1.26.0 Upgrade and Configuration Release Items: November 2021

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Cross-Suite Enhancements
ESTR-IRB Enhancements
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Data Safety Enhancements
OAIR Enhancements

Cross-Suite Enhancements

| Icons below indicate the application(s) impacted by the enhancement. |
| ESTR-IRB | Agreements-DUA | Data Safety | OAIR |

What has changed... | What it means... | How it looks (as applicable) ...

### General View & Navigation

| Project creator buttons removed from Dashboard pages | Upon logging in to a site via the main link (or from the Dashboard), navigate to the parent tab for the preferred application to create a new study, project, or agreement for review. |

| Export to CSV and Settings option on submission listings | All users now have the ability to export submissions listings to a csv file and to personalize how the submissions listings display. |

|  | Personalization options include: |
|  | o Hidding fields from the display, |
|  | o Changing the order of displayed fields, and |
|  | o Setting personal browser-based auto-refresh timing (to support easier list monitoring). |
Recently Viewed pinned option
On the Dashboard, submissions that have been recently viewed can be pinned to allow a user to quickly access pinned submissions.

Items included as lists have banded rows
Lists of projects, team members, or items on a history now display in alternating shaded rows for easier reading and navigation.

Workspaces

Added submission reminder in Pre-Submission or Draft status
The record workspace will now display a reminder to complete the Submit activity when the submission is in Pre-Submission or Draft status.

Workspace tabs have been reorganized
Workspaces across the suite will be migrated to new versions. Tabs in the workspace are now in a different order. The History remains the left-most tab.

Increased consistency of ancillary review assignment and completion
While the suite functions for ancillary assignment and review are different per application, all have been updated to include key attributes:
• Assignment with opportunity to write in a note to the reviewer,
• Notification to reviewer with additional information, and
• View into additional context prior to review completion.

SmartForm
SmartForm has consistent instruction at last page
Completion instructions appear at the end of all SmartForms. In some applications, this is an additional page at the end, and for others it replaces the previous “final page”. These instructions include application-specific next steps for review.
## Notifications

**Updated Related Projects notification to include project status**

The notification sent to a reviewer when a project or agreement is under review and a related project status is updated will now include the current status of the project or agreement under review.

## People and Organizations

**Additional departments/department changes**

New responsible department options:
- Neurology [BIDMC], Harvard Medical School
- Neurology [BWH], Harvard Medical School
- Neurology [BCH], Harvard Medical School
- Neurology [MGH], Harvard Medical School
- Psychiatry [CHA], Harvard Medical School

Revised school for center:
- Edmond J. Safra Foundation Center for Ethics, Faculty of Arts and Sciences (was Harvard Kennedy School)

**Person record update correction**

Corrected issue so that school and email stay visible after Harvard University affiliation or role end.

## Miscellaneous

**Revised support model for tracking flags or elements on submissions**

The support team is reviewing the process for implementing some configurations. This component of configuration is updated to facilitate faster and easier design with the appropriate stakeholders can occur.

**Office 365 integration enhancements**

Addressed key issues blocking consistent interaction with Office 365.

**Browser language setting requirements**

Addressed intermittent “Internal Server Error” message. Applications now allow for various default browser language settings.
### ESTR-IRB Enhancements

| What has changed... | What it means... | How it looks (as applicable) ...
<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>SmartForm</strong></td>
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</table>
| Revised instruction for all fCOI questions | • For Principal Investigators: Instructions are clarified to attach any fCOI details to the Local Site Documents page.  
• For team members: Response to the question is now required* and if yes, instructions are clarified to attach any fCOI details to the study team members page.  
• For Continuing Review: If fCOI reporting has changed, instructions display to create a separate modification to review such changes (and any subsequent changes to the protocol)  
*For any project in pre-submission or in review at the time of upgrade: If this question remains unanswered, the system will block ‘submit’ or ‘submit changes’ until a response is entered and saved. | ![Image](image.png) |
| Main SmartForm Study Scope page revised question regarding research involving devices | Updated wording clarifies the scope of the question. | ![Image](image.png) |
| Continuing Review SmartForm revised question regarding enrollment totals | Updated instruction and removal of “total since last review” to simplify entry at time of continuing review. | ![Image](image.png) |
| External IRB follow-on submission SmartForms additional instruction sections | To support selection of study update or site modification, instructions are visible on-screen to alert users to what they have chosen and to help determine appropriate next steps. | ![Image](image.png) |
| Full update of all question level help text | Help text to provide definitions, descriptions, and links to additional information will be added following upgrade. | ![Image](image.png) |
**Activities**

Items previously tracked via separate “Track Harvard Determinations” activity moved into other review activities

To increase efficiency, Data Security Level determination, rationale, and Harvard determinations can now be entered as part of Submit Pre-Review or Edit Pre-Review activities. For External IRB projects, this can be entered as part of the Confirm sIRB Decision. Entries will still be visible on the Reviews tab of the submission workspace.

Repository added as a Harvard determination/flag

As part of tracked elements, the reviewer can indicate if the submission is review of a repository.

Comment space added to ancillary assignment

Context for ancillary reviewer can be written in at assignment, without a text limit.

Action plan description field required on Review of Required Actions

Field is required for the RNI state to change from review to additional action or post review. Prior to this change, it was possible to remove the required information in error.
<table>
<thead>
<tr>
<th>Assigned IRB Coordinator permission change for submit action response</th>
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</thead>
<tbody>
<tr>
<td>Conversion of custom setting allowing Assigned IRB Coordinator the ability submit action response on behalf of responsible party. Assigned IRB Coordinator will continue to be able to support this action on behalf of the study team, as appropriate.</td>
</tr>
</tbody>
</table>

### Workspaces

<table>
<thead>
<tr>
<th>Revised link to edit training on Person workspace</th>
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<tbody>
<tr>
<td>IRB office staff access to person workspace updated for simplified addition of training information/documentation.</td>
</tr>
</tbody>
</table>

### Updated Institutional Profile listing page

| New column allows for additional filtering or sorting based on profile name. |

### Reporting

<table>
<thead>
<tr>
<th>Updated and added reports (for IRB office staff only)</th>
</tr>
</thead>
</table>
| • Study team members by IRB office: correct IRB office listing  
• Projects with non-US locations: new  
• Studies with Reliance Agreements: correct external IRB  
• All Submissions: correct risk level listed |

### Letters and Notifications

<table>
<thead>
<tr>
<th>Updated templates and template availability (for IRB staff only)</th>
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</table>
| • New External IRB Update letter revised and available on main External IRB workspace so that updates may be confirmed from the main workspace (in addition to the update workspace, as appropriate) following initial activation/reliance.  
• Corrected a bug so that Meeting minutes will generate without requiring a Harvard Determination on any associated Reportable New Information. |

<table>
<thead>
<tr>
<th>Notification revisions and additions</th>
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</table>
| • Additional notification to reviewers when a related project is updated, and an IRB follow on is still in review. *Note: At go-live, there will be a day of “over notification” which will stabilize with the next set of overnight notices.*  
• Ancillary review assignment notice includes Data Security Level for reference.  
• Collection of anniversary reminder criteria updated so that background tasks continue to send annual reminders into 2028. |

### Miscellaneous

<table>
<thead>
<tr>
<th>Enforce consistent availability of follow-on creation to IRB office staff</th>
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<tbody>
<tr>
<td>Addressed a bug where the ability to create a modification on behalf of the study team was not available to those in the IRB office. This is corrected in two parts: a) only the assigned coordinator can consistently take any action on behalf of the study team (as appropriate) and b) due to background operations upon state change on any submission, refreshing the main submission workspace may be required for additional activities to display following initial determination.</td>
</tr>
<tr>
<td>Non-sponsored funding sources update after modification approval</td>
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<tr>
<td>Expedited category correction</td>
</tr>
<tr>
<td><strong>What has changed...</strong></td>
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<tr>
<td>-------------------------</td>
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<tr>
<td><strong>SmartForm</strong></td>
</tr>
<tr>
<td>New Amendment Information page</td>
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<tr>
<td>Agreement Collaborator person chooser excludes inactive users</td>
</tr>
<tr>
<td><strong>Activities</strong></td>
</tr>
<tr>
<td>New Expedite Approval activity for Amendments</td>
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</tbody>
</table>
Redesigned Manage Ancillary Review activity improves notifications

The Manage Ancillary Review activity now includes the option to include a comment to the reviewer and send notification to the reviewer as soon as the activity is completed. Because notifications can now be sent through the Manage Ancillary Review activity, the Notify Ancillary Reviewers activity has been removed.

New Administrative Change activity

The new Administrative Change activity allows reviewers to update agreement documents and supporting documents on an active submission without completing an amendment.

New Manage Admin Contacts activity

The new Manage Admin Contacts activity allows PIs, Proxies, Primary Contact, and Agreements Staff to update the submission Primary Contact and manage the Guest List. This activity replaces the Manage Guest List activity.

Updates to the Email Agreement activity form

The Email Agreement activity form now displays the current Agreement draft to be attached to the email. The Use Email Client link has been moved to the bottom of the activity form.

Workspace
**Main Agreement documents have been separated from Amendment documents**
The Agreement Documents tab for the Main Agreement submission now only displays documents uploaded with the Main Agreement and any finalized agreement documents from Amendments. Documents uploaded with an Amendment will display only on the workspace for the Amendment submission. Documents will no longer copy from Main Agreements to Amendments and vice versa. The Agreement Documents tab has been updated to more clearly indicate whether the displayed documents relate to the main submission or a follow-on.

**Clarified submission contacts on left-hand summary**
The Agreement Creator has been relabeled as the Primary Contact and the Agreement Manager has been relabeled as the Principal Investigator.

<table>
<thead>
<tr>
<th>Reporting</th>
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<tbody>
<tr>
<td>State Entry Date added to ad hoc report</td>
</tr>
<tr>
<td>Amendment details added to Agreements Summary</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Other</th>
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</thead>
<tbody>
<tr>
<td>Added new DUA Terms</td>
</tr>
<tr>
<td>Terminated Agreements can no longer be edited</td>
</tr>
<tr>
<td>Corrected status of re-activated agreements</td>
</tr>
<tr>
<td>Contracting Party will display correctly after it has been changed via amendment</td>
</tr>
<tr>
<td>Corrected bug where amendment approval added multiple copies of agreement to main submission</td>
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</tbody>
</table>
## Data Safety Enhancements

<table>
<thead>
<tr>
<th>What has changed...</th>
<th>What it means...</th>
<th>How it looks (as applicable) ...</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SmartForm</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| New submission type: Amendment + Continuing Review | Using the “Create Amendment/CR” option on an approved record, researchers can choose from three options:  
- Propose changes for review  
- Propose changes with a request for continuing review (or extension of the expiry date), as part of a single submission and review process, or  
- Request continuing review (or extension of the expiry date). | Creating New: Safety Submission  
Amendment / Continuing Review  
1. Type of Submission:  
   - [ ] Amendment  
   - [ ] Amendment/CR  
   - [ ] Continuing Review  
   - [x] Clear  
2. Will technology expenses be ongoing?  
   - [ ] Yes  
   - [ ] No  
   - [ ] Clear  
3. Primary Contact:  
   - Note that this person will not be able to edit or comment.  
   - Also list this person as a member of the protocol team if they should be able to take actions on the protocol.  
   - [ ] Li Lemon  
   - [ ] Clear  

**Improved instructions regarding the Primary Contact role in Safety** | Instruction regarding the Primary Contact role in Safety now appears on the SmartForm and when changing a Primary Contact via activity. | ![Image](image1)  
3. Primary Contact:  
   - Note that this person will not be able to edit or comment.  
   - Also list this person as a member of the protocol team if they should be able to take actions on the protocol.  
   - [ ] Li Lemon  
   - [ ] Clear  

**Added question to Funding Sources page regarding one-time or ongoing costs of technology** | Additional question allows reviewer to understand the technology needs for the project. | ![Image](image2)  
2. Will technology expenses be ongoing?  
   - [ ] Yes  
   - [ ] No  
   - [ ] Clear  

**Added questions to Data Information: series or set details page** | Added required data source country* and if USA, state to help with data management, review, and reporting requirements.  
*For any project in pre-submission or in review at the time of upgrade: If this question remains unanswered, the system will block ‘submit’ or ‘submit changes’ until a response is entered and saved. | ![Image](image3)  
3. Data originates from the following country/countries:  
   - [ ]  
   - Japan  
   - USA  
   - France  
   - [ ] If United States, state(s), if known:  
   - Name:  
   - Postal Code:  
   - [ ]  

**Added instruction to Data Information: series or set details page** | When a Data Security Level is chosen in combination with a resource with a) a lower maximum data security level, or b) no maximum level, instruction will appear on-screen to help support what additional detail may be needed for review. | ![Image](image4)  
Important! The Data Security Level listed above is higher than one or more location(s) chosen to support the data. Please ensure this discrepancy and any relevant compensating controls are described in the “Other locations” details, above.  
*For any project in pre-submission or in review at the time of upgrade: If this question remains unanswered, the system will block ‘submit’ or ‘submit changes’ until a response is entered and saved.
Attestation included on Data Access page includes personal device attestation language based on form selections. When a personal device is chosen, the page will display appropriate Level 3 or Level 4 attestation language, along with links to requirement details.

Clarified instruction on Continuing Review SmartForm. If a change is indicated with question one the Safety Changes page, context relevant instruction appears. If the submission is only a Continuing Review, instructions to amend are included. If the submission is an Amendment/CR, instructions to propose changes in following pages appears.

Added details to Request Closure form. Includes information about data destruction and/or DUA requirements and responsibilities.

**Workspaces**

Document tab displays additional documents. Content of the documents tab have been updated* to view context-relevant attachments.

*As part of the workspace migration in Data Safety, “date modified” will update to the date of upgrade for all submissions.

Safety all submissions includes tab listing items in Pre-Submission. View items not-yet submitted in a pre-filtered list on the Safety all submissions page.

Help Center includes Library of templates and resources. New option for in-application access to templates and reference links to ease navigation for additional information.
<table>
<thead>
<tr>
<th>Tabs updated to show department and school for all submission types</th>
<th>Corrected a bug where department and school did not display for continuing review request. Now all submissions display department and school in project list spaces.</th>
</tr>
</thead>
</table>

### Notifications

Updated lapse notification to include roles and responsibilities after approval period has ended  

The notification sent to researchers when a project has expired is revised to include information about data destruction and/or DUA requirements and responsibilities.

### Activity

Add Comment now includes option to send a notice

When adding a comment*, the author can choose notification recipients who will receive an email indicating that a comment has been added on the record.

*This feature is available on both public and private comments.*

Additional review support permissions

Assigned review specialist can take actions on behalf of others when necessary (including edit the SmartForm or complete the submit activity on behalf of the researcher).

### Miscellaneous

Workspace link available for reports

A new method is available when creating reports so that the workspace web address is part of report export. This may be used for external reference or future integration.

PI name and information displays only once on follow on submission contact list

Corrected a bug where the PI name and information displayed multiple times.

Data Information appears on follow-on workspace

Corrected a bug where data information was not visible on the continuing review workspace.
## OAIR Enhancements

<table>
<thead>
<tr>
<th>What has changed...</th>
<th>What it means...</th>
<th>How it looks (as applicable) ...</th>
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<tbody>
<tr>
<td><strong>SmartForm</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minor clarifications to question prompts and Professional Services options</td>
<td>Clarified that Institutional Responsibilities questions refer to responsibilities at Harvard. Updated Professional Services option for Paid Media Appearances to include written, audio, video, or other digital formats.</td>
<td></td>
</tr>
<tr>
<td>Sorted disclosures on Disclosure Details page in alphabetical order</td>
<td>Disclosures listed on the Disclosure Details page are listed in alphabetical order by Organization name.</td>
<td></td>
</tr>
<tr>
<td>Corrected bug that allowed disclosers to skip the Disclosure Details page even if they already had Disclosures</td>
<td>Previously disclosers were able to indicate that they did not have outside activities or interests on the What to Include page even if they had disclosures currently under modification. Now disclosers will not be able to select the No option for the question on that page if they already have New/Modified Disclosures and/or Previously Reviewed Disclosures.</td>
<td></td>
</tr>
<tr>
<td><strong>Activities</strong></td>
<td></td>
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</tr>
<tr>
<td>Improved Administrative Review Complete timeout</td>
<td>Reviewers have been unable to complete reviews for Certifications that include a large number of Disclosures.</td>
<td></td>
</tr>
<tr>
<td><strong>Notifications</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Added GMAS Project ID to subject of Research Certification notice</td>
<td>The subject line of the Research Certification notice now includes the ID for the GMAS Project the certification is associated with.</td>
<td></td>
</tr>
<tr>
<td>Minor clarifications to notifications</td>
<td>Minor changes to the instructions in the Draft Status Reminder to disclosers and the Research Certification notice.</td>
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<tr>
<td><strong>Reports</strong></td>
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<tr>
<td>Added new reports</td>
<td>Several new reports are available:</td>
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<tr>
<td></td>
<td>- <strong>All Disclosures</strong> – This report displays all active disclosures in the system. The report can be filtered by discloser, department, and/or organization.</td>
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</tr>
<tr>
<td></td>
<td>- <strong>Annual Report</strong> – This report includes information about annual certifications to help support annual reporting requirements.</td>
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<tr>
<td></td>
<td>- <strong>Certification Comments</strong> – This report includes all comments added to certifications during the previous two months for easy reference by reviewers.</td>
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<tr>
<td></td>
<td>- <strong>OAIR Outside Activities for Biosketch and Other Support</strong> – This report includes a discloser’s outside activities to help them complete the Biosketch and Other Support information for sponsored project proposals.</td>
<td></td>
</tr>
<tr>
<td>Minor report updates</td>
<td><strong>Annual Certifications Not Submitted</strong> has been changed to <strong>Annual Certifications in Draft</strong> to clarify report contents.</td>
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</tr>
<tr>
<td>Miscellaneous</td>
<td>Updating links to HMS and OVPR policy pages: Updated the links to HMS policies to the most recent versions and updated OVPR links to point to the new OVPR website in various SmartForm pages, activities, and notifications.</td>
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</tbody>
</table>