1.26.0 Upgrade and Configuration Release Items: November 2021

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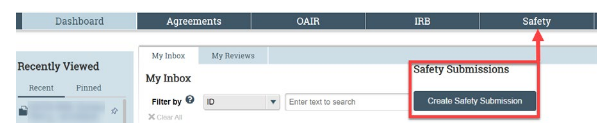
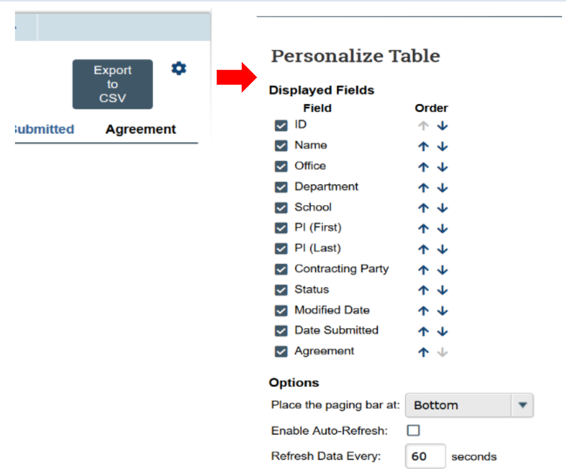
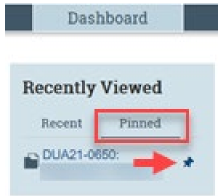
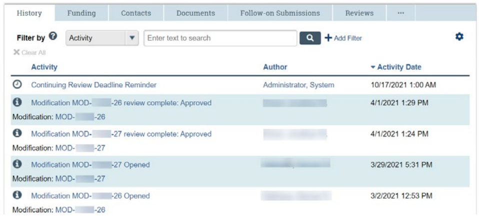
Cross-Suite Enhancements

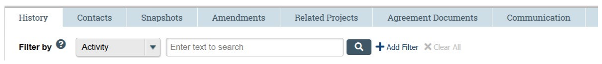
Icons below indicate the application(s) impacted by the enhancement.
ESTR-IRB Agreements-DUA Data Safety OAIR

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.	

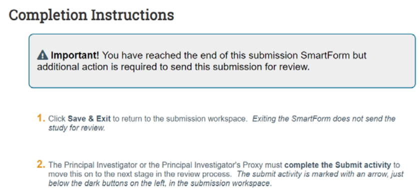
Export to CSV and Settings option on submission listings	• All users now have the ability to export submissions listings to a csv file and to personalize how the submissions listings display.
	• Personalization options include:
	  ○ Hidding fields from the display,
	  ○ Changing the order of displayed fields, and
	  ○ 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

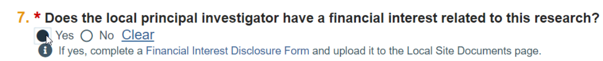
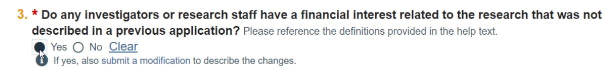
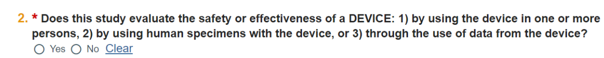
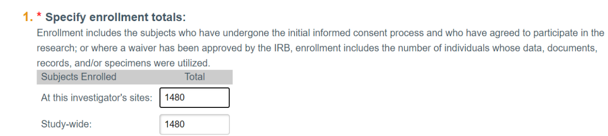
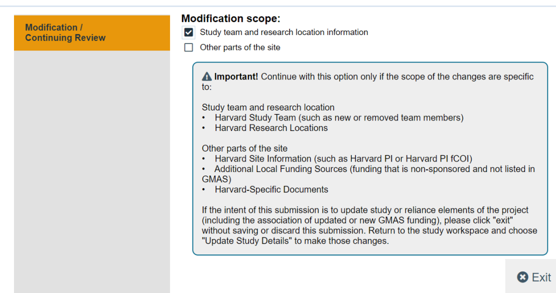
Added submission reminder in Pre-Submission or Draft status	The record workspace will now display a reminder to complete the Submit activity when the submission is in Pre-Submission or Draft status.	
Workspace tabs have been reorganized	Workspaces across the suite will be migrated to new versions. Tabs 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

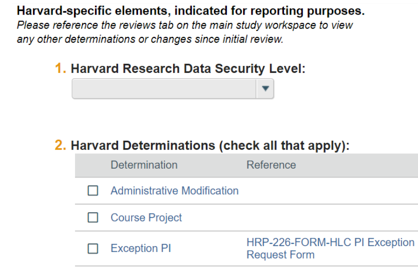
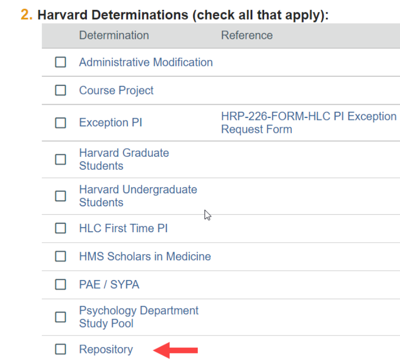
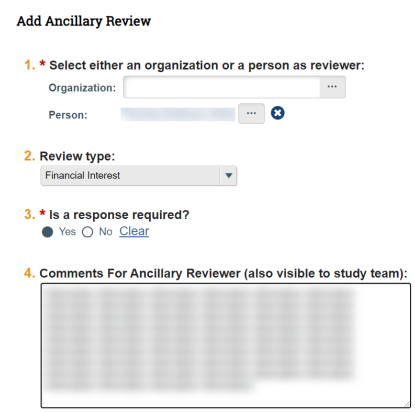
SmartForm has consistent instruction at last page	Completion instructions appear at the end of all SmartForms. In some applications, this is an additional page at the end, and for others it replaces the previous "final page". These instructions include application-specific next steps for review.	

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

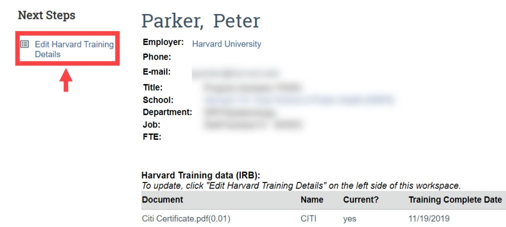
What has changed…	What it means…	How it looks (as applicable) …
SmartForm		
Revised instruction for all fCOI questions	• For Principal Investigators: Instructions are clarified to attach any fCOI details to the Local Site Documents page. • For team members: Response to the question is now required* and 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-submision or in review at the time of upgrade: If this question remains unaswered, the system will block 'submit' or 'submit changes' until a response is entered and saved.*	  
Main SmartForm Study Scope page revised question regarding research involving devices	Updated wording clarifies the scope of the question.	
Continuing Review SmartForm revised question regarding enrollment totals	Updated instruction and removal of "total since last review" to simplfy entry at time of continuing review.	
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.	
Full update of all question level help text	Help text to provide definitions, descriptions, and links to additional information will be added following upgrade.	

Activities

<table>
<tr>
<td>Items previously tracked via separate “Track Harvard Determinations” activity moved into other review activities</td>
<td>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.</td>
<td>
</td>
</tr>
<tr>
<td>Repository added as a Harvard determination/ flag</td>
<td>As part of tracked elements, the reviewer can indicate if the submission is review of a repository.</td>
<td>
</td>
</tr>
<tr>
<td>Comment space added to ancillary assignment</td>
<td>Context for ancillary reviewer can be written in at assignment, without a text limit.</td>
<td>
</td>
</tr>
<tr>
<td>Action plan description field required on Review of Required Actions</td>
<td>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.</td>
<td>
</td>
</tr>
</table>

Assigned IRB Coordinator permission change for submit action response	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.

Workspaces

Revised link to edit training on Person workspace	IRB office staff access to person workspace updated for simplified addition of training information/ documentation. 
Updated Institutional Profile listing page	New column allows for additional filtering or sorting based on profile name.

Reporting

Updated and added reports (for IRB office staff only)	• 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

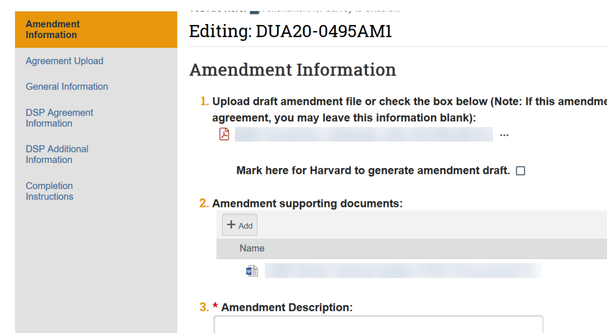
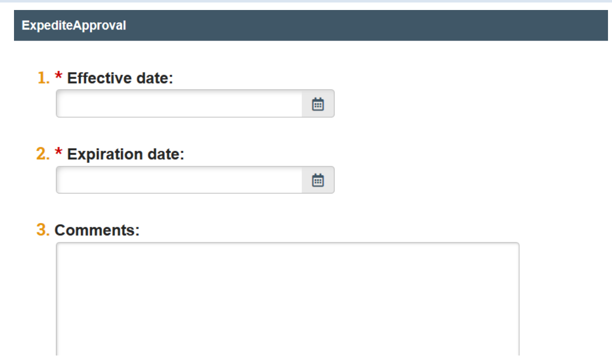
Updated templates and template availability (for IRB staff only)	• New External IRB Update letter revised and available on main External IRB workspace so that updates may be confirmed from the main workspace (in addition to the update workspace, as appropriate) following initial activation/ reliance.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

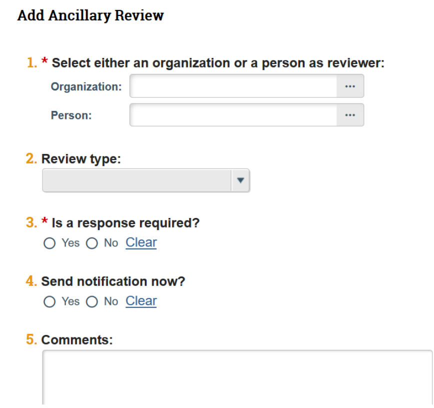
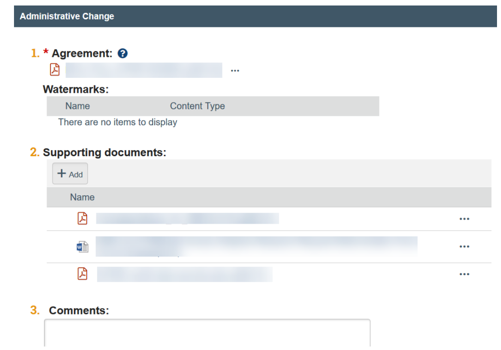
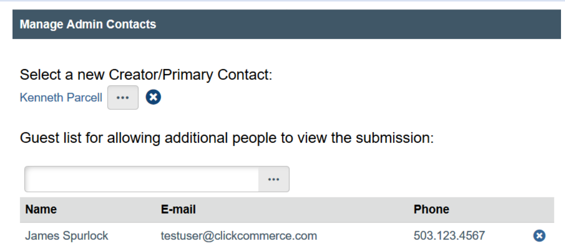
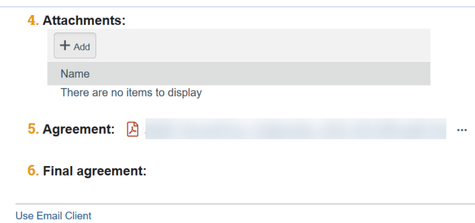
Miscellaneous

Enforce consistent availability of follow-on creation to IRB office staff	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.

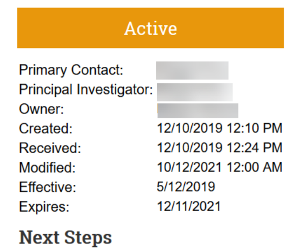
Non-sponsored funding sources update after modification approval	Corrected a bug where non-sponsored funding sources that were written-in to the SmartForm or changed during modification where not showing on the main workspace. These values now copy from the modification to the main, as appropriate. *Note that this functions as expected for future submissions. Any submissions impacted by this bug must be addressed individually.*
Expedited category correction	Converted custom assignment of minor modification and humanitarian use device selection options to the configured settings.

Agreements-DUA Enhancements

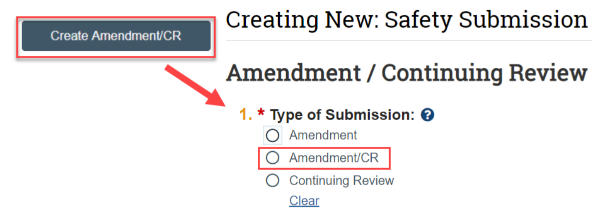
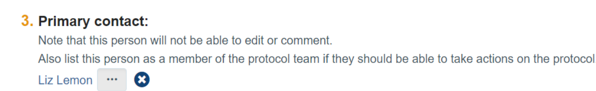
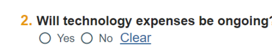
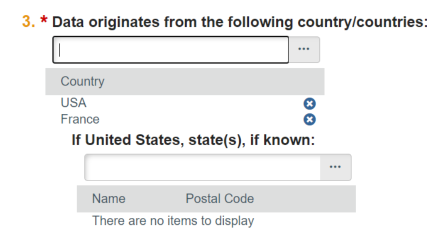
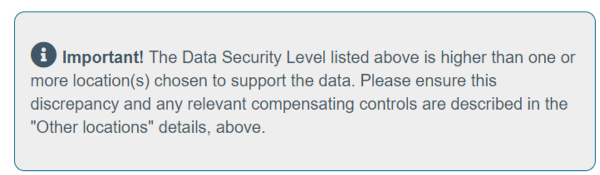
What has changed…	What it means…	How it looks (as applicable) …
SmartForm		
New Amendment Information page	An additional page has been added to the SmartForm for amendments. This page allows for the uploading of documents specific to the amendment, for example, a new agreement document, and for providing a description of the amendment*. Note: Because documents for the amendment are now uploaded on the Amendment Information page, documents will no longer display on the Agreement Upload page for amendments. **For any agreeementin Pre-Submision or Clarifications Requested 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.*	
Agreement Collaborator person chooser excludes inactive users	It is no longer possible to add a person who is no not an active Harvard affiliate or POI as an Agreement Collaborator.	
Activities		
New Expedite Approval activity for Amendments	Amendments that do not require a new signed agreement document can be approved via the Expedite Approval activity, allowing the reviewer to skip the normal review, and signing steps. Note: The Expedite Approval activity replaces the Bypass Signatures activity, which has now been deprecated.	

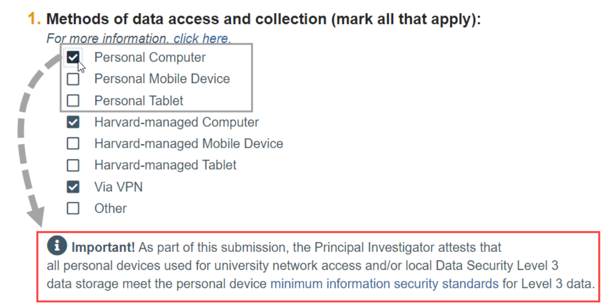
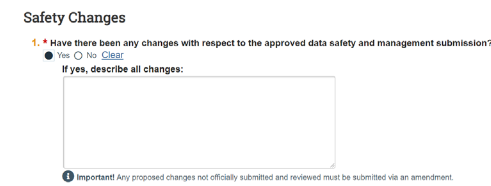
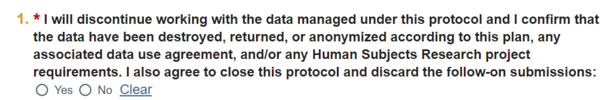
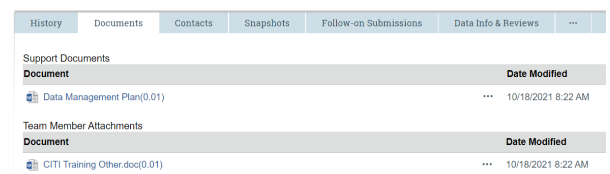
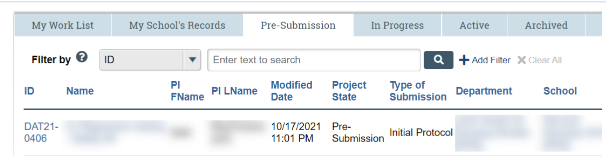
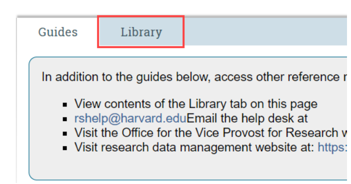
Redesigned Manage Ancillary Review activity improves notifications	The Manage Ancillary Review activity now includes the option to include a comment to the reviewer and send notification to the reviewer as soon as the activity is completed. Because notifications can now be sent through the Manage Ancillary 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.	

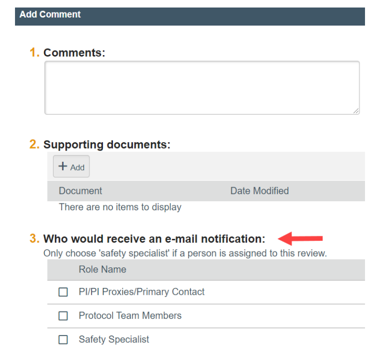
Workspace

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. 
Reporting	
State Entry Date added to ad hoc report	Harvard Report: Agreements ad hoc report now includes the State Entry Date for each submission
Amendment details added to Agreements Summary	The Advanced Report Agreements Summary now includes a separate page/tab for Amendment details.
Other	
Added new DUA Terms	"Destruction required" and "Anonymization required" have been added as DUA Terms to help researchers and reviewers note contracting party requirements for data disposition.
Terminated Agreements can no longer be edited	A bug that allowed reviewers to edit agreements that had been terminated has been corrected.
Corrected status of re-activated agreements	In some places in the application, an Agreement that had been re-activated after expiration were still displaying a status of Expired. This bug has been corrected.
Contracting Party will display correctly after it has been changed via amendment	A bug that prevented the Contracting Party from being correctly updated when an Amendment was approved has been corrected.
Corrected bug where amendment approval added multiple copies of agreement to main submission	A bug that caused multiple copies of the final agreement to be copied from an approved amendment to the main submission has been fixed.

Data Safety Enhancements

What has changed…	What it means…	How it looks (as applicable) …
SmartForm		
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).	
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.	
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.	
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-submision 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.*	
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.	

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 approproate 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.	

Tabs updated to show department and school for all submission types	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.
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

What has changed…	What it means…	How it looks (as applicable) …
SmartForm		
Minor clarifications to question prompts and Professional Services options	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.	
Sorted disclosures on Disclosure Details page in alphabetical order	Disclosures listed on the Disclosure Details page are listed in alphabetical order by Organization name.	
Corrected bug that allowed disclosers to skip the Disclosure Details page even if they already had Disclosures	Previously disclosers were able to indicate that they did not have outside activites 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.	
Activities		
Improved Administrative Review Complete timeout	Reviewers have been unable to complete reviews for Certifications that include a large number of Disclosures.	
Notifications		
Added GMAS Project ID to subject of Research Certification notice	The subject line of the Research Certification notice now includes the ID for the GMAS Project the certification is associated with.	
Minor clarifications to notifications	Minor changes to the instructions in the Draft Status Reminder to disclosers and the Research Certification notice.	
Reports		
Added new reports	Several new reports are available: • **All Disclosures** – This report displays all active disclosures in the system. The report can be filtered by discloser, department, and/or organization. • **Annual Report** – This report includes information about annual certifications to help support annual reporting requirements. • **Certification Comments** – This report includes all comments added to certifications during the previous two months for easy reference by reviewers. • **OAIR Outside Activities for Biosketch and Other Support** – This report includes a discloser's outside activities to help them complete the Biosketch and Other Support information for sponsored project proposals.	

Minor report updates	**Annual Certifications Not Submitted** has been changed to **Annual Certifications in Draft** to clarify report contents.
Miscellaneous	
Updated 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.