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)...
<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>Workspaces</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>My Work List (visible to IRB staff only) and In-Review Tab (visible to everyone) column updates</td>
<td>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.</td>
<td><img src="image1" alt="Workspaces example" /></td>
</tr>
<tr>
<td><strong>Study Workspace</strong></td>
<td></td>
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<tr>
<td>New! Additional tab for “Related Projects” Display</td>
<td>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</td>
<td><img src="image2" alt="Study Workspace example" /></td>
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<tr>
<td><strong>Activity</strong></td>
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<tr>
<td>New! Manage Related Projects: available on main study workspaces.</td>
<td>New activity allows for connecting ESTR-IRB, Agreements-DUA, and Data Safety submissions with one another. IRB and study staff can complete this activity.</td>
<td><img src="image3" alt="Activity example" /></td>
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</tbody>
</table>
### What has changed...

**Track Harvard Determinations: Updated selection options under Data Security Level.**

**What it means...**

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:

- 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.
- Reports and display areas will continue to show the selected option.

### Notifications

Updated contents of External IRB renewal and update reminder notices.

**Notification text for both the reliance anniversary reminder and reliance expiration reminder have been updated with clarified instruction.**

### HRPP Documents

**Added HRP-108 to the IRB Library**

HRP-108-SOP-HLC QIP Referral from IRB is now visible in the IRB Library under the Standard Operating Procedures tab.

### Reports (Custom Reports Tab)

1. **Studies involving GDPR**
2. **External IRB Studies Lapse and Anniversary**

1. **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.**
2. **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**

### Other

**Department Name Updates**

The following department names are changed:

- Diversity and Community Partnership changed to Diversity Inclusion and Community Partnership
- Department of Genetics and Complex Diseases changed to Department of Molecular Metabolism