Getting the green light: Requirements for REB and AHS approval

Resident Research Course 2022
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Department of Pediatrics
Learning Objectives

- Understand the two-stage approval process for research projects
- Become familiar with the IRISS system to submit ethics applications
- Become familiar with the AHS Health System Access system for AHS approval
- Understand when you have the “green light” to start your study
- Know where to go to troubleshoot
What is IRISS?

IRISS

Institutional Research Information Services Solution

- Automates the REB & ACC submission & review process
- Document management system – a place to store and access submission documents
- Allows for easier reporting and automation for other systems (e.g., AHS)
- Automated documentation from IRISS is used to access health records and systems, and obtain permits and licenses
- Failure to maintain certifications will suspend access to external systems (e.g. NetCARE)

http://iriss.ucalgary.ca/
Animal Care Committee (ACC):
- Health Sciences (HSACC)
- Life & Environmental Sciences (LESACC)
- Veterinary Sciences (VSACC)

Research Ethics Board (REB):
- Conjoint Health (CHREB)
- Conjoint Faculties (CFREB)

Over 15,000 users:
- University of Calgary Principal Investigators
- Alberta Health Services
- Covenant Health
- Alberta Innovates
- Study Support Staff
- University Students
- Administrative Staff (U of C and HREBA)
- University of Calgary Grants, Prizes & Awards
- University of Calgary Legal
University of Calgary IT username?

YES

Register
https://iriss.ucalgary.ca

Users receives confirmation of registration approval

Takes 48 hrs

NO

Email
irisssupport@ucalgary.ca

Users must have a UCID

Health Research Ethics Board of Alberta (CC, CHC, CTC)

Register
https://iriss.ucalgary.ca/HREBASelfRegistration
**Business**: Contact your ethics board (chreb@ucalgary.ca)
- How to answer the questions
- What information is required
- What documents need to be attached

**Technical**: iriss.support@ucalgary.ca
- How to use the technology
- How to get access
- Navigation assistance
**Workflow Summary**

**Pre Submission:**
Studies are editable by the research team, and have not yet been submitted to the REB. All documents for review must be uploaded before the PI submits.

**Administrative Review:**
The first stage of the REB review. An internal review by RSO staff before forwarding the submission to the Board.

**REB Review:**
As determined appropriate during the Administrative Review, RSO forwards the study for delegated or full board review.

**Post Review:**
After the REB review, RSO documents the determination, generates a letter, sets the study expiration date, and approves materials attached in pre-submission.

**Post Review States:**
After the REB review, the study will transition to a post review state, indicating that either research can begin or the application is declined.

*Changes or Clarification Requested:
Changes can be requested in any of the stages with a * if the REB determines that additional changes are necessary. When a study is returned for changes, the study is unlocked and the system will allow you to make changes as necessary.*
Administrative Requirements

- PI CV is uploaded to researcher profile
- TCPS2 uploaded into researcher profile
- University of Calgary logos are on all recruitment material (posters, consent forms, etc)
- Department Head approval is uploaded into application
- All students, post docs, medical residents are listed on the ethics application
  
  — Anyone who requires access to AHS records or facilities MUST be listed on the ethics application
Resources

- [http://irss.ucalgary.ca](http://irss.ucalgary.ca)
- View and edit your Researcher Profile
- Navigate IRISS study workspace (home page)
- Update study team (approved study)
- Modify your study

See the full list of help topics – scroll to the bottom.

More is always better! Don’t skimp on the details.
Click **My Home** to return to this page from any other page.

**Edit profile**

**Page for Nicole Romanow**
Update your Researcher Profile

- **Researcher Profile**
  - Links to mandatory ethics training:
    - TCPS2 CORE Tutorial; or
    - CITI Human Subjects Research Course (Biomedical or Social Behavioural-Educational module, whichever is most relevant to your discipline).
### General Layout and Navigation

**Personal Workspace (REB & ACC)**

#### Tab Definition

<table>
<thead>
<tr>
<th>Tab</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inbox</td>
<td>Studies that require PI/study team attention</td>
</tr>
<tr>
<td>REB</td>
<td>All studies that are approved or with ethics for review</td>
</tr>
<tr>
<td>Templates</td>
<td>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)</td>
</tr>
<tr>
<td>Research List</td>
<td>Exportable spreadsheet that lists all studies you are associated with</td>
</tr>
</tbody>
</table>
All studies are given a number at the time of initiation, not submission

<table>
<thead>
<tr>
<th>Certification</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>REB15-7777</td>
<td>U of C: Research Ethics Board; Year of Initiation; Unique Study ID</td>
</tr>
<tr>
<td>AC14-1233</td>
<td>U of C: Animal Care; Year of Initiation; Unique Study ID</td>
</tr>
<tr>
<td>HREBA-CC-15-1234</td>
<td>(HREBA: Cancer Committee; Year of Initiation; Unique Study ID</td>
</tr>
<tr>
<td>HREBA-CTC-15-1234</td>
<td>HREBA: Clinical Trial Committee; Year of Initiation; Unique Study ID</td>
</tr>
<tr>
<td>HREBA-CHC-15-1234</td>
<td>HREBA: Community Health Committee; Year of Initiation; Unique Study ID</td>
</tr>
</tbody>
</table>

Follow on submission:
- REN – means you are viewing a Renewal
- MOD – means you are viewing a Modification
- CLOSE – means you are viewing a Closure
A SmartForm is a series of webpages containing information about a study and links to attached supporting documentation

- Navigate to a study
  - Select the “Name” of the study to enter the study workspace
  - Click “Edit Study” or “View Study” (depends on the state)

- Navigate within the SmartForm
  - Click “Continue” to move to the next page of the form
  - Use the menu on the left side to get to a specific section
  - Use “Exit” to close the SmartForm
Study Workspace Layout

Submission Status = STATE

Roles

Link to correspondence

My Current Actions

Tab | Definition
--- | ---
History | Information about each action taken on a study and view of comments
Attachments | All approved documents associated with a study
Change Log | Summary of changes per modification
Reviewer Notes | Changes or clarifications requested by a reviewer
## Study Activities

<table>
<thead>
<tr>
<th>Activity</th>
<th>On Submission Type</th>
<th>Access to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Create a study</td>
<td>Initial Application (Certification)</td>
<td>PI, Study Team</td>
</tr>
<tr>
<td>Create a modification</td>
<td>Modification</td>
<td>PI, Study Team</td>
</tr>
<tr>
<td>Create a renewal</td>
<td>Renewal</td>
<td>PI, Study Team</td>
</tr>
<tr>
<td>Create a closure</td>
<td>Closure</td>
<td>PI, Study Team</td>
</tr>
<tr>
<td>Prepare changes or clarifications (all types)</td>
<td>Changes Requested</td>
<td>PI, Study Team</td>
</tr>
<tr>
<td>Submit Application</td>
<td>Cert</td>
<td>PI</td>
</tr>
<tr>
<td>Submit Modification</td>
<td>Modification</td>
<td>PI</td>
</tr>
<tr>
<td>Submit Renewal</td>
<td>Renewal</td>
<td>PI</td>
</tr>
<tr>
<td>Submit Closure</td>
<td>Closure</td>
<td>PI</td>
</tr>
<tr>
<td>Submit Changes</td>
<td>Changes Requested</td>
<td>PI</td>
</tr>
<tr>
<td>Withdraw</td>
<td>Cert, Ren, Clos, Mod</td>
<td>PI</td>
</tr>
</tbody>
</table>

- Only members of a study team (PI, Study Team) may make changes to a study.
- Your role dictates the activities you see in the study workspace.
Steps to Create & Submit a New Study

- Log in to IRISS
- You will be directed to your personal workspace
- From your personal workspace, click on the “Research Ethics Board” or “Animal Care Committee” button.
- Complete the SmartForm questions, and navigate the SmartForm as needed
  - Click “Continue” to go to the next page
  - Click the “Jump To” menu to go to a specific section (be careful to save before jumping to another page)
  - To save or exit the SmartForm at any time, click on “Save” and “Exit” button in the top toolbar. Exit will take you to that studies workspace
- Once the initial SmartForm is complete – the PI can submit.

Important: The study is not submitted until the PI submits the study (has to provide attestation)
Prior to submitting the study, Department Approval must be obtained

Certification

- Modifications cannot be processed at the same time as a renewal (modifications cannot be initiated or submitted when the study enters the renewal workflow).
- Three renewal notifications are sent before the expiry date:
  - 30 days
  - 15 days
  - 7 days
- The Principal Investigator & Study team can ‘withdraw’ an application (Cert, Mod, Ren, Closure).
<table>
<thead>
<tr>
<th>To submit this type of information</th>
<th>Click this button</th>
<th>To submit this type of information</th>
<th>Click this button</th>
</tr>
</thead>
<tbody>
<tr>
<td>Select “View Study” to see the submitted SmartForm while the submission is being reviewed or once the review is complete. SmartForm is locked when “View Study” is visible.</td>
<td><img src="#" alt="View Study" /> <img src="#" alt="Printer Version" /> <img src="#" alt="View Differences" /> <img src="#" alt="View SmartForm Progress" /> <img src="#" alt="Create a Modification" /> <img src="#" alt="Request Closure" /> <img src="#" alt="Create Reportable Event" /></td>
<td>Create a Reportable Event for an approved study.</td>
<td><img src="#" alt="View Study" /> <img src="#" alt="Printer Version" /> <img src="#" alt="View Differences" /> <img src="#" alt="View SmartForm Progress" /> <img src="#" alt="Create a Renewal" /> <img src="#" alt="Request Closure" /> <img src="#" alt="Create Reportable Event" /></td>
</tr>
<tr>
<td>Create a renewal for an approved study. Renewals can be created and submitted 30 days before the expiry date.</td>
<td><img src="#" alt="View Study" /> <img src="#" alt="Printer Version" /> <img src="#" alt="View Differences" /> <img src="#" alt="View SmartForm Progress" /> <img src="#" alt="Create a Renewal" /> <img src="#" alt="Request Closure" /> <img src="#" alt="Create Reportable Event" /></td>
<td>Request active study closure. Closures can be submitted at any time.</td>
<td><img src="#" alt="View Study" /> <img src="#" alt="Printer Version" /> <img src="#" alt="View Differences" /> <img src="#" alt="View SmartForm Progress" /> <img src="#" alt="Create a Modification" /> <img src="#" alt="Request Closure" /> <img src="#" alt="Create Reportable Event" /></td>
</tr>
</tbody>
</table>
First step to initiate a modification

Once initiated, the Modification Summary SmartForm is created
Can be edited any time before submission (just click save & close at any time or Save & Exit at the end)
Save & Close DOES NOT submit the modification.

Only the Principal Investigator can submit the modification for review
- Modify your study
- Update study team
FAQs

▪ How long will it take?
▪ I don’t have all the questionnaires or data collection forms finalized, can I still submit my ethics application?
▪ I don’t know what system I need to use to get the data I want, can the REB tell me?
▪ Can I submit a modification before the study gets approved?
▪ I’m doing a study with other sites, do I need ethics approval at each site?
▪ I have REB approval, can I start?
Streamlines the ethics application process for multi-site health research in Alberta

Once a study is approved, Participating Sites (pSites) can be added with a truncated site-specific application

During the course of research, study-wide changes, amendments, documents etc. are submitted by the Lead Site, which are then approved/acknowledged simultaneously for all pSites

https://www.rebexchange.ca/
Research that involves AHS resources (e.g., facilities, data, patients, staff) requires approval.
AHS Administrative Approval Steps

- After ethics approval
- **AHS Health System Access** will contact you
- Complete **HSA Questionnaire**
- Do you need...
  - IT access for research
  - Data
  - Access to clinical areas
  - Purchased services (e.g., pharmacy, lab, DI)

**Tips for submitting to AHS HSA**
Submit request via IT Access request form
Data Requests

- Submit via HSA questionnaire

**Indicate Your AHS Data Sources**

**Resources**
- List of known AHS data sources available for research purposes
- Tips and pointers for data access

Will this collected AHS health information/data need to be transferred to another collaborating academic institution (ie. not an industry sponsor)?

No ▼

If you answered "Yes" to requiring a data transfer and your study does NOT have a Clinical Trial Agreement or Sub-Site Agreement that includes an AHS signatory, please submit your Case Report Form or Data Collection Form to Research.Administration@ahs.ca. We will work with you to de-identify the data in accordance with AHS’ Standard for Non-Identifying Health Information.

**Indicate the method of data access (choose all that applies):**

- Paper Charts: Paper Charts direct access is defined as research staff requiring hands-on access to paper records at the clinic site or from Health Information Management (HIM).

- Extraction: Data extraction is defined as a data product extracted as reports from an data source by an AHS analyst/Information Manager.

- Direct Access: Direct access is defined as research staff requiring a login and view-access to an AHS Clinical Information System (CIS) or Electronic Medical Record (EMR).
Access to Clinical Areas

▪ **“Operational Approval”**
  ─ Must obtain an Operational Approval from each area or department that will be impacted by the study
  ─ Talk to the clinical leads (Patient Care Manager, Section Head) early on

▪ **Be prepared**
  ❑ A description of your research question in lay language
  ❑ Number of subjects from this area and timeframe for study activities
  ❑ Inclusion and exclusion criteria
  ❑ Study activities that you expect to conduct in the clinical area (i.e. Chart review, Patient Interview, Clinical Testing)
  ❑ Describe any assistance you would like from the clinical staff
  ❑ Explain any training you will provide to the staff to support these functions
  ❑ Describe any AHS clinical equipment you may need to use
  ❑ Describe any work or storage space you may need
Purchased Services departments support research on a fee-for-service basis.

Typically have an established price list for their services

Require arrangements to be made ahead of study initiation and documented with a mutually agreed "Service Quotation" or "Purchased Services Agreement" signed by the researcher and the service department

List of Purchased Services departments
✓ Ethics approval
✓ Legal/contracts
✓ Finance/project set up
✓ AHS administrative approval
  ✓ HSA questionnaire
  ✓ IT access request
  ✓ Data request
  ✓ Operational approval
  ✓ Purchased services

GO!!!
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Ashton Chugh
Research Assistant
chughha@ucalgary.ca

Department of Pediatrics research webpage
- Resources for research
- Consult request form