HARVARD
FINANCIAL ADMINISTRATION

Electronic Submission Tracking & Reporting - IRB

Investigator/Staff Lab Session Training

Topics for This Session

Definitions
- What is ESTR?
- Accessing the System
- General Site Layout and Navigation
- Personal Workspace Navigation
- Finding a Submission
- Submission Numbers and Types

Entering a project
- SmartForm Navigation
- Steps to Create & Submit a New Study
- Submission Workspace Layout
- Submission Workspace Navigation

BREAK

- Workflow Definitions
- Other Tips (with entering a project)

Study Management
- Access to a Study and Activities
- Other Actions in a Workspace
- At-a-Glance MOD or CR Steps
- Reportable New Information

Appendix

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.

Accessing the System

To access the system, you must:

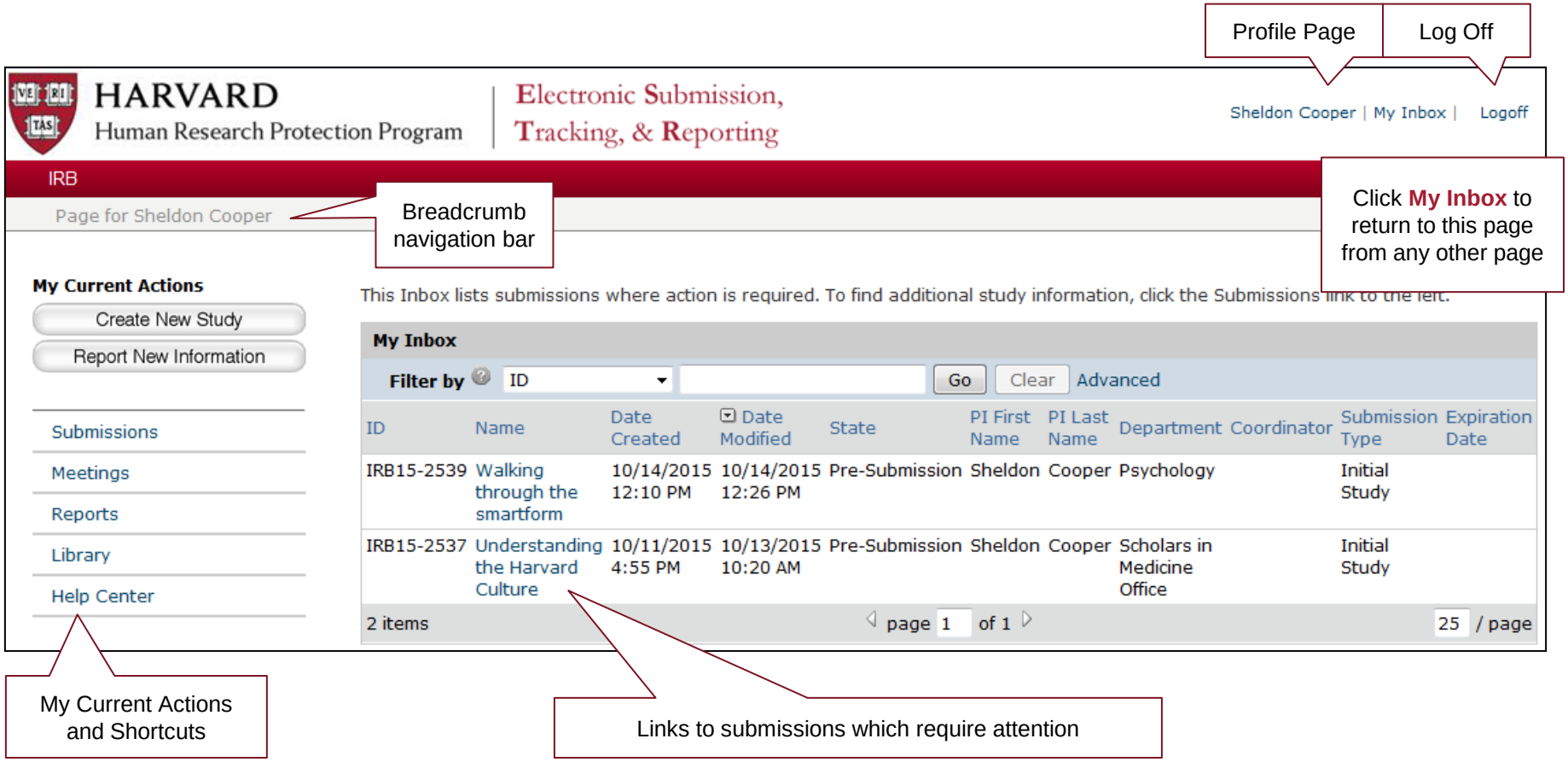
- Have an **internet connection** and have an **HUID**
- Based on your HUID, you will have certain privileges in the system.
- Suggested browsers: Internet Explorer 8 or later, Firefox 7 or later, Chrome 9 or later, Safari 4 or later, and Firefox 3 or later

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.

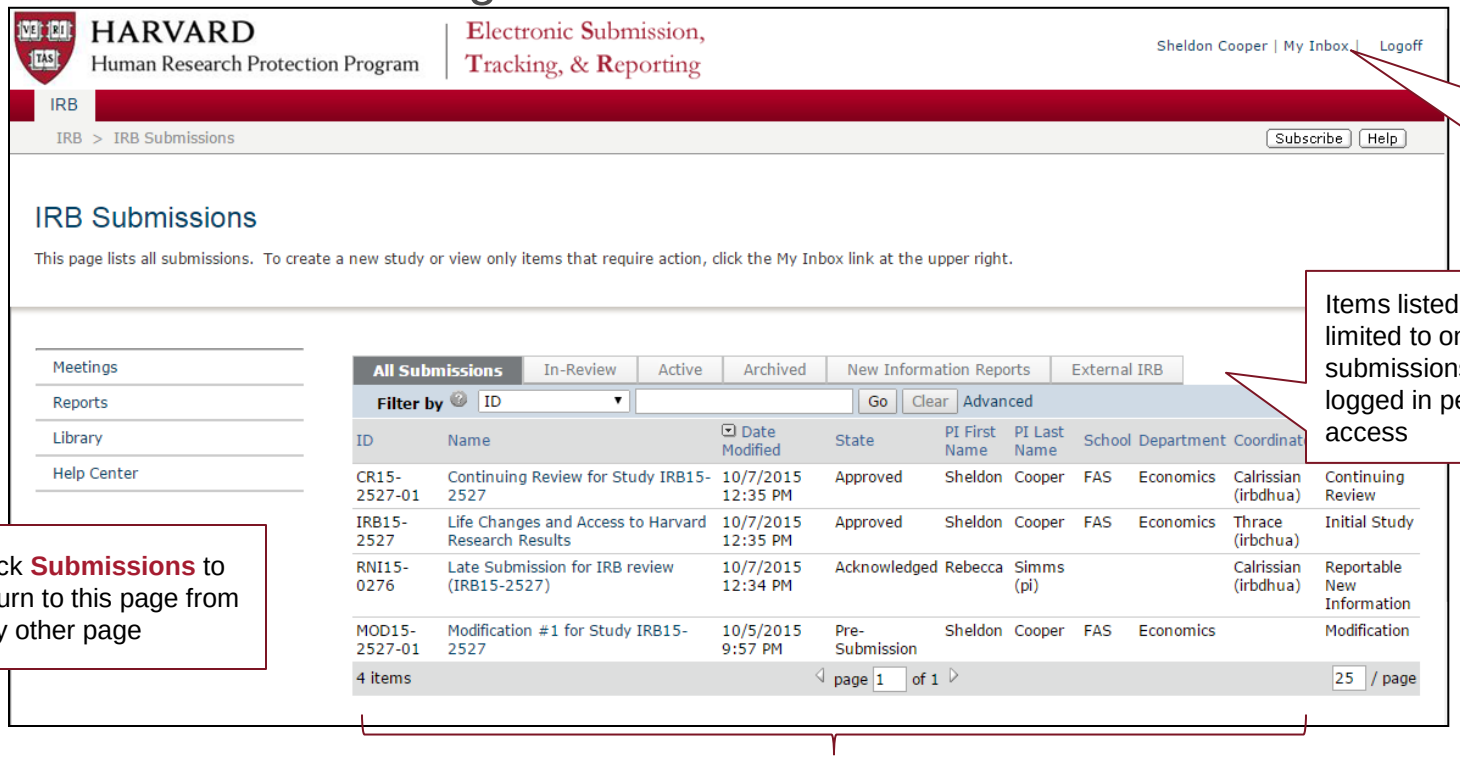
General Site Layout and Navigation

Regions of Personal Page Workspace (My Inbox)



General Site Layout and Navigation

IRB Submissions Page Details



Click **My Inbox** to return to the page that lists only items that require attention

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

Steps to Create and Submit a New Study

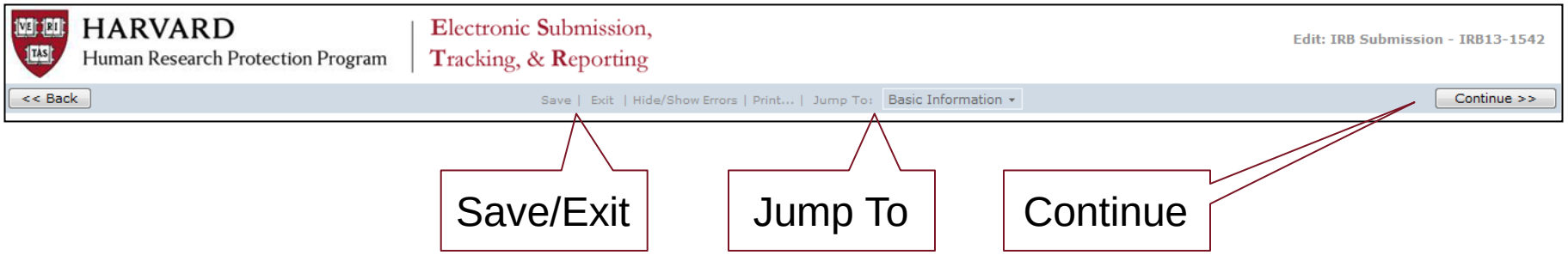
1. Log in to irb.harvard.edu [***Please don't use this link during training***]
2. You will be directed to your personal workspace
3. From your personal workspace, click on the "Create New Study" button.
4. Complete the SmartForm questions, and navigate the SmartForm as needed
   - Click "Continue" to go to save the page and 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 submission's workspace.
5. Reference the Study Submission Guide for details on what is required in each space.
6. Once the initial SmartForm is complete, to transition the submission to the next phase of review, the PI must complete the "**Submit**" activity (marked with the red arrow)

   - Only the PI can submit the initial submission
   - The PI can select a PI Proxy from members of the approved study team, after initial approval
7. Click the "My Inbox" link in the upper right corner to get back to your personal workspace.

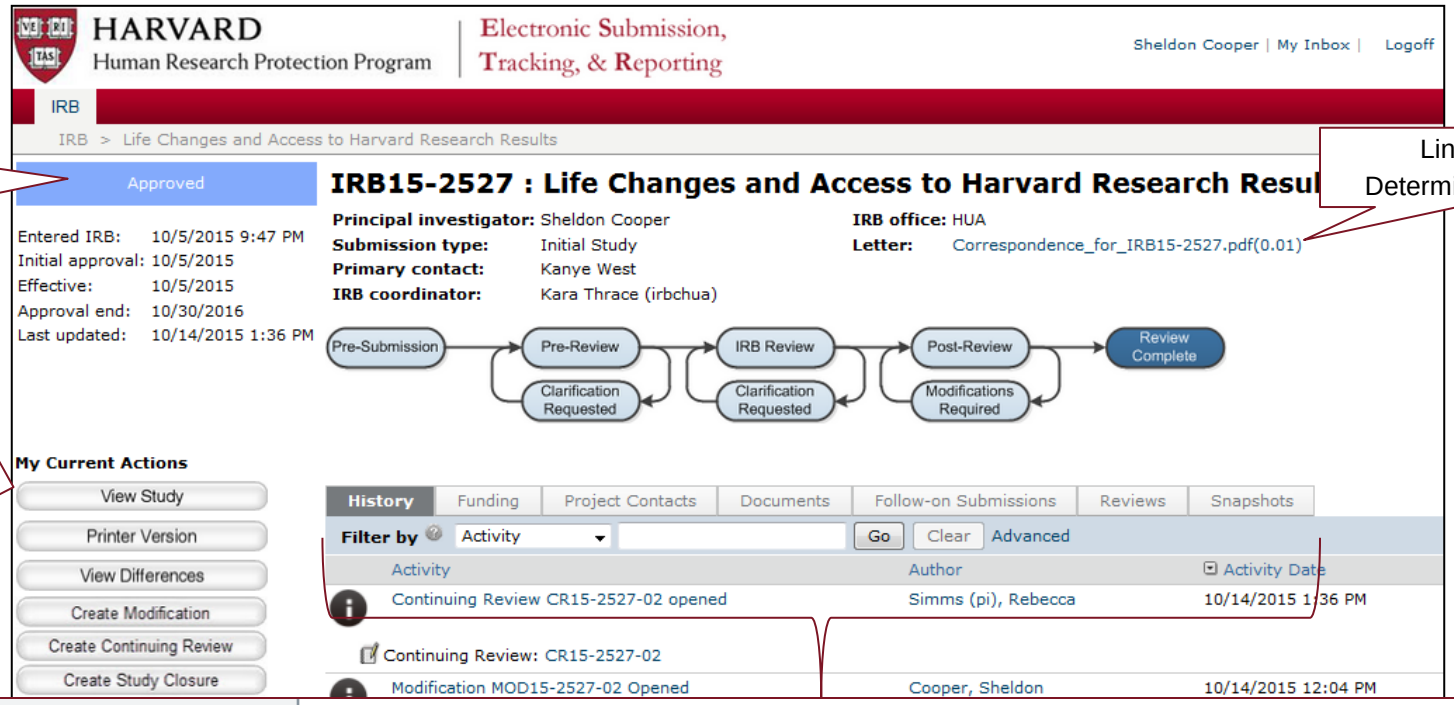
SmartForm Navigation

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



Submission Workspace Layout



Submission Status

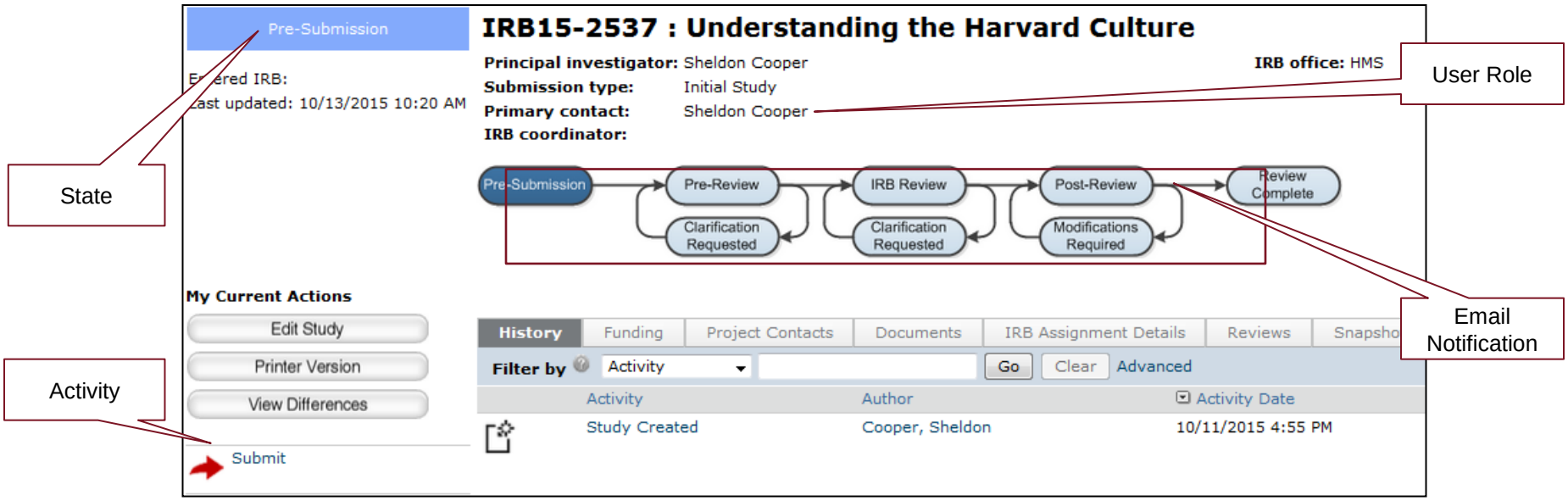
Link to IRB Determination Letter

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.
Funding	List of all funding listed on the SmartForm, with a link to GMAS if applicable.
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*) with quick access to all determination letters
Reviews	Study staff can view details of any completed ancillary reviews, while IRB staff and committee members can view additional details about the review.
Snapshots	View of the application at each change in state (for example, the appearance of the SmartForm between pre-review and changes submitted)

15 MINUTE BREAK

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.

Other Tips

- ✓ Documents that should be included for review and approval MUST be attached to the appropriate section of the SmartForm.

- ✓ When responding to clarifications requested during review:
  - ✓ You will need to make changes directly in the SmartForm
  - ✓ Don't forget to complete the "Submit Response" activity to proceed with the IRB review

- ✓ Upon IRB determination, the Initial Study Submission workspace becomes the main workspace for the study, and is the:
  - ✓ Primary location for all currently approved study information
  - ✓ The starting point for any follow-on submission

- ✓ If you want to make edits to a submission that is in review (where edits cannot be made):
  1. Complete the "Withdraw" activity on a submission
     The system sends a notice to the PI, Primary Contact and IRB Contact if there is one.
  2. Make and save the necessary edits
  3. The PI must complete the submit activity again to resume IRB review

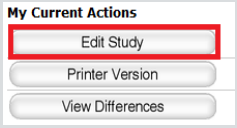
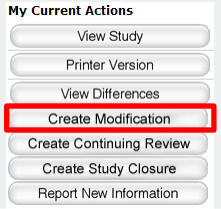
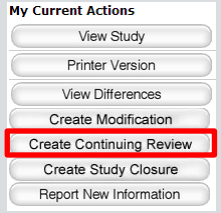
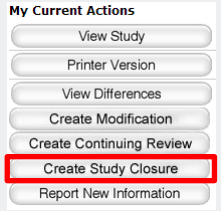
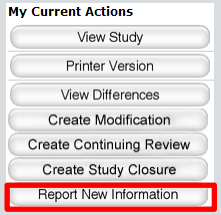
Access to a Study and Activities

Activity		On Submission Type	Can only be seen/ completed by persons with the following role(s) on the study:
Submit	SUBMIT	All Types	PI (PI Proxy* can only submit CR or MOD)
Submit Response	SUBMIT RESPONSE: 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
Create Continuing Review	CREATE A CONTINUING REVIEW	Continuing Review	PI, Primary Contact, Approved Study Team
Create Study Closure	CREATE A CLOSURE	Study Closure	PI, Primary Contact, Approved Study Team, and Faculty Sponsor (if there is one)
Submit	SUBMIT	Reportable New Information (associated with a study)	PI, Primary Contact, Approved Study Team
Submit	SUBMIT	Reportable New Information (NOT associated with a study)	Any person with an HUID

**Only the PI can assign a PI Proxy on an already approved study. A proxy must be an approved study team member.*

- Only members of a study team (PI, Primary Contact, and Study Team Members) 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

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.

At-a-Glance MOD or CR Steps

Once the modification or continuing review is approved; the approval date, SmartForm, and all study documents will update in the main study workspace. **Once a study is initially approved, the main study workspace always represents the currently approved materials for a study.**

1. Log in to irb.harvard.edu [***please do not use during training sessions***]
2. Click the “Submissions” link on the left side of the screen
3. Navigate to an approved study workspace
   - This is a submission numbered without letters or with the prefix “IRB”
   - The main study must not be in the middle of review
4. Click the “Create Modification” or the “Create Continuing Review” button.
5. In the SmartForm, select the type of submission you would like to create (either “Continuing review” OR “Modification”)
6. If you are creating a modification, select one or both scopes of modification:
   - Note that only one of each type of modification can be created at a time.
   - If you are creating a modification, once you fill out the general information about the modification, you will be walked through a copy of the Study SmartForm. Please make all changes directly into the SmartForm.
7. Select “continue” to save and page through the SmartForm. When done, select “finish” to go back to the submission workspace.
8. If you are not the PI or PI Proxy, complete the Add Comment activity to indicate email recipients and inform the PI/Proxy and Primary Contact that the submission is ready for the IRB review. **The PI/Proxy MUST complete the ‘submit’ activity to send the submission for IRB review.**

Tips

- ✓ If you selected the wrong purpose of the submission, select ‘back’ to exit.
- ✓ If you cannot exit or otherwise need to discard a modification or continuing review before it is approved, the discard will not affect the review status of the project.
- ✓ Make sure the Primary Contact is correct. It can be changed from the main study workspace.
- ✓ A continuing review may be completed when a study is ready to be closed.
- ✓ When responding to clarifications during review, you will need to make changes directly in the SmartForm and someone on the approved study team must “Submit Response” to proceed with the IRB review.

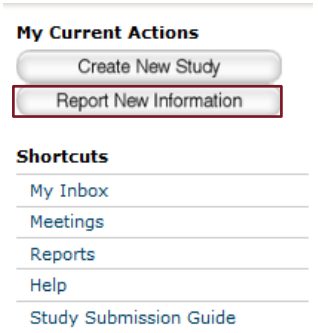
- ✓ **IMPORTANT!** In order to send the Continuing Review OR Modification for IRB review, the study PI or PI Proxy will need to click the “Submit” activity button.

Reportable New Information

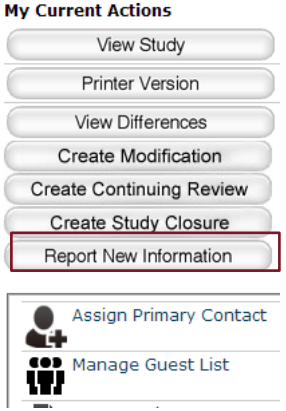
An RNI (Reportable New Information) submission can be created:

- From the **personal workspace** for RNIs NOT associated with a particular study
- From the approved **study workspace** for RNIs related to that specific study

Personal Workspace



Study Workspace



An RNI can be associated with one or many studies or modification submissions.

Note: If you want your report to remain confidential, start the RNI from your personal workspace and do not associate the submission with a study.

The ESTR system: irb.harvard.edu

Tools and Tips: estrsupport.fss.harvard.edu

ESTR Help Desk: ESTRhelp@harvard.edu

QUESTIONS?

SmartForm: Main Study Branching

Workflow States

System Notification Management

APPENDIX

SmartForm: Main Study Branching

Basic Information: Study Title & Description; PI Name, Department and COI; External IRB Application OR Protocol Upload

Attachment: If not External, IRB Protocol or Not Human Subjects Research Request Form

External IRB: Indicate details about the proposed IRB of record

Attachment: Agreement information or Catalyst form

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

External Sites: Details on external sites

Study Team Members: Harvard-Affiliated Study Team Members and their Roles (including Faculty Sponsor)

Attachments: Personnel Forms, HS Training, Positive Disclosures

Drugs: Details of any drugs, including IND Upload

Attachment: Drug brochures and details

Study Scope: Indicate if any of the branched pages are necessary for External Sites, Drugs, or Devices in research.

Devices: Details of any devices, including IDE Upload

Attachment: Device brochures and details

Consent, Assent, and HIPAA Authorization AND Recruitment Materials: Document Upload

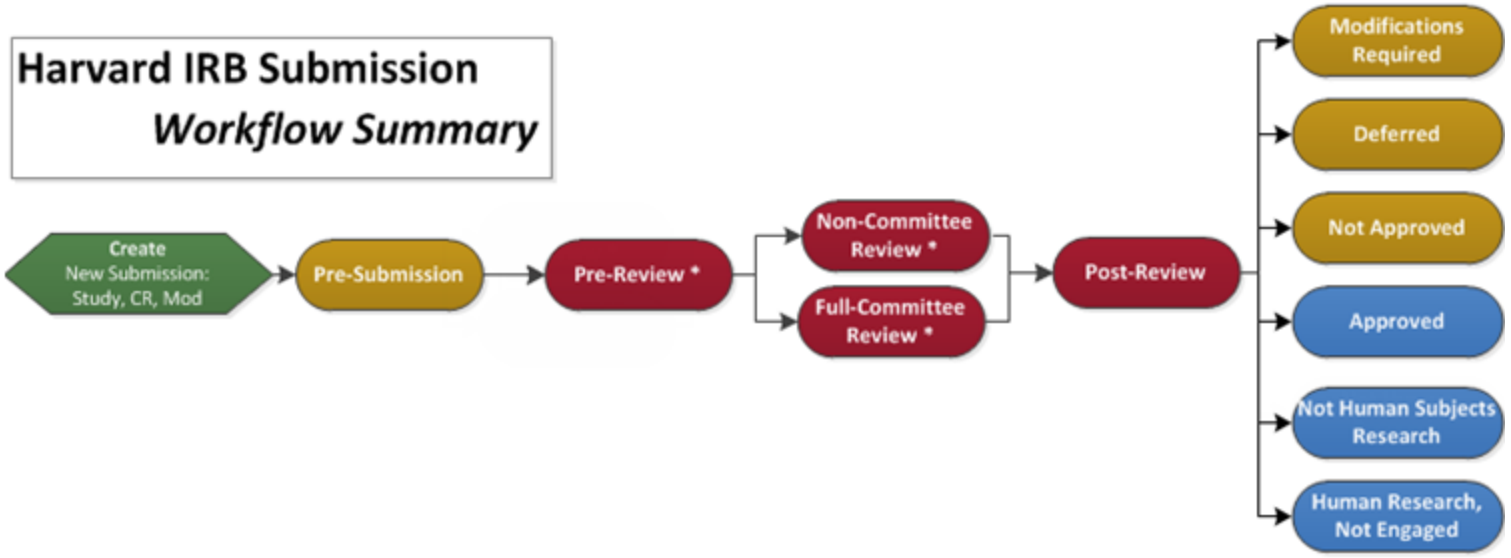
Attachments: Consent, Assent, Parental Permission, and HIPAA Authorization, and recruitment materials

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

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

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:

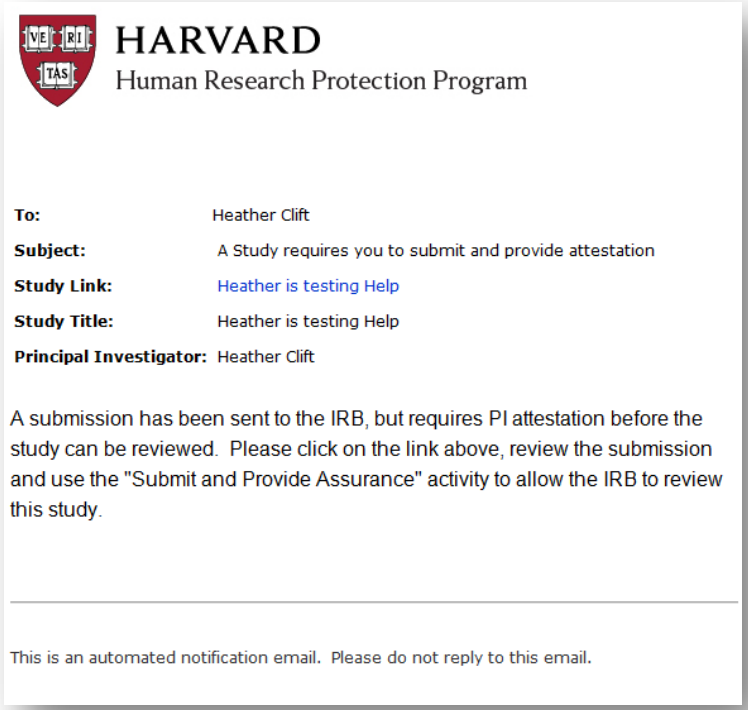
Clarifications Requested

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

System Notifications

Notifications are generated in the system when an action is required and when an item is submitted or withdrawn.

- PI, Primary Contact and PI Proxy (if there is one) are included on all system notifications (by default)
- A person must have access to the study to receive a notice.
- Notifications include a link to the submission workspace for easy access
- If recipients are selected on a comment:
  - A notice is sent with a link to the submission where the content of your message is displayed
  - Anyone with access to the submission can view the content of your message



HARVARD
Human Research Protection Program

To: Heather Clift

Subject: A Study requires you to submit and provide attestation

Study Link: Heather is testing Help

Study Title: Heather is testing Help

Principal Investigator: Heather Clift

A submission has been sent to the IRB, but requires PI attestation before the study can be reviewed. Please click on the link above, review the submission and use the "Submit and Provide Assurance" activity to allow the IRB to review this study.

This is an automated notification email. Please do not reply to this email.