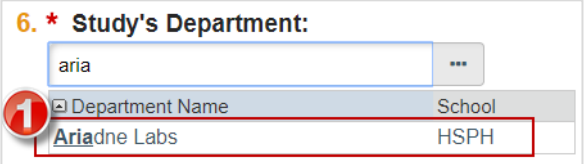
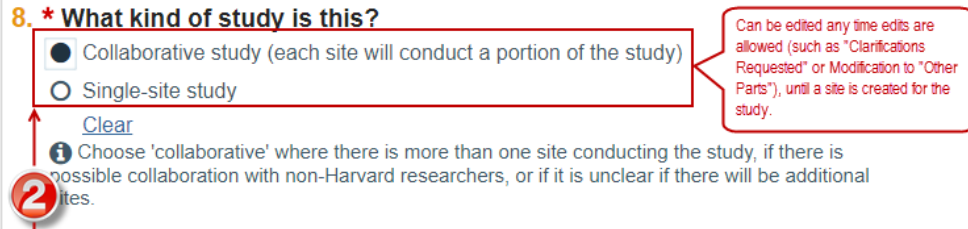
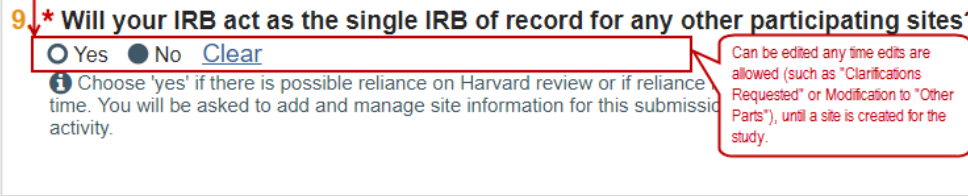
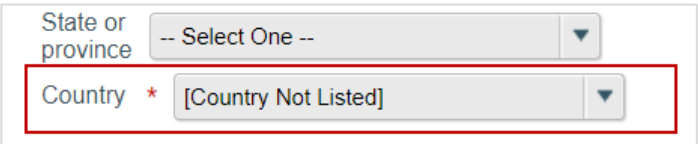
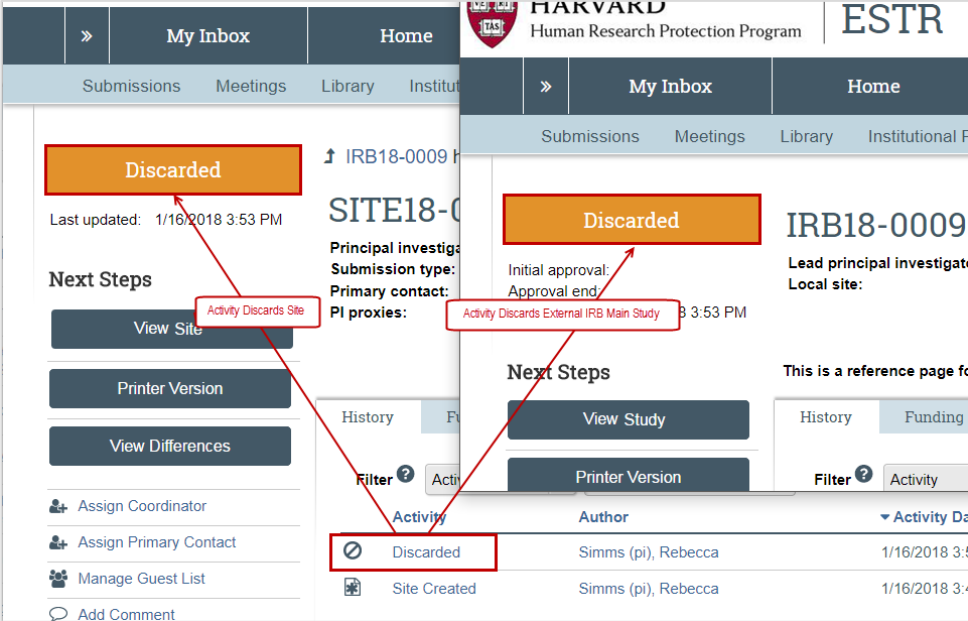
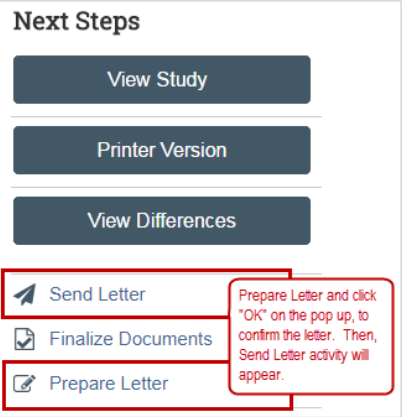
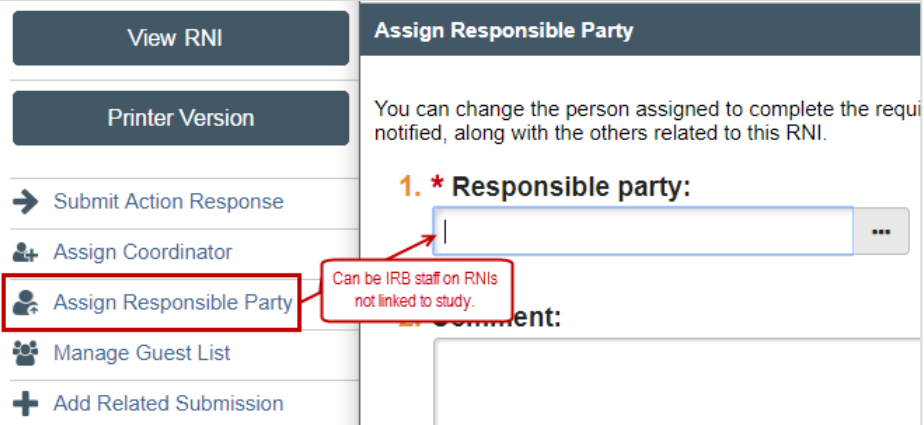


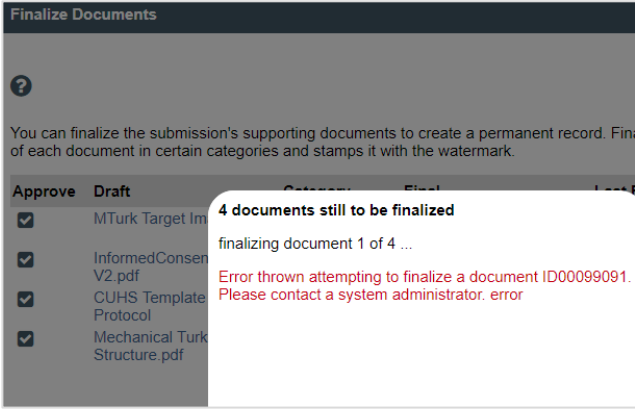
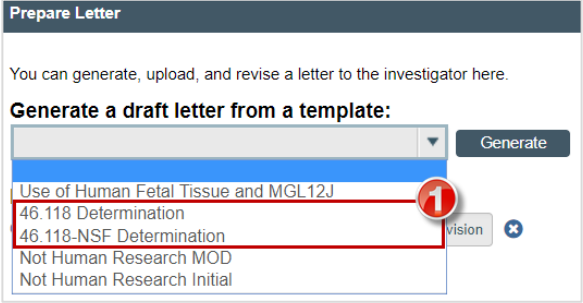
ESTR 1.23.0.1 Hot Fix Release Items: January 25 2018

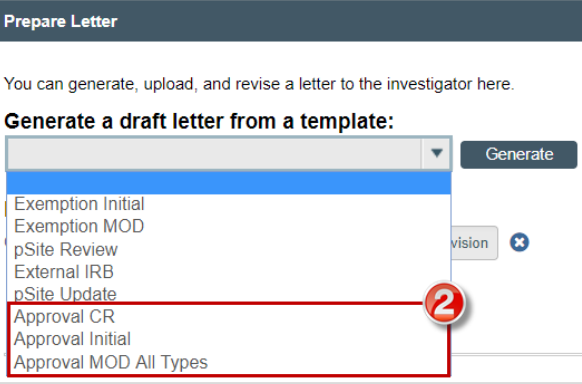
Along with vendor and Harvard bug fixes, this release includes support for the delay to the 2018 Common Rule effective date and the following highlighted changes.

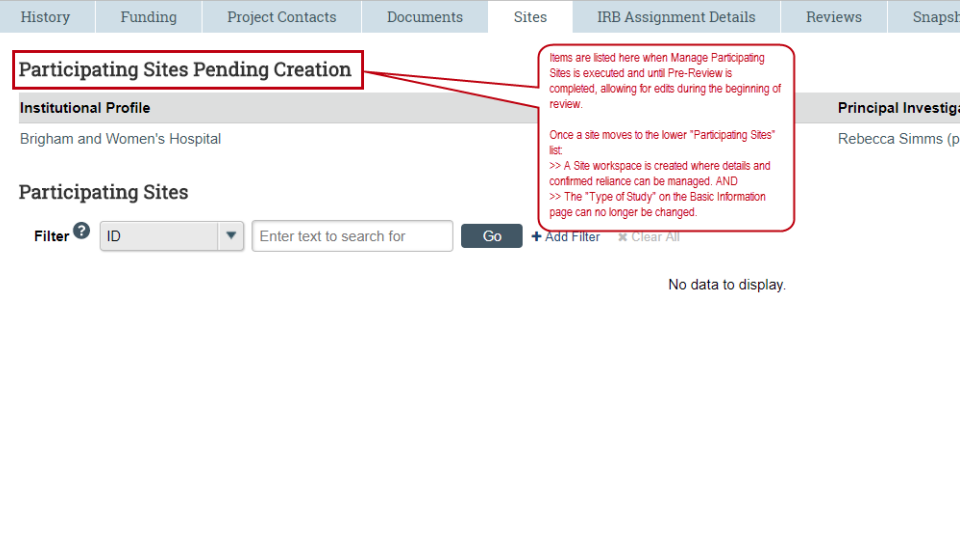
What has changed...	What it means...	How it looks (as applicable)...
SmartForm Pages		
Basic Information		
<p>1. New Responsible Department</p> <p>2. Type of Study and selection of the Harvard IRB as a sIRB can be edited until a site is added</p>	<p>1. The Department, Ariadne Labs can now be selected. Items associated with this department will be reviewed by the HSPH IRB.</p> <p>2. Selections in response to:</p> <ul style="list-style-type: none"> • What Type of Study is This? AND • Will your IRB act as the single IRB of record for any other participating sites? <p>Can be edited at any appropriate time, until a site is created. Existing studies can be revised via modification when needed (such as when new sites are engaged and must rely on Harvard review) and new projects can be edited during Clarifications Requested to correct any entry errors.</p>	 <p>6. * Study's Department:</p> <p>aria</p> <p>1 Department Name School</p> <p>Ariadne Labs HSPH</p>  <p>8. * What kind of study is this?</p> <p><input checked="" type="radio"/> Collaborative study (each site will conduct a portion of the study)</p> <p><input type="radio"/> Single-site study</p> <p>Clear</p> <p>Choose 'collaborative' where there is more than one site conducting the study, if there is possible collaboration with non-Harvard researchers, or if it is unclear if there will be additional sites.</p> <p>2</p>  <p>9. * Will your IRB act as the single IRB of record for any other participating sites?</p> <p><input checked="" type="radio"/> Yes <input type="radio"/> No Clear</p> <p>Choose 'yes' if there is possible reliance on Harvard review or if reliance time. You will be asked to add and manage site information for this submission activity.</p> <p>Can be edited any time edits are allowed (such as "Clarifications Requested" or Modification to "Other Parts"), until a site is created for the study.</p>
<p>Research Locations</p> <p>Countries missing from the list during the last update are added back in for selection.</p>	<p>The following selections for country are once again available: Serbia, Zimbabwe, and "country not listed".</p>	 <p>State or province -- Select One --</p> <p>Country * [Country Not Listed]</p>

What has changed...	What it means...	How it looks (as applicable)...									
<p>Various additional display/ view fixes</p> <ol style="list-style-type: none"> 1. Truncate Follow-on Name if Greater than 255 Characters 2. Local-Site Documents page now displays correct and instructions, even on Modifications. 	<ol style="list-style-type: none"> 1. Since Modification and Continuing review submissions now contain the main study short title in the name, the system has a 'catch' to ensure that Modifications and Continuing review submission names don't exceed system limitations (of 255 characters). 2. The information displayed on the Local-Site Documents page of the SmartForm is now clarified to (a) be specific to the type of submission (specifically, if the Local-Site Documents page is asking for information used by Harvard researchers OR by site researchers); and (b) be consistent when proposing a modification or site modification. 										
Activity (visible to Study Teams)											
<p>External IRB Discard</p> <p>Completing site discard now also discards the associated External IRB record.</p>	<p>For when Harvard may rely on the review of another institution only, if completing a site discard, the associated External IRB record will also transition to the discarded state.</p>	 <p>The screenshot displays the Harvard Human Research Protection Program (ESTR) interface. It shows two overlapping views of a submission page for 'SITE18-0009'. In the left view, a 'Discarded' status is shown with a red box and a callout 'Activity Discards Site'. In the right view, another 'Discarded' status is shown with a red box and a callout 'Activity Discards External IRB Main Study'. Below these, an activity log table is visible with a red box around the 'Discarded' entry.</p> <table border="1" data-bbox="1344 1128 1980 1242"> <thead> <tr> <th>Activity</th> <th>Author</th> <th>Activity Date</th> </tr> </thead> <tbody> <tr> <td>Discarded</td> <td>Simms (pi), Rebecca</td> <td>1/16/2018 3:53 PM</td> </tr> <tr> <td>Site Created</td> <td>Simms (pi), Rebecca</td> <td>1/16/2018 3:48 PM</td> </tr> </tbody> </table>	Activity	Author	Activity Date	Discarded	Simms (pi), Rebecca	1/16/2018 3:53 PM	Site Created	Simms (pi), Rebecca	1/16/2018 3:48 PM
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What has changed...	What it means...	How it looks (as applicable)...
Activities (visible to only to IRB Staff and Committee Members)		
<p>Send Letter Send letter only appears after Prepare Letter is completed.</p>	<p>Send Letter activity was showing for execution when the letter didn't actually exist yet. Now, the Send Letter activity will not become visible for execution until the confirmed version of the correspondence letter exists, which will occur when the Prepare Letter activity is run correctly and without validation errors.</p>	 <p>The screenshot shows a 'Next Steps' menu with three buttons: 'View Study', 'Printer Version', and 'View Differences'. Below these are three items: 'Send Letter' (with a blue arrow icon), 'Finalize Documents' (with a document icon), and 'Prepare Letter' (with a pencil icon). A red box highlights the 'Send Letter' and 'Prepare Letter' items. A callout box points to 'Send Letter' with the text: 'Prepare Letter and click "OK" on the pop up, to confirm the letter. Then, Send Letter activity will appear.'</p>
<p>RNI Assign Responsible Party Allows for the Assigned Reviewer or IRB Coordinator to be selected as the responsible party.</p>	<p>Previously, IRB staff were limited in the ability to assist with the management of a response to RNI-required actions, for RNIs that were not linked to a submission. Now, IRB staff can assist for all RNIs.</p>	 <p>The screenshot shows a sidebar menu with 'Assign Responsible Party' highlighted in red. The main content area is titled 'Assign Responsible Party' and contains the text: 'You can change the person assigned to complete the required action, along with the others related to this RNI.' Below this is a form with a field labeled '1. * Responsible party:' and a dropdown menu. A red box highlights the 'Assign Responsible Party' menu item and the dropdown menu. A callout box points to the dropdown menu with the text: 'Can be IRB staff on RNIs not linked to study.'</p>

What has changed...	What it means...	How it looks (as applicable)...
<p>Finalize Documents</p> <p>To be finalized without error, non-document type attachments must be attached to the SmartForm as a Supporting Document with the category “Other”.</p>	<p>Finalize will only complete on attachments which can be converted as the system is configured/allows. Errors may display on the following non-document attachment types (that may have been previously accepted):</p> <ul style="list-style-type: none"> • Compressed “.zip” files • Video files (such as, with the format extension .mp4) • Web formatted files (such as, with the format extension .htm) <p>To ensure that all approved attachments are finalized, any attachments with the above format extensions (or any other non-document types):</p> <ul style="list-style-type: none"> • Instead must be attached to the SmartForm as a Supporting Document with the attachment category “Other”. • If attached to another location of the SmartForm or associated with any alternate category, those versions should be removed. 	
<p>Prepare Letter</p> <p>1. Prepare Letter displays the “.118”-associated determination letters when making a “Not Human Subjects Research” determination.</p>	<p>1. Previously, when making a “.118” determination (for proposals lacking definite plans for the involvement of Human Subjects), the reviewer chose “Approved” under Exemption category “Other”. Now, the reviewer can choose “Not Human Research” and the correct template will appear when completing the Prepare Letter activity.</p>	

What has changed...	What it means...	How it looks (as applicable)...
<p>2. Prepare Letter displays three types of approval for Expedited or Full Committee Determinations, based on submission type.</p>	<p>2. Due to changes in the pre-review activity (where it can be edited on any submission type), the letters are re-aligned with submission types, now listing:</p> <ul style="list-style-type: none"> • Approval CR for continuing review • Approval Initial for main studies/initial submissions, and • Approval MOD All Types for any type of modification. 	

Workspace		
<p>pSite Participating site (when Harvard may serve as the IRB of record) workspace will only create after Pre-Review is completed on the main study.</p>	<p>Any sites added via the Manage Participating Sites activity will be marked as “pending” until the Submit Pre-Review activity is completed. This allows for the SmartForm to remain edit-able during review. Features to note:</p> <ul style="list-style-type: none"> • Sites listed here in error can be removed by re-completing the Manage Participating Sites activity. • Sites which should create workspaces (to manage reliance) will move from the pending section to the Participating Sites list automatically, after Submit Pre-Review is completed. 	

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<p>Reviews Tab <i>Section visible to IRB Staff and Committee Members Only</i></p> <p>Submissions previously reviewed by Committee have a summary display of Committee review elements.</p>	<p>Committee review information added before upgrade can be viewed on the associated submission review tab under the heading “Committee Review Summary”. To view detailed elements not displayed in this summary (such as vote count), visit the submission history and click on the completed activity to view details.</p>	<table border="1"> <thead> <tr> <th data-bbox="1031 164 1142 196">History</th> <th data-bbox="1142 164 1253 196">Funding</th> <th data-bbox="1253 164 1434 196">Project Contacts</th> <th data-bbox="1434 164 1572 196">Documents</th> <th data-bbox="1572 164 1797 196">Follow-on Submissions</th> <th data-bbox="1797 164 1923 196">Reviews</th> </tr> </thead> <tbody> <tr> <td colspan="6" data-bbox="1031 224 1923 248">Latest Pre-Review</td> </tr> <tr> <td colspan="2" data-bbox="1031 248 1253 272">Date submitted:</td> <td colspan="4" data-bbox="1253 248 1923 272">12/6/2017 9:47 AM</td> </tr> <tr> <td colspan="2" data-bbox="1031 272 1253 297">Regulatory oversight:</td> <td colspan="4" data-bbox="1253 272 1923 297">None of the above</td> </tr> <tr> <td colspan="2" data-bbox="1031 297 1253 321">Special determinations:</td> <td data-bbox="1253 297 1572 345">Prisoners Waiver/alteration of the consent process</td> <td data-bbox="1572 297 1797 345"></td> <td data-bbox="1797 297 1923 345">HRP-415 - Checklist - Research Involvin</td> <td data-bbox="1797 297 1923 345">HRP-410 - Checklist - Waiver or Alteratic</td> </tr> <tr> <td colspan="2" data-bbox="1031 345 1253 370">Type of research:</td> <td colspan="4" data-bbox="1253 345 1923 370">Social / behavioral / educational</td> </tr> <tr> <td colspan="2" data-bbox="1031 370 1253 394">Additional study features:</td> <td colspan="4" data-bbox="1253 370 1923 394"></td> </tr> <tr> <td colspan="2" data-bbox="1031 394 1253 418">Missing materials:</td> <td colspan="4" data-bbox="1253 394 1923 418"></td> </tr> <tr> <td colspan="2" data-bbox="1031 418 1253 443">Notes:</td> <td colspan="4" data-bbox="1253 418 1923 443"></td> </tr> <tr> <td colspan="2" data-bbox="1031 443 1253 467">Supporting documents:</td> <td colspan="4" data-bbox="1253 443 1923 467"></td> </tr> <tr> <td colspan="6" data-bbox="1031 475 1923 500">There is no Non-Committee Review to display at this time.</td> </tr> <tr> <td colspan="6" data-bbox="1031 508 1923 532">There is no Committee Review to display at this time.</td> </tr> <tr> <td colspan="6" data-bbox="1031 548 1923 573">Committee Review Summary</td> </tr> <tr> <td colspan="6" data-bbox="1031 581 1923 605">Date effective: 12/6/2017</td> </tr> <tr> <td colspan="6" data-bbox="1031 613 1923 638">Risk level: No greater than minimal risk</td> </tr> <tr> <td colspan="6" data-bbox="1031 646 1923 670">Determinations and findings:</td> </tr> <tr> <td colspan="6" data-bbox="1031 678 1923 703">Controverted issues:</td> </tr> <tr> <td colspan="6" data-bbox="1031 711 1923 735">Other notes: Resubmitting Committee Review to include uploading of DSL determination checklist.</td> </tr> <tr> <td colspan="6" data-bbox="1031 743 1923 768">Supporting documents:</td> </tr> <tr> <td colspan="6" data-bbox="1031 776 1923 800">HRP-415a - CHECKLIST - Prisoners (4).doc</td> </tr> <tr> <td colspan="6" data-bbox="1031 800 1923 824">HRP-442 - CHECKLIST - Information Security Level Determination (12).doc</td> </tr> </tbody> </table>	History	Funding	Project Contacts	Documents	Follow-on Submissions	Reviews	Latest Pre-Review						Date submitted:		12/6/2017 9:47 AM				Regulatory oversight:		None of the above				Special determinations:		Prisoners Waiver/alteration of the consent process		HRP-415 - Checklist - Research Involvin	HRP-410 - Checklist - Waiver or Alteratic	Type of research:		Social / behavioral / educational				Additional study features:						Missing materials:						Notes:						Supporting documents:						There is no Non-Committee Review to display at this time.						There is no Committee Review to display at this time.						Committee Review Summary						Date effective: 12/6/2017						Risk level: No greater than minimal risk						Determinations and findings:						Controverted issues:						Other notes: Resubmitting Committee Review to include uploading of DSL determination checklist.						Supporting documents:						HRP-415a - CHECKLIST - Prisoners (4).doc						HRP-442 - CHECKLIST - Information Security Level Determination (12).doc					
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<p>Remains Expired notice was missing spaces in the subject.</p>	<p>The display rendering issue where the in-notice subject appeared as “<i>Approval for studyIRB19-1563Remains Expired</i>” has been corrected so that it now appears as “<i>Approval for study IRB19-1563 Remains Expired</i>”</p>																																																																																																																															
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<ol style="list-style-type: none"> Exempt categories display on Exempt Approval Letter Review type displays correctly as main type of review. 	<ol style="list-style-type: none"> Following upgrade, the selected Exempt categories were not displaying properly in Exemption Determination Letters and had to be manually revised. When the letter is prepared, these are now displaying properly, based on the selection made on the Non-Committee Review activity. Previously, submissions reviewed by the Full Committee where an element of Non-Committee review was completed (such as it was initially assigned a Designated Reviewer but was then assigned to a meeting) were displaying with the incorrect review type. This has been corrected so that items reviewed by the Full Committee are indicated as Full Board review type, and items reviewed by Non-Committee review are indicated as Expedited or Exempt accordingly. This also corrects the value that displays in the “Review Type” column on some reports. 																																																																																																																															

What has changed...	What it means...	How it looks (as applicable)...
Security Updates		
Person		
Individuals affiliated with Harvard under additional “Person of Interest” roles can now log in to ESTR or be added to a study team under Question 1, on the Study Team Members page of the SmartForm. Please see the updated guidance “ Getting or reactivating your HUID to log in to ESTR ” for a full list of accepted role types.		
Activity		
<ol style="list-style-type: none"> 1. Previously assigned Guests (to view only access to a submission) had access to the “Manage Guest List” activity. This access has been removed. Guests can once again, only view and add comment. 2. PI Proxy and associated grant information are now updating correctly between sites and associated main study workspaces. 3. Record sIRB RNI Decision did not have a read policy. A policy now limits read access for this activity to Site administrators, IRB staff, committee members, and global IRB viewers as long as they are not the PI or on the study team. 4. Previously the designated reviewer lost read access to several activities when assisting with editing submissions. The designated reviewer will now retain read access expected for an IRB staff member (review activities and private comments). Note that this does not fix the known outstanding issue where an IRB Coordinator assigned on the main study (after initial approval) may see limited history items on previously approved Modification or Continuing Review. 		

Release 1.23.0.1 Summary of HRPP Toolkit-ESTR Revisions

List of items updated (or expected to be updated) since the December 15 upgrade (1.23.0) or with this release.

Document Name	Type	Changes Summary
HRP-301-HUA-WORKSHEET-Review Materials	Worksheet	<i>Details Pending</i>
HRP-301-LMA-WORKSHEET-Review Materials	Worksheet	<i>Details Pending</i>
HRP-305-WORKSHEET-Quorum and Expertise	Worksheet	<i>Details Pending</i>
HRP-306-WORKSHEET-Drugs (and Biologics)	Worksheet	<i>Details Pending</i>
HRP-308-WORKSHEET-Pre-Review	Worksheet	<i>Details Pending</i>
HRP-311-WORKSHEET-Engagement	Worksheet	<i>Details Pending</i>
HRP-318-WORKSHEET-Additional Federal Agency Criteria	Worksheet	<i>Details Pending</i>

Document Name	Type	Changes Summary
HRP-324-WORKSHEET-Contracts	Worksheet	<i>Details Pending</i>
HRP-331-WORKSHEET-FERPA Compliance	Worksheet	<i>Details Pending</i>
HRP-333-WORKSHEET-Certificate of Confidentiality	Worksheet	New document
HRP-830 - WORKSHEET - sIRB Communication and Responsibilities	Worksheet	New document
CUHS Adult Consent Form Template	Template or Form	<i>Details Pending</i>
CUHS Child Assent Form Template	Template or Form	<i>Details Pending</i>
CUHS Parental or Guardian Permission Template	Template or Form	<i>Details Pending</i>
CUHS Protocol Template	Template or Form	Format and content revisions
HLMA Adult Consent Form Template	Template or Form	<i>Details Pending</i>
HLMA Adult Surrogate Consent Form Template	Template or Form	<i>Details Pending</i>
HLMA Child Assent Form Template	Template or Form	<i>Details Pending</i>
HLMA Consent Template for HIPAA-covered entities	Template or Form	<i>Details Pending</i>
HLMA Exempt Human Research Consent Script Template	Template or Form	<i>Details Pending</i>
HLMA Parental or Guardian Permission Template	Template or Form	<i>Details Pending</i>
HLMA Research Protocol	Template or Form	<i>Details Pending</i>
HLMA Short Form Consent Template	Template or Form	<i>Details Pending</i>
HRP-213-FORM-Human Subjects Research Request Form	Template or Form	<i>Details Pending</i>
HRP-502c-HUA Exempt Human Research Consent Script Template	Template or Form	<i>Details Pending</i>

Document Name	Type	Changes Summary
HUA Investigator Manual	Other	New document for reference
LMA Investigator Manual	Other	<i>Details Pending</i>
HRP-520-External Report	Letter	<i>Details Pending</i>
HRP-857a-SiteReview	Letter	<i>Details Pending</i>
HRP-859 - LETTER - Acknowledge External IRB Update	Letter	New document
HRP-410-CHECKLIST-Waiver or Alteration of Consent Process	Checklist	<i>Details Pending</i>
HRP-416-CHECKLIST-Children	Checklist	<i>Details Pending</i>
HRP-430- HUA Investigator Quality Improvement Assessment	Checklist	New document
HRP-431 - HUA Minutes Quality Improvement Assessment	Checklist	New document