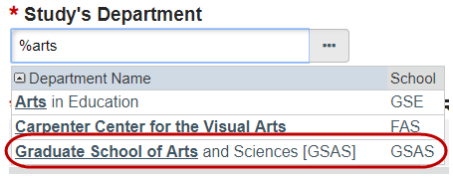
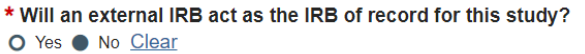
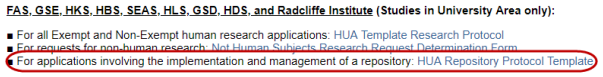
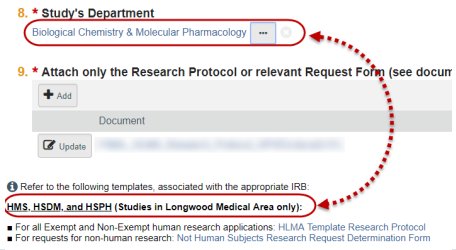
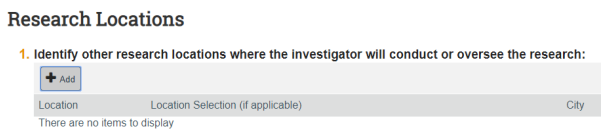
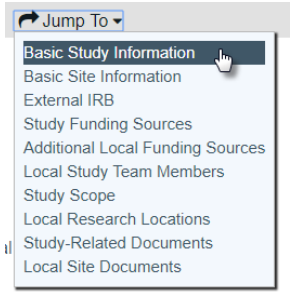
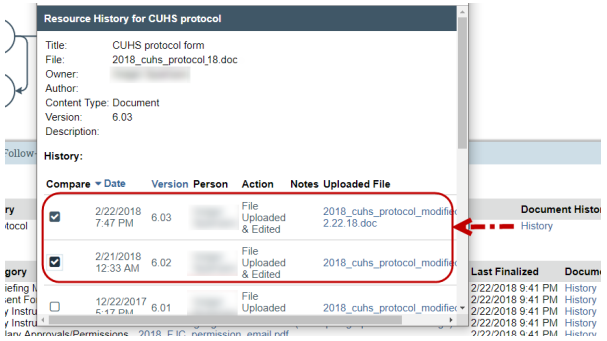
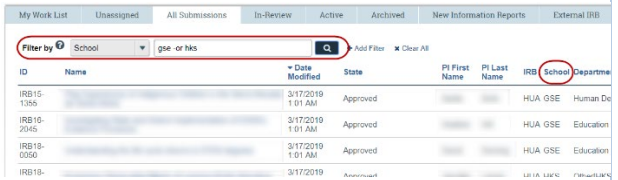
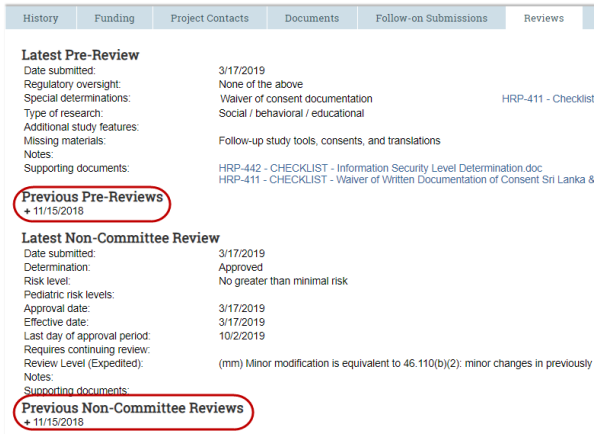
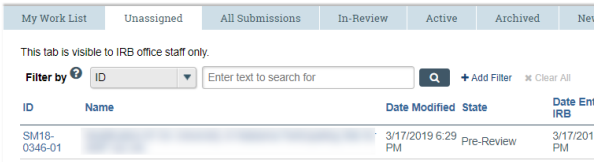
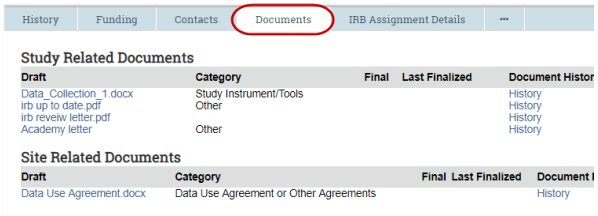
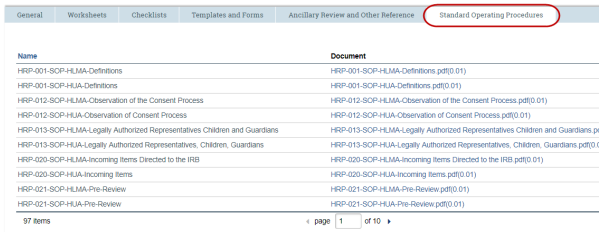
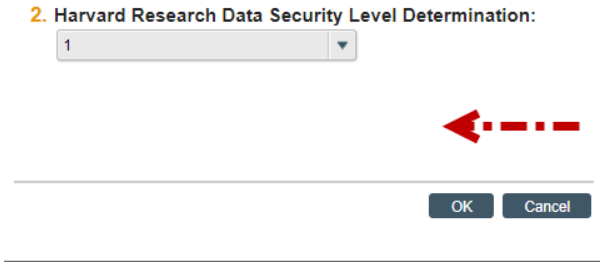
ESTR 1.24.0 Upgrade & Configuration Release Items: April 2019

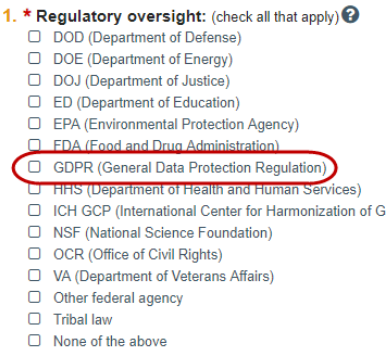
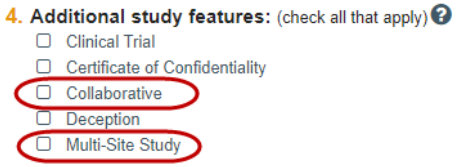
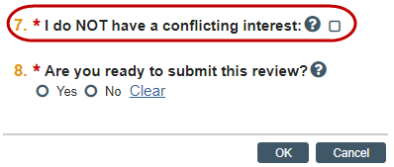
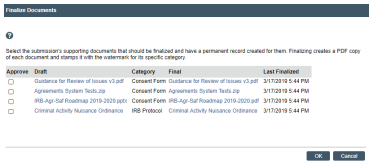
A summary of vendor upgrade elements and Harvard updates.

What has changed…	What it means…	How it looks (as applicable)…
SmartForm Pages		
Basic Information **(Basic Study Information)**		
1. New departments: • Undergraduate Research Training Program [URTP] • Graduate School of Arts and Sciences [GSAS]	1. New submissions for review under HUA can also be associated with Undergraduate Research Training Program or the Graduate School of Arts and Sciences	1. 
2. Question 8 (if an External IRB will act as the IRB of record) can once again be edited during review	2. Since it is not always clear at the time of initial submission if reliance will occur, a selection can be made on the form and then edited during Clarifications Requested (Pre-Review). One pre-review is completed (via the Submit Pre-Review or Confirm Reliance activities), the selection can no longer be edited.	2. 
3. Add a HUA Repository Protocol Application	3. A Repository Protocol Application form is now available for use as part of composing a submission for HUA IRB review.	3. 
4. Hide/Show suggested area-specific attachments based on responsible department selection	4. Once the Responsible Department is selected and saved, only the suggested attachments for that area IRB will show throughout the SmartForm.	4. 

What has changed…	What it means…	How it looks (as applicable)…
Study Scope/Research Locations The local research locations page will always display and no longer has a gateway question on the Study Scope page.	Similar to funding sources, this page will always appear and will sometimes be blank because it is not applicable. This new feature will need to be monitored to ensure accurate information on the SmartForm and clear information about what is expected on this page of the SmartForm.	
External IRB 1. One set of SmartForm pages and one workspace for the management of projects where Harvard relies on the review of another IRB.	1. As part of a comprehensive change to how External IRB review is managed, the previously two SmartForms have been combined to one. See "Upgrade Considerations" section below for additional details.	1. 
2. Content of pre-review is removed from the SmartForm and is in an activity for the reviewer as part of the review process.	2. Since the reviewer is responsible for adding this information, it is removed from the SmartForm and has returned to a review activity.	2. *No image*
Workspace		
General 1. View tracked changes of Microsoft Office attachment types in a version history view	1. An additional column is available on document history which allows for selected comparison of two versions in a third (system created) tracked document. Note: a) to use this feature "upload revision" must be used; and b) be careful to select the right two versions to compare.	1. 

What has changed…	What it means…	How it looks (as applicable)…
2. Search and filter (on lists and in forms) allow for "or" and "and" operators, rather than only "and"	2. Use Boolean Operators for Complex Searches valid Operators: -or, -and to find any of several text values, such as filtering a department column with Center -OR Ctr. Also, find everything between two numbers, such as filtering a numeric column with > 10000 -and <= 50,000.	2. 
3. School-level view should translate to department views across applications	3. The school and university-wide view permissions were limited due to a bug. This is corrected so that assignment as a viewer allows for the expected view of all submissions associated with that group (department, school, or university-wide).	3. *No image*
Submission Type: Initial/Main Study		
4. Fix the issue where the workspace loses workflow image on send letter twice if state deferred	4. The workspace image remains independent of the number of times the sent letter activity is completed.	4. *No image*
5. Reviews tab on main study/site workspace shows current and previous information saved during review.	5. Most current review information is visible on the reviews tab. Just below, the previously completed review information can be clicked and expanded to view. This also fixes the bug regarding notes on non/committee review and notes are updated on the main workspace when updated during review of a follow on submission.	5. 

What has changed…	What it means…	How it looks (as applicable)…
Submission Type: Site Modification 6. The system now receives Site modifications as ordinary submissions into the Unassigned queue, without a notice.	6. Site modifications used to come in assigned to the main study coordinator. They will now come in as unassigned.	6. 
Submission Type: External IRB (initial or site) 7. Documents should display category on Documents tab	7. All documents except for the external IRB determination letter are shown on the documents tab with a category.	7. 
IRB Library Add SOPs and create new document spaces and placeholders	Standard Operating Procedures (SOPs) are now part of the IRB Library in ESTR. Documents traditionally managed via release can also be added or revised as needed and between releases.	
Activities		
Reviewer/IRB Staff Activities 1. Track Harvard Determinations: Remove Data Security Level Checklist/Worksheet link	1. This document is no longer required as part of review so it is no longer referenced on the activity.	1. 

What has changed…	What it means…	How it looks (as applicable)…
2. Pre-Review: a. Add GDPR as a tracking flag. This is now included under the Regulatory Oversight heading.	2. a. GDPR is added as a regulatory oversight component for reporting and tracking. Note that the list is not sorted in any particular order (conceptually or alphabetically).	a. 
b. Additional check boxes for collaborative or multisite to support reporting and tracking, under the Additional Study Features heading.	b. Since this distinction was difficult to manage on the SmartForm (causing study team and edit challenges), the system defers the confirmation to the IRB staff and at the time of Pre-Review. If a SmartForm indicates "Collaborative/multisite" the assigned IRB coordinator is expected to indicate the right type.	b. 
3. Non-Committee Review: The confirmation regarding reviewer conflict is at the bottom of the activity pop up (rather than the top)	3. This required item was often missed during confirmation of determination in non-committee review. This is moved to the bottom of the activity to increase the likelihood of that it will not be missed.	3. 
4. Finalize Documents: This activity is known to be restrictive on attachments that are converted to pdf and displays errors often	4. The method that manages this has been updated to be less restrictive and will cause less errors when attempting to finalize non-standard types of attachments, such as existing pdfs, compressed ("zipped") files, or PowerPoint presentations.	4. 

What has changed…	What it means…	How it looks (as applicable)…
Notifications		
1. Add an annual "you have expedited research" reminder for 2018 rule change reviewed projects	1. For all Expedited research that does not require continuing review, a notification will be sent out to the PI/Proxies and Primary Contacts on the Approval Anniversary Date to remind them of IRB submission and reporting requirements for this type of research.	
2. Site continuing review reminder has draft ID references that require removal	2. The system was sending two reminders of expiry on site submissions; one from the site submission and one from the draft. The draft notice is removed.	
3. Submit response from deferral should send a notice to IRB coordinator	3. Submitting a response will now always send a notice to the assigned IRB coordinator, even when submitting from the deferred state.	
4. Someone should be notified when a Site Modification is created	4. A modification could be submitted on sites where Harvard is the IRB of record. These site modifications were being auto-assigned without notice. This has been corrected where they are not auto-assigned and can be managed via the Unassigned tab (the ordinary process of assignment).	
Reports		
Reviewer/IRB Staff Reports		
1. Add Country/Location report and Report of recent comments for tracking	1. Two requested reports for IRB staff management (on the Custom Reports tab): The Studies with Research locations report shows all research locations and their marked country; the Comments in the last 14 days report shows all public comments in the last 14 days on projects assigned to the person running the report.	
2. AAHRPP Report: Some methods are corrected to capture more accurate values	2. The AAHRPP annual reporting form is updated.	
Common Custom Reports		
3. Add funding to the active studies report	3. A column with funding information is added to the last column (all-the-way right side) of this report.	

Other Upgrade Considerations

Existing External IRB Project Migration

1. Existing External IRB projects where there was a main study workspace and a site workspace were migrated/merged into the associated site workspace.
2. For multi-site or collaborative projects, these are now ID numbered with the Site ID and can be accessed on the site workspace. This allows for easier view of that submission history of activities.
3. Associated External IRB records (ID numbered beginning with “IRB”) have been discarded but can be referenced via a link in the site history.
4. Older External IRB records (that never had an associated site worksapce) still display as legacy submissions with the (incorrect) option to “modify study”. The current practice is to discard a modification if it is submitted as approval would overwrite the External IRB status on those records.

Newly Created External IRB Projects

Newly created External IRB requests are formatted in one of two ways:
(1) Harvard is asked to rely on the review of another institution and it is marked as a multi-site/collaborative project: These will transition to an IRB Site submission types where the end state is "Active"
(2) Harvard is asked to rely on the review of another institution and it is marked as a single site project: These will remain Initial Study submission types where the end state is "External IRB"
Processes are otherwise the same for both types of submissions and all newly created External IRB requests will be numbered beginning with "IRB", independent of the submission type. In documentation, we will refer to any submission where Harvard relies on the review of another IRB as "External IRB", independent of end state in the system.

Other Important Notes

1. On the SmartForm, the Study Team page has modified instruction for studies where Harvard is relying on the review of another IRB. Information about listing non-Harvard researchers has been removed.
2. The study team can create a Study Update to provide updates on existing External IRB project. A Study Update is informal and can be managed by the study team to update the record. The assigned IRB coordinator receives notice if updates, but specific review activities for a Study Update are not required in the system. Study updates are ID numbered, beginning with "SU" so that they are considered different than Site Modifications that are ID numbered, beginning with "SM"

Release 1.24.0 Summary of HRPP Toolkit-ESTR Revisions

With release notes, a list of items updated in ESTR since the last release (1.23.4) is ordinarily included here. However, with the updated regulation in effect as of January 21, 2019, every HRPP document was updated at that time. Please reference the IRB staff internal wiki or IRB Library in ESTR to access updated items.