

ESTR 1.23.0 Upgrade & Configuration Release Items: December 15 2017

Along with the below-detailed vendor upgrade and Harvard updates, this release includes support for two major regulatory changes:

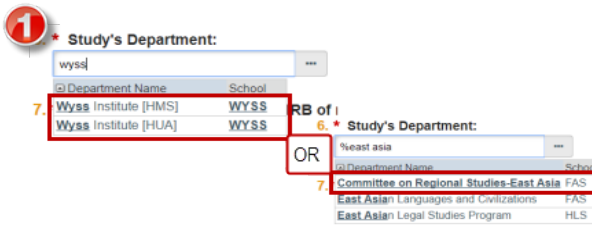
- Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

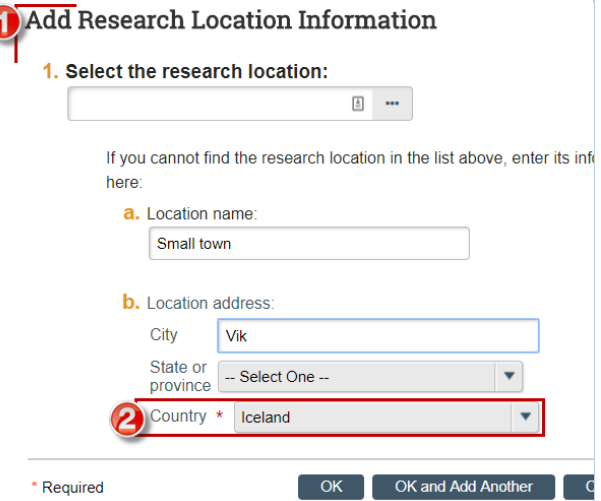
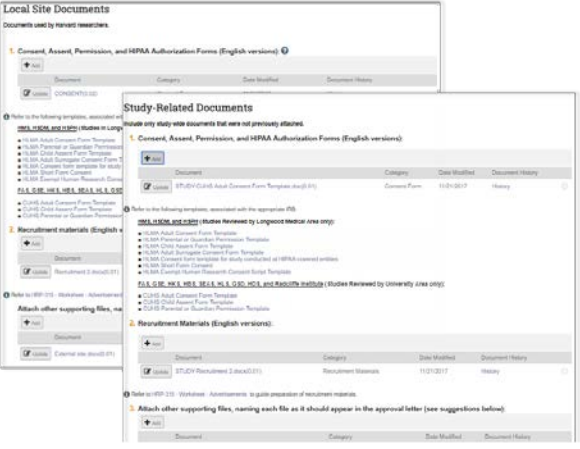
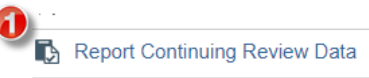
In the system, changes introduce the following **four key concepts**:

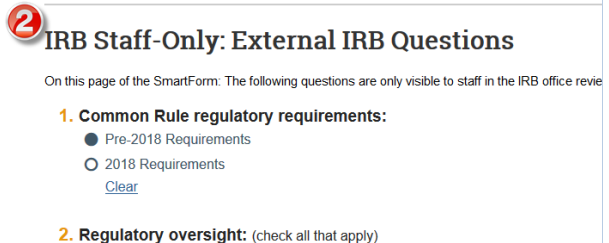
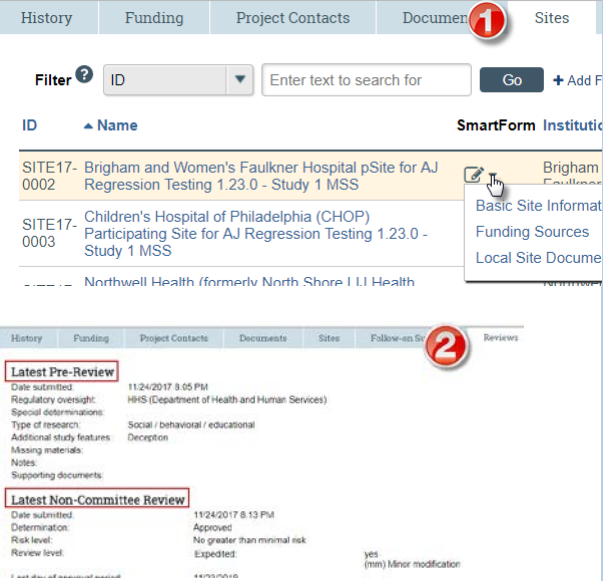
1. **Type of Research.** Categorized as:
 - *Collaborative Study*- some or all research activities (including multi-site research) are being conducted at an institution or organization in addition to Harvard, or
 - *Single Site Study*- research is being conducted at Harvard or by Harvard researchers elsewhere.
2. **Research Location.** A place where research occurs and could include, for example a building, school, or community region.
3. **Site.** An (engaged) institution or organization where research is taking place and where Harvard will either rely on the review of that institution or organization OR Harvard will review for that institution or organization.
4. **Single IRB of Record.** One IRB is conducting the IRB review for at least one another institution or organization.


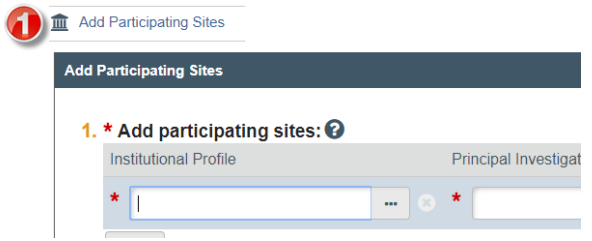
- Final Revisions to the Common Rule

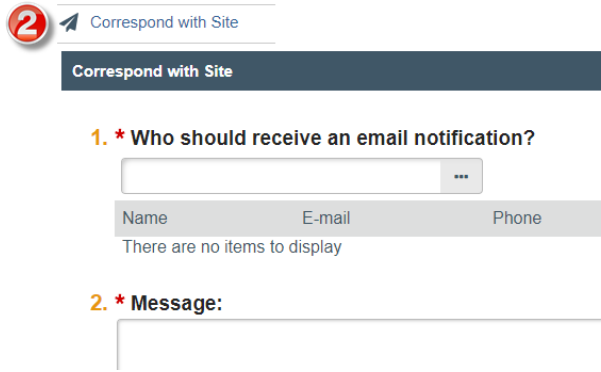

On January 19 2018, the IRB will enable control over when the new Common Rule is applied in the review of research.


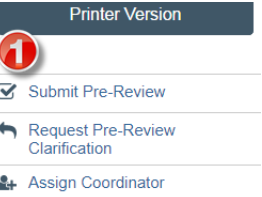
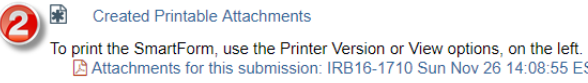
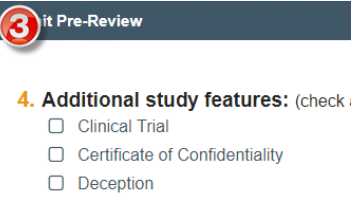
What has changed...	What it means...	How it looks (as applicable)...
SmartForm Pages		
Basic Information		
<p><i>Responsible Department Changes</i></p> <ol style="list-style-type: none"> 1. New departments: <ul style="list-style-type: none"> • Regional Studies-East Asia • Wyss Institute has been split into: <ul style="list-style-type: none"> ▪ Wyss Institute [HMS] ▪ Wyss Institute [HUA] 2. Revise Responsible Departments in any editable-state until initial approval. 	<ol style="list-style-type: none"> 1. Submissions for review under HUA can also now be associated with Regional Studies-East Asia or Wyss Institute [HUA]. Existing Wyss and new HMS-Wyss projects can be associated with Wyss Institute [HMS]. 2. If an incorrect department is selected, the submission no longer needs to be withdrawn for the selection to be fixed. Instead, correction can be managed via “Clarifications Requested”. 	


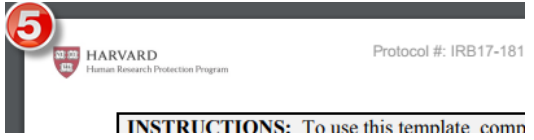

What has changed...	What it means...	How it looks (as applicable)...
<p>Research Locations <i>(formerly External Sites)</i></p> <ol style="list-style-type: none"> The External Sites Page is now referred to as the “Research Locations” page, with the expectation that formal “Sites” will be managed via Site submissions (separately). This allows for the listing of “places where the research will take place” on the SmartForm, rather than a combination of types of places and “sites” Add Morocco to the list of countries 	<ol style="list-style-type: none"> For existing projects, existing site and location information will appear on this page. For new projects, only locations are expected to appear listed here, with “Sites” to be added and managed via separate activity. Note: If an item is in review and a country has not been selected for a location, this will need to be added before the submission or a response to clarifications can be submitted. Morocco is available on the vendor-delivered list of countries. However, the following selections for country are no longer available: Serbia, Zimbabwe, and “country not listed”. 	
<p>Supporting Documents <i>(no longer a separate page)</i></p> <p>Supporting documents are now accessible from a single “attachments” page which is based on study type. This one page has prompts for:</p> <ul style="list-style-type: none"> Consent, Assent, Permission and HIPAA Authorization forms Recruitment materials All other attachments (to be categorized by the person adding/updating attachments) 	<p>Non-Protocol or Non-Study Team related attachments are split into two page types, to be further categorized per page:</p> <ul style="list-style-type: none"> Local Site Documents page is visible: for all studies that Harvard reviews. Study-Related Documents page also appears: for a project that requires Harvard review of an additional site (if it is a collaborative type project where Harvard will review for at least one site). 	
<p>External IRB</p> <ol style="list-style-type: none"> The previous option to close an External IRB project during study update has been removed. Additionally, the “Study 	<ol style="list-style-type: none"> To close an External IRB project, one must complete the “report continuing review data” activity and request closure. 	

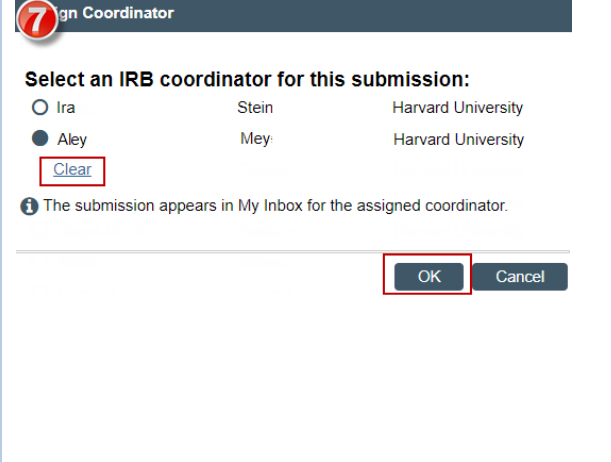
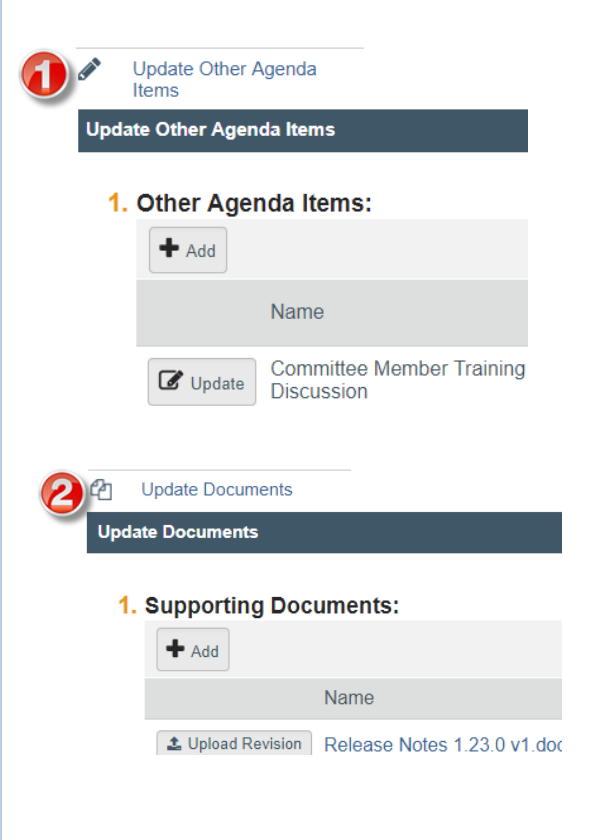
What has changed...	What it means...	How it looks (as applicable)...
<p>Update" submission type no longer exists.</p> <p>2. Pre-review is removed from External IRB and is managed on the corresponding Site workspace. The External IRB page of the SmartForm must be updated by IRB staff to include IRB of record decisions/determinations.</p>	<p>To update an External IRB project, one must modify from the site.</p> <p>2. The IRB of record determination of regulatory oversight and risk must be managed by IRB staff via an IRB staff-only section of the External IRB SmartForm page.</p>	
<h2>Workspace</h2>		
<p>Submission Type: Initial/Main Study</p> <p>1. New Site tab appears and lists all sites for a multisite or collaborative project with added sites. Quick SmartForm view and activity (on CR space only) options appear from this list for use as needed. One can still visit the Site workspace to take appropriate action.</p> <p>2. Main study reviews tab (sections visible to IRB staff only): Pre review and for non/committee review sections show "most recently completed" values for determinations, risk and dates rather than only first set of determinations.</p> <p>3. Follow On Submissions Tabs also show sites relative to the study, for a single reference list of associated submissions.</p> <p>4. Snapshots and documents appear in an order again (by date or by edit respectively).</p>	<p>1. Single reference tab for all sites with quick link and activity options limit the need to visit a Site workspace to take multisite/collaborative study based actions.</p> <p>2. Intended to be a quick reference for current status, first determinations can still be viewed from the submission history. Also, all follow on determinations list now includes sites where applicable.</p> <p>3. The Sites or Follow On Submissions tabs can be used to navigate to a Site workspace.</p> <p>4. Newest or most recently changed items will appear at the top of these tabs containing lists of items.</p>	

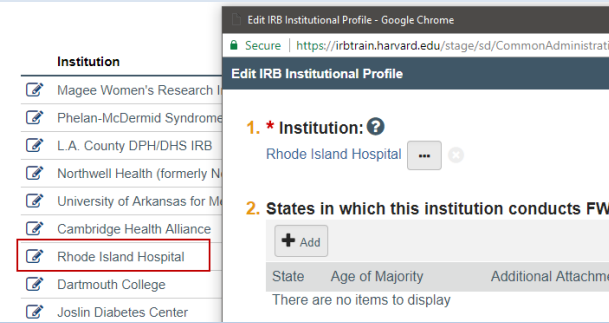
What has changed...	What it means...	How it looks (as applicable)...
<p>Submission Type: External IRB</p> <p>Pages marked in the “External IRB” state are now considered a reference page for external IRB review. Added instructional text block under the workflow image to help guide the management of this submission type.</p>	<p>When creating an initial submission and choosing “yes” to question 7, the initial study will automatically transition to the External IRB state. A site workspace will also automatically be created and will be the location of review and determination documentation.</p> <p>The External IRB space is meant to represent the IRB of record information. For projects where Harvard relies on the review of another institution, use the Site workspace to manage updates to the content and review.</p>	
<p>Submission Type: RNI</p> <p>RNI Submission workspace now refreshes after completion of activity, rather than staying static and not displaying the recently completed activity.</p>	<p>Expect to see the workspace refresh upon completion of an activity, without having to refresh the browser to see changes.</p>	
<p>General Submissions/IRB</p> <p>The Unassigned tab (visible to IRB staff and Committee members only) will now display External IRB submissions that do not have an assigned coordinator.</p>	<p>When an External IRB submission is created, a corresponding site is also created and must be submitted. Since this represents a significant change to process, adding External IRB submissions to the unassigned tab is intended to help manage monitoring possible Sites submissions that remain in pre-submission in error.</p>	
Activities		
<p>New! Site-Related Activities</p> <ol style="list-style-type: none"> 1. Add Participating Sites: activity available to study teams and IRB staff, visible on a collaborative research study workspace to create a workspace for managing the Harvard review of additional study sites. 	<ol style="list-style-type: none"> 1. From newly created Site workspaces, study teams can add site-specific details and following approval, report renewal information and create site modifications (beginning “SM”). 	

What has changed...	What it means...	How it looks (as applicable)...
<p>2. Correspond with Site: activity available to study teams and IRB staff, visible on Site workspaces to send public comments to associated study team/site IRB contacts at the site.</p> <p>3. Report Continuing Review Data: activity allows for site-specific continuing review data to be reported to the IRB for consideration.</p>	<p>2. From a Site workspace, where Harvard either reviews for (sIRB) or relies on (pSite) another institution, using this activity, a message can be sent from ESTR to the study team or IRB and is recorded in the Site workspace history. Recipients are defined by name and can be either people who are named in ESTR (with HUIDs) or separately defined “contacts” who cannot otherwise log in to ESTR.</p> <p>3. On a Site workspace, where Harvard either reviews for (sIRB) or relies on (pSite) another institution, information about site status can be shared. This activity is always available after initial site activation and completion is required under certain circumstances (see IRB determination or procedures for review-specific guidelines)</p> <p>Comments on this activity may be used note a requested closure or deactivation of a site. The assigned IRB staff member is notified when continuing review data are reported and can take necessary actions to review the update.</p>	 <p>The screenshot shows a form titled 'Correspond with Site'. It includes a search bar for recipients, a table with columns for Name, E-mail, and Phone, and a message text area.</p>
<p>Submit Ancillary Review Increased availability so that ancillary approval can be completed after assigned and in any submission state, even after IRB review is completed.</p>	<p>Ancillary review and approval can be issued by the assigned ancillary reviewer(s) even after IRB approval. Additionally, those required and assigned ancillary reviews will appear in an individual InBox (1) until the review is completed or IRB approval is issued and (2) only if the person assigned is not also a member of the study team. Independent of the inbox visibility, the activity always remains available to complete on the submission workspace.</p>	 <p>The screenshot shows a button labeled 'Submit Ancillary Review' with a checkmark icon.</p>

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<p>Manage Guest List Guests can be added on RNI submissions.</p>	<p>With limited visibility for RNIs, this provides an option to view for individuals which may not have full view permissions who are (a) nor on the study team or (b) on a study not properly linked to an RNI.</p>	
<p>Activities only available to IRB staff and Committee members</p> <ol style="list-style-type: none"> Generally, state changing action-based activities are higher up in the order of activities. Create Printable Attachments (formerly Create Printable Packet): Activity is revised to create a pdf of only SmartForm attachments and instructs to use the “printer version” on the workspace to print the SmartForm. Submit/Edit Pre-review: <ol style="list-style-type: none"> Has additional tracking spaces for other regulatory oversight and features: Clinical Trials, Deception, and Certificate of Confidentiality. Activity is able to be edited with every follow on submission. 	<ol style="list-style-type: none"> Re-ordered activities means that some appear in different locations than previously, but the same order of activities is required. Attachments can be printed as one pdf (in the same format as the current format/order). However, to ensure the correct SmartForm is printed, those creating the packet are instructed to use the system generated “Printer Version” where available. <ol style="list-style-type: none"> Additional tracking allows for increased reporting capabilities. Review local IRB procedures for specific definitions regarding when these items should be marked in review. These items do not trigger additional system-based requirements or workflows. Allows for update on any relevant submission. For convenience, selected items from the most recently completed pre-review appear pre-selected for review and edit, where needed. Note that risk level selection is no longer available on this activity. 	 <p>1</p> <p>Submit Pre-Review</p> <p>Request Pre-Review Clarification</p> <p>Assign Coordinator</p>  <p>2 Created Printable Attachments</p> <p>To print the SmartForm, use the Printer Version or View options, on the left.</p> <p>Attachments for this submission: IRB16-1710 Sun Nov 26 14:08:55 EST</p>  <p>3 Submit Pre-Review</p> <p>4. Additional study features: (check)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Clinical Trial <input type="checkbox"/> Certificate of Confidentiality <input type="checkbox"/> Deception

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<p>c. Pre-review for all submission types expect RNI is no longer visible to study teams.</p> <p>4. Submit Non-Committee/Committee review: a. The option to select a “Not Human Research” determination is now available on follow on. b. Risk level determination is available only on this activity.</p> <p>5. Finalize Documents: Watermark prints high on the document, rather than with such a low margin, reducing the possibility of the watermark obstructing the document text.</p> <p>6. Send Letter: Activity shows more preview options prior to sending the letter.</p>	<p>c. The activity recorded on the history of the workspace was previously visible to study staff. Visibility is once again restricted to IRB staff and Committee members.</p> <p>4. a. The appropriate determination can be re-confirmed and changes in determination and review type on a follow on will now update the determination on the main study workspace. b. Risk level determination can be confirmed with final review.</p> <p>5. Watermarks appear at the upper-left and center on documents, outside of ordinary margins to ensure greater visibility.</p> <p>6. Additional information in a single space allows for immediate option to double-check entries before sending the letter.</p>	 <p>4 Submit Designated Review</p> <p>2. * Determination:</p> <table border="1"> <thead> <tr> <th>Name</th> <th>Related Worksheet</th> </tr> </thead> <tbody> <tr> <td><input type="radio"/> Approved</td> <td>HRP-314 - Worksheet Approval and Additio Considerations</td> </tr> <tr> <td><input type="radio"/> Modifications Required to Secure "Approved"</td> <td>HRP-314 - Worksheet Approval and Additio Considerations</td> </tr> <tr> <td><input checked="" type="radio"/> Not Human Research</td> <td>HRP-310 - Worksheet Research Determinat</td> </tr> </tbody> </table>  <p>5 HARVARD Human Research Protection Program Protocol #: IRB17-181</p> <p>INSTRUCTIONS: To use this template, com</p>  <p>6 Send Letter</p> <p>Determination: Approved</p> <p>Approval date: 11/22/2017</p> <p>Effective date: 11/24/2017</p>	Name	Related Worksheet	<input type="radio"/> Approved	HRP-314 - Worksheet Approval and Additio Considerations	<input type="radio"/> Modifications Required to Secure "Approved"	HRP-314 - Worksheet Approval and Additio Considerations	<input checked="" type="radio"/> Not Human Research	HRP-310 - Worksheet Research Determinat
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<input checked="" type="radio"/> Not Human Research	HRP-310 - Worksheet Research Determinat									

What has changed...	What it means...	How it looks (as applicable)...
<p>7. Assign Coordinator: Selection can be cleared and saved.</p> <p>8. Private Comment: Permissions updated for consistent IRB staff view.</p>	<p>7. This allows for removing assignment (or “un-assigning”) the submission and returns it to the ‘unassigned’ tab of the submission page, allowing for queue and re-assignment to another team member.</p> <p>8. Taking actions to support the study team (such as submitting response) will not remove IRB Staff visibility into private and review comments.</p>	
<p>New! Meeting Activities</p> <p>1. Add other agenda items: allows for the inclusion of non-submission related discussion topics.</p> <p>2. Update Documents: allows for the inclusion of reference documents for discussion.</p>	<p>1. Items are recorded on the meeting workspace. At this time, information can be added to the workspace but this temporarily needs to be manually written in to the official agenda or minutes documents. The agenda and minutes will be revised to include these items in a future update.</p> <p>2. Updated documents are expected to be non-study related reference items. All study related documents must still be included in the appropriate spaces of the corresponding submissions.</p>	

What has changed...	What it means...	How it looks (as applicable)...
Settings		
<p>New! Institutional Profiles</p> <p>IRB Staff can manage institutional profiles to:</p> <ol style="list-style-type: none"> identify institutions with potential reliance, manage the list of institutions able to be selected as sites, and add specific features of those institutions. 	<p>Additional details of an institution can be collected and centrally managed by IRB staff so that there are known IRB contacts identified, along with area-specific features (such as local context, requirements, and oversight).</p>	
Notifications		
<ol style="list-style-type: none"> Modifications Required to Secure Approval New! External IRB continuing review reminder Notification of Ancillary Review 	<ol style="list-style-type: none"> Removed the extra "the" in notice text, correcting grammar. Reminder will be sent seven days prior to, on, and seven days after expiry for External IRB projects marked as 'greater than minimal risk' by the IRB of record. The notice will be sent to the Harvard PI/Proxy and Primary Contact. Upon completion of the "Submit Ancillary Review" activity, a notice is sent to the assigned IRB coordinator, PI/Proxy and Primary Contact. This notice informs recipient of the status of the ancillary approval and includes suggested next steps (specifically, "If this ancillary review is part of Clarifications Requested, completion of the submit response activity (on the left side of the submission workspace, marked with a red arrow) must occur in order for IRB review to proceed."). 	
Determination Letter		
<ol style="list-style-type: none"> External IRB letter Approval Letter 	<ol style="list-style-type: none"> Available in approved states so that it can be created from a Site workspace. No longer displays funding as part of the attachments list. 	

Other Upgrade Considerations

Existing Studies at Upgrade

1. All existing projects are set to “Single Site” studies and sites will continue to be managed under “pre-upgrade” processes.
2. Studies which have any submissions that are in review Pre-Submission or Clarifications Requested that have listed Research Locations will need to add country before they are able to submit response.
3. Due to the functions of the Basic Information page, executing the Copy Submission activity on a study copies the saved read-only selections regarding external IRB and type of study of the original project.
4. Archived projects display all dates (including most recently entered expiration date), this does not affect the determination or state of the submission (and does not mean that expiration notices will be sent from these submissions).

Site-Related Specifics

1. Assigned ancillary reviewers cannot see site-specific workspaces. They can however see the addition of sites on the study History, and some elements by clicking on the activity in the History.
2. Site workspace will take a moment to process background tasks and update with main study details. This can require a pause between approving a site immediately after approving a main study.
3. Sites cannot be discarded by the study team. If a site is created in error, it must be made ‘inactive’ by IRB staff (specific activity to do this depends on the state of the site submission).
4. For studies with sites, the Institutional Profile MUST have contacts for a study with sites to be approved. Only IRB staff can update Institutional Profile details and contacts.
5. When managing continuing review on a project with sites, the Sites tab on the continuing review workspace show the “report completed?” column as ‘no’ even when continuing review data is reported via the necessary activity. This can happen when the displayed box is marked in Internet Explorer or Firefox. This records properly when using Chrome. Note that the ‘yes’ or ‘no’ indicator is for reference and has no impact on system-based review activities.
6. External IRB Projects
 - a) External IRB submission related-sites can only be submitted if the Harvard Principal Investigator is named in the site Principal Investigator space (which can be edited from the Site workspace).
 - b) Some External IRB projects created before October 2015 do not have a corresponding Site workspace. To update features of these projects, these submissions must be re-created under the new External IRB submission SmartForm.

Release 1.23.0 Summary of HRPD Toolkit-ESTR Revisions

List of items updated in ESTR since the August 2017 release 1.22.2 or with this release.

Document Name	Type	Changes Summary
HRP-224-FORM-IRB Cede Request	Form	Revised to include only scenarios where Harvard relies on the review of another institution

Document Name	Type	Changes Summary
HRP-513-Not Human Research	Form	Update to clarify response items/availability of N/A
HRP-510a-Harvard-Approval CR MOD Team	Letter	Removed additional funding source reference at the bottom of the document list (LMA only)
HRP-510a-Harvard-Approval MOD Other	Letter	Removed additional funding source reference at the bottom of the document list (LMA only)
HRP-510-Harvard-Approval INTIAL	Letter	Removed additional funding source reference at the bottom of the document list (LMA only)
HRP-541-Harvard-ExternalIRB	Letter	Updated to include merge fields for FWA – for use during the Prepare Letter activity.
HRP-541a-Harvard-SiteReview	Letter	NEW! Letter for use during the Prepare Letter activity, when Harvard is the IRB of record for a participating site.
HRP-103-Investigator Manual	Reference	Non-specific content revision
Principal Investigator Assurance-Reference	Reference	NEW! Reference available as a standalone document in the IRB library. Content of assurance remains unchanged.
CUHS Protocol Template	Template	Non-specific content revision plus revision to include prompt for site information
HLMA Adult Consent Form Template	Template	Right align header to correct view with updated watermark
HLMA Adult Surrogate Consent Form Template	Template	Right align header to correct view with updated watermark
HLMA Consent Template for HIPAA-covered entities	Template	Right align header to correct view with updated watermark
HLMA Parental or Guardian Permission Template	Template	Right align header to correct view with updated watermark
HLMA Research Protocol	Template	Non-specific content revision plus revision to include prompt for site information