

Office of the Vice President (Research)



UNIVERSITY OF
CALGARY

IRISS Training (Beginner)

version 5— Oct, 2018

- Definitions
 - What is IRISS?
 - Who does IRISS Support
 - Accessing IRISS
 - Roles
 - Platform Customers
 - Terms of Reference
 - General Layout & Navigation
 - Finding a Study
 - Study Numbers & Types
 - General Workflow
- Entering a Study
 - SmartForm Navigation
 - Steps to Create & Submit a New Study
 - Study Workspace Layout
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- Study Management
 - Access to a Study & Activities
 - Other Actions in a Workspace
 - Renewal & Modification

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)



Animal Care Committee (ACC):

- Health Sciences (HSACC)
- Life & Environmental Sciences (LESACC)
- Veterinary Sciences (VSACC)

! July 4th, 2011



Research Ethics Board (REB):

- Conjoint Health (CHREB)
- Conjoint Faculties (CFREB)

! Mar 8th, 2013

HREBA | Health Research Ethics
Board of Alberta

HREBA

- Health Research Ethics
Board of Alberta
Community Health Committee
- Health Research Ethics
Board of Alberta
Clinical Trials Committee
- Health Research Ethics
Board of Alberta
Cancer Committee

! Dec 22nd, 2013



- irissupport@ucalgary.ca

HREBA

Health Research Ethics
Board of Alberta

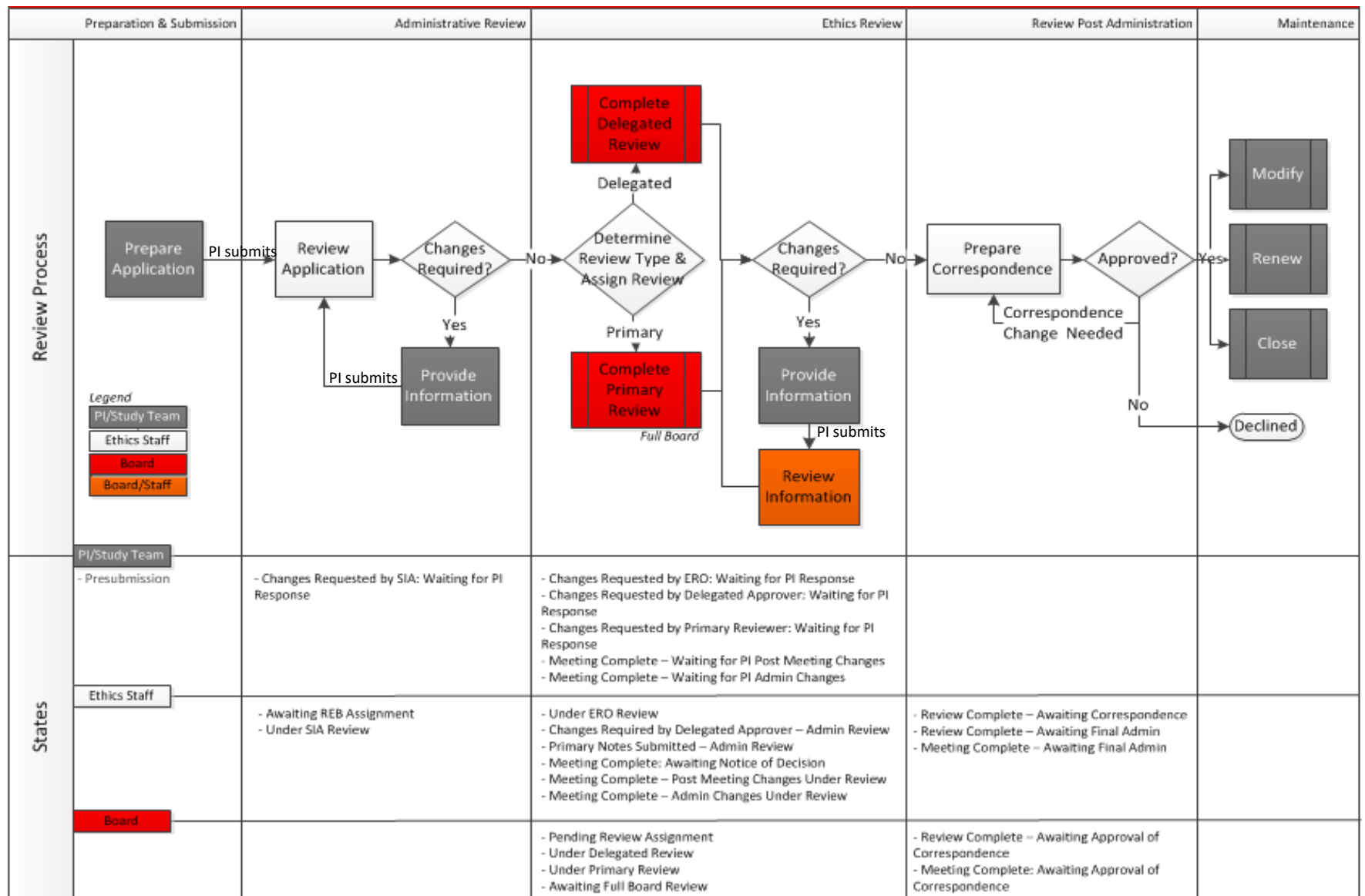
- Register for IRISS for each committee
 - <https://iriss.ucalgary.ca/HREBASelfRegistration>



HREBA

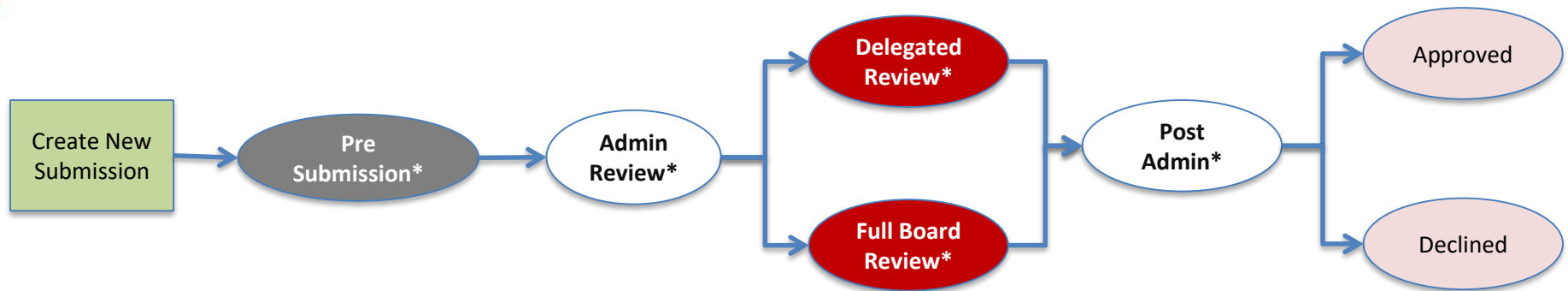
Health Research Ethics
Board of Alberta

- The business determines what role a user has in the system
- Roles determine what action a user can take
- The actions permitted are determined by the Board



Inactive States: Dormant Due to Inactivity, Suspended, Expired, Completed, Closed by Administrator

Workflow Summary



CREATE A NEW SUBMISSION:

Using the REB Approval button in your personal workspace, you can create a new study.

PRE SUBMISSION:

Studies in this state are editable by the research team, and have not yet been submitted to the REB for review. All documents for review must be uploaded before the PI submits.

ADMINISTRATIVE REVIEW:

The first stage of the REB review will include an internal review by RSO staff before forwarding the submission to the Board.

REB REVIEW:

As determined appropriate during the Administrative Review, RSO will forward the study for delegated or full board review.

POST REVIEW:

After the official REB review, RSO will document the determination, generate a letter, set the study expiration data, and approve appropriate material attached in pre-submission.

POST REVIEW STATES:

After the official REB review and the letter has been sent, the study will transition to a post review state, indicating that either research can begin or the application is declined.

Workflow Legend:

SmartForm
Editable

SmartForm
Locked

End State

SmartForm
Locked

Workflow Path ->

* CHANGES or CLARIFICATION REQUESTED:

Note that changes can be requested in any of the above stages with an "*" if the REB determine 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.

»

My Home

Researcher Profile

Help

View your profile

Hello, **Test Test** ▼

My Profile
Logoff

Study / Teaching Staff

My Roles

Study / Teaching Staff

Create an application for:

Animal Care Committee

Create ACC Incident Report

Create an application for:

Research Ethics Board

Quick Links

Edit your profile

Contact iriss support

Log Off

Page for Test Test

Inbox

ACC

REB

Reportable Events

Templates

REB Protocols Research List

...

Filter ?

ID

▼

Enter text to search for

Go

+ Add Filter

✕ Clear All

ID	Name	Short Title	▼ Date Modified	Type	Legacy File#	State	Last State Change
REB18-1389	Test study IV_ STUDY WORKSPACE		2018-10-09 3:41 PM	REB Certification		Pre Submission	2018-10-03 2:22 PM
REB18-1380_MOD?	Modification 2 for REB Certification #REB18-1380	Test account- Study title here	2018-10-09 3:21 PM	REB Modification		Changes Requested by ERO – Waiting For PI Response	2018-10-09 10:03 AM
REB18-1388	Test study III		2018-10-05 4:38 PM	REB Certification		Changes Requested by ERO- Waiting For PI Response	2018-10-05 4:38 PM

8 items

page 1 of 3

3 / page

Link to studies which require study team attention

»

My Home

Researcher Profile

Help

Hello, **Test Test**

My Profile
Logoff

Study / Teaching Staff

My Roles

Study / Teaching Staff

Create an application for:

Animal Care Committee

Create ACC Incident Report

Create an application for:

Research Ethics Board

Quick Links

Page for Test Test

Inbox
ACC
REB
Reportable Events
Templates
REB Protocols Research List

Filter
ID
Enter text to search for
Go
Add Filter
Clear All

ID	Name	Short Title	Date Modified	Type	Legacy File#	State	Last State Change
REB18-1389	Test study IV STUDY WORKSPACE		2018-10-09 3:41 PM	REB Certification		Pre Submission	2018-10-03 2:22 PM
REB18-1380_MOD2	Modification 2 for REB Certification #REB18-1380	Test account- Study title here	2018-10-09 3:21 PM	REB Modification		Changes Requested by ERO – Waiting For PI Response	2018-10-09 10:03 AM
REB18-1388	Test study III		2018-10-05 4:38 PM	REB Certification		Changes Requested by ERO- Waiting For PI Response	2018-10-05 4:38 PM

Tab	Definition
Inbox	Studies that require PI/study team attention
ACC	All studies entered into IRISS for ACC applications
REB	All studies that are approved or with ethics for review
Incident Reports	Incident reports submitted to the Animal Care Committee
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

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

Certification	Definition
REB18-7777	U of C: <u>R</u> esearch <u>E</u> thics <u>B</u> oard; Year of Initiation; Unique Study ID
AC18-1233	U of C: <u>A</u> nimal <u>C</u> are; Year of Initiation; Unique Study ID
HREBA-CC-15-1234	HREBA: <u>C</u> ancer <u>C</u> ommittee; Year of Initiation; Unique Study ID
HREBA-CTC-15-1234	HREBA: <u>C</u> linical <u>T</u> rial <u>C</u> ommittee; Year of Initiation; Unique Study ID
HREBA-CHC-15-1234	HREBA: <u>C</u> ommunity <u>H</u> ealth <u>C</u> ommittee; Year of Initiation; Unique Study ID

- Follow on submission:
 - **REN** – means you are viewing a Renewal
 - **MOD** – means you are viewing a Modification
 - **CLOSE** – means you are viewing a Closure

»
My Home
Researcher Profile
Help
Hello, **Test Test** ▼

Current State

Pre Submission

Edit Study

Printer Version

View Differences

View SmartForm Progress

My Activities

- Send Email to Study Team
- Edit Guest List
- Study Team Training Certificates
- Edit Email List
- Log Comment to REB Admin
- Copy
- Withdraw
- Submit Application

REB Certification File:Test study IV _ STUDY WORKSPACE (REB18-1389)


Formal Title:	Test study title - Study Work Space	Legacy File Number:	
Application Type:	Faculty/Staff Research	Reviewing Board:	
Principal Investigator:	Test Test	Current Owner (REB Administrator):	
Primary Admin Contact(s):	Test Account Test Test	Last Updated:	2018-10-09 3:41 PM
Initiated by:	Test Test		

History
Attachments
Change Log
Reviewer Notes

	Activity	Author	▼ Activity Date
	Study Created	Test, Test	2018-10-05 11:29 AM

- A study will transition through **States** during the review lifecycle.
- Certain **Activities** can be performed in each state. These may change access to a study or move a study to the next state.
- **Roles** are defined on each study. This affects who can perform the activity in a particular state.
- Email notifications are triggered at specific points in the process, when action is required or a determination is made.

- Studies that require action appear in **My Inbox** with a link to the study
- To access studies where action is required:

Inbox	ACC	REB	Reportable Events	Templates	...		
Filter ?	ID		Enter text to search for	Go	+ Add Filter	✕ Clear All	
ID	Name	Short Title	▼ Date Modified	Type	Legacy File#	State	Last State Change
 REB18-1389	Test study IV STUDY WORKSPACE		2018-10-09 3:41 PM	REB Certification		Pre Submission	2018-10-03 2:22 PM

To search in any list of studies, use the “Filter By” box:

- ID - Must be **FULL ID** (REB18-1389)
 - Tip: if you don't remember full ID – use %, then last 4 digits (example: **%1389**)
- Name
- Short Title
- State
- Last State Change

Submission status =STATE

Current State

Approved

View Study

Printer Version

View Differences

View SmartForm Progress

Create a Renewal

Request Closure

Create Reportable Event

My Activities

Send Email to Study Team

Edit Participate in Research External Post

Study Team Training Certificates

Manage My Funding

Update Study Team

Log Comment to REB Admin

Copy

Request PI Proxy

Researcher Profile

Help

Hello, **Test Test**

REB Certification File:Test Study 2 (REB18-1387)

Formal Title:

Test study title - long title placeholder

Legacy File Number:

Submission Type:

Faculty/Staff Research

Principal Investigator:

Test Test

Approving Board:

CHREB

Primary Admin Contact(s):

Test Account
Test Test

Certificate of Approval:

View

Original Approval Date:

October 3, 2018

Letter of Approval:

Last Approval Date:

October 1, 2017

Expiration Date:

October 3, 2018

Link to Correspondence

History

Attachments

Change Log

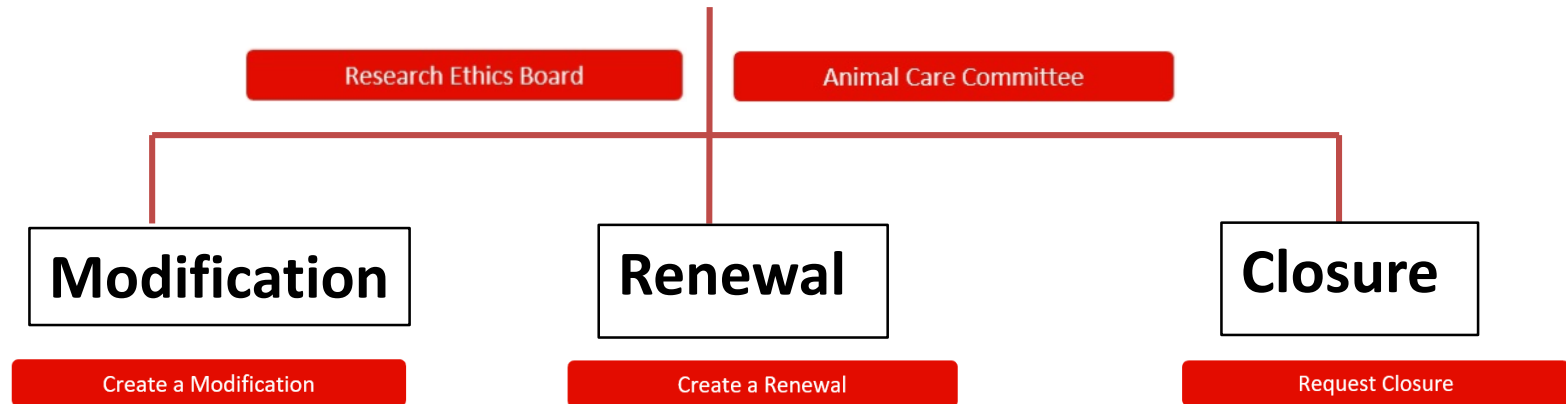
Reviewer Notes

Activity	Author	Activity Date
Project Snapshot Generated	Krecsy, Ashley Cassandra	2018-10-03 2:23 PM
View Project Snapshot		
Correspondence Sent to PI	Krecsy, Ashley Cassandra	2018-10-03 2:22 PM
Notified Study Team - Forward for Delegated Review	Krecsy, Ashley Cassandra	2018-10-03 2:12 PM
Application Submitted	Test Test	2018-10-03 2:00 PM












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

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).


Activity		On Submission Type	Access to
	Create a study	Initial Application (Certification)	PI, Study Team
	Create a modification	Modification	PI, Study Team
	Create a renewal	Renewal	PI, Study Team
	Create a closure	Closure	PI, Study Team
 Response Required! Click here to respond...	Prepare changes or clarifications (all types)	Changes Requested	PI, Study Team
 Submit Application	Submit	Certification	PI
 Submit Modification	Submit	Modification	PI
 Submit Renewal	Submit	Renewal	PI
 Submit Closure	Submit	Closure	PI
 Submit Changes	Submit	Changes Requested	PI
 Withdraw	Withdraw	Cert, Ren, Clos, Mod	PI

- 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.

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

ID	Name	Short Title	▼ Date Modified	Type	Legacy File#	State	Last State Change
 REB18-1389	Test study IV _ STUDY WORKSPACE		2018-10-09 3:41 PM	REB Certification		Pre Submission	2018-10-03 2:22 PM

- 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 “Jump To:” to get to a specific section
- Use “Exit” to close the SmartForm


You Are Here:  Test study IV _ STUDY WORKSPAC...


Edit: REB Certification - REB18-1389


« Back

 Save

 Exit

 Hide/Show Errors

 Print

 Jump To ▼

Continue »


Exit

Jump To:


Continue


- **Add** = New document

Protocol:
Attach supporting documents, naming them as you want them to appear in the approval letter:



Document Name	Document	Version	Document Date	Upload Date
Study Protocol	Protocol.pdf	V.2	10 Oct 2018	10 Oct 2018





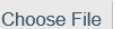


- **Update** = Another version of an existing document
- All versions can be found by clicking "History".

- **Delete** (deletes document from IRISS)


Edit DocumentIRISS


Add Attachment
(* indicates a required field)

1.0 * **Document to attach:**
Study Protocol(V.2)   

2.0 **Name:** (if not supplied, the file name will be shown)

3.0 **Version:**

4.0 **Date:**
 


Resource History for Study Protocol 

Title: Study Protocol
File: Protocol.pdf
Owner: Stacey D. Beck
Author:
Content Type: Document
Version: V.2
Description:

History:

Date	Version	Person	Action	Notes	Uploaded File
2018-10-10 1:28 PM	0.01	Test Test	File Uploaded & Edited	Version: V.2 Date: October 10, 2018	Protocol.pdf
2018-02-12 9:22 AM	0.01	Stacey D. Beck	Created	Version: Not Defined Date: Not Defined	AHS.jpg

« 1-2 of 2 »



Copy or Create a Template

- Every state has an activity called “Copy”



Copy

This activity will create a copy of this Certification File. The Principal Investigator will remain the same and the new file will be placed in your Inbox.

All attachments will also be copied over from the original.

* **New Short Title:**

Copy this Certification to your 'Templates': ☐ Yes ☒ No [Clear](#)

(Selecting 'YES' will allow this Certification to be used as a starting point for other applications. The copy you create will appear under the 'Templates' tab on your personal home page).

This activity takes time but can save you work! We thank you for your patience.

Use Background Processing: ☐

(Checking this box will allow you to proceed with other work while IRISS creates your copy. If you do not check this box, you will need to wait until the copying process is complete before engaging in a new activity).

- Templates can be used so 'base' information is not entered multiple times for multiple studies.
- “Copy” the template, select ‘No’ to template, and it will copy the template and place in your **INBOX**.

Creates a study and places it under the “Template” tab.

Creates a study and places it under the “INBOX” tab.

Overview of Actions Within a Study

Current State

Pre Submission

Edit Study


Printer Version


View Differences

View SmartForm Progress

My Activities

 Send Email to Study Team

 Edit Guest List


 Study Team Training
Certificates

 Edit Email List

 Log Comment to REB Admin

 Copy

 Withdraw

 Submit Application

REB Certification File:Test study IV _ STUDY WORKSPACE (REB18-1389)

Formal Title: Test study title - Study Work Space

Legacy File Number:

Application Type: Faculty/Staff Research

Principal Investigator: Test Test

Reviewing Board:

Primary Admin Contact(s): Test Account
Test Test

**Current Owner
(REB Administrator):**

Initiated by: Test Test

Last Updated: 2018-10-10 1:38 PM

History

Attachments

Change Log

Reviewer Notes

	Activity	Author	▼ Activity Date
	Study Created	Test, Test	2018-10-05 11:29 AM

Other Actions in a Workspace





































Pre Submission

To submit this type of information	Click this button
Updates on a study that has not been submitted for review	<div> <div>Edit Study</div> <div>Printer Version</div> <div>View Differences</div> <div>View SmartForm Progress</div> </div>
View print version of the study	<div> <div>Edit Study</div> <div>Printer Version</div> <div>View Differences</div> <div>View SmartForm Progress</div> </div>
View differences between the original application and from one modification to the next	<div> <div>Edit Study</div> <div>Printer Version</div> <div>View Differences</div> <div>View SmartForm Progress</div> </div>
View how much of the application is complete and what is remaining	<div> <div>Edit Study</div> <div>Printer Version</div> <div>View Differences</div> <div>View SmartForm Progress</div> </div>

- Select **“Edit Study”** to edit the submitted SmartForm only while a study is in:
 - Pre submission
 - Clarifications or changes are requested
 - Modifications are required

Other Actions in a Workspace

Pre Submission

To submit this type of information	Click this button	To submit this type of information	Click this button
Send email to all users listed on study team (except Co-I).	<p>My Activities</p> <ul style="list-style-type: none">  Send Email to Study Team  Study Team Training Certificates  Update Study Team  Log Comment to REB Admin  Copy  Request PI Proxy 	Send a comment to an ethics administrator.	<p>My Activities</p> <ul style="list-style-type: none">  Send Email to Study Team  Study Team Training Certificates  Update Study Team  Log Comment to REB Admin  Copy  Request PI Proxy
Shows whether training certificate are uploaded into Researcher Profile of study team.	<p>My Activities</p> <ul style="list-style-type: none">  Send Email to Study Team  Study Team Training Certificates  Update Study Team  Log Comment to REB Admin  Copy  Request PI Proxy 	Copies current study: gives you the option to save as a template (for future use) or new (will place under INBOX tab).	<p>My Activities</p> <ul style="list-style-type: none">  Send Email to Study Team  Study Team Training Certificates  Update Study Team  Log Comment to REB Admin  Copy  Request PI Proxy
Add or delete study team members.	<p>My Activities</p> <ul style="list-style-type: none">  Send Email to Study Team  Study Team Training Certificates  Update Study Team  Log Comment to REB Admin  Copy  Request PI Proxy 	Permits a study team member to execute activities on behalf of the PI.	<p>My Activities</p> <ul style="list-style-type: none">  Send Email to Study Team  Study Team Training Certificates  Update Study Team  Log Comment to REB Admin  Copy  Request PI Proxy

To submit this type of information

Click this button

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.

View Study

Printer Version

View Differences

View SmartForm Progress

Create a Modification

Request Closure

Create Reportable Event

Create a renewal for an approved study. Renewals can be created and submitted 30 days before the expiry date.

View Study

Printer Version

View Differences

View SmartForm Progress

Create a Renewal

Request Closure

Create Reportable Event

To submit this type of information

Click this button

Create a Reportable Event for an approved study.

View Study

Printer Version

View Differences

View SmartForm Progress

Create a Renewal

Request Closure

Create Reportable Event

Request active study closure. Closures can be submitted at any time.

View Study

Printer Version

View Differences

View SmartForm Progress

Create a Modification

Request Closure

Create Reportable Event

Other Actions in an Approved Workspace-Modification

1

View Study

Printer Version

View Differences

View SmartForm Progress

Create a Modification

Request Closure

Create Reportable Event

- First step to initiate a modification

2

You Are Here: [Test study title](#) [Amendment](#) New: REB Modification

[« Back](#) [Save](#) [Print](#) [Continue »](#)

Getting Started – Modification

By completing the information on this first page and clicking either 'Save' or 'Continue' you will create a new REB Modification. You will be able to access this application through your Personal Page. As you complete this form, you can save your work, exit and come back at any time.

All questions preceded by a red asterisk (*) are required responses that map you to the application sections that are relevant to your study. All questions within the section to which you are mapped **must be addressed**.

BE AWARE that while some navigation features in this form will prompt you to save, if you click the 'Back' button either in this form or in your web-browser before saving your work, you will lose your information without any warning. Save your work often!

[« Back](#) [Save](#) [Print](#) [Continue »](#)

- 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.

Save & Close

3

Edit Modified Study

Printer Version

View Changes

Edit Modification Summary

Printer Version (Summary)

View SmartForm Progress

- Edit Modified Study opens up the application for the modification.
- Modification summary was initiated in step 2.
- Modification Summary + Modified Study = Modification to be submitted for review.

Only the Principal Investigator can submit the modification for review



Submit Modification

Business: resetethics@ucalgary.ca / info@hreba.ca

- **How** to answer the questions
 - What information is required
 - What documents need to be attached
-

Technical: iriss.support@ucalgary.ca

- Drop-in support available at Integrated Service Center
- **How** to use the technology
- How to get access
- Navigation assistance

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)