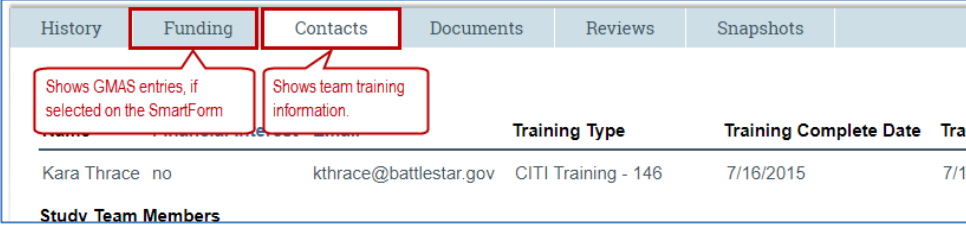


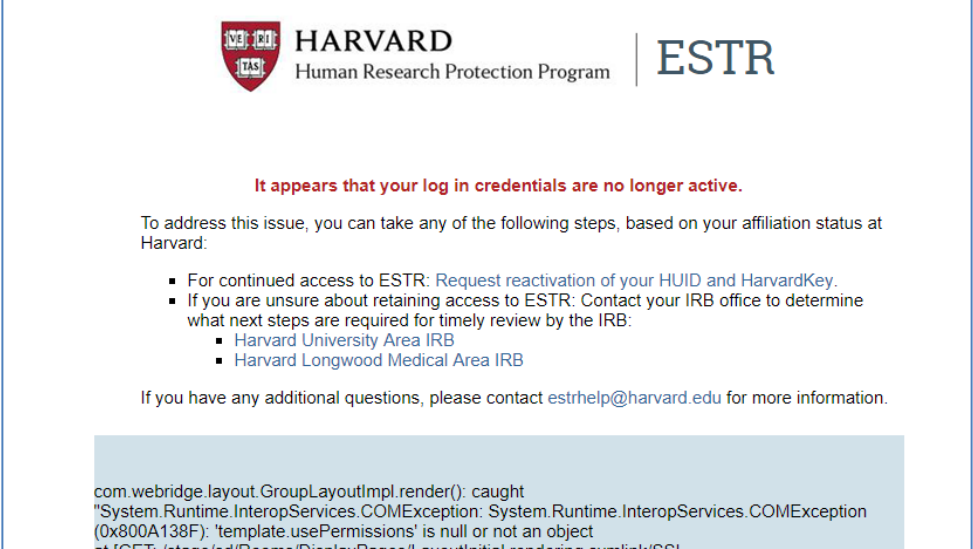
ESTR 1.23.1 Configuration Release Items: April 12 2018

This release includes some select Harvard configuration updates along with slight revisions to HRPP Toolkit and IRB Staff support materials.

What has changed...	What it means...	How it looks (as applicable)...				
SmartForm Pages						
<p>Basic Information</p> <p>Question 7 about External IRB was able to be saved without an entry (and then could not be edited).</p>	<p>The system will no longer allow this question to be unanswered when saving the first page of the SmartForm. Since the selection still cannot be edited after it is saved, this element of the submission must be known at the time of initial entry on the SmartForm.</p>	<p><i>When saving without entry:</i></p> <div data-bbox="1018 451 1976 581" style="border: 1px solid black; padding: 5px;"> <p>7. * Will an external IRB act as the IRB of record for this study?</p> <p><input type="radio"/> Yes <input type="radio"/> No Clear</p> <p>You must select whether an external IRB is the IRB of record for this study or not.</p> <p>i Once this selection is saved, it cannot be changed.</p> <div data-bbox="1780 467 1961 570" style="border: 1px solid red; padding: 2px; color: red; font-size: small;"> Error message shows only when attempting to save without making a selection. </div> </div> <p><i>After entry:</i></p> <div data-bbox="1018 656 1766 764" style="border: 1px solid black; padding: 5px;"> <p>7. * Will an external IRB act as the IRB of record for this study?</p> <p><input type="radio"/> Yes <input checked="" type="radio"/> No Clear</p> <p>i Once this selection is saved, it cannot be changed.</p> </div>				
<p>Local Site Documents</p> <p>1. The last space to attach supporting documents is hard to find without a number.</p> <p>2. Remove Cede Review Request Form suggested attachment from the SmartForm.</p>	<p>1. Due to some configuration limitations, a number cannot be added. However, the page format has been slightly revised with clear-er indenting of reference materials, to support increasing visibility of the last document upload space.</p> <p>2. This is only a change on site submissions, where Harvard relies on the review of another IRB (External IRB). Since this form is being considered for retirement, the Cede Review Request Form is now only available in the IRB Library.</p>	<div data-bbox="1018 808 1640 1096" style="border: 1px solid black; padding: 5px;"> <p>Documents used by Harvard researchers.</p> <p>1. Consent, Assent, Permission, and HIPAA Authorization</p> <p>+ Add</p> <table border="1" data-bbox="1155 933 1640 1006"> <thead> <tr> <th>Document</th> <th>Cate</th> </tr> </thead> <tbody> <tr> <td>Update PDM Verbal Consent (0.01)</td> <td>Cons</td> </tr> </tbody> </table> <p>Indented → i Refer to the following templates, associated with the appropriate</p> <p>HMS, HSDM, and HSPH (Studies in Longwood Medical Area on</p> </div> <div data-bbox="1018 1136 1453 1289" style="border: 1px solid black; padding: 5px;"> <p>i Suggested Submission Attachments for this Site (if not all)</p> <ul style="list-style-type: none"> ▪ Completed SmartIRB Cede Request Application ▪ IRB Authorization Agreement (IAA) ▪ Data use agreements or other Agreements ▪ Financial Interest Disclosure Form ▪ Funding Source Attachments </div>	Document	Cate	Update PDM Verbal Consent (0.01)	Cons
Document	Cate					
Update PDM Verbal Consent (0.01)	Cons					

What has changed...	What it means...	How it looks (as applicable)...
<p>Continuing Review/ Closure</p> <p>Question 3 now has information about positive disclosure-related requirements with a link to the supplemental form.</p>	<p>Rather than capturing any required financial conflict of interest information during review, and after a positive disclosure is indicated, the instructions and form are visible during SmartForm completion.</p>	
Activities (visible to only to IRB Staff and Committee Members)		
<p>Move to Approved</p> <p>The activity previously for use when a study is terminated or suspended can now be used for when a study lapses in error.</p>	<p>Only for Approved projects where a transition to “Lapsed” occurred in error (due to an incorrectly entered expiration date), the Move to Approved activity will transition the study back to the Approved state for further correction of the expiration date or associated determinations. Note when using this activity:</p> <ol style="list-style-type: none"> 1. This can only be used for studies that were previously approved (not for studies that were in any other state, like Not Human Research, for example). 2. Immediately after completing this activity, the expiration date must be changed (or removed, as appropriate) or the study will transition back to lapsed again at midnight. 	
Determination Letter		

What has changed...	What it means...	How it looks (as applicable)...
Approval letter now displays study team documents.	For approval letters where the study team documents must be referenced (ordinarily included on determination letters issued by the Longwood Medical Area), documents attached to the Study Team Members page will appear on the letter draft for further edit (inclusion or exclusion) as needed, when drafting the final letter.	
Reports		
<ol style="list-style-type: none"> 1. New: All Submissions with Letters 2. Revised: Studies with Funding 	<ol style="list-style-type: none"> 1. A new report is available at Reports>Custom Reports which shows select information for all submissions along with a link to the determination letter. For individuals who are seeking only determination letters, this reduces some navigation. 2. The studies with funding report has been revised to exclude “funding type”. It was found that this value is not always accurate and until the bug is fixed, it has been removed so that it does not cause confusion. 	
Workspace		
<p>pSite Participating site (when Harvard may serve as the IRB of record) workspace now shows Harvard-configured information on the Funding Sources and Study Team Tabs.</p>	This corrects an issue where configurations were inconsistently displaying, depending on the site submission state.	
<p>Institutional Profiles FWA added to the list.</p>	The Institutional Profiles page (for IRB staff only) now shows FWA as part of the listed information.	
Technical Update		
<p>Log In For inactive profiles, in addition to an error, provide instructions when log in fails.</p>	Individuals with an inactive HUID would receive a confusing error when attempting to log in. The error is revised to include instructions for reactivating an HUID or taking steps to contact the appropriate IRB office.	

What has changed...	What it means...	How it looks (as applicable)...
		 <p>The screenshot shows the Harvard Human Research Protection Program (HRPP) website. At the top, there is the Harvard logo and the text "HARVARD Human Research Protection Program ESTR". Below this, a red message states: "It appears that your log in credentials are no longer active." This is followed by instructions: "To address this issue, you can take any of the following steps, based on your affiliation status at Harvard:" and a bulleted list: <ul style="list-style-type: none"> For continued access to ESTR: Request reactivation of your HUID and HarvardKey. If you are unsure about retaining access to ESTR: Contact your IRB office to determine what next steps are required for timely review by the IRB: <ul style="list-style-type: none"> Harvard University Area IRB Harvard Longwood Medical Area IRB Below the list, it says: "If you have any additional questions, please contact estrhlp@harvard.edu for more information." At the bottom of the screenshot, there is a light blue box containing a technical error message: "com.webridge.layout.GroupLayoutImpl.render(): caught 'System.Runtime.InteropServices.COMException: System.Runtime.InteropServices.COMException (0x800A138F): 'template.usePermissions' is null or not an object at GET: /stane/sd/Rooms/DisplayPages/LayoutInitial.rendering.svmlink/SSI".</p>

Release 1.23.1 Summary of HRPP Toolkit-ESTR Revisions

List of items updated (or expected to be updated) since the January 2018 update (1.23.0.1) or with this release. Note that the HRPP Toolkit page on the wiki for IRB Staff only has been significantly revised to include all current Toolkit items for reference.

Document Name	Type	Changes Summary
HRP-301-WORKSHEET-HLMA Review Materials.docx	Worksheet	File name change
HRP-301-WORKSHEET-HUA Review Materials.docx	Worksheet	File name change
HRP-312-WORKSHEET-Exemption.docx	Worksheet	File name change
HRP-318-WORKSHEET-Additional Federal Agency Criteria.docx	Worksheet	Minor content revision

Document Name	Type	Changes Summary
HRP-335-WORKSHEET-Provost Review.docx	Worksheet	Minor content revision
HRP-503-HLMA Research Protocol.docx	Template	Minor content revision
HUA Adult Consent Form Template.docx	Template	File name change, footer update
HUA Child Assent Form Template.docx	Template	File name change, footer update
HUA Exempt Human Research Consent Script Template.docx	Template	File name change, footer update
HUA IAA Template.docx	Template	File name change, footer update
HUA Parental or Guardian Permission Template.docx	Template	File name change, footer update
HUA Protocol Template.docx	Template	File name change, footer update
HUA Short Form Consent Template.docx	Template	File name change, footer update
HRP-501a-Meeting_Minutes.doc	Letter	File name change, footer update
HRP-501b-HLMA_Chair_Agenda.doc	Letter	File name change, footer update
HRP-501-Meeting_Agenda.doc	Letter	File name change, footer update
HRP-510a-Approval_CR.doc	Letter	File name change, footer update
HRP-510-Approval_Initial.doc	Letter	File name change, footer update
HRP-510b-Approval_MOD_All_Types.doc	Letter	File name change, footer update
HRP-510c-Exempt_Initial.doc	Letter	File name change, footer update
HRP-510d-Exempt_MOD_All_Types.doc	Letter	File name change, footer update

Document Name	Type	Changes Summary
HRP-511-Closure.doc	Letter	File name change, footer update
HRP-512a-Mods_Required_for_NHSR.doc	Letter	File name change, footer update
HRP-512-Mods_Required_for_Approval.doc	Letter	File name change, footer update
HRP-513a-NHSR_MOD_All_Types.doc	Letter	File name change, footer update
HRP-513-NHSR_Initial.doc	Letter	File name change, footer update
HRP-515-Suspension_or_Termination.doc	Letter	File name change, footer update
HRP-516-Deferral.doc	Letter	File name change, footer update
HRP-517-Disapproval.doc	Letter	File name change, footer update
HRP-519-Information_Item.docx	Letter	File name change, footer update
HRP-520-External_Report.docx	Letter	File name change, footer update
HRP-521-Significant_Risk_Device_Determination.doc	Letter	File name change, footer update
HRP-522-Certification_of_Approval_of_Prisoner_Research.doc	Letter	File name change, footer update
HRP-523-Review_of_Not_Otherwise_Approvable_Research.doc	Letter	File name change, footer update
HRP-526a-Mods_Required_for_Not_Engaged.doc	Letter	File name change, footer update
HRP-526-Not_Engaged_Initial.doc	Letter	File name change, footer update
HRP-528-NIH_GDS_Institutional_Certification.docx	Letter	File name change, footer update
HRP-545-Use_of_Human_Fetal_Tissue_and_MGL12J.docx	Letter	File name change, footer update

Document Name	Type	Changes Summary
HRP-546-46.118_Determination.docx	Letter	File name change, footer update
HRP-547-NSF_46.118_Determination.docx	Letter	File name change, footer update
HRP-857a-pSite_Review.doc	Letter	File name change, footer update
HRP-857-External_IRB.doc	Letter	File name change, footer update
HRP-859-External_IRB_Update_Acknowledge.doc	Letter	File name change, footer update
HRP-202-FORM-HLMA IRB Member Information.docx	Form	File name change
HRP-202-FORM-HUA IRB Member Information.docx	Form	File name change
HRP-213-FORM-Not Human Subjects Research Request Determination Form.docx	Form	Minor content revision
HRP-226-FORM-HLMA PI Exception Request Form.doc	Form	File name change