

1.26.1 Configuration Release Items: January 2022

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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...
Miscellaneous	
Added site search for office staff   	Site search is available to reviewing office staff. This feature allows for keyword search of information on submission records and within record attachments.
Updated system generated report links to use friendly naming convention    	The applications allow for navigation to submissions using the convention: Base application address + "ProjectID=" + Project ID. Reports which generate a friendly url have been updated to display this simpler web address convention.

History Funding Contacts Documents Follow-on Submissions **Reviews** Images/Photos Related Projects

External IRB Summary Information for Reviewers (during review only)

Harvard Manages Data: Yes
Conditions:
Data will be directly labeled with personal identifying information (identifiable)

PI: Deborah Asnes | PI ICDI: No
Harvard Team Members:

Name	Roles	Financial Interest	E-mail
Cathy Barber	Co-Investigator	no	cbarber@rshp.harvard.edu

Expand the following sections to view full content

- Reason for External IRB
- Study Description
- Site Description (if applicable)

What has changed...	What it means...	How it looks (as applicable) ...
Main Submission: Added related projects tab for External IRB workspace	Related projects tab was missing. During development for this release, this was fixed where possible. Note that some workspaces will not update until the next submission state change.	
Reporting		
New reports available in the Reports-Custom Reports section (for IRB office staff)	- Document list for export report: Additional report available to IRB staff only for use when a list of documents is needed for a determination letter. Please follow instructions in report summary to generate the list. - All Ancillary Reviews: Additional report that shows all ancillary review details for monitoring and analysis.	
Letters and Notifications		
Completing the withdraw activity sends a single notification	Prior to this fix, completing the Withdraw activity sent a duplicate notice to recipients. Now only one is sent.	

Agreements-DUA Enhancements

What has changed...	What it means...	How it looks (as applicable) ...
SmartForm		
Agreement Upload: Added instruction when a non-faculty or staff Principal Investigator/ Agreement Manager is entered	Instruction about additional information displays on the page and those that review the record can see the status of the Principal Investigator/ Agreement Manager.	
Agreement Information: Added indication of non-US data and possible additional policies or regulations which may apply	Additional questions* <i>Is this expected to include international data? And if yes, please write in the country/ies, if known.</i> The follow up text box allows the person to write in country/ies of origin.	
Agreement Information: Added ability for requestor to indicate the duration of data access	Additional question* <i>How long would you like access to the data (in years)?</i> allows requestor to indicate the number of years data access is needed.	
Agreement Information: Added ability for requestor to indicate if there are fees to access the data	Additional question* <i>Do you anticipate you will have to pay fees for the data?</i> allows requestor to indicate if there are known fees	

What has changed...

Additional Information: Added indication of if Harvard or Harvard researchers will have custody of the data

What it means...

Additional question* *Will the data be stored or managed at Harvard or otherwise using Harvard resources (e.g. physically on the premises or in Harvard Cloud Storage)?* allows for clarity regarding appropriate terms for the agreement.

* These required questions additionally impact records which are not yet submitted or are in review.

Responses need to be filled in prior to completing the submit activity or prior to submitting changes/response during review.

Track Agreement Elements (and section for tracking during activation): Included the ability to track for when PIPL applies

Additional tracking element of *Subject to China PIPL requirements* will show in reports and Agreement Document tab when marked by reviewer and can be used to ensure appropriate management.

Discard: Included optional comment on discard activity

There is a new optional comment field on the discard activity pop up. Information written into this space will appear on the record history.

Changed question on Submit Ancillary Approval Activity

When completing ancillary review, the prompt “Do you accept the proposed agreements?” is incorrect for the scope of review and has been updated for all types of ancillary review.

What has changed...

Manage Related projects: Allow reviewers to relate projects

What it means...

Enhanced permissions allow reviewers to relate projects even if they are not named contacts on the project.

Workspaces

Help Center includes Library of resources

New option for in-application access to templates and reference links to ease navigation for additional information.



Reporting

Status added to report by contracting party

Harvard Report: Agreements by contracting party now includes the record status

Letters and Notifications

Added reference to tracked elements in system notices

Activation, expiration and lapse notices reference the location of highlighted terms (including if destruction is required). Note that the tracked items and specific terms can only be accessed on the record Agreement Documents tab of the workspace and in the agreement/agreement amendment itself.

Updated expiration reminder subject

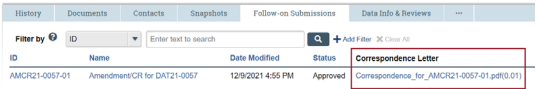
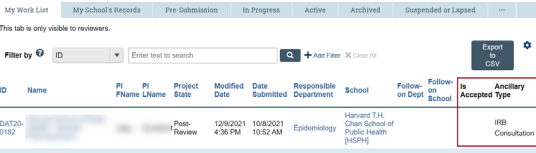
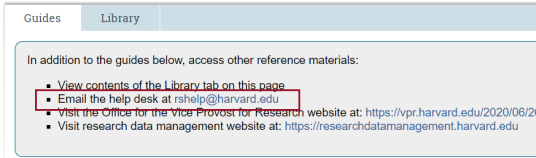
Some expiration reminders were missing the project ID, and this is now included.

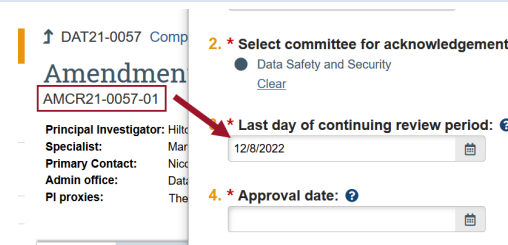
Miscellaneous

Updated document handling to not copy finalized documents to the custom extension

Fixed legacy use of a “custom extension” for document management. Documents are now more efficiently stored with the record and not duplicated on the extension.

Data Safety Enhancements

What has changed...	What it means...	How it looks (as applicable) ...
SmartForm		
Data Information-details: Show instruction for selection of USA on data information	The country label "USA" is prescribed by the application vendor and cannot be changed to "United States", so on-screen instruction is added.	3. * Data originates from the following country/countries: For United States enter "USA". Country There are no items to display
Data Information-details: Added option to indicate that data not stored at Harvard	Additional question <i>Will all of this data be stored or managed at Harvard or otherwise using Harvard resources (e.g. physically on the premises or in Harvard Cloud Storage)?</i> allows researcher to indicate if any other party will manage data. If yes, additional instruction appears.	7. Will all of this data be stored or managed at Harvard or otherwise using Harvard resources (e.g. physically on the premises or in Harvard Cloud Storage)? ☐ Yes ☒ No Clear 1 If any data are not stored or managed at Harvard, a data use or similar agreement may be required if one is not already in place. Please reference the Policy on Data Use Agreements to address any requirements.
Data Access: Additional instruction regarding destruction requirements.	New instruction about data destruction along with a link for details appears with the question.	4. Is there a requirement for data destruction? For example, partial destruction of identifiers only, complete destruction. ☐ Yes ☒ No Clear 1 Note that destruction requirements may be based on a policy, contract terms, or data source regulation (such as GDPR). Please reference information about data retention to address any requirements.
Workspaces		
Submission Workspace: Follow on tab now displays determination letter	Corrected bug where determination letter link was not visible on the Follow-On tab of the workspace.	
Safety: Added column to "My Work List" to indicate ancillary status (Reviewers Only)	List allows for easier prioritization based on the status of ancillary reviews.	
Help Center: Fixed minor text error on help center page template	Help text has typo on the line presenting the help desk email address and has been corrected.	
Letters and Notifications		
Added data information details to determination letter	Reviewers will see three options when generating a determination letter. Each template is available for each submission type and will include a) review notes when notes only have been added and b) data information details.	

What has changed...	What it means...	How it looks (as applicable) ...
Ancillary Review No Longer Needed notice will send when record is withdrawn or discarded, or when the review is removed	Corrected a bug so assigned ancillary reviewers are notified if their review is not complete and no longer needed.	
Approve Submission: Correctly populate expiry date on MODCR approval	When completing the approve activity, the expiration date should re-calculate on CR or AMCR.	
Miscellaneous		
Selecting reviewer as a recipient of a comment notice should only send to the assigned reviewer(s)	Addressed some elements of a bug so that the specialist is assigned as early in the creation of a record as possible. This will allow for sending a notice to the single assigned reviewer/review team. There are some less frequent circumstances where a notice can send to all reviewers, but the fix addresses the more common occurrence of the bug.	

What has changed...	What it means...	How it looks (as applicable) ...																		
SmartForm Added validation to require disclosers to add Disclosures if they indicated they had interests/activities to disclose	Previously disclosers could indicate that they had interests/activities to disclose on the What to Include page and submit the certification without adding any disclosures. Now if the discloser tries to submit with not disclosure, they will be prompted to update their answer to the question on the What to Include page or add disclosures before submitting.	You Are Here: 📄 Annual Disclosure Certificatio... Editing: DC00005505 Go to forms menu Print Help Could not update the Disclosure Certification due to one or more errors: Validation Failed: You indicated that you have interests to include but did not add any. Please go back to the Disclosure Details page and add relevant interests or go back to the What to Include page and change your answer at the bottom of the page to No. Assurance and Certification - I hereby acknowledge that I have read and understand the Financial Conflicts of Interest Policy and the Statement on Outside Activities of Holders of Academic Appointments (to the extent that it applies to me and my role at the University), including the requirement to update this report within 30 days of a new outside activity or acquiring a new interest. - I affirm that the information provided is, to the best of my knowledge, true and complete and does not misstate any facts. - I will provide any additional information as requested. - I agree to cooperate in the development of any needed management plan to manage, reduce, or eliminate existing conflicts of interest or conflict of commitment related to my research, teaching and university activities.																		
Is Foreign question is required for write-in organizations	When disclosers create or update a Disclosure for a write-in organization, they will be required to indicate whether the organization is foreign. The possible responses are Yes, No, or Don't Know. The question prompt has been updated to be consistent with other University guidance regarding disclosing activities with foreign organizations. Previously provided responses to the question have been retained.	Organization Information The organization you are reporting on does not already exist in the database. Please provide some information abo ★ Organization name: Boston Cognitive Solutions - Is this organization publicly traded? ☐ Yes ☒ No Clear - Is this organization for profit? ☐ Yes ☒ No Clear ★ Is this organization a foreign entity, i.e. organized outside the United States? 																		
Added Professional Services types to the Disclosure Details page	On the Disclosure Details page of the Certification SmartForm, the Professional Services types will display for any disclosures that include Professional Services or Employment.	New/Modified Disclosures: <table><tr><th>View/Edit</th><th>Organization</th><th>Is Public Company</th><th>Relationships</th><th>Disclosure Types</th><th>Professional Services</th><th>Total Value</th><th>Last Updated</th><th>Remove</th></tr><tr><td></td><td>Targanta Therapeutics</td><td></td><td>Self</td><td>Professional Services or Employment</td><td>Consulting Speaking engagement, invited lecture, or presentation</td><td>\$3,000.00</td><td>12/13/2021 5:21 PM</td><td></td></tr></table>	View/Edit	Organization	Is Public Company	Relationships	Disclosure Types	Professional Services	Total Value	Last Updated	Remove		Targanta Therapeutics		Self	Professional Services or Employment	Consulting Speaking engagement, invited lecture, or presentation	\$3,000.00	12/13/2021 5:21 PM	
View/Edit	Organization	Is Public Company	Relationships	Disclosure Types	Professional Services	Total Value	Last Updated	Remove												
	Targanta Therapeutics		Self	Professional Services or Employment	Consulting Speaking engagement, invited lecture, or presentation	\$3,000.00	12/13/2021 5:21 PM													
Removed the Choose Yes instruction from the What to Include page	Previously instructions might display to the discloser on the What to Include page if they already had active disclosures on file. However, these instructions were not always accurate and have been removed.	If you have any questions about what <u>else</u> needs to be included, keep in mind the following: - Include any relationship that relies upon the experiences and professional expertise that serve as the basis for your faculty appointment and/or role at this institution. - In determining relatedness to your institutional responsibilities, faculty and researchers should apply a standard of common sense -- include interests that you would reasonably expect your peers to disclose and when in doubt, disclose. - Finally, these reporting requirements are independent of whether your activities or financial interests represent a potential, perceived, or actual conflict of interest. ★ Do you have any outside professional activities and/or other relevant int ☒ Yes ☐ No Clear Choose yes. You have active disclosures on file that require review and possible update. For reference when completing the remaining elements of this form, the information on What to Include can be accessed at any time via the help icon in the upper right corner of the form or on the Office of the Vice Provost Research website. This instruction has been removed.																		

What has changed...

What it means...

How it looks (as applicable) ...

Added Clarifications and Comment activities to Summary tab of Certification workspace

Clarifications requested, changes submitted, and comments added will display on the Summary tab of the Certification workspace in addition to the History tab, when the Certification is in review.

Added GMAS Project ID to Awaiting Submissions and All Certifications tabs

The GMAS Project ID will display for research certifications on the Awaiting Submissions and All Certifications tab.

Added Export button to Administrative Review, Awaiting Submission, and Under Management tabs

The contents of the any of the submissions tab can now be exported to Excel.

Notifications

Added notification to reviewers when a research certification is submitted

When a research certification is submitted and requires review, the reviewers for the discloser's school of affiliation and for the project school, if different, will receive a notification.

Link: Research Initiated Certification for [redacted]: GmasSegment26044110

A research certification has been submitted for review. Please click on the link above to review the submission. Note: If you do not have access to the certification, you will need to contact a reviewer for the Discloser's school.

Discloser: [redacted]

Discloser's School: Harvard Medical School [HMS]

Project Title: [redacted]

Project ID: 26044110

Project School: Harvard John A. Paulson School of Engineering and Applied Sciences [SEAS]

Discloser Guest Orgs:

Wyss Institute [HMS]

This is a system notice, please do not reply.

Office of the Vice Provost for Research

Minor updates to notifications

- The extra spacing between the reviewer recipients' first and last name was removed from the Update Certification Submitted and Changes Submitted notifications.
- The text of the Reminder of Changes Requested notification now references the details of the clarifications request on the Summary tab rather than the History tab of the Certification.

What has changed...	What it means...	How it looks (as applicable) ...
Reports		
Added new report with certification links	Added a new report Harvard Report: Certifications in Draft with Links that includes all Certifications in Draft status and displays a direct link for each certification.	
Updated reports to include new Is Foreign question responses	Updated Harvard Report: All Disclosures, Harvard Report: OAIR Outside Activities for Biosketch and Other Support to include discloser responses to the new Is Foreign question.	
Miscellaneous		
Fixed bug related to long GMAS Project Titles	Previously the GMAS-OAIR approval process would fail if the GMAS project title was longer than about 240 characters. This bug was corrected.	
Updated link to OVPR website in the Help Center	Corrected link to the OVPR website to reflect recent website updates.	