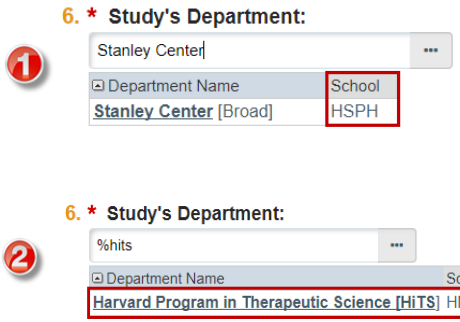
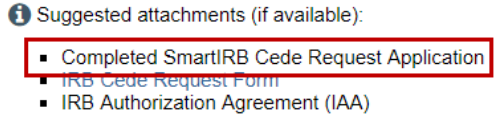
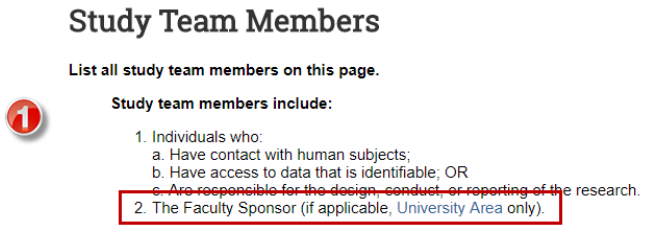
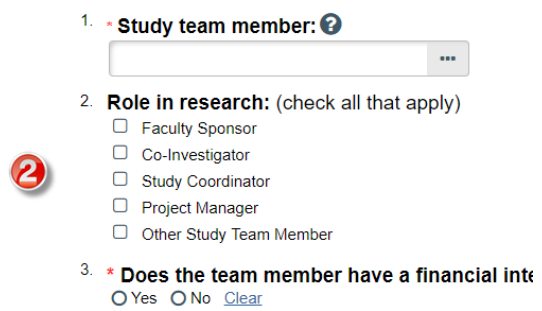
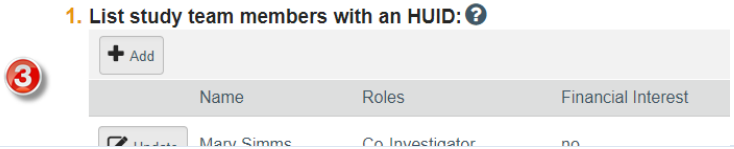
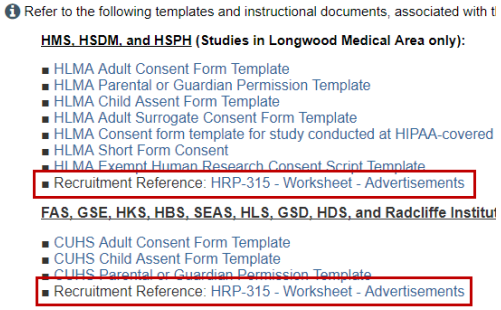
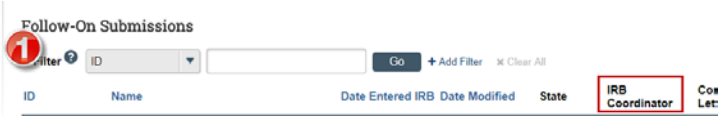
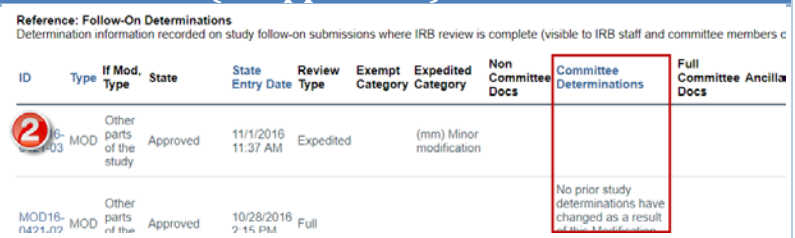
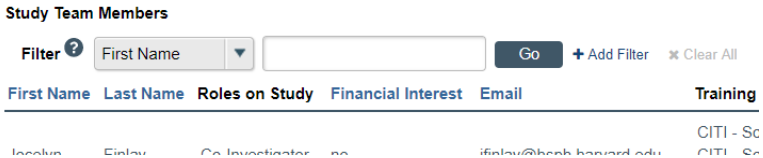
ESTR 1.22.2 Configuration Release Items: August 31 2017

This release includes minor fixes and instruction revisions, along with revisions to documents linked in the system.

What has changed…	What it means…	How it looks (as applicable)…
SmartForm Pages		
Basic Information *Responsible Department Changes* 1. Stanley Center is now associated with HSPH (rather than HMS) 2. Harvard Program in Therapeutic Science (HiTS) is an additional department at HMS	1. Submissions associated with the Stanley Center will be routed for review by the HSPH IRB. 2. Submissions can now be associated with HiTS.	
External IRB Change Catalyst Form reference to SmartIRB	The Catalyst system for reliance has been retired and the current system, SmartIRB, is referenced.	
Study Team Members 1. Change instructions to read: *Faculty Sponsor (if applicable, University-Area only)*	1. There is change in policy. However, the parenthetical reference to University Area clarifies IRB-specific requirements.	

What has changed…	What it means…	How it looks (as applicable)…
2. Hide involved in consent question	2. Based on current training and team requirements, this question is not relevant to the review.	
3. Hide involved in consent column	3. Since the question is no longer asked, the column is hidden from view on the Study Team page table.	
Consent/Recruitment Add reference to advertisement worksheet	The additional reference is available to provide easy access to recruitment/ advertisement requirements.	
Workspace		
Active and Archived Main Study 1. Follow On Submissions Tab: Fix spelling of “IRB Coordinator”	1. N/A	

What has changed…	What it means…	How it looks (as applicable)…
2. Reviews Tab: Add Committee Determinations Column to Reviews Tab Reference List	2. For submissions where information is written into space "8. Determinations and findings that require documentation" on the Submit Committee Review activity, text will be visible on the main study reviews tab for reference. This space is ordinarily used for committee determinations that require documentation in the minutes but have no other space in ESTR (such as a determination that the next continuing review may be completed on an Expedited basis or a device risk determination). Note that the table size expands with this additional at-a-glance information.	
Main Study and Follow-On Project Contacts tab: hide the 'involved in consent column'	The question is no longer visible to those completing the form, so the column is no longer necessary. For follow on submissions where review is complete, the column will still appear (as a 'read only' snapshot) and values are null where no response was provided.	
Activities		
Add Public/Private Comment On notice, remove the "To" line in the body of the email	The "To" line is removed so that it is clearer to all recipients that no individual person was targeted as a recipient of the email. Action related to these notices should continue according to office practice (such as, the IRB contact that ordinarily works with a particular study is responsible for follow-up on these general notices).	

What has changed…	What it means…	How it looks (as applicable)…
Track Harvard Determinations In the Harvard Special Determinations section, hide "genomic data sharing" from the list	The option to select "genomic data sharing" on has been removed. This change has no impact on the necessary completion of worksheets HRP-333 and HRP-332. If "genomic data sharing" was previously selected, it will still appear on the activity and in reports.	
Prepare Letter Fix bug where one cannot Prepare Letter when there are no funding sources on the study	The system would occasionally block the creation of letters because of an issue with reading funding sources. This issue has been addressed and letters can be created without this error.	
Manage Ancillary Reviews Add to the approved state	Processes and policies related to ancillary review remain the same. However, the Manage Ancillary Reviews activity is now available to IRB staff after an approval letter is sent. The intended purpose of this change is to allow for IRB staff to update ancillary review status on the submission where it is indicated that a review is needed. Note that if an ancillary review is indicated as needed during the review of a modification or continuing review, to preserve the context and timing of the ancillary review, the documentation of review should be recorded on that submission (even though the Manage Ancillary Reviews activity is also available on the main study workspace).	
Determination Letters, and Meeting Agenda and Minutes		
1. Add two .118 template letters to approved determination state 2. Add Committee Determinations field to the approval letter 3. Add member status to the list that feeds in the minutes	1. When a .118 determination is made, a system generated template is available for use. 2. For submissions where information is written into space "8. Determinations and findings that require documentation" on the Submit Committee Review activity, text will be visible in the generated letter. 3. Additional baseline information is available in the minutes template for further editing when drafting meeting minutes.	

Release 1.22.2 Summary of HRPP Toolkit-ESTR Revisions

List of items updated in ESTR since the April 2017 release 1.22.1 or with this release.

Document Name	Type	Changes Summary
HRP-547-Harvard-NSF 46.118 Determination	Letter	**NEW!** This letter is now available when completing the 'prepare letter' activity. Select this letter only for .118 determinations on NSF projects.
HRP-546-Harvard-46.118 Determination	Letter	**NEW!** This letter is now available when completing the 'prepare letter' activity. Select this letter only for .118 determinations.
HRP-520-External Report	Letter	Updated VA reference
HRP-521-Significant Risk Device Determination	Letter	Updated VA reference
HRP-519-Information Item	Letter	Added IRB specific text for edit when drafting the letter
HRP-513a-Harvard-NHSR MOD Approval	Letter	Corrected header (so IRB information is displayed)
HRP-501-Meeting Agenda	Letter	Minor text revision
HRP-501b-LMA Chair Agenda	Letter	Reordered item display
HRP-501a-Meeting Minutes	Letter	Added reference tables with IRB member details, for further edit when drafting the minutes
HRP-333-WORKSHEET-Genetic Resources	Worksheet	ESTR system document ID change. This has no impact on the content and version of the document.
HRP-332-WORKSHEET-NIH GDS Institutional Certification	Worksheet	ESTR system document ID change. This has no impact on the content and version of the document.
HRP-225-FORM-Individual Investigator Agreement	Form	Updated addresses
HRP-224-FORM-IRB Cede Request	Form	Change Catalyst reference to SmartIRB
HRP-220-FORM-Non-Harvard Study Personnel	Form	Add column regarding institutional affiliation, removed "involved in consent" checkboxes
HRP-213-FORM-Not Human Subjects Research Request Determination Form	Form	Corrected text/field options
HLMA Research Protocol	Template	Team revision and accreditation-related updates

Document Name	Type	Changes Summary
HLMA Parental or Guardian Permission Template	Template	Accreditation-related updates
HLMA Consent Template for HIPAA-covered entities	Template	Accreditation-related updates
HLMA Adult Surrogate Consent Form Template	Template	Accreditation-related updates
HLMA Adult Consent Form Template	Template	Accreditation-related updates
CUHS Parental or Guardian Permission Template	Template	Updated addresses
CUHS Adult Consent Form Template	Template	Updated addresses