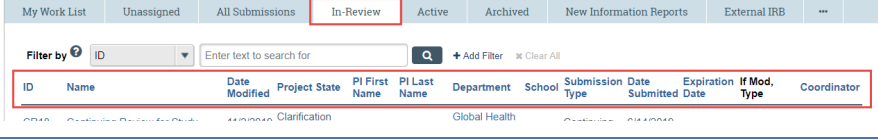
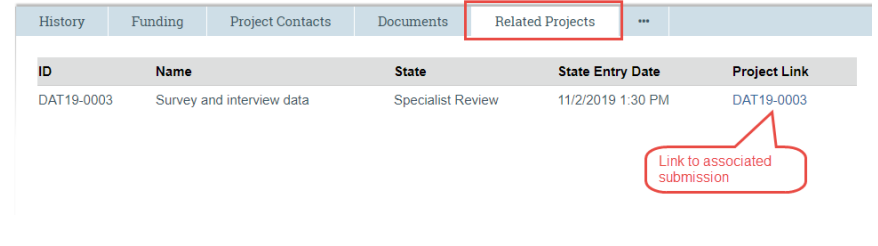
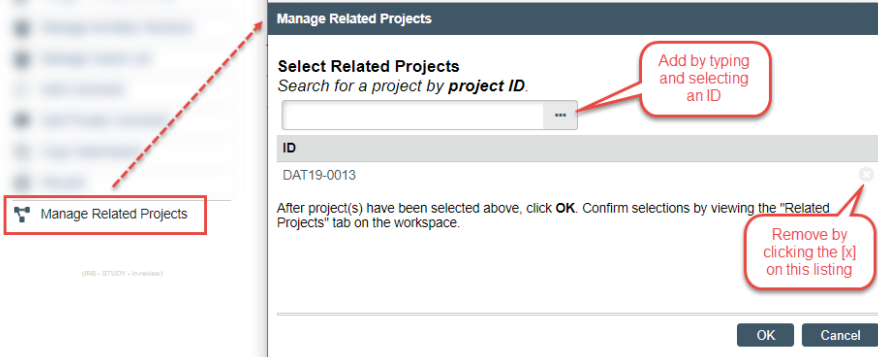


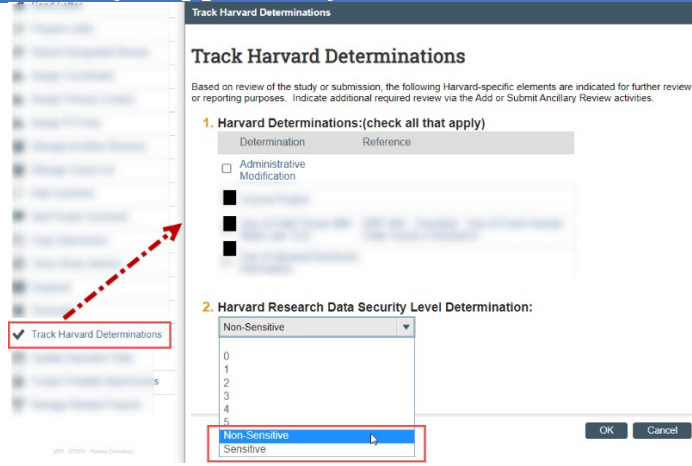
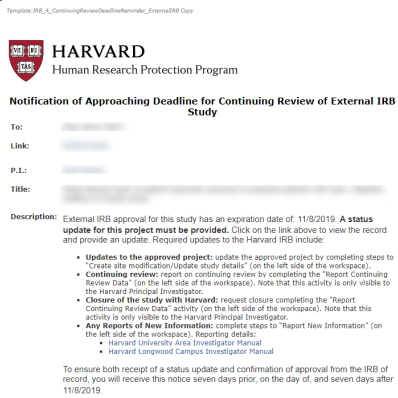
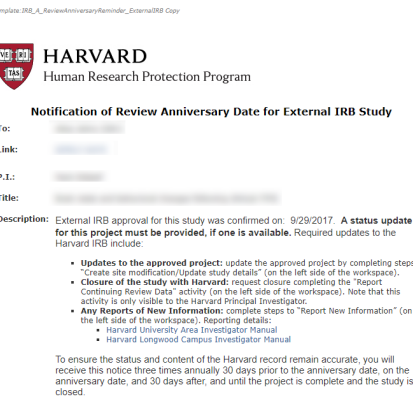
# ESTR 1.24.2 Configuration Release Items: December 2019

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>		
<p>My Work List (visible to IRB staff only) and In-Review Tab (visible to everyone) column updates</p>	<p>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.</p>	
<b>Study Workspace</b>		
<p><b>New!</b> Additional tab for “Related Projects” Display</p>	<p>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</p>	
<b>Activity</b>		
<p><b>New!</b> Manage Related Projects: available on main study workspaces.</p>	<p>New activity allows for connecting ESTR-IRB, Agreements-DUA, and Data Safety submissions with one another. IRB and study staff can complete this activity.</p>	

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>		