

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)

The screenshot shows the Harvard IRB My Inbox page. At the top left is the Harvard logo and the text 'HARVARD Human Research Protection Program'. To the right is the text 'Electronic Submission, Tracking, & Reporting'. In the top right corner, there are links for 'Profile Page', 'Log Off', 'Kara Thrace | My Inbox', and 'Logoff'. Below the header is a red bar with 'IRB' and a breadcrumb navigation bar 'Page for Kara Thrace'. The main content area is titled 'Page for Kara Thrace' and contains a message: 'This Inbox lists submissions where action is required. To find additional study information, click the Submissions link to the left.' Below this is a 'My Current Actions' section with buttons for 'Create New Study' and 'Report New Information', and a sidebar with links for 'Submissions', 'Meetings', 'Reports', 'Library', and 'Help Center'. The main part of the page is a table titled 'My Inbox' with a filter by ID and a table of submissions. The table has columns for ID, Name, Date Created, Date Modified, State, PI First Name, PI Last Name, PI Department, Coordinator, Submission Type, and Expiration Date. The table contains three rows of submission data. At the bottom of the table, it says '8 items' and 'page 2 of 3' with a '3 / page' indicator.

Profile Page | **Log Off**

Kara Thrace | My Inbox | Logoff

IRB

Page for Kara Thrace

Page for Kara Thrace

This Inbox lists submissions where action is required. To find additional study information, click the Submissions link to the left.

My Current Actions

Create New Study

Report New Information

Submissions

Meetings

Reports

Library

Help Center

My Current Actions and Shortcuts

My Inbox

Filter by ID [Go] [Clear] Advanced

ID	Name	Date Created	<input checked="" type="checkbox"/> Date Modified	State	PI First Name	PI Last Name	PI Department	Coordinator	Submission Type	Expiration Date
MOD14-1804-01	Modification # 1 for Study IRB14-1804	9/18/2014 4:16 PM	12/18/2014 9:06 PM	Pre-Submission	Morgan	Packer	Immunology and Infectious Diseases		Modification	9/17/2015
MOD14-1741-04	Modification # 4 for Study IRB14-1741	6/13/2014 3:58 PM	9/12/2014 12:01 AM	Pre-Submission	Kara	Thrace	Scholars in Medicine Office	Stein (irbd)	Modification	6/12/2015
CR14-1741-02	Continuing Review for Study IRB14-1741	6/13/2014 1:58 PM	9/12/2014 12:01 AM	Pre-Submission	Kara	Thrace	Scholars in Medicine Office	Stein (irbd)	Continuing Review	6/12/2015

8 items

page 2 of 3

3 / page

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

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.

My Inbox

Meetings

Reports

Library

Help Center

All Submissions	In-Review	Active	Archived	New Information Reports	External IRB					
Filter by ? ID Go Clear Advanced										
ID	Name	<input checked="" type="checkbox"/> 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	

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

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

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



HARVARD
Human Research Protection Program

Electronic Submission,
Tracking, & Reporting

Kara Thrace | My Inbox | Logoff

IRB

IRB > Coffee, Tea, and Ice Cream

Submission Status


Approved

IRB14-1845 : Coffee, Tea, and Ice Cream

Created: 11/4/2014 11:39 AM
 Modified: 11/4/2014 12:31 PM
 Initial Approval: 11/4/2014
 Expiration: 11/3/2015

Principal investigator: Kara Thrace
Submission type: Initial Study
Primary contact: Rebecca Simms (pi)
IRB contact:

Letter: Correspondence_for_IRB14-1845.pdf(0.01)



Link to IRB Determination Letter

My Current Actions & Shortcuts

always on the left side of the screen

- View Study
- Printer Version
- View Differences
- Create Modification
- Create Continuing Review
- Create Study Closure
- Report New Information

My Current Actions

History | Project Contacts | Documents | Follow-on Submissions | Snapshots

Filter by

Activity	Author	Activity Date
Modification MOD14-1845-01 opened	Simms (pi), Rebecca	11/4/2014 12:43 PM
Modification: MOD14-1845-01		
Comment Added	Thrace, Kara	11/4/2014 12:31 PM
here's a comment!		

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 <i>initial study workspace</i>)
	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

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



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

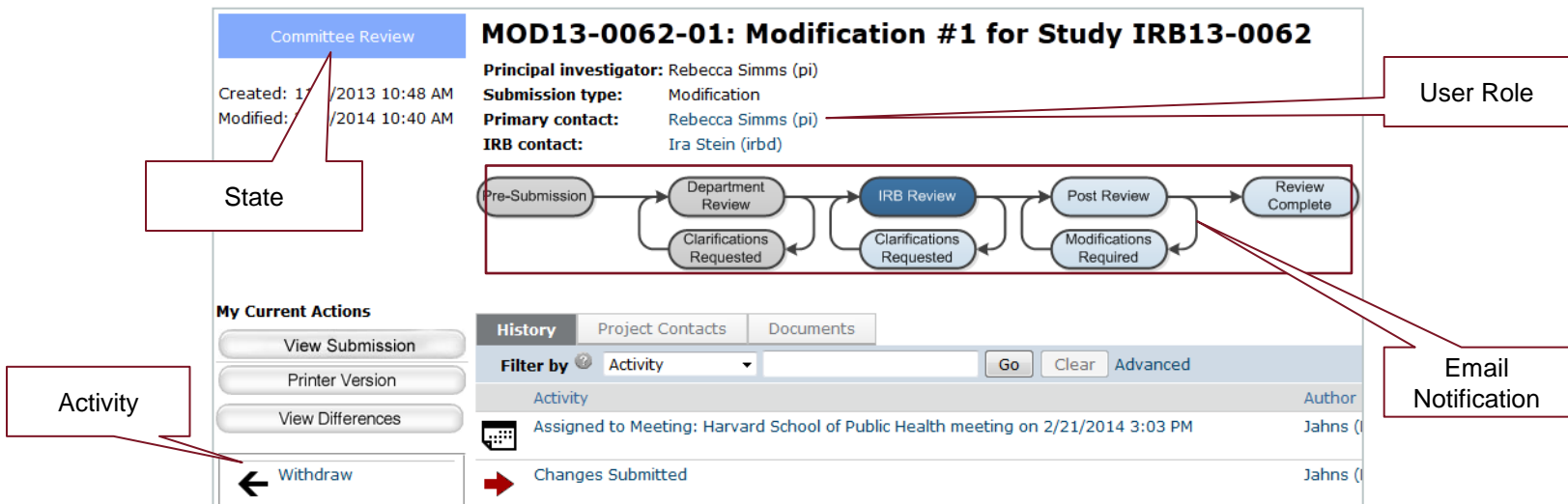
← Add a private comment, visible to only IRB staff and Committee members



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



Save/Exit

Jump To

Continue

The ESTR system: irb.harvard.edu

Tools and Tips: estrsupport.fss.harvard.edu

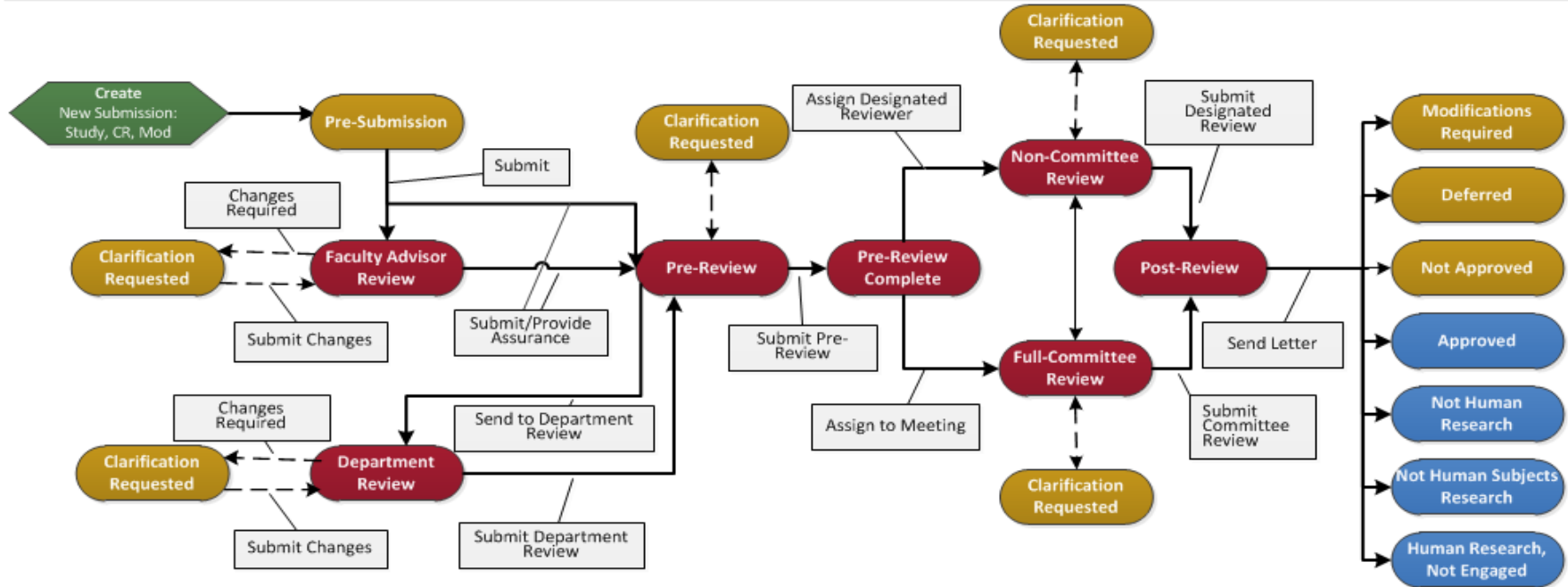
ESTR Help Desk: ESTRhelp@harvard.edu

QUESTIONS?

Appendix: Activities on the Workflow

Harvard IRB Submission

Workflow Summary



Workflow Legend:



→
Workflow Path