1.25.0 Upgrade and Configuration Release Items: May 2020

Jump To

Cross-Suite Enhancements

Note that not all system enhancements apply to all applications. Use the legend below to determine whether the enhancement applies to your application.
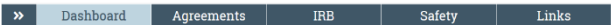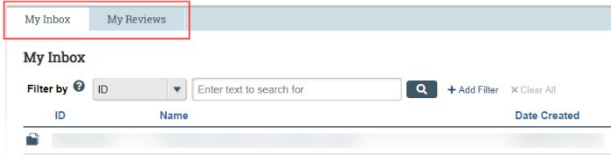
💻 Safety   🔵 IRB   📝 Agreements

What has changed...	What it means...	How it looks (as applicable)...
Dashboard		
The Inbox tab is now the Dashboard	The **Inbox** has been renamed **Dashboard** to better describe its enhanced functionality. 💻 🔵 📝	
The Dashboard includes two project listing tabs	The project listing in the Dashboard has been split into two separate tabs. The **My Inbox** tab includes all projects the user needs to take action on. The **My Reviews** tab includes only projects for which the user is named as a reviewer. This is particularly	

useful for faculty members who serve as committee members and also conduct their own research.

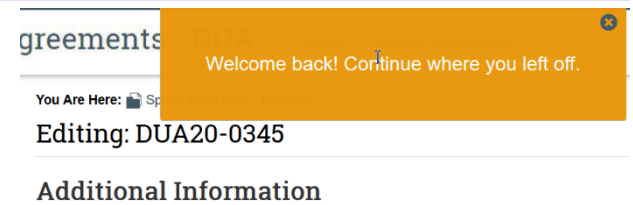| Recently Viewed projects display on the Dashboard | The Dashboard now includes a sidebar that links to the last 10 projects viewed by the signed-in user. These links allow users to quickly resume their work where they left off. | |
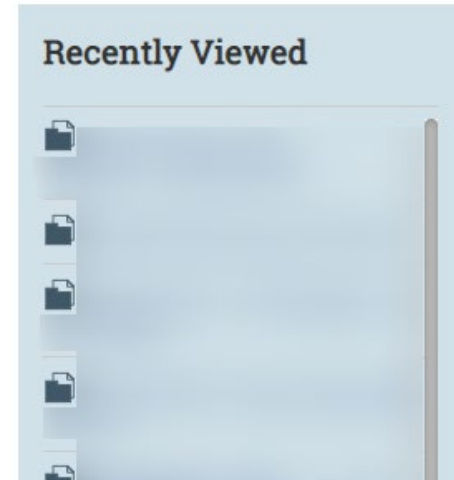
SmartForm

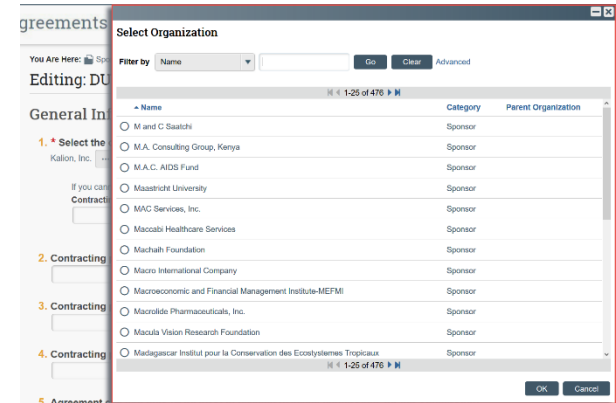| Jump To navigation has been replaced with a sidebar | The Jump To menu has been replaced by a sidebar that allows users to navigate between SmartForm pages. Elements of SmartForm validation and version comparison display in this sidebar as well. | |

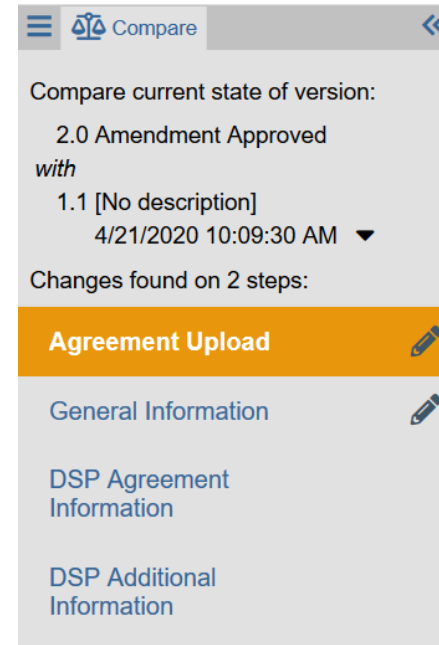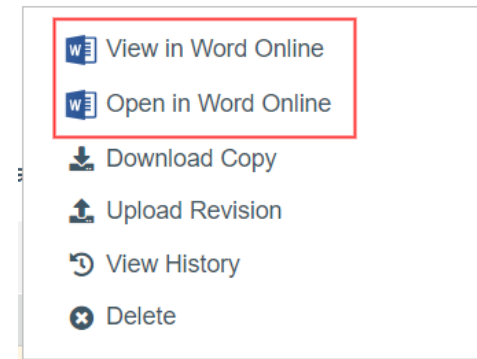|		
SmartForm location saves on exit	Whenever users return to the SmartForm, they are returned to the section of the form where they left off.	
Slide-in Views replace pop-up windows	Slide-ins replace pop-up windows. The slide-ins help to keep the form organized and prevent users from losing data from inadvertently closing pop-ups in the incorrect order.	
Improved SmartForm validation	A Validate tab on the sidebar allows researchers to easily see which pages are missing required information.	
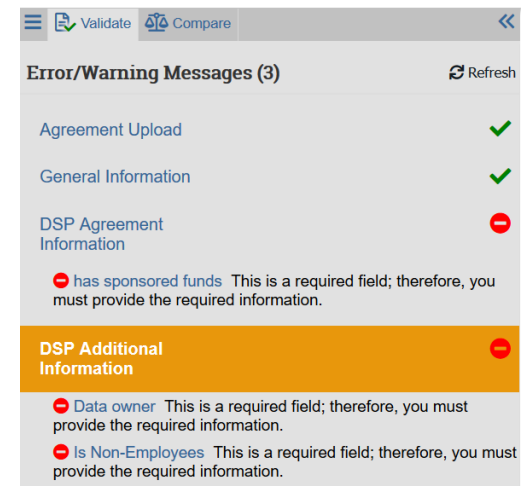
View Differences has been replaced with Compare	The View Differences button has been removed from the Workspace and replaced with the in-SmartForm compare tab. Clicking on the Compare tab will display previous versions available for comparison with current version. A pencil icon will display next to sections where differences exist.	
Online viewing and editing of Word, Excel, PowerPoint, and Visio files	Documents in Office formats may now be viewed or edited (when in an editable state and user has appropriate permissions) directly in the browser using Office 365. Document changes made in Office 365 are saved automatically and document history updated accordingly. Online editing is only available for Microsoft XML documents (file extensions .docx, .xlsx, .pptx, and .vsdx)	
Improved accessibility for users with disabilities	The SmartForm now has improved keyboard navigation, metadata for screen readers, and color contrast for users with visual impairment.	

Reviewer Experience

SmartForm displays as single page when read-only	The SmartForm now displays as a single, continuous page when you unable to edit a submission. This allows for a quicker review and easier searching within the project.

"Reviewer Mode" added for ease of tracking review	When a submission is in a review state (i.e. Specialist Review, Committee Review, Non-Committee Review), and the logged in user is assigned to review it, the submission will now be in Review Mode. This allows the Reviewer to indicate whether a SmartForm section has been reviewed. If the study team resubmits a project after making changes to a previously reviewed section, the indicator will reset to alert the reviewer that the section has changed and will need to be reviewed again.

Above section has been reviewed: ☑

Compare current state of version:

0.2 Specialist Review - Response Submitted

with

0.1 Submitted to Safety Committee 3/18/2020 2:10:04 AM ▼

Changes found on 1 step:

▼ **Basic Information & Funding**

Basic Information ✓

Protocol Team Members ✏ ✓

Activities

Related Projects Status Update

An automated activity provides email notifications when related projects are updated	For submissions currently in review, the submission owner will be notified by email when a related project is updated. The update activity will also be logged to the submission History.

IRB Enhancements

What has changed…	What it means…	How it looks (as applicable)…
SmartForm		
Biologics Question added on Drugs page	We have added a question to the Drugs pop-up, asking the study team whether a Drug is a Biological material. This field can be included in reports.	**Edit Drug Information** 1. **Select the drug:** ❓ Pinavir [⋯] ⊗ 2. **Is this considered a biologic?** ○ Yes ○ No Clear
Improved change tracking for added/removed Funding Sources	A new column has been added to the Funding Sources table for "Internal ID." This number is displayed when change tracking is turned on and allows the reviewer to easily identify which Funding Source was added to the submission.	1. List any grant proposal that has been submitted to the sponsored programs office (SPA or OSP), any proposal that wa… sponsored funding for the study: Project # GMAS Status Abbreviated GMAS Title PI Fund Sponsor GMAS Link ▼ Differences CV Curtis Van Slyck (DEV) · modified a few seconds ago · version 1.2 (MOD19-0664-01: Modification submitted to IRB) Added: 62388
Workspaces		
Project listing tabs have been re-ordered	New project listing tab order is: My Work List (IRB staff only), Unassigned (IRB staff only), In-Review, Active, Archived, New Information Reports, External IRB, Sites, All Submissions.	
Asynchronous tabs turned off on project listings	We have turned off the feature that triggers the automatic refresh of tabs on the IRB listing page to help improve system performance and avoid timeouts. **Important: This means that tabs no longer refresh automatically and must be manually refreshed.**	
Deferred Submissions added to "In Review" tab	Previously, Deferred submissions only appeared on the "All Submissions" tab. Now, they can be found on the "In Review" tab as well.	

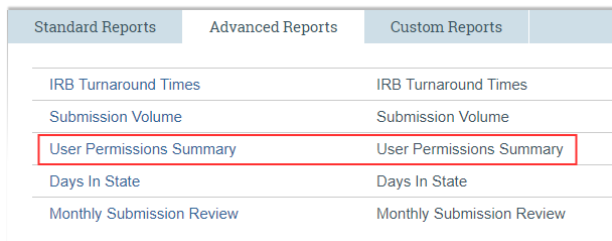|		
Department of Justice and/or Food and Drug Administration may be selected for studies under the 2018 Common Rule	Previously, studies under the 2018 Common Rule would need to be reverted to Pre-2018 Requirements in order to list DOJ or FDA oversight. Now, you can select DOJ and/or FDA. This is indicated on the workspace as demonstrated in the image at right.	**Regulatory authority:** 2018 Requirements + FDA + DOJ
Updated Workspace Template for External IRB projects (HLC Only)	Older HLC External IRB submissions which had been using the Review Complete template have now been migrated to the External IRB template. The External IRB template allows for closure and update of External IRB studies. HUA External IRB submissions on the Review Complete template have not been migrated.	

Activities

"First Time PI" no longer available in Track Harvard Determinations activity	QIP has developed a different system for tracking first-time PIs so this is no longer needed. However, it will continue to display for studies which already have it selected.

Reporting

New Report: User Permissions Summary	A new Advanced Report is available that allows for easy lookup of a user's roles and permissions in ESTR.	Standard Reports Advanced Reports Custom Reports IRB Turnaround Times IRB Turnaround Times Submission Volume Submission Volume User Permissions Summary User Permissions Summary Days In State Days In State Monthly Submission Review Monthly Submission Review
Added Supporting Documents to the Submissions with Ancillary Review Report	The "Submissions with Ancillary Review" report now includes direct links to all supporting documents provided as part of the Ancillary Review assignment.	

Letters and Notifications

PI Assurance and submission notice updated to reflect revised HRDSP	References to "DSL 2" have been replaced with "non-sensitive" in the PI Assurance and Submit Activity text, the Assign PI Proxy Activity text, the	*Full text of the Principal Investigator Assurance can be found on the ESTR Wiki here.*

	Faculty Sponsor Ancillary Guidance, and the PI Assurance reference document.
Annual Notice includes reminder about fCOI disclosure requirements	The Anniversary Reminder notice for studies where Harvard is the reviewing institution now includes a link to the PI assurance statement. For studies where Harvard relies on another institution's review, the Anniversary Reminder has been updated to clarify the purpose of the notification.
Anniversary Reminder schedule change	This reminder now goes out on the first night of the approval anniversary month instead of on the approval anniversary date. Previously, Harvard used a custom activity to send out annual reminder notices when continuing review is not required. Huron now delivers a notification for this with the IRB product, so we have retired our notification in favor of theirs to minimize customizations.

People and Organizations

Updated QIP Department Name	"LMA-QIP" is now "HLC-QIP" in the system to reflect the initiative nomenclature shift toward "Harvard Longwood Campus."
Split Microbiology & Immunology departments	Microbiology and immunology are now separate departments, each with their own chair. Departmental Ancillary Review notifications will now only be sent to the appropriate chairperson.

Agreements Enhancements

What has changed…	What it means…	How it looks (as applicable)…
SmartForm		
Updated Agreement Collaborators question	Question 5 on the General Information page has been changed from "Harvard team members who need access to this Agreement:" to "Agreement collaborators (Harvard staff needing read/edit permissions for this submission):" to clarify that persons listed on this page should have access to the submission in the system rather than access to the data.	
Data storage plan question has been removed	The data storage plan question has been removed from the Additional Information page for all new submissions. This field will be visible and can still be changed for submissions where the information has been added prior to this release.	
IRB and Data Safety reminders have been added	On the first page of the SmartForm, users are reminded to include the Investigator Self-Determination Form in the Supporting Documents section or to link their Harvard IRB application to the Agreements submission. On the last page of the SmartForm, users are reminded to create and/or link a Data Safety submission to the Agreements submission.	
Workspaces		
Project listing tabs have been re-ordered	New project listing tab order is: My Work List (DUA staff only), Unassigned (DUA staff only), My Office's Agreements (DUA staff only), In-Review, Active, Archived, All Submissions. The Pre-Submission tab has been removed.	
Additional document view options on the Agreement Workspace	Next to each document on the Agreements Documents tab is an ellipsis, which when clicked, displays options for viewing documents and their version history.	

Amendment disposition displays on the History tab	Previously when an amendment was closed (either approved or discarded), the activity was not recorded on the parent agreement History. Now the parent agreement History will display the amendment disposition information.	

Amendment Printer Version displays properly	A bug preventing the Printer Version of amendments from displaying properly has been fixed.
Agreement summary correctly displays Contracting Party organization name	Previously if the Contracting Party organization name was changed, the Agreement summary at the top of the Agreement Workspace would continue to display the former name of the organization. The summary now displays the updated organization name. Other locations where the Contracting Party displays may still display the former name.

Activities

Assign Owner

When an Owner is assigned, the owner will be notified	The system now notifies the owner when a submission is assigned so that DUA staff do not have to regularly monitor assignments in the system.

Email Agreement

PIs will no longer receive notifications when the Email Agreement activity is completed	Notifications for the Email Agreement Activity will now go only to the party selected on the activity form.

Track Agreement Elements

Data Security Level field has been removed	The Data Security Level field has been removed for all new submissions. The Data Security Level will be visible and can still be changed for submissions where the information has been added prior to this release.

Related Projects Status Update

An automated activity provides email notifications when related projects are updated	For Agreements submissions currently in review, the submission owner will be notified by email when a related project is updated. The update activity will also be logged to the submission History.

Approval (for Amendments)

Contact Set updates properly upon amendment approval	A bug preventing the Contact Set from updating properly upon amendment approval has bee fixed. Previously new study team members could be added via amendment, but they would not have permission to access the submission.

Reports
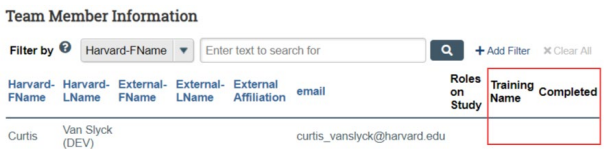
SSRS Reports tab has been renamed Advanced Reports	The **SSRS Reports** tab has been renamed **Advanced Reports** to clarfiy the contents of the tab to end users.
New Agreements Summary report is available	A new Advanced Report summarizing Agreements submissions and activities is available to Agreements Managers. This report includes informiation on submission volume by month, submission volume by school, average review times, and more.

Data Safety Enhancements

What has changed...	What it means...	How it looks (as applicable)...
SmartForm		
Extra VPN Value Removed	Question 1 on the Data Access page previously had options for both "Via VPN" and "Via VPN Only." The "Via VPN Only" option has been removed for easier reporting and to reduce confusion. The "Via VPN Only" value will still be visible on studies which previously had it selected so no data will be lost.	
Renamed CITI reference to "CITI Information Security"	Question 3 on the Protocol Team Members page now refers to "CITI Information Security" training instead of "CITI training" to avoid confusion with the IRB-required CITI Human Subjects training.	
Primary contact defaults to submission creator	We have removed the Primary Contact field from the SmartForm. The user who creates the project is automatically listed on the Study Team, and will now be designated Primary Contact by default. The Primary Contact may still be changed via the "Assign Primary Contact" activity on the submission workspace.	
Project Contacts tab now displays CITI training	Users' completed CITI Information Security training is now displayed on the Project Contacts tab under the "Team Member Information" section. The training name and date completed are displayed on the left-most columns of the table.	
Activities		
Discard		
Specialists may now complete the Discard activity	The system now allows Specialists to Discard a submission on behalf of the Study Team.	
Approve Submission (Admin)		
Committee for Acknowledgment Selected by Default	Question 2 on the Data Access page previously required the Specialist to select a Committee for Acknowledgment. Since "Data Safety and Security" is the only option, it is now selected by default.	

Notifications

Department Added to Specialist Assignment Notice	The Specialist Assignment notification now contains a line indicating the Responsible Department as selected on the SmartForm. This gives specialists at-a-glance insight into the department without the need to delve into the system.	**Notification of Specialist Assignment** To: Curtis Van Slyck (DEV) Link: Does the Specialist have Edit Rights in Clarifications Requested? PI: Rebecca Simms (PI) Department: Chemistry and Chemical Biology You have been assigned as the security officer responsible for the Safety submission above. Please follow the link above to access the materials for this submission and begin the Specialist Review.
Pre-Submission Notice Updated	Minor grammatical and spelling errors were fixed in the Pre-Submission Reminder notification. The content and frequency of this notification remains unchanged.	

Using Office 365

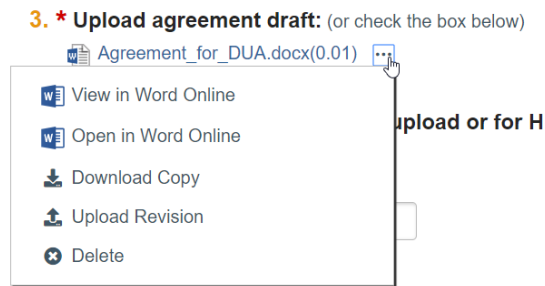## Editing Documents Using Office 365

Protocols, Letters, Agreements, and Supporting Documents may be edited in the browser using Office 365 when:

- the submission is in an editable state,
- the document is in a Microsoft XML documents (file extensions .docx, .xlsx, .pptx, and .vsdx), and
- the document is not a locked form.

Documents can be edited from within the **SmartForm** and on certain **Activities** related to generating/updating documents.

1. Editing Documents Within the SmartForm

In Agreements and Data Safety, documents uploaded to the SmartForm can edited online by clicking on the ellipses next to the document and selecting the Open Online option. The document will open in Office Online in a new tab.

Ex. Agreement Draft
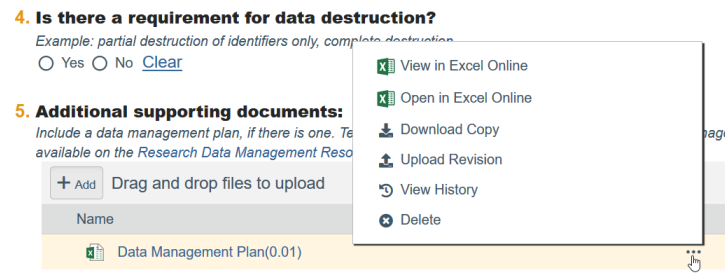
Ex. Data Safety Supporting Documents

In IRB, documents uploaded to the SmartForm can edited online by clicking on the document name and clicking the Edit in Browser button when the document opens in Office Online in a new tab.

Make edits, enabling the Tracked Changes feature as needed, and close the tab once you have finished editing. Changes to the document will be saved automatically.

Note: You will not see the document version change on the SmartForm, but it will update when you close the Form.

2. Editing Documents on Activities

Documents that are generated or updated via activities can be edited online from the activity form. Documents can be edited in the following activities:

Agreements:	Generate Agreement
	Revise Agreement
Data Safety:	Prepare Letter
IRB:	Send Letter
	Prepare Agenda

Ex. Data Safety Prepare Letter

Note: The document will open in a tab in your main browser window. When you have finished editing the document and closed the document tab, go back to the Activity pop-up and click OK to complete the activity.

Viewing Documents Using Office 365

Microsoft Office documents in both non-XML and XML formats (e.g. .doc and .docx) can be viewed online in Office 365, regardless of submission state. The option to view documents online can be accessed:

- **In Agreements**, within the SmartForm and on the Agreement Documents tab;
- **In Data Safety**, within the SmartForm; and
- **In IRB**, within the SmartForm.

To view a document online, click on the ellipsis next to the document and select the View Online option or click on the document name.

5. Additional supporting documents:

Include a data management plan, if there is one. Templates and additional resources for creating a data management plan to upload here are available on the Research Data Management Resources website.

Name
📄 Not a Generic Text Doc(0.01)
📝 Generic Word Doc.docx(0.01)

Ex. Data Safety SmartForm

History	Communication	Agreement Documents

For each document listed below, click the ⋯ icon to download a copy

Highlighted terms
There are no items to display

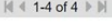**Most recent draft agreement**
📝 Agreement_for_DUA.docx(0.02) ⋯

- 📝 View in Word Online
- ⬇ Download Copy
- 🕘 View History
- ↔ Compare with Previous Version
- ⊗ Delete

Ex. Agreement Documents Tab

Document History

Revisions made using Office 365 will show in the history as **Modified with Office Online.**

Resource History for Agreement_for_DUA.docx   ❓ Help

History:

Compare	Date	Version	Person	Action	Notes	Uploaded File
☐	4/24/2020 2:46 PM	0.04	Liz Lemon (agrrev)	Modified with Office Online		Agreement_for_DUA.docx
☐	4/24/2020 2:43 PM	0.03	Paul Lastname (pi30)	Modified with Office Online		Agreement_for_DUA.docx
☐	4/24/2020 2:32 PM	0.02	Paul Lastname (pi30)	Modified with Office Online		Agreement_for_DUA.docx
☐	4/24/2020 2:11 PM	0.01	Marilyn Rackley (Test)	Created		Agreement_for_DUA.docx

1-4 of 4

Compare

OK