ESTR Release 1.22.0 Release Items: January 27 2017

With this release, Harvard is adding new configurations to the over 217 enhancements and bug fixes provided by the IRB application vendor. The following is a summary of key changes:

Site design and general navigation
Page views are enhanced to improve usability and simplify navigation.

- **My InBox (Dashboard) and All Submissions**
  - Additional information on the list of items that require attention (date submitted and mod type)
  - Top-bar navigation to InBox and all IRB submissions always visible, with secondary menu on some pages
  - Ability to Create a New Study from the InBox or Submissions pages
  - All submissions page load time improved
  - Easier line-item reading via whole-row highlighting when hovering with the mouse.

- **Submission Workspaces (webpages)**
  - Increased visibility of submission current state at-a-glance (at upper left text and image on-screen)
  - SmartForm Next Step and Activities highlighted more clearly via the left menu
  - Clarified options to Modify, or Continue or Close Study
  - Simplified activity and submission history visibility, with icon changes
  - Specialized workspaces for External IRB projects
• **SmartForms**

- Easy to read larger font and spacing of questions and form menu (at the top and bottom of the page)
- Some form questions have been simplified, with revised instructions on the Funding Sources page and expanded selection options for departments and countries
- To help clarify that an activity must be completed after the SmartForm is edited and closed, the last page of the SmartForm now indicates “Save & Exit”, rather than “Finish”
- On the Continuing Review SmartForm, the progress report summary is no longer required before submitting

• **Other General Navigation**

1. Breadcrumb: The navigation feature, displaying associated or previously viewed pages (referred to as the “breadcrumb bar”) is now hidden. Click on the double arrows on the left of the primary menu to view the breadcrumb bar.
2. Library: With checklists and worksheets, the IRB Library now includes all blank templates and forms for reference.
3. Log Out: The log out option appears at the upper-right of workspaces, by clicking on the drop-down arrow beside greeting, name.
4. Search Filters: All list search filters allow for managing multiple criteria using the “Add Filter” and “Clear All” options. Note that the percent symbol (%) is still a search “wildcard” allowing to search for parts of criteria.
5. Ellipses: Where three dots appear (ellipses), it means that more views are available. Click on the ellipses to view and select the additional items.
External IRB Submission and Process

Additional features are available to support the External IRB process, where the Harvard IRB relies on the review of another IRB.

- **The External IRB workspace and workflow includes three key new features:**
  1. Study teams can now complete an “Update Study” task which allows for closure or proposed changes to the originally ceded project.
  2. IRB Staff can prepare and send a decision letter with notification to the PI and Primary Contact.
  3. The Harvard IRB determination letter is available at a glance at the upper-right, along with name and letter for the External/Reviewing IRB.

- **Added space on the SmartForm to describe the rationale for the external IRB request**

- **External IRB SmartForm extended to allow for the inclusion of funding source**
Enhancements to review activities for IRB staff and Reviewers
Review activities updated to correct bugs and support better tracking.

- **Continuing Review determination letter lists Continuing Review SmartForm attachments**

- **Date Handling on Review Activities**
  - Follow-on effective date copies to the main study once a follow-on has been approved
  - The last day of approval will no longer block ability to complete review on a modification

- **Ability to record pediatric risk level on committee and non-committee reviews**
  Selection only appears when minors are marked as a participant group on the pre-review form.

- **Administrative Closure on a study automatically sends a notice to the PI/Proxy and Primary Contact**

- **Track Harvard Determination on follow-on submission shows initial determinations for reference**

- **IRB Staff can update Human Subjects Training and PI Restriction status on person profiles**
• Improved ancillary review assignment and tracking elements
  - A notice is sent to the assigned IRB Coordinator when the Submit Ancillary Approval activity is completed.
  - Person selection displays email address to assist with choosing the correct name