

## 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.

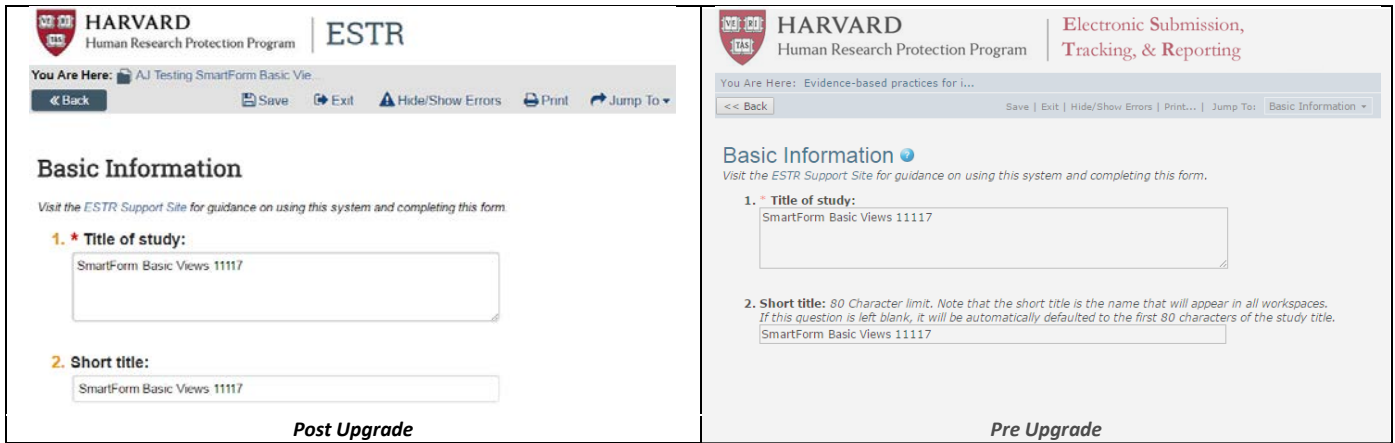
- **My InBox (Dashboard) and All Submissions**

- 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

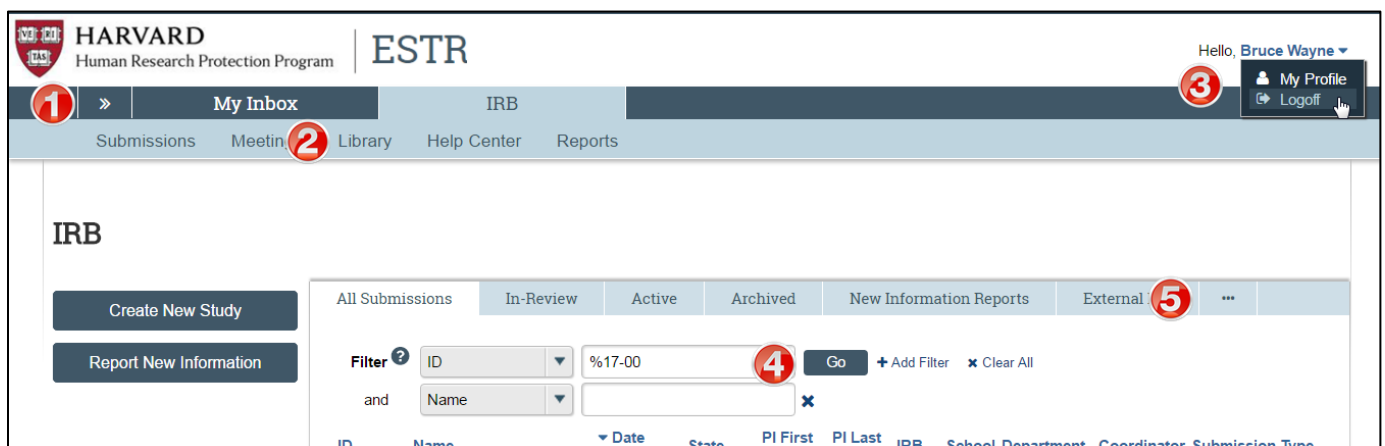
- **SmartForms**



- 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.

The screenshot shows the IRB16-1691 workspace for the study "Finding new worlds". It includes submission details, a workflow diagram, and an activity history table.

**Submission Details:**

- Entered local IRB: 10/17/2016 1:10 PM
- Locally confirmed: 10/28/2016
- Initial approval: 9/22/2016
- Approval end: 8/30/2019
- Last updated: 1/13/2017 3:38 PM
- Principal investigator: Jean-Luc Picard
- Submission type: Initial Study
- Primary contact: Tasha Yar
- IRB coordinator: William Riker
- IRB Office: HSPH
- Local IRB Acknowledgement Letter: Correspondence\_for\_IRB16-1691.pdf(3)
- External IRB: Massachusetts General Hospital
- External IRB Approval Letter: MGH Approval Letter (0.05)

**Next Steps:**

- View Study
- Printer Version
- View Differences
- Update Study (1)
- Report New Information

**Workflow Diagram:**

```

    graph LR
      A[Pre-Submission] --> B[Pre-Review]
      B --> C[Post-Review]
      C --> D[Review Complete]
      B --> E[Clarification Requested]
      E --> B
      C --> F[2]
  
```

**Activity History Table:**

Activity	Author	Activity Date
Letter Sent	Jahns (DEV), Alisa	1/13/2017 3:34 PM

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

The screenshot shows a SmartForm with the following fields:

- 5. Last date of approval period: 9/30/2019
- 6. \* Specify the reason the study should be reviewed by an external IRB: (Empty text area)

**Suggested attachments (if available):**

- Completed Catalyst Request Form
- IRB Code Request Form
- IRB Authorization Agreement (IAA)

- **External IRB SmartForm extended to allow for the inclusion of funding source**

The screenshot shows the "Funding Sources" section of the SmartForm. A dropdown menu is open, showing the following options:

- Basic Information
- External IRB
- Funding Sources (highlighted)
- Study Team Members
- Supporting Documents

**NOTE: If questions 1 and 2 are blank, it indicates to the IRB and confirms that there is no active or pending funding for this study.**

- Include any pending/awarded funding sources or financial support for this study.
- Reminder: If the funding status changes following IRB determination, submit a modification to this study.
- Visit the ESTR Support Site for [GMAS search tips](#)

## 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

5. Dates:

\* Approval date: 1/18/2017

Effective date: 1/18/2017

Last day of approval period: 6/13/2017

- **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.

3. Pediatric risk levels:

- 21 CFR §50.51/45 CFR §46.404: Not involving greater than minimal risk
- 21 CFR §50.52/45 CFR §46.405: Greater than minimal risk; prospect of direct benefit for individual subjects
- 21 CFR §50.53/45 CFR §46.406: Greater than minimal risk; no prospect of direct benefit but likely to yield generalizable knowledge
- 21 CFR §50.54/45 CFR §46.407: Not otherwise approvable

Complete and attach the following checklist: [HRP-416 - Checklist - Research Involving Children](#)

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

Close Study (Admin)

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

Track Harvard Determinations

### Track Harvard Determinations

Based on review of the study or submission, the following Harvard-specific elements are indicated for further review or reporting purposes. Indicate additional required review via the Add or Submit Ancillary Review activities.

Reference determinations made on the initial submission. Re-enter or update in the spaces provided below.

Initial Determinations: Initial Data Security Level: 2  
PI Exception for Non-Exempt

1. Harvard Determinations:(check all that apply)

Determination	Related Worksheet
<input type="checkbox"/> Course Project	
<input checked="" type="checkbox"/> FERPA	<a href="#">HRP-331 - Worksheet - FERPA Compliance</a>

- **IRB Staff can update Human Subjects Training and PI Restriction status on person profiles**

Fast Find

Find: Contacts

Organization: [text input]

Contact Last: [text input] simms

Contact First: [text input] r

Find Now

Contacts 1 - 1 of 1

Simms (pi), Rebecca

2. Default study team (IRB and Agreements):

+ Add

Name	Roles	Consent?	F1?
There are no items to display			

3. Training data (IRB):

+ Add

Document	Name	Current?	Training Complete Date	Training Expiration Date
	CITI Training		1/1/1999	1/1/2002

- **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

**1. \* Select either an organization or a person as reviewer:**

Organization:  ...

Person:  ...

Last Name	First Name	Email
Simms (pi)	Rebecca	testuser@clidcommerce.com

**2. Review type**