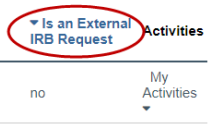

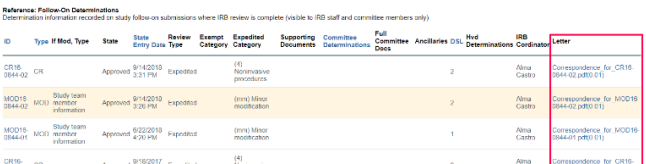


# ESTR 1.24.1 Configuration Release Items: September 2019

A summary of Harvard updates.

What has changed...	What it means...	How it looks (as applicable)...
<b>Workspaces</b>		
<b>All Submissions Page</b>		
<p>1. Added sites to the Unassigned and External IRB tabs</p> <p><b>Unassigned Tab</b></p> <p>2. Added a column to indicate which initial submission are requests for “External IRB” review</p> <p>3. Added the “Assign Coordinator” activity to the Unassigned tab</p>	<p>1. You will no longer have to navigate to the All Submissions tab to view site</p> <p>2. To facilitate easier submission assignment, the column “Is an External IRB Request” denotes if an initial submission is intended to request review by another IRB</p> <p>3. You may now assign an IRB coordinator directly from the list of projects</p>	<p>1. <i>No image</i></p> <p>2.</p>  <p>3.</p> 
<b>Study Workspace</b>		
<p>1. Removed “Harvard Committee Review Summary” from the Reviews tab</p> <p>2. Added a link to follow-on submission determination letters on the “Reviews” tab of the main protocol workspace</p>	<p>1. The “Committee Review Summary” was a legacy section of text that is now replicated by this historical view of previous review activities. This extra custom representation was removed.</p> <p>2. Follow on approval letters will appear on a single list with the determinations</p>	<p>1.</p> <p>Meeting date and start time:</p> <p><del>Committee Review Summary</del></p> <p>Date effective: 9/19/2019</p> <p>Risk level:</p> <p>Determinations and findings:</p> <p>2.</p> 

3. Validate that Study Update workspace has link to parent at the top	3. Allows for easy access to main study workspace from the follow-on submission workspace	3. <a href="#">↑ IRB16-0844 CTG vs allograft Study</a> <b>MOD16-0844-02: Modification</b>
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**SmartForm**

<p>1. Added HLC Repository Protocol to the SmartForm</p> <p>2. Added RNI Guidance link on the RNI SmartForm</p>	<p>1. Longwood study teams can now access the Repository Protocol Template from the first page of the SmartForm</p> <p>2. Study teams now have quick access to the ESTR Support Site for guidance on using ESTR and completing the SmartForm</p>	<p>1.</p> <p>📌 Refer to the following templates, associated with the appropriate IRB:</p> <p><b>HMS, HSDM, and HSPH (Studies in Longwood Area only):</b></p> <ul style="list-style-type: none"> <li>■ For all Exempt and Non-Exempt human research applications: <a href="#">HLMA Template Research Protocol</a></li> <li>■ For requests for non-human research: <a href="#">Not Human Subjects Research Request Determination Form</a></li> <li>■ For applications involving the implementation and management of a repository: <a href="#">HLC Repository Protocol Template</a></li> </ul> <p>2.</p> <p><b>Reportable New Information</b></p> <p>The purpose of this form is to provide required information to the IRB that does not qualify as a continuing review of the IRB, visit the IRB website:</p> <ul style="list-style-type: none"> <li>■ HMS, HSDM, and HSPH (studies in the Longwood Area)</li> <li>■ FAS, GSE, HKS, HBS, SEAS, HLS, GSD, HDS, and Radcliffe Institute (Studies in University Area only)</li> </ul> <p><a href="#">Also visit the ESTR Support Site for guidance on using this system and completing this form.</a></p>
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**Notifications**

<p>1. Administrative closure on External IRB projects should send a notification</p> <p>2. Confirmed correction of system lapse for Not-Human Subjects</p>	<p>1. Harvard Principal Investigator (PI), sIRB PI, PI proxies, and primary contacts receive a confirmation upon closure of projects where Harvard relies on an External IRB</p> <p>2. The system will not transition projects with a Not Human Subjects Research determination to the Lapsed state</p>	
<p>3. Notification for External IRB approaching expiry and review anniversary</p> <p>4. Anniversary date notice revised to clarify that continuing review is not required</p>	<p>3. The system will send periodic notices of approaching expiry or approval anniversary date where Harvard relies on the review of an External IRB</p> <p>4. Text added to clarify when continuing review is not required.</p>	

**HRPP Documents**

1. Create a “Not Engaged” modification letter	1. The “Human Research, Not Engaged” determination letter is now available for follow-on submissions when generating a letter from a template
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2. Fixed: Modification letter should not show current and previous notes	2. When generating a letter using the modification template, only the current notes will display for further edit by the IRB contact
<b>Activity</b>	
Track Harvard Determinations: Removed “HLMA” designation from the Exception PI flag to allow for combined use	All IRB offices may use the “Track Harvard Determinations” activity to indicate the IRB has granted an exception to PI requirements
<b>Reports (Custom Reports Tab)</b>	
1. Added External IRB Studies Monitoring Report	1. This report provides an at-a-glance summary of information about active and in-review external IRB studies. Available to IRB staff only.
2. Added a “Regulatory Authority” column to the Active Studies and All Submissions reports	2. “Regulatory Authority” is now viewable at a glance from the Active Studies and All Submissions reports
3. Added the Comments in the Last 14 Days – Inactive Coordinators Only report	3. This report was added temporarily and the inclusion is now confirmed on the list of reports. Available to IRB staff only.
4. Updated the Restricted PI List by Study	4. Removed additional persons listed in error and removed the redundant “IRB Restricted” column from the Restricted PI List by Study report
<b>Other</b>	
Updated all LMA IRB webpage references	1. The previous website site associated with the Office of Human Research Administration (OHRA) will be sunset, and referenced by the Office of Regulatory Affairs and Research Compliance (ORARC). All links should now be updated to reference the new Harvard Longwood Campus (HLC) webpage under ORARC rather than the previous Longwood Medical Area (LMA) OHRA site.

## Release 1.24.1 Summary of HRPP Toolkit-ESTR Revisions

With release notes, a list of items updated in ESTR since the last release (1.24.0) is ordinarily included here. However, with completion of the annual HRPP portfolio review and the change to the Longwood Campus IRB office, near-every HRPP document has been updated since the last upgrade. Please reference the IRB staff internal wiki or IRB Library in ESTR to access updated items.