

1.26.5 Minor Configuration Release Items: December 2023

Jump To

[Cross-Suite Enhancements](#)

[ESTR-IRB Enhancements](#)

[Agreements-DUA Enhancements](#)

[Data Safety Enhancements](#)

[OAIR Enhancements](#)

Icons below indicate the application(s) impacted by the enhancement.



ESTR-IRB



Agreements-DUA















Data Safety



OAIR

Cross-Suite Enhancements

What has changed...	What it means...	How it looks (as applicable) ...
SmartForm		
Department selection enhancements   	The following departments are additionally visible for selection across the suite: Collaborative on Academic Careers in Higher Education [COACHE] and Reach Every Reader [RER].	8. * Study's Department  Collaborative on Academic Careers in Higher Education [COACHE]   8. * Study's Department  Reach Every Reader [RER]  
Workspace		
Visual enhancement to submission reminder and relationship reminder across the suite: red “!” icon and red border around alert text.   	Submit reminder now includes red exclamation point “!” icon and with red border surrounding the text box. This change will appear only in workspaces where the user can take action.	<div style="border: 1px solid red; padding: 5px;">Important! The submit activity must be completed for review to begin. Only the Principal Investigator or Proxy can see and complete the submit activity on the left.</div>

What has changed...

Related Projects tab enhancement across the suite



What it means...

Related Projects region now displays additional fields for context and allows user to sort, filter and export as .csv.

How it looks (as applicable) ...

ID	Name	Date Created	Date Modified	Owner	Status	Contracting Party	Contracting Party Org	PI	IRB IRB Team	IRB Expiry
IRB22-0155		2/4/2022 4:07 PM	3/29/2022 1:50 AM	Bean, Kathryn Megan	Clarification Requested (Pre-Review)			Jiahua Freedman	Yuhua HUA Wang Julu Li	
DUA22-0246		2/22/2022 10:07 AM	3/8/2022 5:15 PM	Lee, Chrissy	Internal Review	Research Center on Data and Governance at Tsinghua University				
IRB22-0283		3/3/2022 4:02 PM	3/4/2022 9:17 AM	Sewards, Shannon	Not Human Research			Jon Star	HUA	3/3/2023
IRB20-1004		6/2/2020 1:46 PM	6/5/2020 3:58 PM	Parsons, Elizabeth B	Approved			Hannah Riley Bowles	HUA Logan Berg	

Personalize Table



Displayed Fields

Field	Order
<input checked="" type="checkbox"/> ID	↑ ↓
<input checked="" type="checkbox"/> Name	↑ ↓
<input checked="" type="checkbox"/> Date Created	↑ ↓
<input checked="" type="checkbox"/> Date Modified	↑ ↓
<input checked="" type="checkbox"/> Owner	↑ ↓

Options

Place the paging bar at:

Enable Auto-Refresh:





Refresh Data Every: seconds

[Export to CSV](#)

ESTR-IRB Enhancements

What has changed...	What it means...	How it looks (as applicable) ...
N/A		
<p>No enhancements to ESTR-IRB for 1.26.5 (beyond the following cross-suite enhancements noted above: Workspace submit alert with red icon and border; Expanded Related Projects information; ability to select COACHE and RER as study departments).</p>		

Agreements-DUA Enhancements

What has changed...	What it means...	How it looks (as applicable) ...
Activity		
Enhancement to available activities to allow Update Expiration Date.	In Agreements-DUA, reviewer can now execute Update Expiration Date activity while DUA is not in lapsed status. This eliminates the need to create an Amendment/CR for review and approval for this administrative change to the DUA.	<ul style="list-style-type: none"> Administrative Change Manage Related Projects Add Comment Update Expiration Date

What has changed...

What it means...

How it looks (as applicable) ...

SmartForm


Enhancement to selection of ancillary review types for reviewer.

Safety Reviewer can now assign ancillary review for data type “Data Source\CMS PI Attestation,” which will generate a message in PI’s workspace requiring attestation.

Reviewer view:

Manage Ancillary Reviews

1. Identify each organization or person who should provide additional review:

Ancillary Person	Organization	Type	Required	Accepted	Comments	Documents	Date Submitted
	OVRP-Research Data	Data Source/CMS PI Attestation	yes				
	Aston Martin (PI)	Data Source/CMS PI Attestation	yes				

PI view:

Submit Ancillary Review

1. * Select the review you are submitting:

Organization	Person	Review Type	Required
<input type="checkbox"/>		Data Source/CMS PI Attestation	yes

2. * Do you accept the proposed protocol?
 Yes No [Clear](#)

3. Comments:

4. Supporting documents:

Document	Date Modified
There are no items to display	

Displays for the PI only when the appropriate review type is chosen

! This project is related to one or more Data Use Agreements with the Centers for Medicare and Medicaid Services (CMS). As PI, you are being asked to review and confirm the following.

The Centers for Medicare & Medicaid Services (CMS) - Data Use and Protection Requirements Summary

1) Introduction
 CMS data is critical for researchers across several Harvard University schools. Research with CMS data is subject to strict rules and strictly enforced requirements imposed by the CMS.


Each Data Use Agreement (DUA) includes specific requirements regarding proper storage and management of the data. All persons named on the DUA must become familiar with and strictly follow these requirements.


CMS strictly enforces these requirements based on CMS Policy. Any violation will result in severe penalties, which may include:

- a) Permanent revocation of an individual researcher's privilege to receive or access CMS data.

Revised wording for Data Source selection and help text.

SmartForm directs PI/researcher to select “Other” if External data source does not appear in the drop-down list. Help text defines externally provided data as “data obtained from another institution.”

2. * Data source: 

Externally provided
 Indicate external source (if source does not appear, choose other):
 Other 

Provide a description of the source:

Help

researchsafetytrain.harvard.edu/Data/app/portals/HelpContent/ContentId=ContentFor...

Data Source

Indicate whether data is internally generated (e.g. data collected by research conducted by the study team), externally provided (e.g. data obtained from another institution), or a combination of both internal and external.

If external or a combination, select the source and provide information about any physical media on which the data will be received.

If the source is not listed, choose "other" and type in the name of the source.

What has changed...

Activity enhancement for approval date and approval activity.

What it means...

Approval and expiry date are now hidden in the summary until safety record is in post-review state.

Upon approval, reviewer can now manually update approval end date.

Reviewer can now suppress renew and track safety elements via the Approve activity: reviewer can check "Continuing review is required and approval cannot be extended via the Renew activity" to suppress renew and indicate risk (if appropriate).

How it looks (as applicable) ...

Notification

Notification enhancement for PI upon renew safety submission activity.

PI receives notification email with message "DATXX-XXXX: Renew Confirmation" when renew safety submission activity is executed.

Renewal Confirmation Complete

Allows a PI to renew a protocol via attestation.

Nov 17 2023	Author: Carlos Herrera (dev) (Harvard University)
	Logged For (Safety Submission): Benefits of Corgi pets on Medicare enrollees
	Activity Date: 11/17/2023 3:44 PM

Activity Form	Property Changes	Documents	Notifications	Recipients
Job Name	Subject			Recipients
<D>: Renewal Confirmation	This subject was generated by script and therefore could be different for each recipient. Here is an example rendering for recipient Aston Martin (PI): "DAT23-0026: Renewal Confirmation"			Aston Martin (PI) (Harvard University) email-asto

OAIR Enhancements

What has changed...

N/A

No enhancements to OAIR for 1.26.5 (beyond cross-suite Workspace submit alert with red icon and border noted above).

What it means...

How it looks (as applicable) ...