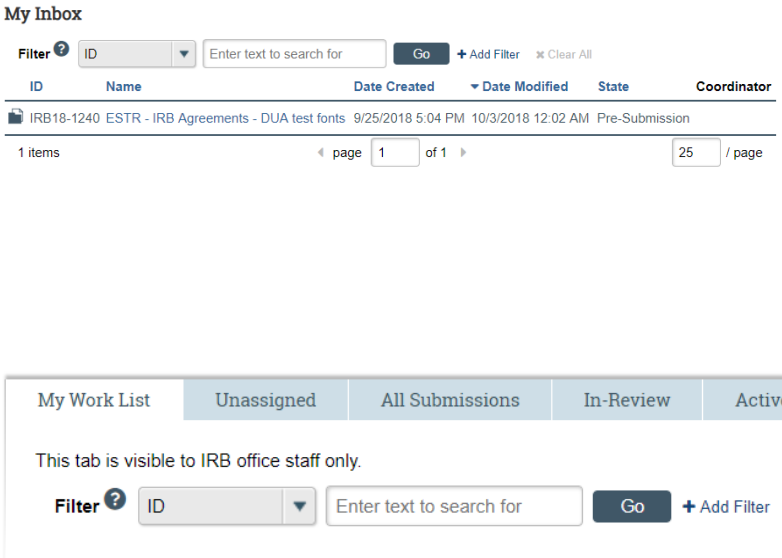

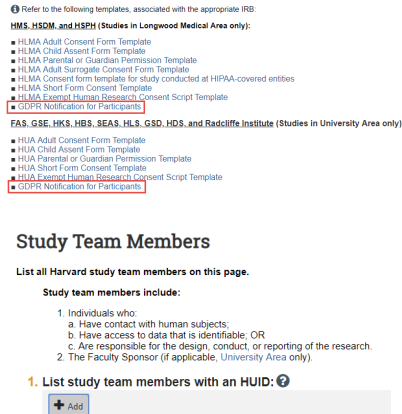


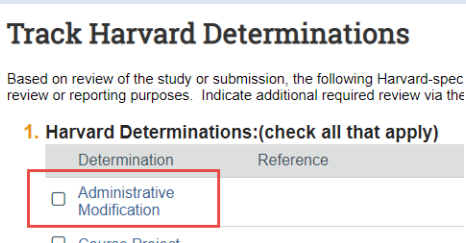
ESTR 1.23.3 Configuration Release Items: November 2018

This release includes preparation for integration with the new Harvard Agreements System for DUAs, along with a few Harvard configuration updates.

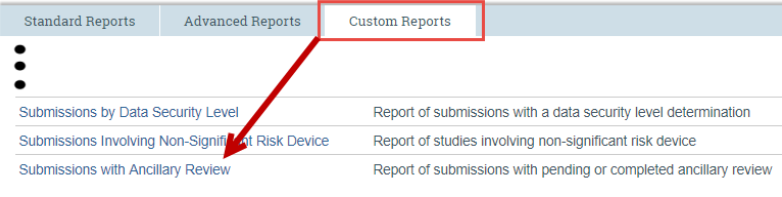

What has changed...	What it means...	How it looks (as applicable)...												
Workspace														
<ol style="list-style-type: none"> In Box: The inbox is now reset to the standard version, with less columns. Submissions: Added tab to IRB Submissions to show "My work list", visible to IRB staff only. 	<ol style="list-style-type: none"> Simplifying the presentation of this list allows for a (soon to be) future combined/unified to do list with the agreements system. IRB staff can still manage larger to-do list items, with increased context than the new unified in box provides. This tab allows for exporting the displayed list. Please note that special export instructions apply. <p>As part of this change, the Unassigned tab is now visible (to IRB staff only) as the second tab on this page.</p>	 <p>My Inbox</p> <p>Filter ? ID <input type="text" value="Enter text to search for"/> <input type="button" value="Go"/> <input type="button" value="+ Add Filter"/> <input type="button" value="x Clear All"/></p> <table border="1"> <thead> <tr> <th>ID</th> <th>Name</th> <th>Date Created</th> <th>Date Modified</th> <th>State</th> <th>Coordinator</th> </tr> </thead> <tbody> <tr> <td>IRB18-1240</td> <td>ESTR - IRB Agreements - DUA test fonts</td> <td>9/25/2018 5:04 PM</td> <td>10/3/2018 12:02 AM</td> <td>Pre-Submission</td> <td></td> </tr> </tbody> </table> <p>1 items <input type="button" value="◀ page 1 of 1 ▶"/> <input type="text" value="25"/> / page</p> <hr/> <p>My Work List <input type="button" value="Unassigned"/> <input type="button" value="All Submissions"/> <input type="button" value="In-Review"/> <input type="button" value="Active"/></p> <p>This tab is visible to IRB office staff only.</p> <p>Filter ? ID <input type="text" value="Enter text to search for"/> <input type="button" value="Go"/> <input type="button" value="+ Add Filter"/></p>	ID	Name	Date Created	Date Modified	State	Coordinator	IRB18-1240	ESTR - IRB Agreements - DUA test fonts	9/25/2018 5:04 PM	10/3/2018 12:02 AM	Pre-Submission	
ID	Name	Date Created	Date Modified	State	Coordinator									
IRB18-1240	ESTR - IRB Agreements - DUA test fonts	9/25/2018 5:04 PM	10/3/2018 12:02 AM	Pre-Submission										

What has changed...	What it means...	How it looks (as applicable)...
<p>3. Study/Submission Workspace: Show department and school on the submission workspace for easier reference.</p>	<p>3. Primarily added for review-context for IRB staff and Ancillary Reviewers, the department and school are now displayed on the Reviews tab section: Harvard Tracked Items.</p>	

SmartForm Pages		
<p>1. Consent Spaces: Add GDPR Notification to Participants to the LMA set of consent documents.</p> <p>2. Site: Site Modification shows whole study team page, should show just the site team instruction</p>	<p>1. Consent sections now display this document in the appropriate areas for easy reference.</p> <p>2. The bug has been corrected so that only</p>	

Activities		
<p>Track Harvard Determinations (IRB Staff Only): Add "Administrative Modification" to Track Harvard Determinations list.</p>	<p>Additional tracking item allows for reporting off this type of modification review. Administrative Modifications are often initiated by IRB staff to assist with updating an element of the study record.</p>	

Report

What has changed...	What it means...	How it looks (as applicable)...
<p>Add report of all ancillary and status (like Data Security Level) with expiration date.</p>	<p>To assist with the management of ancillary review in various statuses, including those not required at initial approval, but required before the next continuing review (which can be considered based off the expiration date).</p>	
Notification		
<p>Add comment content to comment notice</p>	<p>Information written into a comment activity text space will now appear in the email notification sent (if a notice recipient is selected).</p>	

Release 1.23.3 Summary of HRPP Toolkit-ESTR Revisions

List of HRPP toolkit items in ESTR updated (or expected to be updated) since the May 2018 update (1.23.2) or with this release.

Document Name	Type	Changes Summary
HRP-308-WORKSHEET-Pre-Review.doc	Worksheet	Update to include additional Burden Reducing Provision details

Document Name	Type	Changes Summary
HRP-310-WORKSHEET-Human Research Determination.doc	Worksheet	Update to include additional Burden Reducing Provision details
HRP-325-WORKSHEET-GDPR.docx	Worksheet	Update to include additional GDPR revisions
GDPR Notification for Participants.docx	Template	Minor GDPR updates
HLMA Adult Consent Form Template.doc	Template	Minor GDPR updates
HLMA Adult Surrogate Consent Form Template.doc	Template	Minor updates
HLMA Child Assent Form Template.doc	Template	Minor GDPR updates
HLMA Consent Template for HIPAA-covered entities.doc	Template	Minor GDPR updates
HLMA Debriefing Statement.docx	Template	Minor updates
HLMA Exempt Human Research Consent Script Template.doc	Template	Minor updates
HLMA Parental or Guardian Permission Template.doc	Template	Minor updates
HLMA Research Protocol.docx	Template	Minor updates
HUA Adult Consent Form Template.docx	Template	Minor GDPR updates
HUA Child Assent Form Template.docx	Template	Minor GDPR updates
HUA Exempt Human Research Consent Script Template.docx	Template	Minor GDPR updates
HUA Parental or Guardian Permission Template.docx	Template	Minor GDPR updates
HUA Protocol Template.docx	Template	Format and content revision
HRP-510a-Approval with Expiry Date.doc	Letter	Revision/Split for application of Burden Reducing Provisions and Standard Letters

Document Name	Type	Changes Summary
HRP-510-Approval Without Expiry Date.doc	Letter	Revision/Split for application of Burden Reducing Provisions and Standard Letters
HRP-510b-Approval_MOD_All_Types.doc	Letter	Revision/Split for application of Burden Reducing Provisions and Standard Letters
HRP-510c-Exempt_Initial.doc	Letter	Formatting revisions
HRP-510d-Exempt_MOD_All_Types.doc	Letter	Formatting revisions
HRP-510f- Approval CR Without Expiry Date.doc	Letter	Revision/Split for application of Burden Reducing Provisions and Standard Letters
HRP-510g- Approval CR with Expiry Date.doc	Letter	Revision/Split for application of Burden Reducing Provisions and Standard Letters
HRP-511-Closure.doc	Letter	Formatting revisions
HRP-513a-NHSR_MOD_All_Types.doc	Letter	Regulatory clarification
HRP-513-NHSR_Initial.doc	Letter	Regulatory clarification
HRP-515-Suspension_or_Termination.doc	Letter	Formatting revisions
HRP-516-Deferral.doc	Letter	Formatting revisions
HRP-517-Disapproval.doc	Letter	Formatting revisions
HRP-520-External_Report.docx	Letter	Formatting revisions
HRP-545-Use_of_Human_Fetal_Tissue_and_MGL12J.docx	Letter	Regulatory clarification
HRP-528-NIH_GDS_Institutional_Certification.docx	Letter	No longer listed in ESTR, but still to be referenced on the wiki. This is not a system-based merge template.
HRP-103-HLMA Investigator Manual.pdf	General	Revisions for GDPR, Burden Reducing Provisions and other
HRP-103-HUA Investigator Manual.pdf	General	Revisions for GDPR, Burden Reducing Provisions and other

Document Name	Type	Changes Summary
HRP-226-FORM-HLMA PI Exception Request Form.doc	Form	Minor updates
HRP-224-FORM-IRB Cede Request.doc	Form	Retired from ESTR: no longer available in the system
HRP-410-CHECKLIST-Waiver or Alteration of Consent Process.doc	Checklist	Update to include additional Burden Reducing Provision details
HRP-446-CHECKLIST-Common Rule BRP.doc	Checklist	Update to include additional Burden Reducing Provision details