

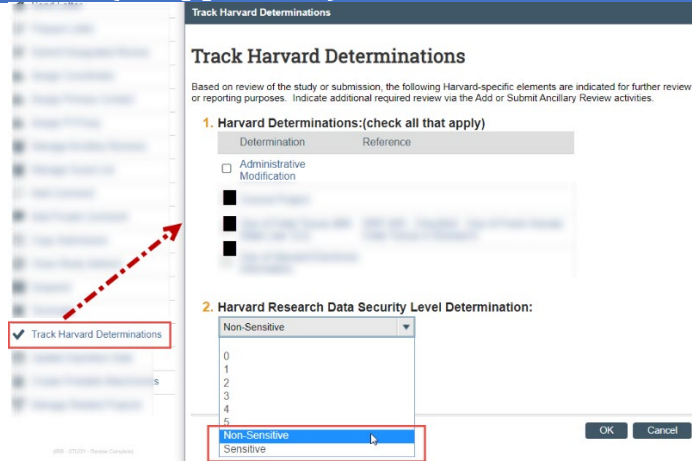
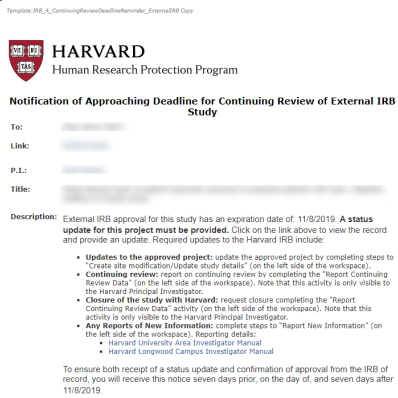
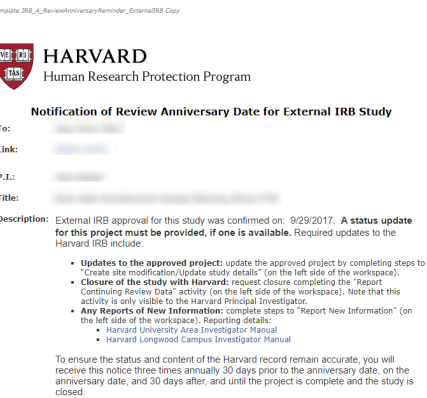
# ESTR 1.24.2 Configuration Release Items: December 2019

As part of the December release, a new Data Safety and Security application will be made available in our increasingly integrated system. As part of this new application, ESTR will have new functionality to:

1. Establish and display relationships between studies and submissions in ESTR-IRB, Agreements-DUA, and the Data Safety systems. A relationship defined on one project will show on both workspaces where the relationship has been identified; and
2. Allow for additional methods for determining data security level on a submission.

The following release notes describe these changes relative to the component areas of the system.

What has changed...	What it means...	How it looks (as applicable)...
<b>Workspaces</b>		
<b>All Submissions Workspace</b>		
My Work List (visible to IRB staff only) and In-Review Tab (visible to everyone) column updates	Tab contents were previously in different order between tabs. Now navigating between tabs can provide an easier to read and compare listing of submission status.	
<b>Study Workspace</b>		
<b>New!</b> Additional tab for “Related Projects” Display	A new tab will appear with linked submissions when the Manage Related Projects activity is completed either: a) on this study to other studies or b) on another submission to this submission	
<b>Activity</b>		
<b>New!</b> Manage Related Projects: available on main study workspaces.	New activity allows for connecting ESTR-IRB, Agreements-DUA, and Data Safety submissions with one another. IRB and study staff can complete this activity.	

What has changed...	What it means...	How it looks (as applicable)...	
<p>Track Harvard Determinations: Updated selection options under Data Security Level.</p>	<p>In preparation for any Research Data Security Policy-based process revision, selection options have expanded from 1-5 to also include a “sensitive” or “non-sensitive” determination. With this change:</p> <ul style="list-style-type: none"> <li>Any ancillary assignment reference materials will be updated. However, in general; for any projects involving sensitive data, IRB staff can assign ancillary review to the school security officer, as needed.</li> <li>Reports and display areas will continue to show the selected option.</li> </ul>		
<h3>Notifications</h3>			
<p>Updated contents of External IRB renewal and update reminder notices.</p>	<p>Notification text for both the reliance anniversary reminder and reliance expiration reminder have been updated with clarified instruction.</p>		
<h3>HRPP Documents</h3>			
<p>Added HRP-108 to the IRB Library</p>	<p>HRP-108-SOP-HLC QIP Referral from IRB is now visible in the IRB Library under the Standard Operating Procedures tab.</p>		
<h3>Reports (Custom Reports Tab)</h3>			
<ol style="list-style-type: none"> <li>Studies involving GDPR</li> <li>External IRB Studies Lapse and Anniversary</li> </ol>	<ol style="list-style-type: none"> <li>Added report of all studies marked on pre-review as involving GDPR data or involving a research location in a country covered by GDPR. The compliance date for GDPR is May 25 2018.</li> <li>Added report of all studies reviewed by an External IRB, where the expiry date passed or the approval anniversary date is over 3 years passed</li> </ol>		
<h3>Other</h3>			
<p>Department Name Updates</p>	<p>The following department names are changed:</p> <ul style="list-style-type: none"> <li>Diversity and Community Partnership changed to Diversity Inclusion and Community Partnership</li> <li>Department of Genetics and Complex Diseases changed to Department of Molecular Metabolism</li> </ul>		