

ESTR Release 1.21.0 Release Items: June 9 2016

Submission Webpage (Workspace) Enhancements

- View of Data Security Level and Harvard Determinations**

IRB-identified data security level can be referenced on each submission under the “Reviews” tab.

There are no Ancillary Reviews to show at this time.

Harvard Tracked Determinations

Submission Data Security Level: 2

Submission Tracked Elements:
 Harvard Undergraduate Students
 Psychology Department Study Pool

- Dates now save correctly for Modifications Required to Secure Approval**

Fixed an issue where changing the Approval Date and/or Effective Date in the Review Required Modifications activity now saves correctly and appears on the submission workspace.

Approved

Entered IRB: 2/10/2016 12:48 PM
 Initial approval: 3/18/2016
 Effective: 5/2/2016
 Approval end: 3/17/2017
 Last updated: 5/2/2016 4:11 PM

IRB15-8938: Deer m

Principal investigator: Jonathan
 Submission type: Initial Study
 Primary contact: Emily
 IRB coordinator: Shannon

Pre-Submission → Pre-Review
 Clarification Requested

My Current Actions

Edit Study
 Printer Version
 View Differences
 Create Modification
 Create Continuing Review
 Create Study Closure
 Report New Information
 Assign Coordinator
 Submit Designated Review

History | Funding | Project Cont

Filter by Activity

Letter Sent
 Correspondence_for_IRB15-3938...
 Prepared Letter
 Finalized Documents
 Required Modifications

- Date added to Follow-on Submissions**

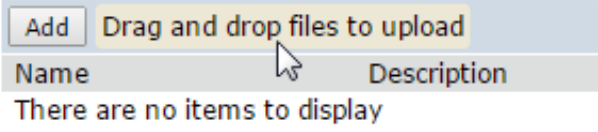
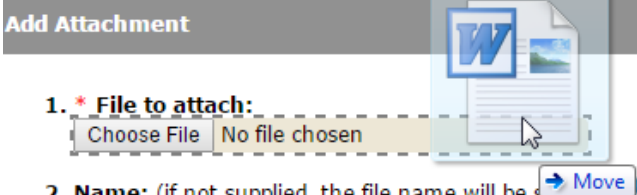
Date entered IRB is now visible as a column to further sort and filter the list of follow on submissions listed on a main-study workspace.

| ID | Name | Date Entered IRB | Date Modified | State |
|---------------|--|---------------------|--------------------|------------------------|
| MOD13-2794-21 | Modification #21 for Study IRB13-2794 | 3/8/2016 10:30 AM | 5/10/2016 12:00 AM | Modifications Required |
| MOD13-2794-20 | Modification #20 for Study IRB13-2794 | 3/1/2016 2:14 PM | 5/6/2016 12:00 AM | Modifications Required |
| MOD13-2794-19 | Modification #19 for Study IRB13-2794 | 2/16/2016 12:54 PM | 2/19/2016 9:04 AM | Approved |
| MOD13-2794-18 | Modification #18 for Study IRB13-2794 | 1/7/2016 3:15 PM | 1/11/2016 3:02 PM | Approved |
| CR13-2794-02 | Continuing Review for Study IRB13-2794 | 1/5/2016 2:49 PM | 1/28/2016 2:44 PM | Approved |
| MOD13-2794-17 | Modification #17 for Study IRB13-2794 | 10/26/2015 11:38 AM | 12/3/2015 3:05 PM | Approved |
| MOD13-2794-16 | Modification #16 for Study IRB13-2794 | 8/18/2015 12:00 AM | 10/19/2015 4:41 AM | Approved |

Online Form (SmartForm) Enhancements

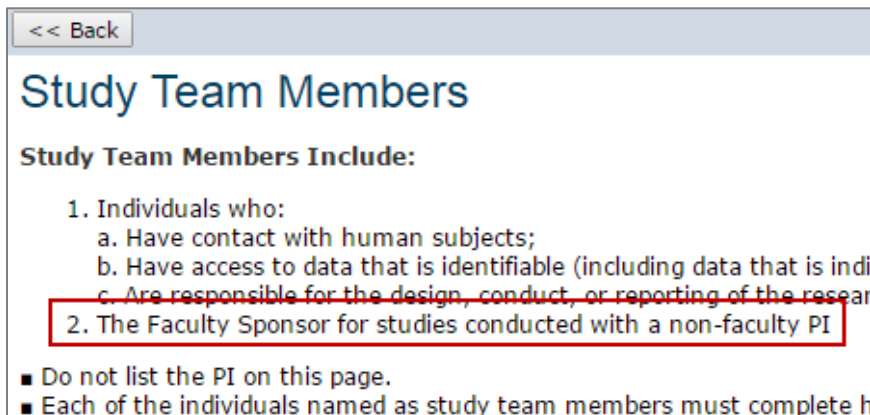
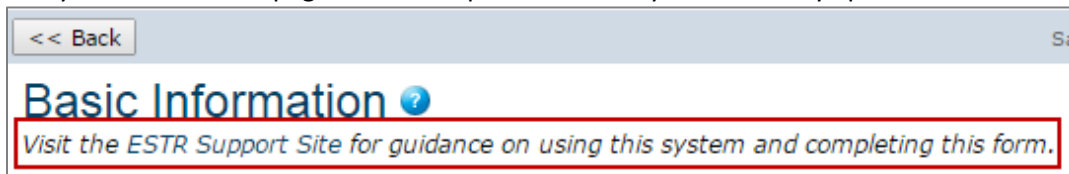
- Ability to drag and drop upload Documents**

Drag and drop file upload has been added to all document upload spaces. There are two types of drag and drop as shown and described below. *Please Note: 1. this feature is not supported in IE8 or IE9; and 2. drag and drop will accept the file name as the document name.*

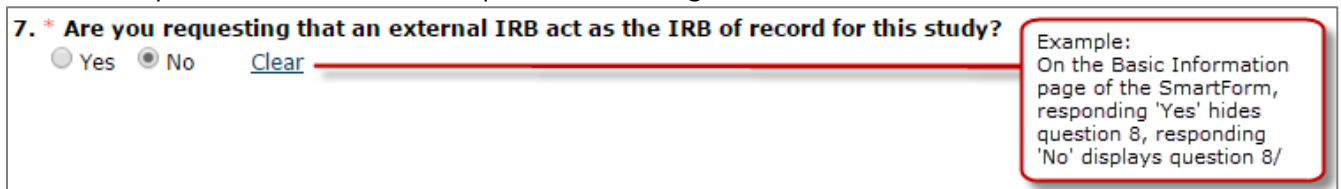
| Drag and Drop Document Sets | Drag and Drop Single Attachments |
|--|--|
| Mouse-over to identify if documents can be added from the main page. This does not work in every attachment space. | Drag in single attachments after clicking the “add” button. |
| <p>2. Supporting documents:</p>  |  |
| <p>Reminder: Always name document files wisely (such as with the study number and the document type in the name). The suggested best practice for file names: <i>StudyNumber_DocumentName_VersionNumber</i></p> | |

- Instruction Clarifications**

A link to the ESTR Support site now appears on the first page of the main SmartForm and the instructions on the Study Team Members page has been updated to clarify when Faculty Sponsor a should be included on the team.



- Conditional Display (aka Hide/Show)** - The conditional display on the Basic Information page of the SmartForm immediate updates when the value for question 7 is changed.



Activity Enhancements

- Discard Activity visibility increased**

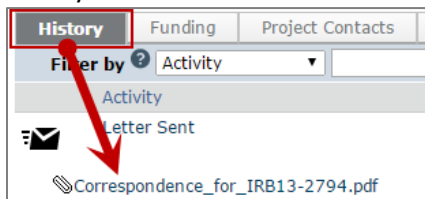
The Discard activity will now be displayed in the Modifications Required state. IRB Staff also have increased ability to assist with submission status with the option to complete discard on behalf of study team on any submission type, as needed.

- Notify (Meeting) Reviewers now occurs via selected actions**
 To ensure proper notification, reviewers should be assigned in one set of actions, from the meeting workspace. Specifically; 1) identify appropriate reviewers; 2) complete the Assign Reviewers activity; and 3) mark 'yes' to notify reviewers. Please note that subsequent changes to reviewers may not send notices in all cases.
- Finalizing Documents have improved security**
 Documents that are finalized now have the appropriate security and will not be accessible unless the user has the appropriate permissions.
- Prepare Letter Updates**
 Configured changes to Letter contents including correction of the version numbers that appear beside documents and the formatting of spaces from bullets to the document listing.
- Track Harvard Determinations additional element**
 PI Exception for Non-Exempt projects is now included as an item to track on this activity.

1. **Harvard Determinations:** (check all that apply)

| Determination | Rela |
|--|------|
| <input type="checkbox"/> Course Project | |
| <input type="checkbox"/> FERPA | HRP |
| <input type="checkbox"/> Genetic Resources | HRP |
| <input type="checkbox"/> Harvard Employees | |
| <input type="checkbox"/> Harvard Graduate Students | |
| <input type="checkbox"/> Harvard Undergraduate Students | |
| <input type="checkbox"/> PAE / SYPA | |
| <input type="checkbox"/> PI Exception for Non-Exempt | |
| <input type="checkbox"/> Psychology Department Study Pool | |
| <input type="checkbox"/> Scholars in Medicine | HRP |
| <input type="checkbox"/> Use of Harvard Electronic Information | |

- Send Letter History has correct file attached**
 Send Letter activity will now correctly display the PDF version of the correspondence letter in the activity history.



Enhancements to Reports

- Hyperlinks to departments have been removed in some areas**
 Previously, when an Organization reference was displayed in an Entity View, a hyperlink to that organization was seen. This hyperlink would navigate to Process Manager (aka RMConsole), which is not always desirable. The View control properties dialog has been enhanced with a configuration option for disabling this hyperlink. The Person and Project link target settings now include a 'Disable' option as well.
- Ability to filter by items that are part of a list**
 It is now possible to filter rows by data values that are within sets. For example, if a Custom Search is displaying

a list of study team members within a row representing a submission, it is now possible in the Custom Search component to filter the set to display any submission with a contact with the first name "%Harold%".

| IRB | School | Department | ID | Name | Harvard Determinations | Status |
|-----|--------|----------------------------|---------------|--|--|-----------------------|
| HMS | HMS | Wyss Institute | MOD13-2794-20 | Modification #20 for Study IRB13-2794 | Harvard Graduate Students Harvard Employees Harvard Undergraduate Students | Modification Required |
| HMS | HMS | Wyss Institute | MOD15-0869-11 | Modification #11 for Study IRB15-0869 | Harvard Employees | Approved |
| HUA | FAS | Human Evolutionary Biology | CR14-2316-01 | Continuing Review for Study IRB14-2316 | Harvard Employees | Approved |
| HMS | HMS | Wyss Institute | MOD-22086-34 | Modification #34 for Study 22086 | Harvard Graduate Students Harvard Employees Harvard | Approved |

- **New / Updated Reports (under “custom reports” tab)**

Additional reports *Submissions by Data Security Level* and *Submissions Involving Non-Significant Risk Device* are available along with the updated: *Expedited Submissions Approved in the Last 45 Days*, and *All Submissions*.

| IRB Reports |
|---|
| Submissions |
| Meetings |
| Library |
| Help Center |
| Standard Reports |
| Custom Reports |
| Name |
| All Submissions |
| Exempt Initial Submissions Reviewed in the Last 45 Days |
| Expedited Actions Completed in the Last 45 Days |
| Studies by Associated Department |
| Studies by Expiry Date |
| Studies by Initial Approval Date |
| Studies by IRB Contact |
| Studies Involving Greater Than Minimal-Risk |
| Studies Involving Harvard Determinations |
| Studies Involving HIPAA |
| Studies that Have Expired |
| Studies with Faculty Sponsor |
| Studies with Funding |
| Studies with INDs and IDEs |
| Study Notice Recipients |
| Submissions by Data Security Level |
| Submissions Involving Non-Significant Risk Device |

Notification Enhancements

- **Continuing Review and Clarifications Requested Notices**

Text corrected on the Continuing Review notice to include clarification regarding the timing of review in-text. Email recipients are now listed by role or name at the bottom of the notice.

- **Meeting Agenda and Reviewer Notices**

Formatting is corrected so that text is left-aligned for ease of reading.

General Items

- **Site speed enhancements**

Background methods have been updated for continued improvements on the speed of viewing submissions and “view differences” pages.

- **IRB/All Submissions webpage (workspace) tabs updated**

The “Active” tab now only includes a listing of active main studies. All extraneous line items have been removed.