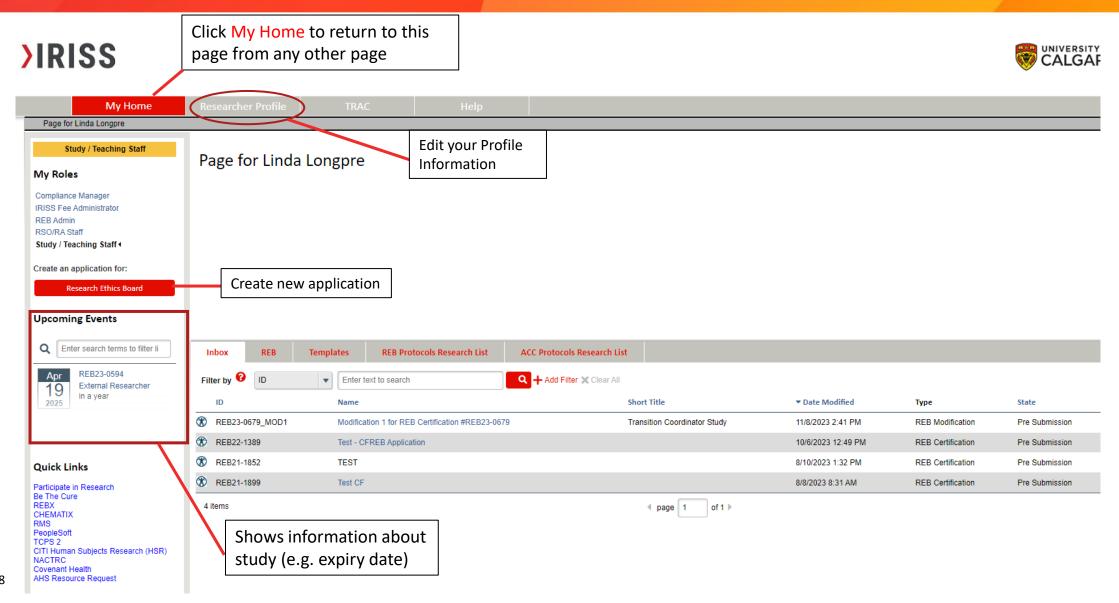
- Upload your CV
- The CHREB requires all members of the study team to have completed <u>TCPS2 Core Tutorial</u> or <u>CITI</u>
 <u>Human Subjects Research Course</u> (Biomedical or Social Behavioural-Educational module, whichever is most relevant to your discipline).

REB Application

- Refer to <u>REB consent/assent templates</u> when creating consent forms
- Department Head approval is uploaded in the application
- All students, post docs, medical residents are listed on the application
 - Anyone who requires access to AHS systems MUST be listed on the ethics application
- Refer to the <u>CHREB Submission Checklist</u> before hitting submit.
- Every application requires a budget.
 - If you are working on a funded study, you can upload your detailed budget (grant or sponsor budget)
 - If you are working on an unfunded budget, use the <u>Budget Summary</u> form to list in kind hours for the study.



General Navigation: Personal Workspace





General Navigation Cont.



| Tab | Definition | |
|---------------|--|--|
| Inbox | Studies that require PI/study team attention | |
| REB | All studies that are approved or with ethics for review | |
| Templates | Templates are not active studies – are used as a baseline for new studies (use templates so you do not have to repeatedly enter the same information into a new study) | |
| Research List | Exportable spreadsheet that lists all studies you are associated with | |



Study Numbers and Types

All studies are given a number at the time of initiation, not at submission

| Certification Number | Definition |
|-----------------------------|---------------------------------------|
| REB23-1000 | UofC REB application ID |
| pSite-23-1000 | UofC REB Exchange ID |
| pSite00001000 | External REB Exchange ID |
| HREBA.CC-23-1000 | HREBA Cancer Committee application ID |
| AC23-1000 | UofC Animal Care application ID |

- Post approval submission:
 - REN Means you are viewing a Renewal report
 - MOD Means you are viewing a Modification (amendment)
 - RE Means you are viewing a Reportable Event (serious adverse event, protocol violation)
 - CLOSE Means you are viewing a Closure



SmartForm Navigation

- Navigate to a study
 - Select the "Name" of the study to enter the workspace

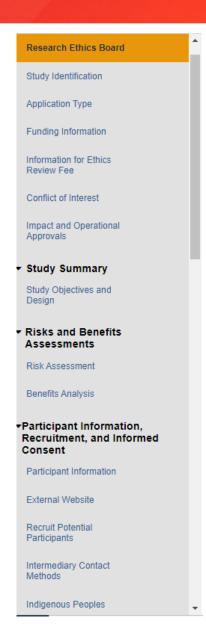


Then click "Edit Study" (or "View Study")





SmartForm Navigation

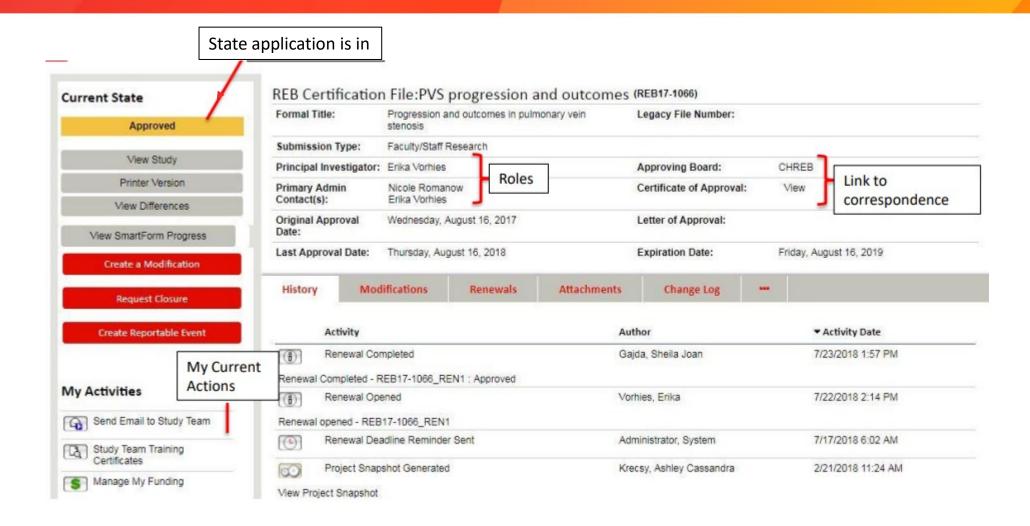


- Navigating within the SmartForm
 - Click "Continue" to move to the next page of the form
 - Use the menu on the left-hand side to get to a specific section
 - Use "Exit" to close the SmartForm





Study Workspace Layout





Steps to Create & Submit a New Study

- Log in to IRISS
- You will be directed to your personal workspace
- From there, click on the "Research Ethics Board" button
- Complete the SmartForm questions, and navigate the SmartForm as needed
 - Click "Continue" to go to the next page
 - Click on the section you are looking for on the left hand column (be sure to save before jumping to another page)
 - Click "Save" and then "Exit" to leave the application
- Once the application is complete, the PI can submit

Important: The study is not submitted until the PI submits the study (PI attestation is required)



After submission

- The Research Ethics Analysts (REA) will conduct an admin review to ensure the application is complete enough for the REB members to review.
 - If anything is outstanding or clarification is required, they will send the application back to you to correct
- Once complete, the REA will forward the application for REB Review (Delegated or Full Board)
 - Delegated review minimal risk -Research in which the probability and magnitude of possible harms implied by participation in the research are no greater than those encountered by participants in those aspects of their everyday life that relate to the research.
 - Full Board Review Any study the REB deems above minimal risk
- Questions and requests for clarifications are sent back to study team
 - The REB could request further information or clarification if responses are unclear, or prompt further questions
- Study is either approved or declined

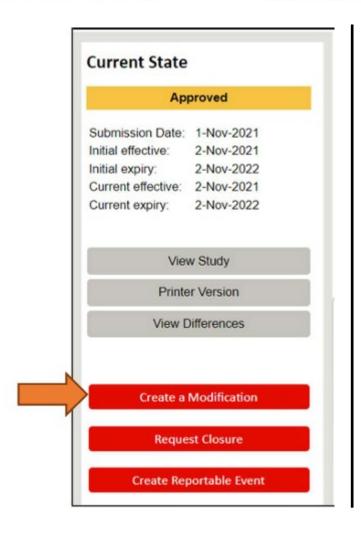


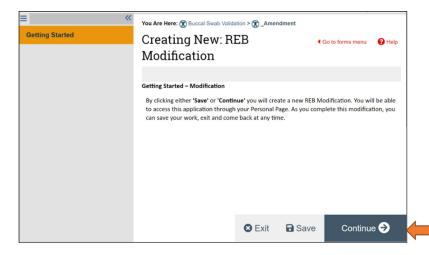
Post Approval Submissions: Renewals

- The REB cannot approve a study for longer than 1 year. It may however approve for a shorter period if deemed necessary.
- The ability to submit a renewal only opens 30 days before the expiry date
- Three renewal notifications will be sent automatically by IRISS
 - 30 days, 15 days, and 7 days before study expires
- If study expires, you will need to request Chair consideration.
 - If approved, you will have 7 days to submit your renewal
- Once renewal is complete, click "Exit" or "Finish". You will be redirected to the renewal workspace. If ready to submit, click "Submit Renewal" activity button on the left-side menu.

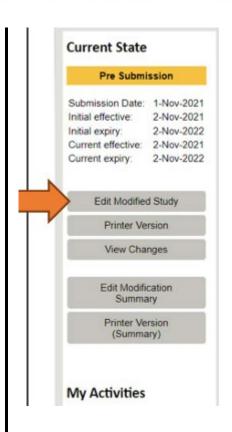


Post Approval Submissions: Modifications





- Once initiated, the Modification Summary form is created
- Can be edited any time prior to submission (remember to click "Save" often)
- "Save" and "Finish" DOES NOT submit the modification.



Next Steps

- "Edit Modified Study" opens the application for modification
- Modify all required sections and upload any new/revised documents (track changes and clean versions.)

UNIVERSITY OF

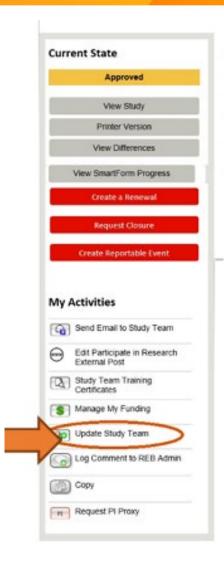
CALGARY

Modification summary + modified study = modification to be submitted to CHREB.

Post Approval Submissions: Update Study Team

- For studies involving AHS systems, maintaining an accurate study team list is extremely important. Only those named in the IRISS application (PI, Co-Is, Student Co-Is, and Study Staff) will have access to AHS systems
- This activity is available to any member of the study team.
- The activity is available only when the study is in 'Approved', 'Pending Expiry' or 'Expired' state.
- When a member of the study team is changed it will take effect immediately.

Note: A new approval certificate cannot be issued using the Update Study Team activity. If a new approval certificate is required, the PI must submit a modification to add the study team member. Please ensure that you indicate in the modification summary that an approval certificate is required.





Post Approval Submissions: Reportable Events

- Reportable Events include: Serious Adverse Events (SAEs), Adverse Events, Protocol Deviations, Protocol Violations, DSMB and other reports
- For more information on Reportable Events, including detailed descriptions of each category and reporting criteria, visit the following:

https://research.ucalgary.ca/research-services/ethics-compliance/ethics-resources





Things to Remember

REB approval does not mean you can go forward with your project.
 Any of the areas impacted by your research could not allow your research.

Approval by the REB does not necessarily constitute authorization to initiate the conduct of this research. The Principal Investigator is responsible for ensuring required approvals from other involved organizations (e.g., Alberta Health Services, community organizations, school boards) are obtained.

- Ensure all sections in your IRISS application are complete and, in enough detail, to allow the CHREB to fully understand your study.
- Refer to the CHREB Consent templates when creating your consents.
- When unsure, ask.



REB EXCHANGE

A Harmonized Process

REB Exchange is a collaboration between Alberta institutions. The initiative is funded by Alberta Innovates, the University of Calgary, the University of Alberta, and Huron Consulting, with in-kind contributions from Alberta Health Services, to collectively support research ethics harmonization in Alberta.



By **connecting directly** with institutional platforms, the REB Exchange:





By **connecting directly** with institutional platforms, the REB Exchange:

- accepts both <u>health</u> AND <u>non-health</u> studies
- **streamlines processes** across institutions
- <u>retains</u> local compliance
- <u>saves</u> time, money, and duplication of work
- offers <u>visibility</u> into current status and turnaround times
- <u>integrates</u> with other institutional systems





Lead Site Local pSite review Determination









Lead Site







The study is submitted through **THE LEAD SITE's** REB platform.





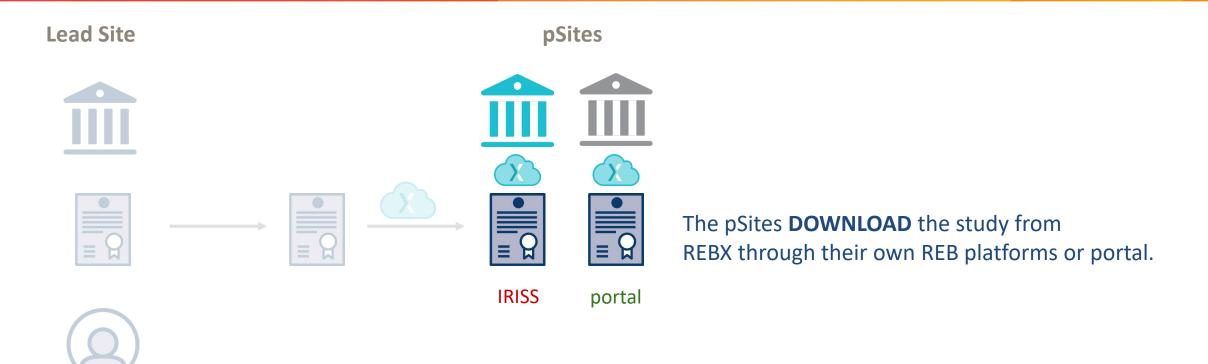


Lead Site pSites

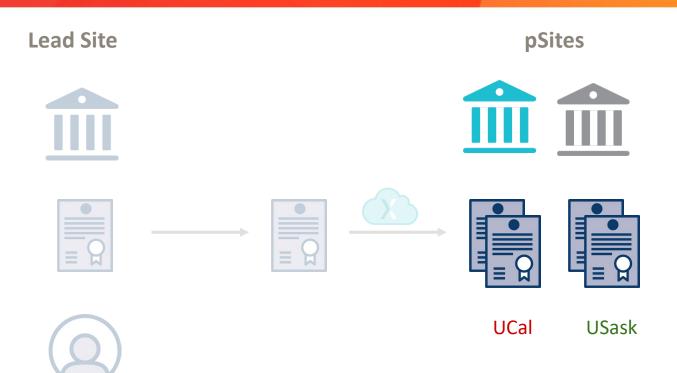
PSites

Using the REBX, the Lead Site invites **PARTICIPATING SITES** (pSites) to join the study.



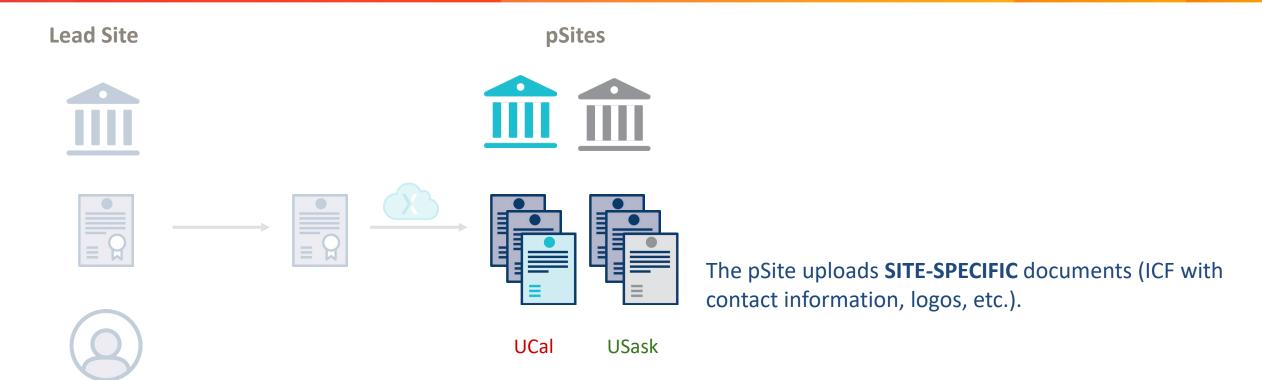






pSites will complete a **LOCALIZED APPLICATION** in accordance with their current local requirements and processes.



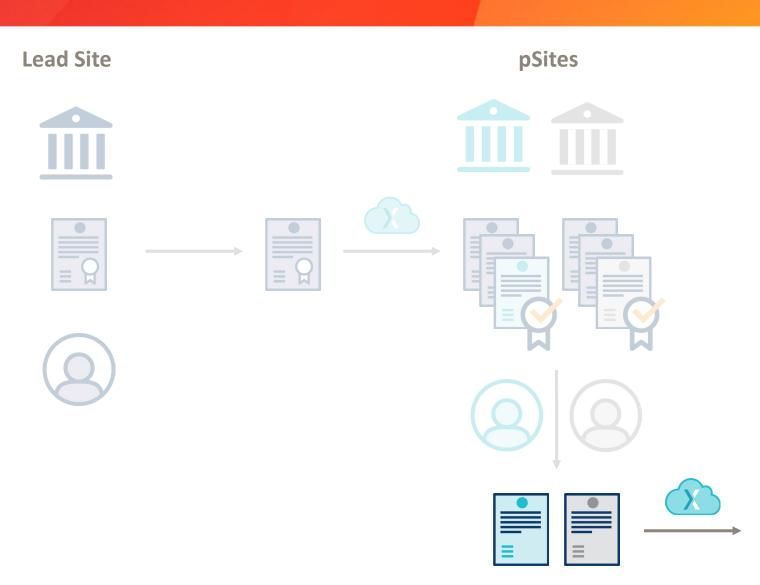






pSite REB coordinators review the pSite application and documents to ensure **LOCAL** and institutional requirements are met.



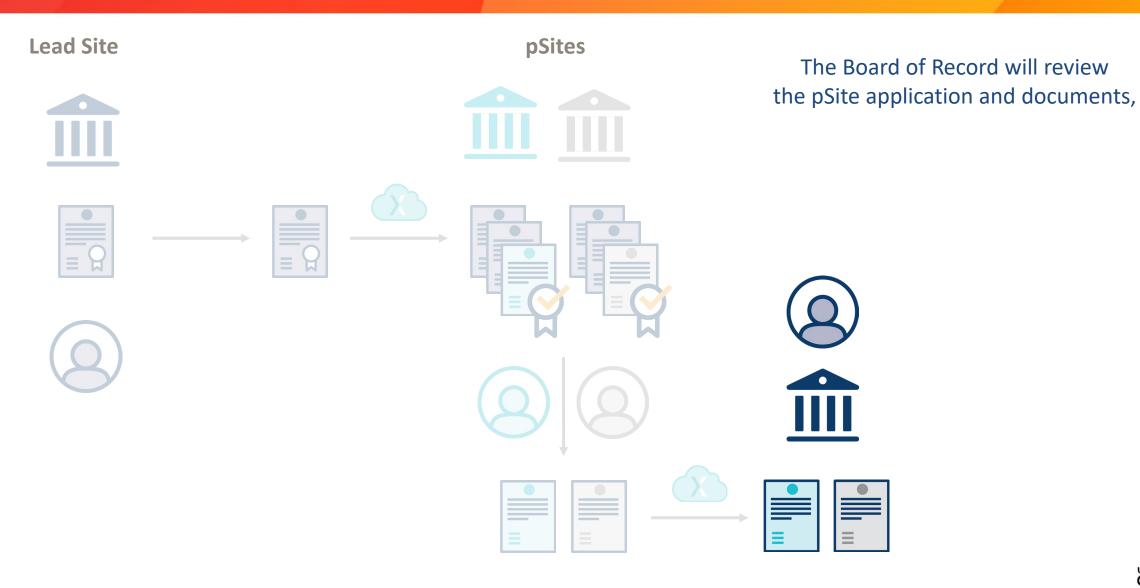






Once reviewed locally, pSite documents are **TRANSFERRED** to the BoR for review through the Exchange.

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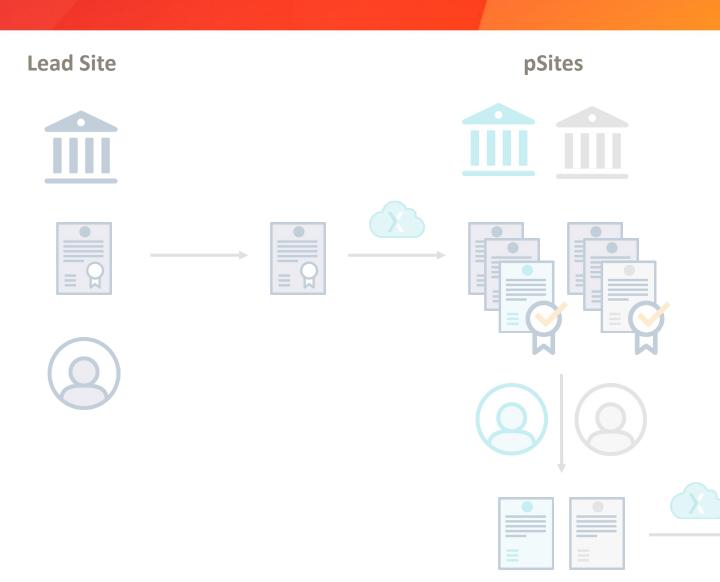


The Board of Record will review the pSite application and documents,

ISSUE ETHICS DETERMINATION,







The Board of Record will review the pSite application and documents,

ISSUE ETHICS DETERMINATION,

and share back through REBX.





















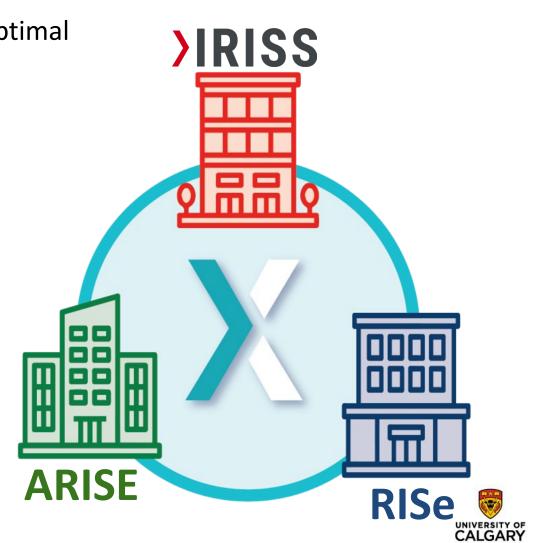


REB Exchange: multi-site management

REB Exchange (REBX) connects enterprise systems for optimal efficiencies for multi-site human ethics applications.

- University of Alberta
- University of Calgary | HREBA
- University of British Columbia

With **OVER 25,000** active studies



REB Exchange: pSite access

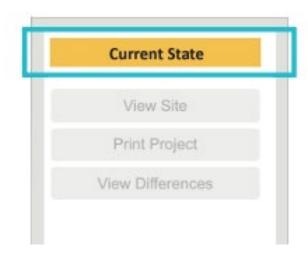
- After a pSite has been invited to join your approved study, a new tab titled "Sites" will be listed in your study workspace.
- To access, open the REB tab, and click on approved study name.
- You will now see the "Sites" tab. This is where you can view and quickly see each pSite's state of review.
- Note: You can only see the pSite submissions once it has been sent by the host institution to the Board of Record (BOR).





REB Exchange: States

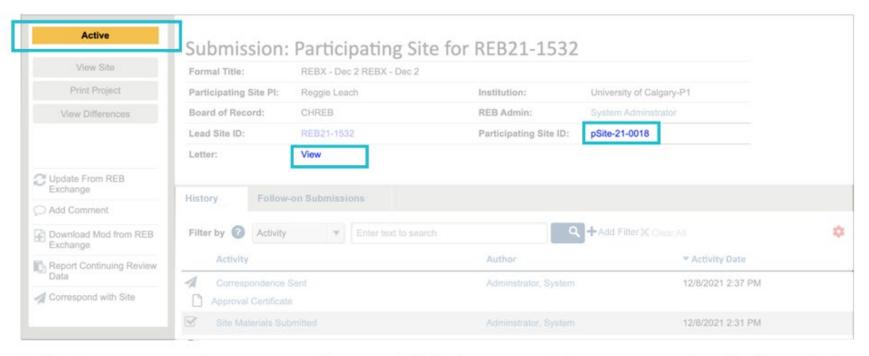
- **Invitation Pending** BoR is in the process of approving the addition of a pSite. At this time the pSite workspace is not visible in the pSite's institutional REB.
- Awaiting Site Materials The BoR has approved the pSite invitation and it is now with the pSite institution.
- Pre-Review State The pSite has been received by the BoR and will be assigned for ethics review.
- Delegated/Board Review State pSite ID Once the application is received by the BoR, documents and the application for the pSite can be viewed by the Lead Site.
 - By going through the REBX and a common BoR for all site approvals:
 - communication and documentation is streamlined,
 - collaboration visible,
 - and required documentation is drastically reduced.
 - Timelines for participating site approvals are condensed because all additional applications are reviewed within the context of the Lead site's approved application and shared documentation.
- **Active pSites** Once a pSite has been approved by the Board of Record, the state will change to ACTIVE and the certificate can be viewed by the Lead Site.





REB Exchange: workspace layout

While a pSite is in review with the BoR, the Lead site can **open the SITES tab** and **click on the name of the pSite** to open the pSite application view.



In this view you can see: the current state, the **pSite ID** (which also acts as a link to **the application**), activity history for the pSite, and a link to the **letter of approval** once issued.



REB Exchange: lead site vs. pSite responsibilities

Lead Site vs. pSite Responsibilities in REBX

| STUDY-WIDE SUBMISSIONS | SITE-SPECIFIC SUBMISSIONS |
|---|---|
| Lead Site Application | pSite Application |
| Study Amendments: Changes to protocol Changes to consent/assent form(s) Changes in other participant materials Updated IB/PM Other changes in previously submitted information | pSite Amendments: Changes to local consent/assent form(s) Changes in other site-specific participant materials Other changes in previously submitted site-information Changes in local study team |
| Study Annual Renewal | pSite Annual Renewal |
| Study Reportable Events DSMB/C Report Interim Analysis Results Safety Notice/Update (e.g., Action Letter), Periodic External (non-local) AE/SUSAR Summary Report, Single External (non-local) Adverse Event meeting reporting definition | pSite Reportable Events Local (internal) Serious Adverse Event meeting reporting definition Protocol Deviation/Violation Privacy Breach Audit/Inspection Report Participant Complaint |
| Study Closure/Completion Can only be submitted after each pSite has submitted their own Study Closure form. | pSite Closure/Completion Submit once research activities at the site are complete and ethics approval is no longer required for the site. |

For more information and resources, visit:

https://www.rebexchange.ca/



REB Exchange: Stats

REBs Involved in REBX

Alberta

- UCalgary
- UAlberta
- HREBA
 - HREBA.CC
 - HREBA.CTC
 - HREBA.CHC

<u>BC</u>

- UBC
- Clinical REB
- Vancouver Behavioural
- Okanogan Behavioural
- Providence Health Care
- BC Women's Hospital and Health Centre

Between all of these REBs, we have well over 1,000 sites using REBX.

UCalgary Stats

- 258 pSites in REBX
 - 11 x BC
 - 22 x UCalgary
 - 225 x UAlberta
- We are BoR for 273 pSites
 - 15 x BC
 - 225 x UAlberta
 - 33 x UCalgary

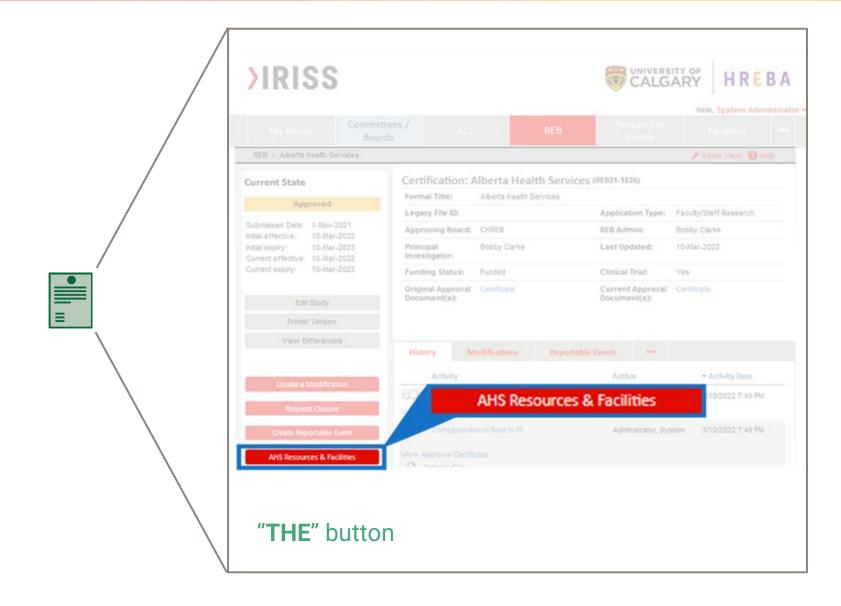


AHS Module

AHS module is triggered by the AHS trigger question in the ethics application BUT is a completely independent submission. REBs have NO view access to AHS module and cannot assist with your submission!



AHS Application — launched in IRISS April 2023





AHS Approval Process

How do I use the AHS request in IRISS?

Automations and streamlined processes – all in one-place.



1

INITIATE

The AHS Resources and Facilities button is found in the sidebar of your IRISS dashboard. It appears when you indicate that you require access to AHS services or facilities in your ethics application. To access, you must be listed on the ethics application.



4

FILL OUT

After completing the first section, the application is assigned an ID number and can then be saved, closed, and continued at a later date. You can access your submission again using the AHS resources and facilities tab in your study workspace.



SUBMIT

Once complete, teams will receive email notification prompting to submit the application directly through IRISS using the **submit to AHS** button. Eligibility to submit is dependent on the type of study.



TRACK

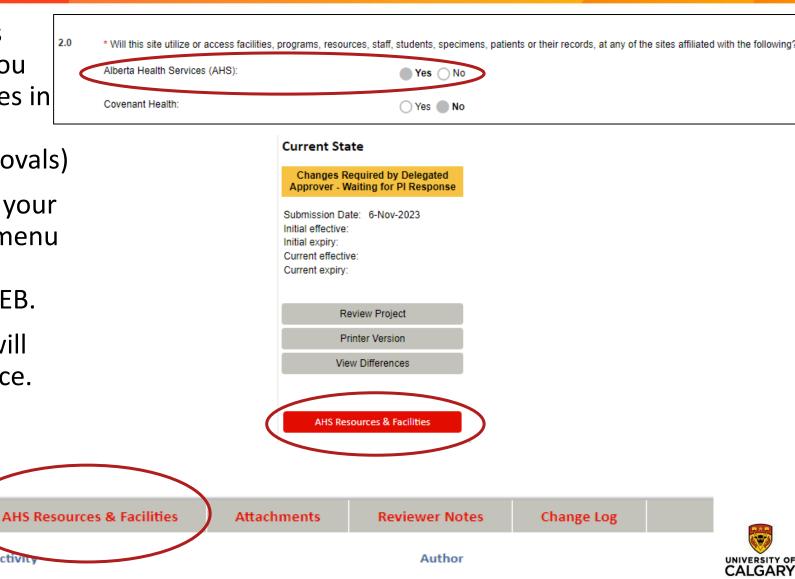
The review state of an application will always be current and visible in your AHS Resources workspace. All communication and notifications will appear in IRISS for reference and archiving.



AHS Application

- The AHS application process is triggered when you indicate you require AHS services or facilities in your ethics application. (Q2.0 Impacts and Operational Approvals)
- The AHS button will appear in your main REB workspace sidebar menu as soon as you indicate AHS resources NOT visible to the REB.
- Once initiated, a tab for AHS will appear in your home workspace. Use this tab to access your application

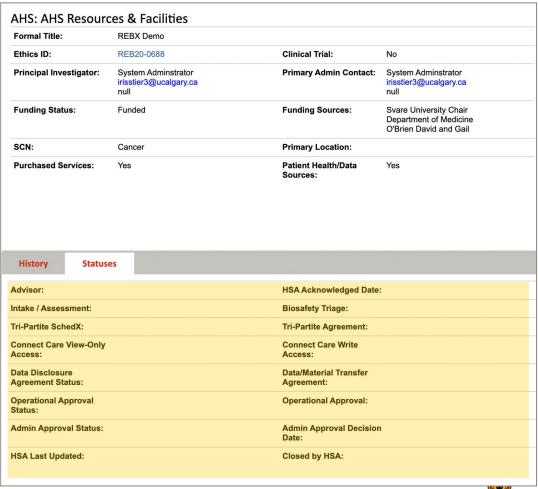
History



AHS: proven benefits

Data exchange allows for:

- Automated system notifications and triggers
- Record of submission
- Nightly status updates from AHS
- Updates to records are reconciled between systems without researcher involvement
- Direct communication with AHS within IRISS
- Eliminates the duplication of data entry for both administrators (EDGE) and researchers (SharePoint)
- Validation of roles for study teams
- Automated gates within ENCAPS for administrative approval
- Extended dashboard capability
- Web page with resources and FAQs to guide users





AHS Module: looking forward

Alberta today:

More leverage to influence AHS and improve health processes ongoing

Alberta tomorrow:

- Record of communication between AHS and researchers in IRISS.
- Better AHS application for **non-clinical trials**
- Better submissions from researchers and processing from AHS
- Operational approvals improve process within facilities



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Thank you for attending

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