HARVARD
FINANCIAL ADMINISTRATION

Electronic Submission Tracking & Reporting - IRB Committee Member Training

Overview of ESTR-IRB for Committee Reviewers

Topics

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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)

Profile Page

Log Off

Click **My Inbox** to return to this page from any other page

Breadcrumb navigation bar

My Current Actions and Shortcuts

Links to submissions which require attention

General Site Layout and Navigation

IRB Submissions Page Details

HARVARD
Human Research Protection Program

Electronic Submission, Tracking, & Reporting

Kara Thrace | My Inbox | Logoff

IRB

IRB > IRB Submissions

IRB Submissions

This page lists all submissions. To create a new study or view only items that require action, click the My Inbox link to the left or at the upper right.

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

My Inbox
Meetings
Reports
Library
Help Center

All Submissions	In-Review	Active	Archived	New Information Reports	External IRB

Filter by ⑦ ID ▾ [   ] Go Clear Advanced

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

ID	Name	⊡ Date Modified	State	PI First Name	PI Last Name	School	Department	Coordinator	Submission Type
MOD14-1865-01	Modification #1 for Study IRB14-1865	1/27/2015 2:21 PM	Post-Review	Rebecca	Simms (pi)	HMS	Global Health and Social Medicine	Stein (irbd)	Modification
IRB14-1836	AJ Regression testing release 1 16 0 #9	1/27/2015 2:13 PM	Post-Review	Rebecca	Simms (pi)	HMS	Biological Chemistry & Molecular Pharmacology		Initial Study
MOD14-1829-03	Modification #3 for	1/14/2015	Withdrawn	Rebecca	Simms	FAS	Harvard X	Stein (irbd)	Modification

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

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)

Activities for Committee Members

My Current Actions

Button	Description
View Study	← View the submitted SmartForm and Attachments
Printer Version	← View the flat "printer version"
View Differences	← View differences following any revisions between state changes

| Action	Description
Assign Designated Reviewer	← Assign a project to yourself (will appear in your in-box), or someone else
Edit Pre-Review	← Allows editing of the Pre-Review form completed by the IRB Contact
Request Clarification by Designated Reviewer	← Sends the submission *DIRECTLY* back to the investigator for clarifications.
Submit Designated Review	← Complete your review and enter a determination (Approve, Changes Required, etc)
Assign To Committee Review	← Send the study back to Pre-Review, indicating that Full-Committee review required
Add Private Comment	← Add a private comment, visible to only IRB staff and Committee members
Add Comment	← Add a public comment, visible by anyone who can view this study

Workflow Definitions
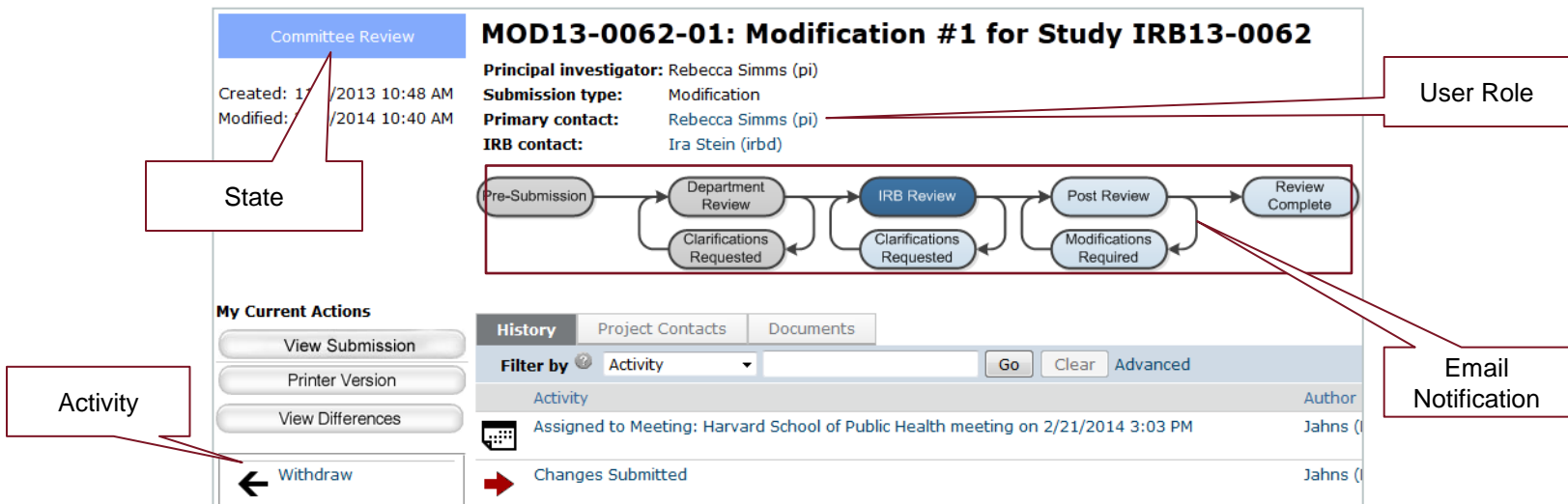
- A submission will transition through **States** during the review lifecycle.

- 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.

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

The ESTR system: irb.harvard.edu

Tools and Tips: estrsupport.fss.harvard.edu

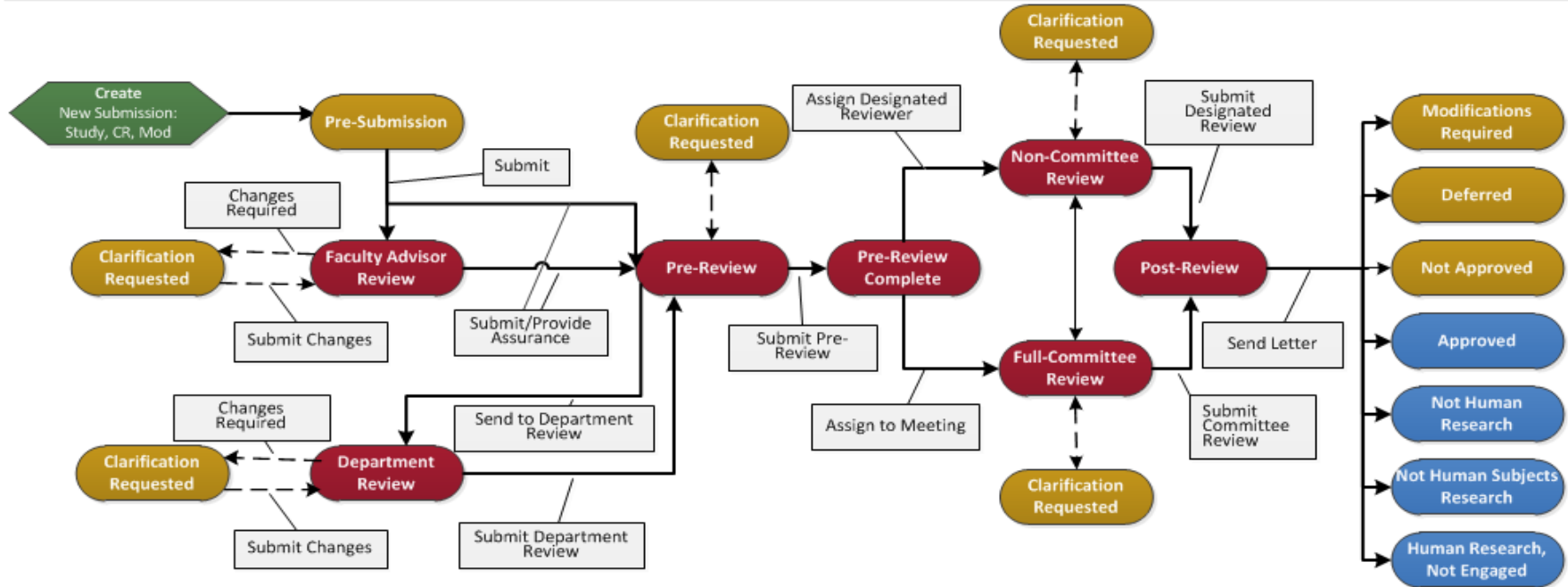**ESTR Help Desk:** ESTRhelp@harvard.edu

QUESTIONS?

Appendix: Activities on the Workflow

Harvard IRB Submission
Workflow Summary