HARVARD
FINANCIAL ADMINISTRATION

Electronic Submission Tracking & Reporting - IRB

New IRB Staff Training

Topics for This Session

- Basics
- Personal Workspace and Navigation
- SmartForm and Study Workspace
- Definitions (Workflow, Roles, and Activities)
- Review and Post Review Activities

Appendix

- *Migrated Study Information*
- *Workflow States and Activities*

Before We Begin

- The ESTR system: irb.harvard.edu
- Study Staff Site - Tools and Tips for Study Staff: estrsupport.fss.harvard.edu
- WIKI -Tools and Tips for IRB Staff (plus all the other training documents to share): https://wiki.harvard.edu/confluence/display/FSS/ESTR-IRB+Reference+Materials
- ESTR Help Desk: ESTRhelp@harvard.edu

What is ESTR?

ESTR is our Electronic Submission Tracking & Reporting system.

- Automates the IRB submission and review processes.
- Is a place to store and access submission documents and meeting documentation.
- Allows for easier reporting for business process and regulatory purposes.

For Reference - HIRBERT is the legacy system: Harvard IRB Electronic Reporting Tool

Accessing the System

To access the system, you must:

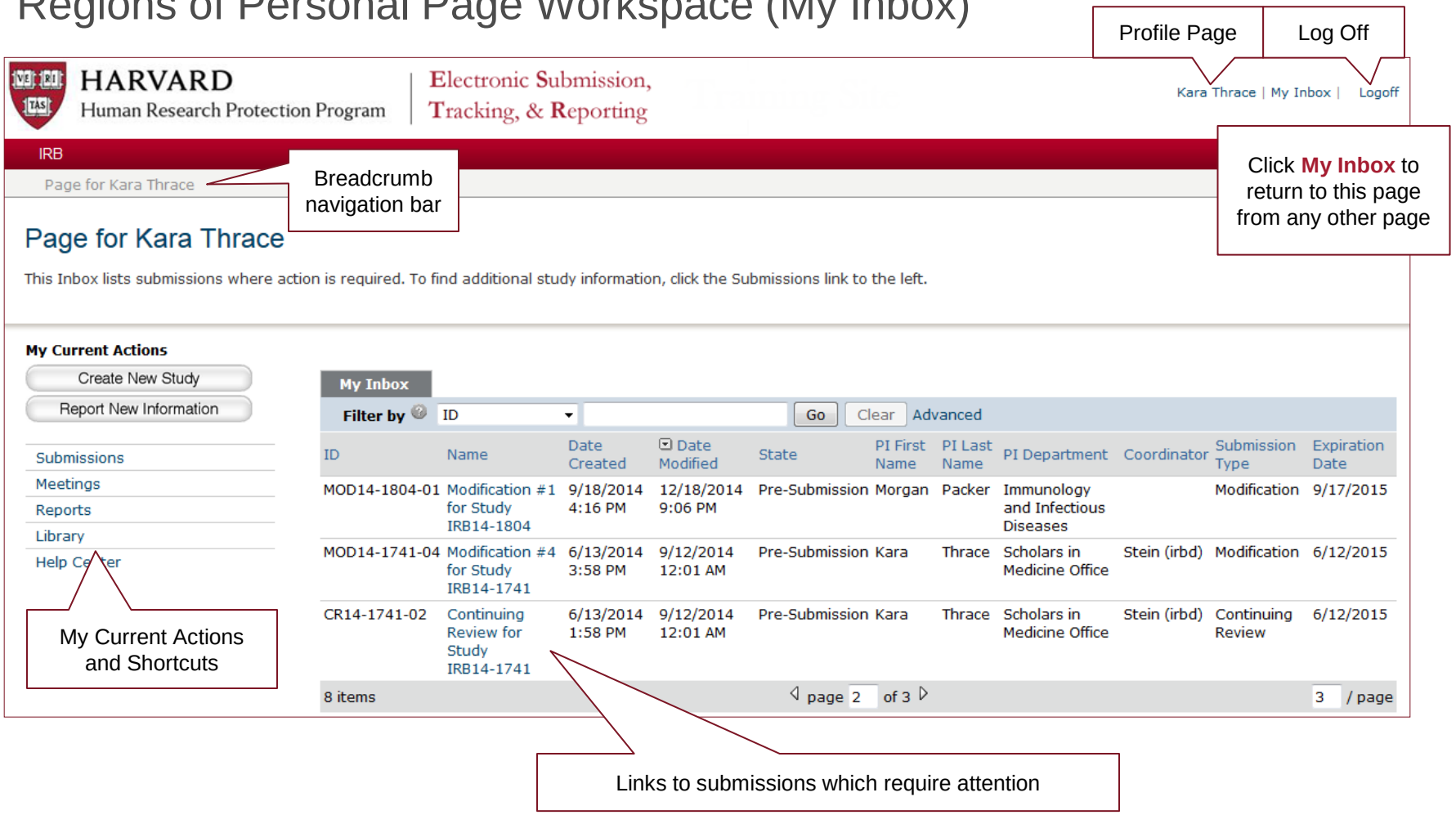
- Have an **internet connection** and have an **HUID**
- Based on your HUID, you will have certain privileges in the system.
- Suggested browsers: Internet Explorer 8 or later, Firefox 7 or later, Chrome 9 or later, Safari 4 or later, and Firefox 3 or later

Things to Remember

- ESTR is an active database, NEVER use the “back” browser option. Only use the in-window navigation options.
- The system will timeout after being idle for 30 minutes. Be careful to save your work.

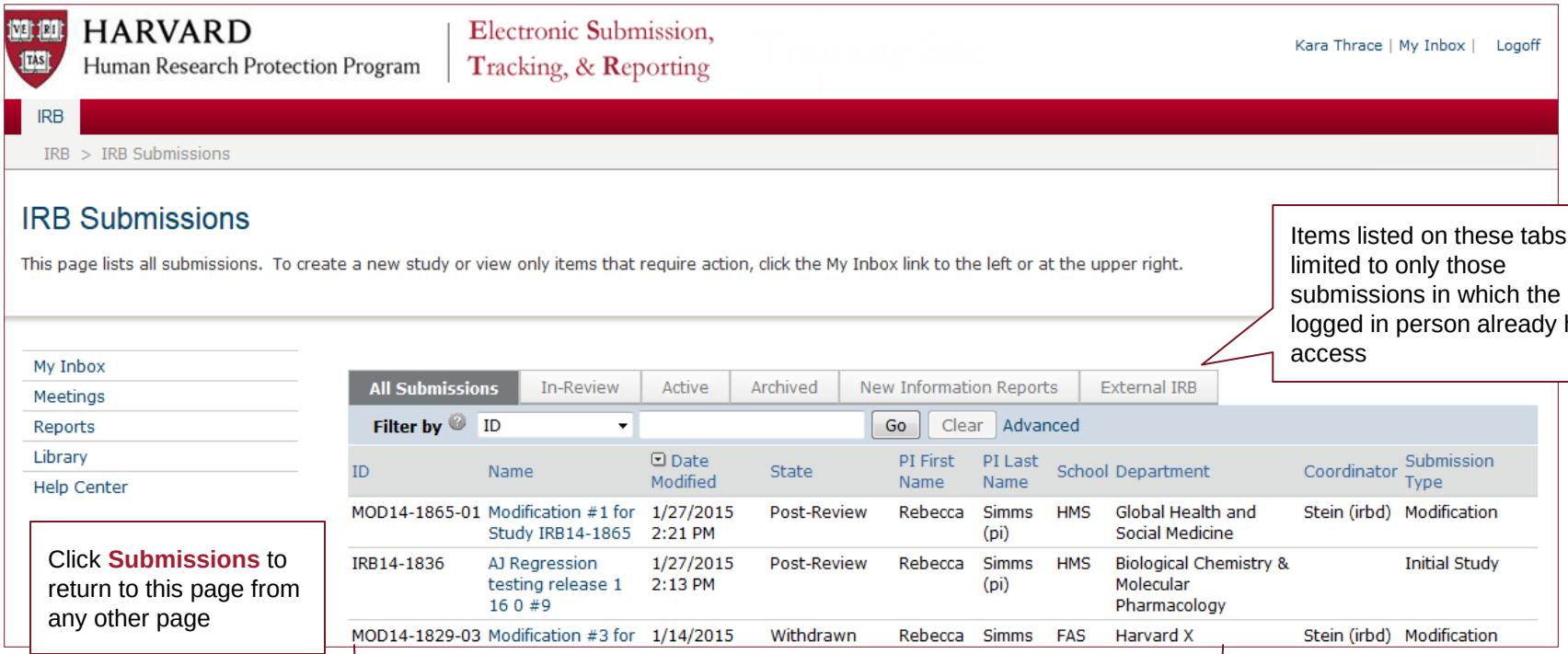
General Site Layout and Navigation

Regions of Personal Page Workspace (My Inbox)



General Site Layout and Navigation

IRB Submissions Page Details



Items listed on these tabs are limited to only those submissions in which the logged in person already has access

Click **Submissions** to return to this page from any other page

Page Tab List Contents	
All Submissions	All submissions entered into the system
In-Review	Submissions where IRB review is not yet complete
Active	Studies that are approved by the IRB and currently in progress
Archived	Submissions which are closed or withdrawn
New Information Reports	All Reportable New Information (RNI) submissions
External IRB	Studies where the IRB is relying on another institution's review

Finding a Submission

- IRB submissions that require action appear in My Inbox with a link to the submission.
- To access submissions where action is required:
  1. Click the My Inbox link in the top right navigation header.
  2. Identify the reason it appears in My Inbox by looking at the State column.
  3. View the details of the submission by clicking its short title in the Name column.
- To access all submissions (including a presorted list of active studies), click the Submissions link in the left shortcuts menu.

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

- Select the field you want to search in the drop-down
- Type the text you are looking for
- Use a “%” as a wildcard.
  For example, searching on name for “%Stu%” will find all submissions with the word “study” somewhere in the name.

Submission Numbers and Types

Applications are given a number.

- Initial submission or main study workspace where all currently approved materials may be accessed
  - If a submission number does not have a prefix of letters
    - It is a study that was submitted before ESTR
    - The record was ‘migrated’ from our legacy system.
  - **IRB** prefix means you are viewing the parent record for a study or an initial application.
- Follow on Submissions
  - **CR** means you are viewing a Continuing Review
  - **MOD** means you are viewing a Modification
  - **RNI** means you are viewing Reportable New Information

ID	Name
CR-22494-01	Continuing Review for Study
IRB13-1385	Roller-skates, Rainbows, and
RNI13-0310	New Information 9/9/2013 9:
MOD-19067-01	Modification #1 for Study 19
MOD-22086-06	Modification #6 for Study 22
22086	Warrior Web
MOD-22086-05	Modification #5 for Study 22
22494	Effects of suppressing illness

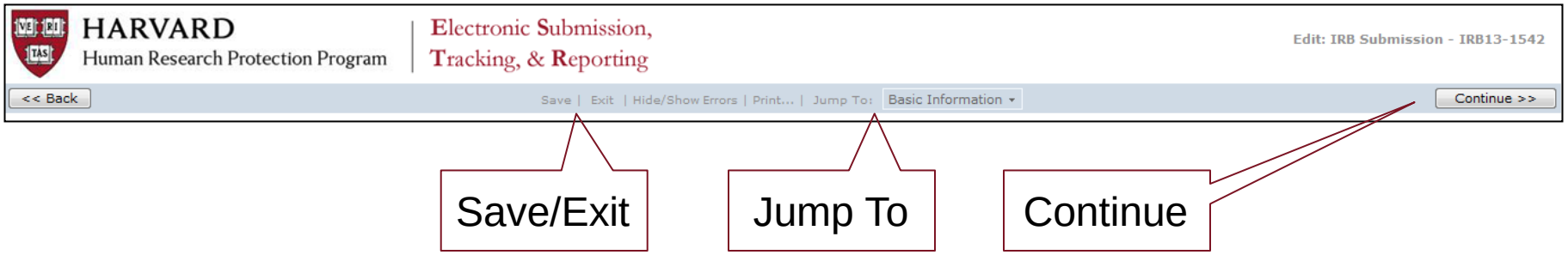
User Questions Preview

- How do I get an HUID to log in?
- Why don’t I see any studies in my in-box?
- How do I search for a study?
- When a study is migrated from HIRBERT, which tab is it under?
  Hint: What’s the status of the project?
- When a study is submitted, which tab is it under?

SmartForm Navigation

A SmartForm is a series of webpages containing information about a study and links to attached supporting documentation.

- Navigate the to a SmartForm
  1. Navigate to a submission workspace
  2. Select ‘View Study’ on the left side of the screen
- Navigate within a SmartForm
  1. Click Continue to move to the next page of the form.
  2. Use Jump-to to get to a specific section
  3. Use exit to close the SmartForm



SmartForm Branching

Basic Information: Study Title & Description; PI Name, Department and COI

Funding Sources: Link to a grant in GMAS; Identify other non-sponsored funding source

Study Team Members: Harvard-Affiliated Study Team Members and their Roles

Attachments: Personnel Forms, HS Training, Positive Disclosures

Study Scope: Indicate if any of the branched pages are necessary; Protocol Upload

Attachment: Protocol or Not Human Subjects Research Request Form

Devices, Drugs and External Sites Pages only display if selected on the Study Scope Page

***Devices**: Details of any devices, including IDE Upload*

***Attachment:** Device brochures and details*

***Drugs:** Details of any drugs, including IND Upload*

***Attachment:** Drug brochures and details*

***External Sites:** Details on external sites, including document upload*

***Attachment:** Site Approvals or IAA*

Consent, Assent, and HIPAA Authorization Materials: Document Upload

Attachments: Consent, Assent, Parental Permission, and HIPAA Authorization materials

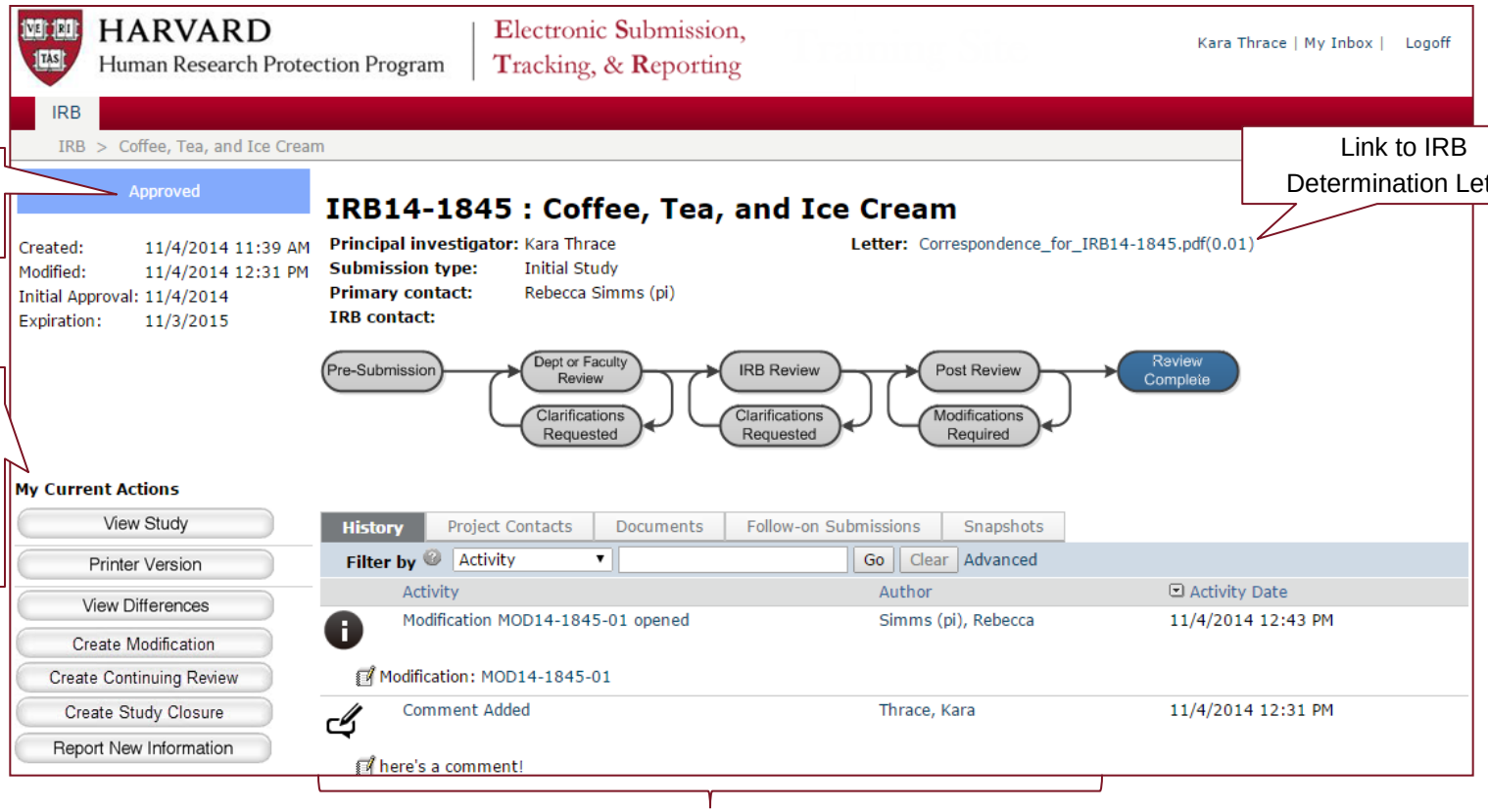
Supporting Documents: Upload for any supporting documents not uploaded elsewhere

Attachments: List of requirements on SmartForm page or available in the Study Submission Guide

Final Page: Submission Instructions

Review-associated documents MUST be attached to the relevant section of the SmartForm.

Submission Workspace Layout



Submission Status

Link to IRB Determination Letter

My Current Actions & Shortcuts
always on the left side of the screen

Page Tab List Contents	
History	Information about each action taken on a submission and in-brief view of comments.
Project Contacts	List of study team members listed on the SmartForm, including current Human Subjects Training information on file.
Documents	Draft and finalized documents submitted for review, with versioning information for each document
Follow-on Submissions	Links to Continuing Review, Modification, or Reportable New Information workspaces for a study (only visible on the *initial study workspace*)
Snapshots	View of the application at each change in state (for example, the appearance of the SmartForm between pre-review and changes submitted)

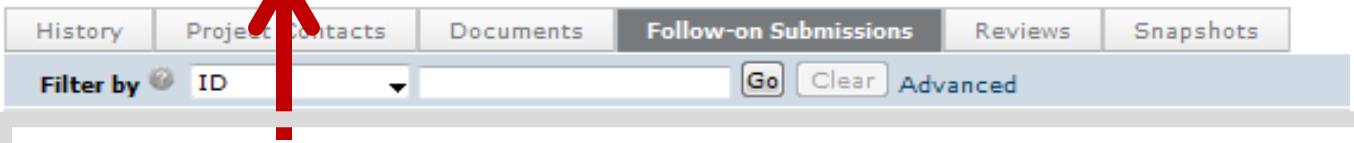
Construct of a Study Record - Workspaces

Location of ALL currently approved materials.

Initial/Main Study

Study Information via Study SmartForm including documents

Review Information for this Submission (including determination letter and review history)



Upon approval, main study SmartForm and Documents update.

MODIFICATION

DRAFT Study Information via Study SmartForm including documents

Review Information for this Submission

Makes no change to any other workspaces. Confidential RNI should not be a follow on.

REPT. NEW INFO

Item/Issue Information via RNI SmartForm

Review Information for this Submission

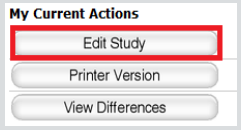
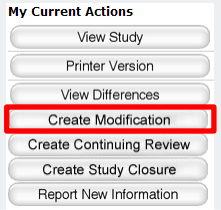
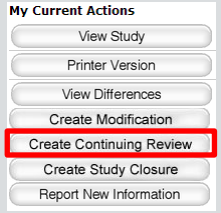
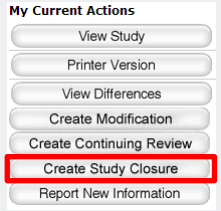
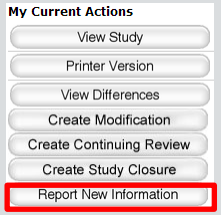
Upon approval main study expiration date updates.

CONTINUING REVIEW

Study Progress Information via CR SmartForm

Review Information for this Submission

Other Actions in a Workspace

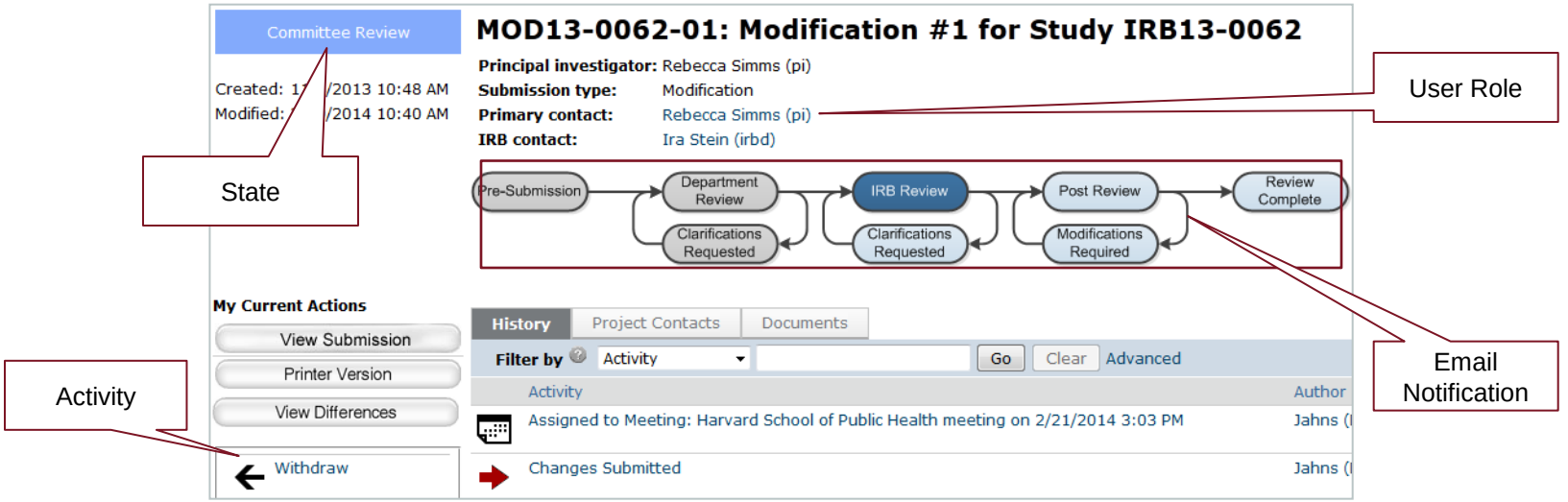
To Submit this type of Information	Click this button	Notes
Updates on a study that has not been submitted to the IRB for review.		To edit a SmartForm that has not yet been submitted to (or back to) the IRB.
Modifications for active study		There are two types of modifications: Personnel and Non-Personnel The first form prompts for the type of information to submit.
Continuing review updates for an active study		The first form prompts for the type of information to submit
Request active study closure		The first form prompts for the type of information to submit. Select "continuing review" to request study closure.
Reportable New Information (Adverse event)		The form identifies the type of information that must be reported.

- Select 'View Study' to see the submitted SmartForm while a submission is in IRB review or once review is complete.
- Select 'Edit Study' to edit the submitted SmartForm only while a submission is in:
  - Pre-submission
  - Clarifications are requested
  - Modifications are required
  - Deferred
- Otherwise, to request a change to a study where review was completed; "Create Modification" must be initiated.

User Questions Preview

- What do I need to prepare before I start a SmartForm?
- Where is the submission determination letter?
- Where can I find currently approved information about my study (including documents and study team members)?
- **Bonus word problem:** I work in the IRB office and requested clarifications on a submission. The Study Team attached the revised consent forms that I requested to a comment on the history. Is this the right thing to do? If not, what do I do to make things right on the submission?

Workflow Definitions



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

Harvard IRB Submission
Workflow Summary

CREATE NEW SUBMISSION:
Using the project creator buttons in your personal workspace, you can create a new study; Using the project creator buttons in your study workspace you can create a new Continuing Review, Modification, or RNI submission.

PRE-SUBMISSION:
Studies in this state are editable by the research team, and have not yet been submitted to the IRB or to the department/faculty advisor for review.

FACULTY ADVISOR or DEPARTMENT REVIEW:
If a Student Investigator is identified, the study will be routed to the faculty advisor for review.
If appropriate, the IRB will route submissions to the Department Chair for review.

PRE-REVIEW:
The first stage of IRB review will include an internal review by the IRB Staff before forwarding the submission to a designee or to the full committee for review.

IRB REVIEW:
As determined appropriate during Pre-Review, the IRB Office will forward your submission to a designee (non-committee review) or to the full committee (full committee review).

POST REVIEW:
After the official IRB review, the IRB Office will document the determination, generate a letter, set the study expiration date, and stamp appropriate recruitment materials.

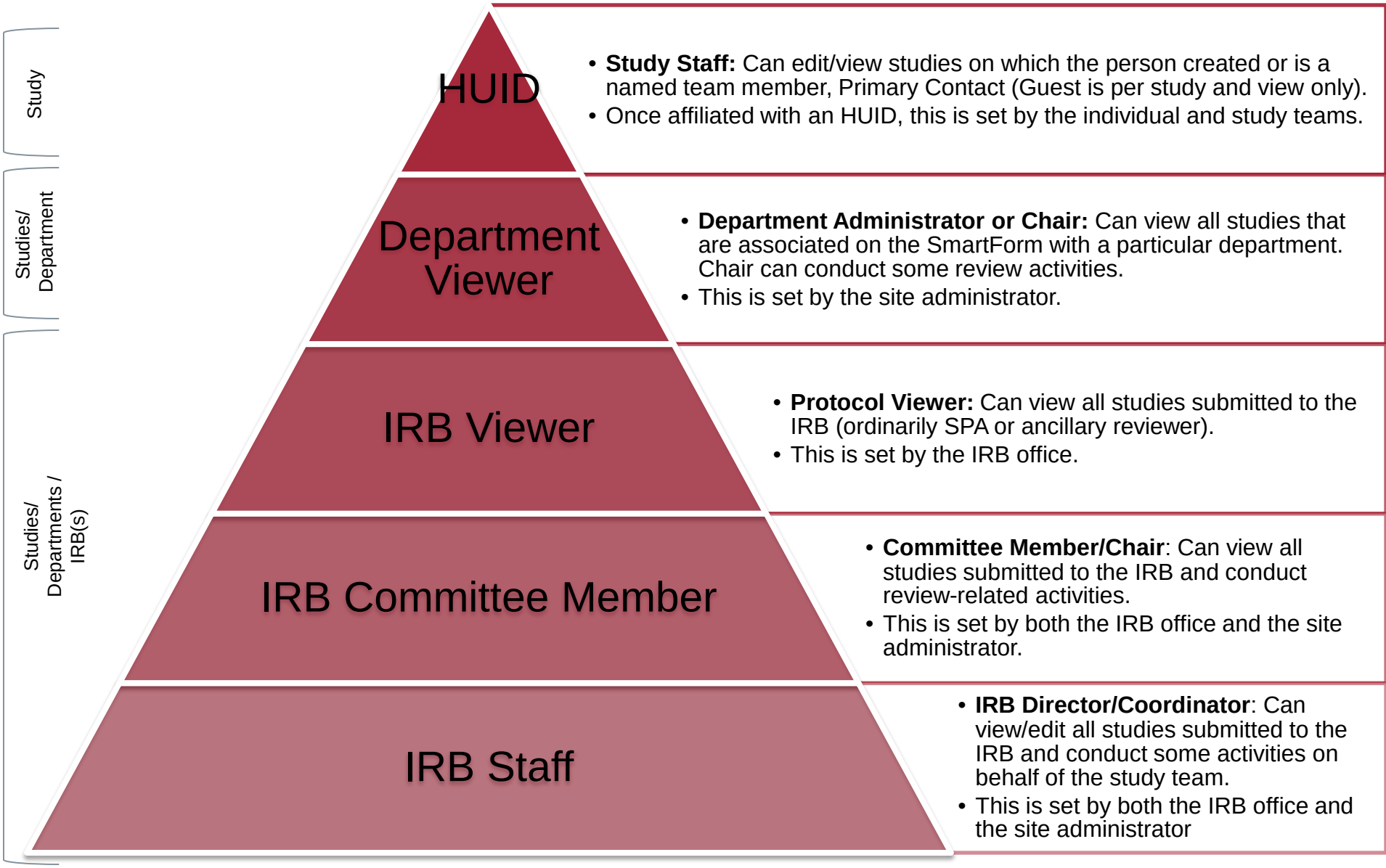
POST REVIEW STATES:
After the official IRB review and the letter has been sent, the submission will transition to a post-review state, indicating that either research can begin, or further changes are required.

Workflow Legend:

Changes or Clarifications Requested

*** CHANGES or CLARIFICATION REQUESTED:**
Note that Changes can be requested in any of the states above with an "*" if the IRB or Department/ Faculty Reviewer determine that additional changes are necessary. In this state, the submission form is unlocked and the system will allow you to make changes as necessary.

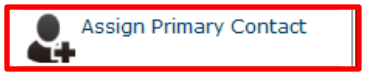
Access Types: Roles



Access to a Study and Activities

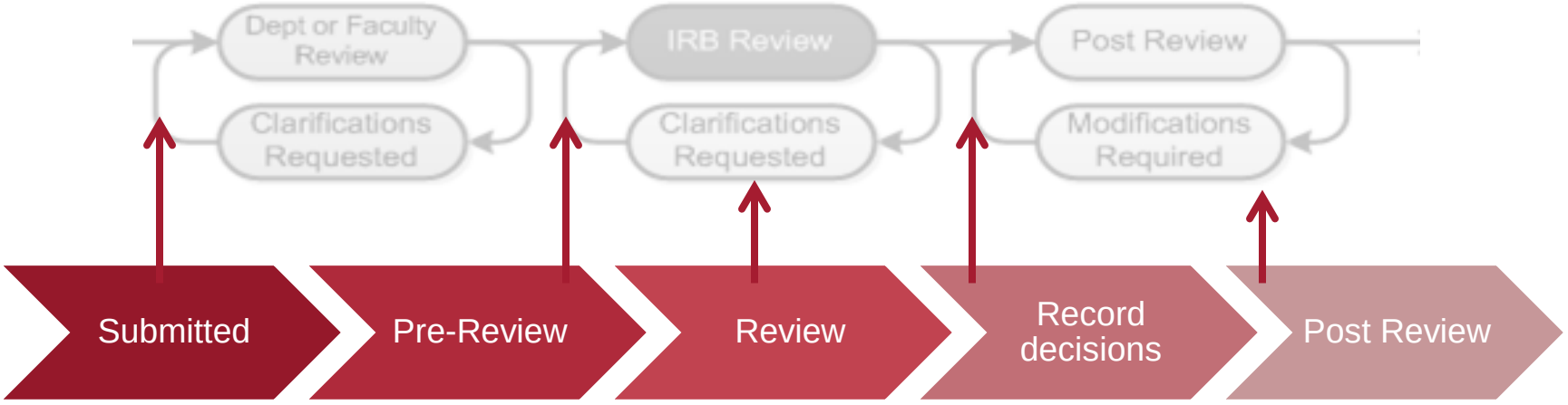
Activity		On Submission Type	Can only be seen/ completed by persons with the following role(s) on the study:
Submit	SUBMIT (WITHOUT PI ASSURANCE)	Initial Application	Study team or Primary Contact
Submit and Provide Assurance	SUBMIT AND PROVIDE ASSURANCE	Initial Application	PI and Faculty Sponsor (if there is one)
Submit Changes	SUBMIT CHANGES: RESPOND TO CLARIFICATION REQUEST	All Types	PI, Primary Contact, Approved Study Team, and Faculty Sponsor (if there is one)
Submit Changes	SUBMIT CHANGES: RESPOND TO MODIFICATIONS REQUIRED OR DEFERRAL	All Types	PI and Faculty Sponsor (if there is one)
Create Modification	CREATE A MODIFICATION	Modification	PI, Primary Contact, Approved Study Team, and Faculty Sponsor (if there is one)
Create Continuing Review	CREATE A CONTINUING REVIEW	Continuing Review	PI, Primary Contact, Approved Study Team, and Faculty Sponsor (if there is one)
Create Study Closure	CREATE A CLOSURE	Study Closure	PI, Primary Contact, Approved Study Team, and Faculty Sponsor (if there is one)
Submit	SUBMIT	Continuing Review & Modification	PI and Faculty Sponsor (if there is one)
Submit	SUBMIT	Reportable New Information (associated with a study)	PI, Primary Contact, Approved Study Team, and Faculty Sponsor (if there is one)
Submit	SUBMIT	Reportable New Information (NOT associated with a study)	Any person with an HUID

- Only members of a study team (PI, Primary Contact, and Study Team Members, or Faculty Sponsor) may make changes to a study.
- Your role dictates the activities you see in the study workspace.
- The primary contact of the study may be changed at any time
  - Complete the “Assign Primary Contact” activity, without IRB review.
  - If this person is also working on the study, he or she should also be included on the study team members page



“SUBMIT” means complete the activity to move the submission to the next state.

Project Review - Workflow Overview



- Study team members may submit initial applications.
- The PI and Faculty Sponsor (if there is one) must provide assurance.
- If the Faculty Sponsor does not provide assurance, IRB review cannot begin.

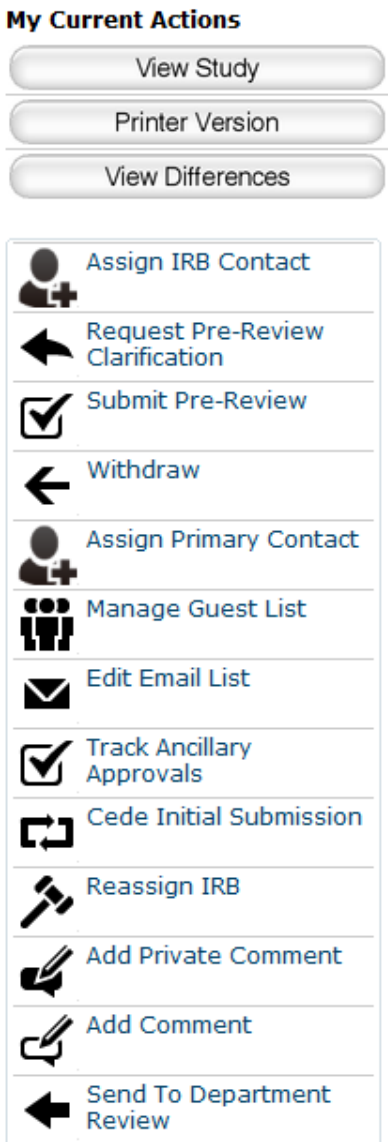
- Features of the project preliminarily identified. If Department Review is required, it is initiated prior to completion of Pre-Review.

- Non Committee: Assign designated reviewer
- Full Committee: Assign to Committee Meeting
- Ceded Review

- Examples
  - Approved
  - Modifications required
  - Deferred or Disapproved

- Finalize documents
- Set Expiration Date
- Prepare and Send Letter

Review Activities for IRB Staff

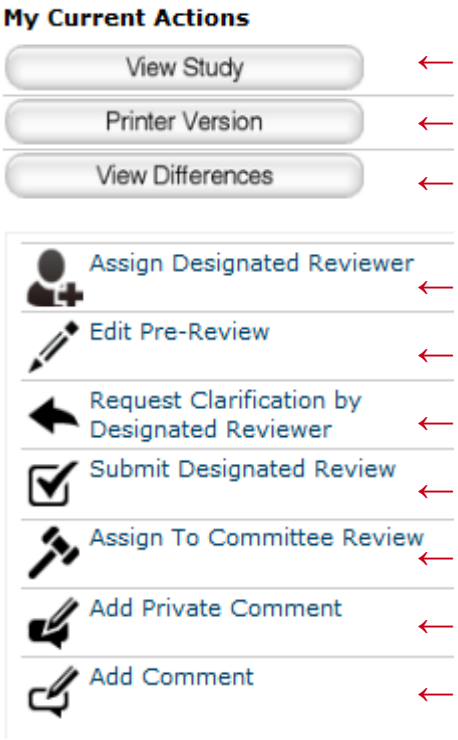


- View the submitted SmartForm and Attachments
- View the flat “printer version”
- View differences following any revisions between state changes.

- Assign a project to yourself (will appear in your in-box).
- Request Clarifications (opens the SmartForm for edits, notice sent)
- Opens the Pre-Review Form for drafting or completion.
- Withdraw the application (a notice is sent)
- Assign the Primary Contact for the study
- Allow guests with an HUID to view the study (such as consultants)
- Edit who receives notifications (other than PI and Primary Contact)
- Open a form to edit and track ancillary reviews and approval documentation.
- Cede review of the study to another IRB
- Assign the project to another Harvard IRB
- Add a private comment, visible to only IRB staff and Committee members
- Add a public comment, visible by anyone who can view this study
- Once an initial application is submitted, IRB staff may determine if Department review is required.

Some Activities have pop up forms that provide for suggested attachments or where required determinations may be made.

Non-Committee Reviewer Activities



← View the submitted SmartForm and Attachments

← View the flat “printer version”

← View differences following any revisions between state changes.

← Assign a project to yourself (will appear in your in-box).

← Allows editing of the Pre-Review form completed by the IRB Contact

← Sends the submission *DIRECTLY* back to the investigator for clarifications.

← Complete your review and enter a determination (Approve, Changes Required, etc)

← Send the study back to Pre-Review, indicating that Full-Committee review required

← Add a private comment, visible to only IRB staff and Committee members

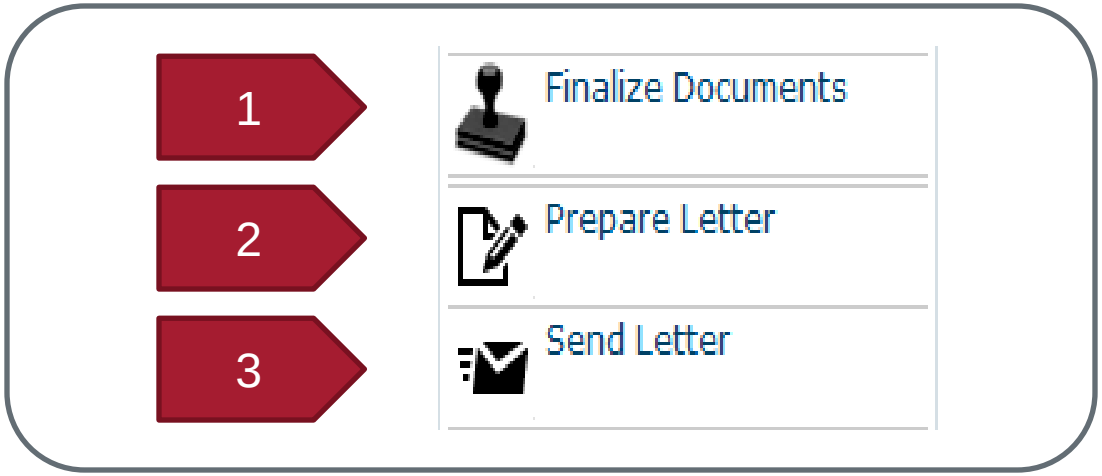
← Add a public comment, visible by anyone who can view this study

Non-Committee (Designated) and Committee Review forms function similarly but have different questions.

Project Review - Post Review

- Post Review means a determination has been made but the documents have not been watermarked or finalized and letter has not yet been prepared.
- This is where a “modifications required to secure approval” cycle may occur.

The following steps must occur to transition the submission to the next appropriate state (approved or modifications required).
Note: A letter must be sent.



User Questions Preview

- Why can’t I see a study workspace?
- Where do I find out the status of my project?
- Why don’t I see the ‘submit’ activity?
- Why don’t I see the ‘submit designated review’ activity?
- As the person completing pre-review, can I make edits to the SmartForm for the PI? When?
- Where to I attach any completed review checklists?
- If I am completing review as both IRB Staff and Committee Member, when do I request clarifications?
- How do I manage tracked changes documents?

The ESTR system: irb.harvard.edu

Tools and Tips: estrsupport.fss.harvard.edu

ESTR Help Desk: ESTRhelp@harvard.edu

QUESTIONS?

Migrated Study Information

Workflow States & Activities

APPENDIX

Working with a Migrated Study

- Study team members are responsible for updating all additional information, including uploading important study documents (protocol, consent forms, etc.) at the time of the first modification or continuing review.
- This process is completed by submitting a modification, and updating all of the appropriate SmartForm questions.
- Studies pre-populated from HIRBERT will contain limited information.

- HIRBERT Number
- Study Title
- PI with Department
- Additional Person to Notify
- Initial Approval Date
- Review Type
- Current Approval and Expiration date
- Funding (ONLY if GMAS number was provided)
- First Designated Institution
- FDA, if triggered

Steps to “populate a migrated study”

1. Go to irb.harvard.edu
2. Navigate to the migrated study workspace
3. Click the “Create Modification” button.
4. Select “Modification”
5. Select BOTH types of modification on the first page of the SmartForm.
6. Clarify the rationale for the modification.
   If the request includes ONLY updating information in ESTR, clearly indicate that you are ONLY “populating a migrated study”.
7. Select “continue” to page through the SmartForm and make edits.
8. Make all changes directly into the SmartForm (for example, if you are making changes to the approved protocol document, navigate to the “Study Scope” page and “Update” the protocol document with the newest version).
9. When all the changes are complete, select ‘finish’.
10. You will be directed to the submission workspace.
11. Contact the study PI to complete the ‘submit’ activity on the submission workspace.

Harvard IRB Submission

Workflow Summary