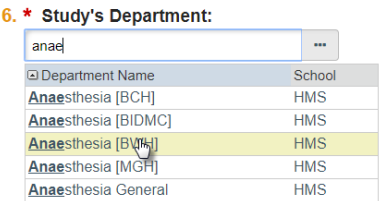
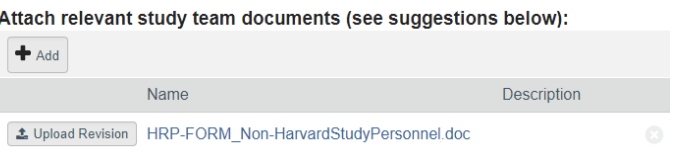
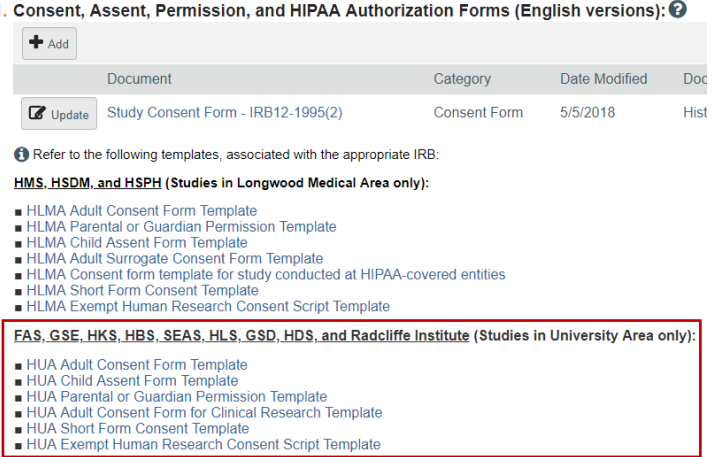


ESTR 1.23.2 Configuration Release Items: May 24, 2018

This release includes a few Harvard configuration updates.

What has changed...	What it means...	How it looks (as applicable)...
SmartForm Pages		
<p>Basic Information</p> <p>Responsible departments have been updated to (a) revise the name of the Graduate School of Design department, Critical Conservation and (b) update 59 Harvard Medical School affiliate hospital departments.</p>	<p>There are additional options available when selecting a study's responsible department at question 6 on the Basic Information page of the SmartForm.</p>	
<p>Study Team Members</p> <p>The document attachment prompt on the study team members page has been updated to clarify that the space is only for relevant study team documents.</p>	<p>The prompt has changed from “<i>Attach relevant documents (see suggestions below):</i>” to “<i>Attach relevant study team documents (see suggestions below):</i>”</p>	
<p>Local Site and Study Documents</p> <p>Revised HUA consent form templates have been added to the list of reference documents.</p>	<p>Additional reference templates are available on the SmartForm pages and in the IRB Library.</p>	

What has changed...	What it means...	How it looks (as applicable)...
Reports		
1. Created External IRB Monitoring Report(s) 2. Removed out of use CUHS reports	1. A new report is available at Reports>Custom Reports which shows select information for all External IRB submissions is now available to IRB staff members, to assist with monitoring studies where Harvard relies on another IRB review. 2. The following IRB staff reports at Reports>Custom reports have been removed from the list: CUHS Expedited Actions Report, CUHS Unassigned Submissions HUA FAS, and CUHS Unassigned Submissions HUA Graduate Schools.	
Workspace		
In Box Added site submissions to display in the InBox/Personal Page when action is required.	This corrects an issue where assigned site submissions were not displaying on the InBox list.	

Release 1.23.2 Summary of HRPP Toolkit-ESTR Revisions

List of HRPP toolkit items in ESTR updated (or expected to be updated) since the April 2018 update (1.23.1) or with this release.

Document Name	Type	Changes Summary
HUA Adult Consent Form Template.docx	Template	Content updates policy and GDPR
HUA Child Assent Form Template.docx	Template	Content updates policy and GDPR
HUA Parental or Guardian Permission Template.docx	Template	Content updates policy and GDPR
HUA Exempt Human Research Consent Script Template.docx	Template	Content updates policy and GDPR
HLMA Adult Consent Form Template.doc	Template	Content updates policy and GDPR

Document Name	Type	Changes Summary
HLMA Adult Surrogate Consent Form Template.doc	Template	Content updates policy and GDPR
HLMA Child Assent Form Template.doc	Template	Content updates policy and GDPR
HLMA Consent Template for HIPAA-covered entities.doc	Template	Content updates policy and GDPR
HLMA Exempt Human Research Consent Script Template.doc	Template	Content updates policy and GDPR
HLMA Parental or Guardian Permission Template.doc	Template	Content updates policy and GDPR
GDPR Notification for Participants.docx	Template	New shared GDPR resource. For this release, will be in the ESTR Library for use by both offices, but will be listed on the SmartForm under HUA materials.
HLMA Protocol Template.docx	Template	Updated questions for policy revision
HUA Investigator Manual.pdf	Other	Revised content
HLMA Investigator Manual.pdf	Other	Revised content
HRP-416-CHECKLIST-Children.docx	Checklist	Content update for clarity
HRP-411-CHECKLIST-Waiver of Written Documentation of Consent.docx	Checklist	Content update for clarity and removed reference to newborn blood spot
HRP-410-CHECKLIST-Waiver or Alteration of Consent Process.docx	Checklist	Content update for clarity
HRP-510a-Approval_CR.doc	Letter	Updated DOD contact
HRP-510-Approval_Initial.doc	Letter	Updated DOD contact
HRP-510b-Approval_MOD_All_Types.doc	Letter	Updated DOD contact
HRP-510c-Exempt_Initial.doc	Letter	Updated DOD contact

Document Name	Type	Changes Summary
HRP-510d-Exempt_MOD_All_Types.doc	Letter	Updated DOD contact
HRP-511-Closure.doc	Letter	Updated DOD contact
HRP-513a-NHSR_MOD_All_Types.doc	Letter	Updated DOD contact
HRP-513-NHSR_Initial.doc	Letter	Updated DOD contact
HRP-515-Suspension_or_Termination.doc	Letter	Updated DOD contact
HRP-517-Disapproval.doc	Letter	Updated DOD contact
HRP-520-External_Report.docx	Letter	Updated DOD contact
HRP-522-Certification_of_Approval_of_Prisoner_Research.doc	Letter	Updated DOD contact
HRP-523-Review_of_Not_Otherwise_Approvable_Research.doc	Letter	Updated DOD contact
HRP-528-NIH_GDS_Institutional_Certification.docx	Letter	Move to only available on IRB staff wiki
HRP-545-Use_of_Human_Fetal_Tissue_and_MGL12J.docx	Letter	Updated DOD contact