




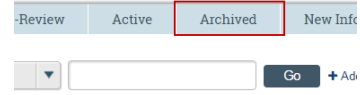

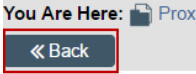





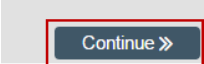



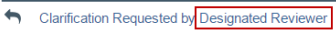
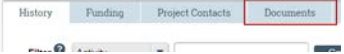
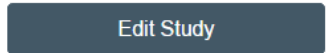
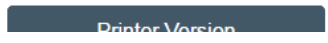

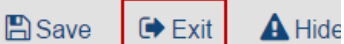
ESTR Glossary

Summary of terms associated with features of the Electronic Submission Tracking and Reporting (ESTR) system. For terms and definitions associated with regulatory review, please consult your IRB website: [University Area IRB](#) or [Longwood Medical Area IRB](#)


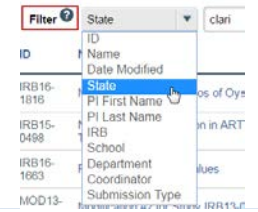

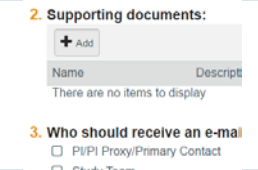
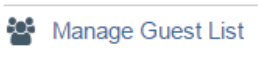
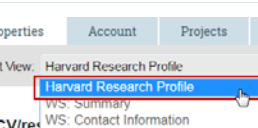
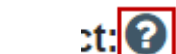
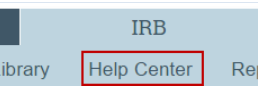

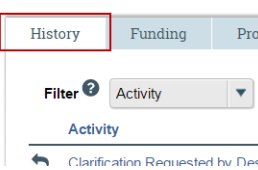
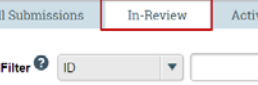

Jump to Letter: [A](#) [B](#) [C](#) [D](#) [E](#) [F](#) [G](#) [H](#) [I](#) [J](#) [K](#) [L](#) [M](#) [N](#) [O](#) [P](#) [Q](#) [R](#) [S](#) [T](#) [U](#) [V](#) [W](#) [X](#) [Y](#) [Z](#)

Term	Description	In the system
A Active	This tab on the IRB Submissions page displays links to all studies in one of the following states: Approved; Not Human Subjects Research; or Human Research, Not Engaged.	
Active (state)	The final site status while the study is underway. This is similar to a single site study's "Approved" status.	
Activity	A link that when clicked will cause an action to occur on a submission. Actions can include: record a decision, change a state, grant someone access to the study, or send a notification. Activities are visible for completion based on the state of the submission and the logged in person's permissions in the system.	
Ancillary Review	Review by a person, group, committee or office other than the IRB. Ancillary review may occur during the IRB review process. However, documentation of a completed ancillary review may be necessary as part of a complete submission for IRB review or it may be required for before the IRB may issue a determination.	
Add Participating Sites	Activity in post submission that allows for adding/removing sites and notify those at other institutions about initiating site review activity.	
Archived	This tab on the IRB Submissions page displays links to all submissions in one of the following states: Discarded, Closed, or Terminated.	
Assign PI Proxy	The Principal Investigator on an approved study can complete this activity to assign members of the approved study team as a system proxy. A Proxy can submit follow-on submissions on behalf of the PI and is a default recipient of study notifications.	
B Back	Allows for navigation within a SmartForm. Use of this button returns the user to the previous screen without saving changes on the current screen.	
Breadcrumb	Links at the upper left of a submission workspace, by clicking the double arrow [>>] that allow navigation between workspaces associated with a specific study. Also displays the study title when within a follow on submission workspace.	



C	Clarifications Requested	This state in the process indicates that review has stopped and the submission is able to be edited. Often it indicates that the reviewer has requested that the study team revise an element of the submission. A submission will remain in this state until the Submit Changes activity is completed.	
	Comment	Add a comment on a submission workspace to record text or reference attachment on the submission history. Select comment recipients to also send a notice to specific individuals associated with the submission.	
	Continue	Allows for navigation within a SmartForm. Use of this button checks the page to ensure required items (marked with a red asterisk) have been completed, saves the page, and advances the user to the next page of the SmartForm.	
	Collaborative Research	Option on the Basic Information page of the SmartForm, selection indicates that each site will conduct at least a portion of the study.	8. * What kind of study is this? <input checked="" type="radio"/> Collaborative study (each site will c <input type="radio"/> Single-site study
	Contact	Contact is a person that can be defined by any individual with access to ESTR by name and email only. Contacts can only receive emails and cannot log in to ESTR.	<i>Available only to Reliance Coordinators</i>
	Correspond with Site	A public activity in the site workspace which allows for sending a notice/documents to a person who is with another site. Recipients may be IRB staff/reviewers or study teams.	
D	Date Modified	A system date related to activities completed on the submission. This date is not related to the regulatory review of a submission.	 2/7/2017 12:00 AM
	Discard	Removes the submission from further review. If a follow on submission is discarded it does not affect the status of the study.	
	Designated Review	Review activities, states and determinations for submissions which are not reviewed by the full committee. See also: Non-Committee Review	 Hi Sara,
	Documents	A tab in a submission workspace which displays a linked list of all the documents attached within the SmartForm.	
E	Editable State	State in the workflow where review has stopped and the submission may be edited. These states include: Pre-Submission; Clarifications Requested; Modifications Required to Secure Approval; Deferred; and Disapproved. After edits are completed, the submission must be submitted (or response submitted) to move to the next state of review.	Next Steps  
	End State	The last state of review for a submission. These states include: Approved, Not Human Subjects Research, Human Research, Not Engaged, External IRB, Closed, Discarded, Lapsed, or Terminated	
	Exit	Allows for navigation within a SmartForm. Click the text to exit the SmartForm screen and return to the submission workspace.	


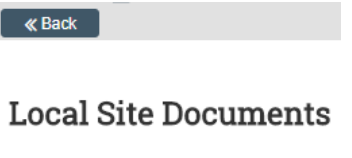
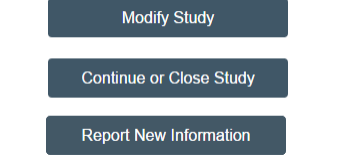
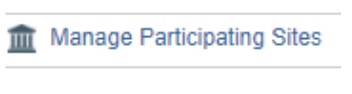
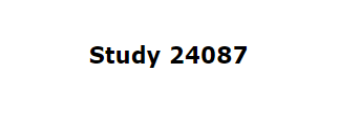
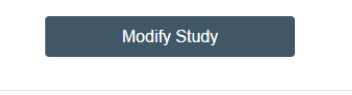

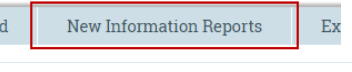
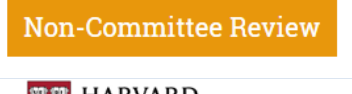




	External IRB	Indicates a study or list of studies where a Harvard IRB is formally relying on the review of another IRB. See also: Ceded Review	
F	Filter	Optional dropdown menu available when a list of items is displayed. Selecting an item from this dropdown menu allows the user to search on content of the selected column in the table.	
	Follow On Submission	All submissions associated with a study after the initial determination is made. This includes: Modification/Update, Continuing Review, and Reportable of New Information	
	Form	Space in the system which allows for different types of data entry.	
G	Guest	An individual with an HUID, who has view only access to study information. This person is identified by the study team via completion of an activity.	
H	Harvard Research Profile	System location where Human Subjects Training certification is stored for each person. Non-IRB staff may view their own research profile and IRB staff may view all and update all user research profiles.	
	Help	There are two forms of help within ESTR: 1. pop-up boxes of additional context-relevant details which can be accessed by clicking on the blue circled question mark and 2. Link to all current reference materials, including the help desk email address which can be accessed by clicking on the “help” link on the lower left of submission and personal workspaces.	
	Help Center	Location where guides and links to the IRB and ESTR support websites are available for reference.	
	Hide/Show Errors	Allows for navigation within a SmartForm. Click this link to display form-required items (marked with a red asterisk) that have not yet been completed. Click once to show this list and once more to hide it again.	
	History	This tab in a submission workspace displays all activities which have occurred on the submission. Messages to and from the Study Team will appear in this space. Visibility into some activities is restricted by role on the study and role in ESTR.	
I	In Review	This tab on the IRB Submissions page displays links to all submissions which have been submitted but where review is not yet completed.	
	Inactive (state)	When a site is created via the Manage Participating Sites activity, and at some stage in the review, the site is no longer active. This is similar to a single site study’s “closed” status.	



	InBox	This personal page/Dashboard displays links to all submissions which require action to move to the next state of review. The specific action, and person required to complete the action depends on 1. The state of the submission and 2. The role of the person accessing the submission. See also: Personal Page	
	Initial Study	Represents both the initial study submission and the location of the currently approved version of the study. See also: Main Study	<p>IRB16-1663</p> <p>Looking to the future</p> <p>Principal investigator: Sarah Connor Submission type: Initial Study Primary contact: Kyle Reese</p>
	Institutional Profile (IP)	<p>A set of information about a potential site that includes Name, FWA, contacts and any executed IAAs associated with the site. May also include generalized local context information for reference, as appropriate.</p> <p>Defined and managed by IRB Reliance Coordinator and/or Site Manager.</p>	
	Invitation Pending (state)	When a site is created via the Manage Participating Sites activity, it starts in this state. This is similar to a single site study's "Pre submission" status.	
	IRB Contact	The person in the IRB office who works with the submission through the review process. See also: IRB Coordinator	IRB contact: Kanye West
	IRB Coordinator	The person in the IRB office who works with the submission through the review process. See also: IRB Contact	
	IRB Exchange	A centralized resource for many institutions to share information about studies. Harvard has not enabled this function so the activity will not be visible, but may be 'referenced' in some spaces.	<i>Referenced in documentation only.</i>
	IRB Library	Location where IRB reference materials including guides, checklists, worksheets, templates, ancillary information and HRPP forms are available for reference.	
	IRB of Record	See "Single IRB (sIRB)"	<i>Referenced in documentation only.</i>
	IRB Reliance Coordinator	<p>Person(s) defined by the IRB office who have the ability to:</p> <ul style="list-style-type: none"> • Receive notices sent through the exchange (based on activities completed by other institutions). • Update Institutional Profiles. • Update External IRB and site submissions on behalf of study teams. • Get submissions from the exchange (general) 	<i>System role for a person in the IRB office.</i>
J	Jump To	Allows for navigation within a SmartForm. Click the dropdown beside the prompt to display the pages of the SmartForm. Select an item from the menu to navigate directly to the page. Navigating via this method does not automatically save the current page before advancing to the next page.	
K			



L	Lead Site	The single IRB (sIRB), and the institution of the lead PI.	<i>Referenced in documentation only.</i>
	Letter	The determination letter from the IRB. Letters are linked at the upper left of a workspace and on the Follow on Submissions tab of the main study workspace.	
	Local Site-Specific Documents	Documents to be used at “this institution”. When a study is designated on the SmartForm as Multi-Site or Collaborative, a study team will have the opportunity to define what will be used at Harvard, specifically.	
M	Main Study	The location of 1. all current information about a study, after an initial study submission type reaches an end state and 2. activities to create follow on submissions for the study. See also: Initial Study	
	Manage Participating Sites	Activity in pre-submission that allows for adding/removing sites and notify those at other institutions about initiating site review activity.	
	Migrated Study	A study which was considered active when Harvard transitioned from the old electronic IRB system to ESTR. These active studies were transitioned to the new system with limited detail and retain their legacy study number.	
	Modification	A submission type created to request IRB review of changes to a study after initial IRB determination. Modifications are numbered MOD##-####-##.	
	Multi-Site Study (MSS)	More than one site will conduct the entire study	<i>Referenced in documentation only.</i>
N	Name	The text label for a submission. For example; this may be the title of the study or the label “Modification #1 for study ...”	
	New Information Reports	This tab on the IRB Submissions page displays links to all Reportable New Information (RNI).	
	Non-Committee Review	Review activities, states and determinations for submissions which are not reviewed by the full committee. See also: Designated Review	
	Notice	Email sent from the system because of activity completion or as a reminder of IRB requirements.	
O			
P	Participating Site (pSite)	The site identified as an institution relying on the review of the Single IRB. Referenced in documentation, activates, and site submission type names.	


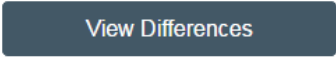






	Personal Page	Webpage which displays immediately after successful log in and provides search and access to submission workspaces where action is required. After navigation to a submission, users can return to this page by clicking the “In Box” link at the upper right of the screen. See also: In Box	
	Post Review	Means a determination has been made but the documents have not been watermarked or finalized and letter has not yet been prepared.	
	Pre-Submission	Means a submission has been created, is not yet complete, and has not yet been submitted to the next state of review.	
	Primary Contact	A person identified by the PI or study team who will assist with the IRB submission and review process. This defaults to the person who completed the initial submission and can be changed at any time. This individual: will receive all notifications by default, can create and edit submissions when the system allows, and is not considered a member of the IRB-reviewed study team. If this person is also working with participants or identifiable data, s/he must also be listed on the SmartForm.	
	Printer Version	A single HTML page which displays all the information in the completed SmartForm, including links to the attached documents.	
	Project Contacts	Individuals indicated as members of the study team on the SmartForm.	
Q			
R	Report New Information	A submission type created to indicate New Information items (as defined in IRB policies) for review by the IRB after initial IRB determination. Also referred to as “RNI”.	
	Reports	Pre-Sorted and filtered lists of studies which can be exported to Excel. These lists only display submissions to which the logged in user already has access. The Standard Reports tab displays reports created by Click, and the Custom Reports tab displays a list of reports created based on Harvard-user feedback.	
	Research location	A place under the umbrella of the reviewing institution where research activities will occur. If an institution is considered a “Site”, it is not expected that it would be listed in this space of the SmartForm.	
S	Short Title	The study name, abbreviated to 80 characters. This can be entered on the study SmartForm by the study team or is assigned by the system based on the full title first entered on the SmartForm. This is the name displayed for the study throughout the system.	



	Single IRB (sIRB)	The IRB chosen to conduct review of a study and activities at all Participating Sites.	<i>Referenced in documentation only.</i>
	Single-site Study	Project being conducted at one location	<p>8. * What kind of study is this?</p> <ul style="list-style-type: none"> <input checked="" type="radio"/> Collaborative study (each site will c <input type="radio"/> Single-site study
	Site	<p>Location of research that will conduct IRB review or rely on a single IRB review. It is anticipated that this institution is engaged in the research.</p> <p>In the system: A Site submission represents the site-associated review history and site-specific submission details (including documents).</p>	<p>SITE17-0016: Brigham Demo of Release Revi</p> <p>Principal investigator: Rebecca Simms (pi) Submission type: IRB Site Primary contact: Institution: Brigham and Women's Fau</p>
	SmartForm	A series of web pages which contain form fields that are organized to display step-by-step context-relevant information, and only show required questions based on user responses.	<p>You Are Here: From Young Adulth... <input type="button" value="Back"/></p> <p>Basic Information</p> <p>Visit the <i>ESTR Support Site</i> for guidance on using this :</p>
	Snapshots	A saved printer version of the SmartForm and all attachments, taken at specific points in time. Allows for historical reference of study changes.	<p>Documents Reviews Snapshots</p>
	State	Point in time during the review process. An action or activity may be required to move the submission to the next state. A state may indicate if a submission can be edited or if it is only able to be viewed. See also: Status	<p style="background-color: #f4a460; color: white; padding: 5px; text-align: center;">Pre-Submission</p>
	Status	Point in time during the review process. An action or activity may be required to move the submission to the phase of review. Status may also be a reference to approved versus not or not-yet approved. See also: State	<p style="background-color: #f4a460; color: white; padding: 5px; text-align: center;">Lapsed</p>
	Study Related Documents	Documents to be used at the "other site(s)"	<p><input type="button" value="Back"/></p> <p>Study-Related Documents</p>
	Study Update	<p>Deprecated with upgrade 1.23.0 in December 2017: Submission to report an update in the review type, content, or status for an already determined External IRB project. Study Updates are numbered SU##-####-##.</p>	<p style="background-color: #4a697d; color: white; padding: 5px; text-align: center;">Update Study</p>
	Submission	Item prepared for IRB review. Types of submission include: Initial, Modification, Continuing Review, and Report of New Information	<p>Next Steps</p> <p style="background-color: #4a697d; color: white; padding: 5px; text-align: center;">Edit Submission</p>
	Submit	Activity within the system which indicates that the submission is ready for the next stage of review. If submit activity is visible to the logged in user it means that the submission is awaiting his/her action.	<p style="text-align: center;"> Submit</p>
T	Tab	Sections of a workspace where information is sorted or organized based on the indicated category.	<p>History Project Contacts Docum</p>



U	Unassigned	This tab on the IRB Submissions page displays links to all submissions which have not yet been assigned to an IRB Coordinator to begin the review process. This tab is only visible to IRB Staff.	
V	View Differences	A series of webpages designed to compare versions of the SmartForm when changes are made. Versions which are compared are based on Snapshots. This will indicate when document versions change, but will not display changes made within document attachments.	
W	Wildcard	% [percent symbol]. Used in search spaces to find known elements at the beginning, middle, or end of a field. For example; a percent symbol at the beginning of some known elements indicates that the user would like search results to display all items where known elements are at the middle or end.	
	Withdraw	Returns a submission to the study team for further edits. The submit activity may be completed on the submission to reinitiate IRB review.	
	Workflow	Structured states of review which are controlled by IRB processes and activities completed within the system.	
	Workspace	A webpage associated with a specific set of information or actions. Types include: Personal Page, Main Study and Submission	
X			
Y			
Z			