1.26.4 Minor Configuration Release Items: July 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.
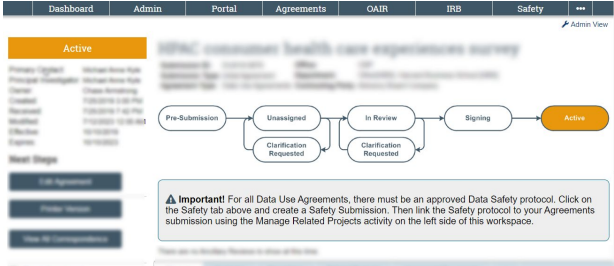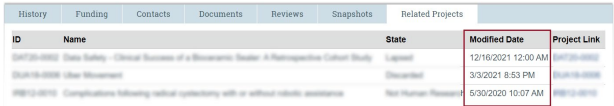>
> 👥 ESTR-IRB   📄 Agreements-DUA   🔒 Data Safety   👥 OAIR

Cross-Suite Enhancements

What has changed…	What it means…	How it looks (as applicable) …
Workspace		
Main study: New instruction when there is a missing relationship 👥 📄 🔒	Where the relationship to another project is indicated based on the information on the record, new warnings appear with instructions on the main study workspace. Instruction appears: • *ESTR-IRB: When use of sensitive data is confirmed by a reviewer or by the committee and no Data Safety record is linked.* • *Agreements-DUA: If no Data Safety record is linked.* • *Data Safety: If no relationship exists.*	
Main study: Related projects listing display by date modified 👥 📄 🔒	Projects will automatically display with most recently changed or updated items at the top.	

ESTR-IRB Enhancements 👥

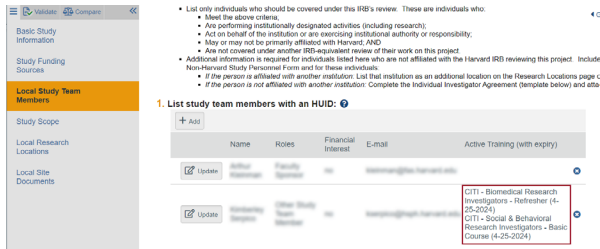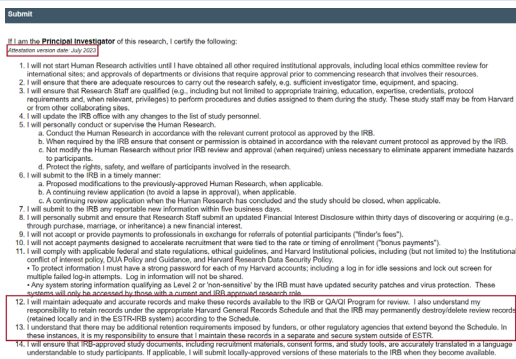| What has changed...	What it means...	How it looks (as applicable) ...
SmartForm		
Study Team Members: Active Human Subjects Training displays on list of team members	Active training type and expiry date displays for Harvard team members both on the SmartForm page where the team member is added and on the Project Contacts tab in the workspace. Since only active training displays, a blank space means active training may not be on file with the IRB.	
External IRB: Additional questions regarding research activity	Additional information about activity can be entered directly into the SmartForm and support more efficient review and reporting. Some new questions are also required.* Reference the study submission guide for a full list of new questions and option information.	

* New 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.

Activity		
Submit and Assign PI Proxy: Revised attestation language	Updated record management practices (and process for record deletion) are now described the researcher attestation (and supporting documentation). An attestation language version date is also included for reference within the ESTR.	

What has changed...	What it means...	How it looks (as applicable) ...
Discard: Display instruction regarding the scope of the discard	Information about discarding a follow-on submission displays on the discard activity pop-up when discarding a follow on.	**Discard** Discard this submission? ⓘ **Caution: This activity will permanently remove the current submission from consideration.** Completion of this activity on a continuing review, modification, update, or report of new information will not impact the status of the main study (if there is one) or other related records.
Manage Ancillary Review: Ancillary review type now a required entry	Requiring entry will reduce errors and support the ability to report on review types.	**Add Ancillary Review** 1. * Select either an organization or a person as reviewer: Organization: [ ] ... Person: [ ] ... 2. *Review type: [▼] 3. * Is a response required? ○ Yes ○ No Clear

Workspace

Meetings: (IRB staff and committee members only) Past meetings tab display Report by Agenda Item	This new report allows for display of all agenda items in one list so information can be filtered by study (or its follow-on submissions).	
Meetings: (IRB staff and committee members only) Correct assigned reviewers display	Previous assignments display more reliably on the meeting workspace. Note that the display format has also changed.	

Agreements-DUA Enhancements

What has changed...	What it means...	How it looks (as applicable) ...
SmartForm		
Agreement information: If data are international, additional question displays to choose country	Applicable local laws may be considered during the review process and the specific source information can also be referenced in reports.	
Notification		
Activate and expiration notices include tracked items and highlighted terms	In addition to the current important link to the full Data Use Agreement which contains all associated terms and conditions, the emails include helpful reference highlighted terms and summary attributes of the agreement.	
Activity		
Activate and Track Agreement Elements: (reviewers only) Added elements	New items to mark: • State specific regulation applies per the terms of the DUA. • Non-custodial agreement (i.e. the data will not be stored at Harvard)	

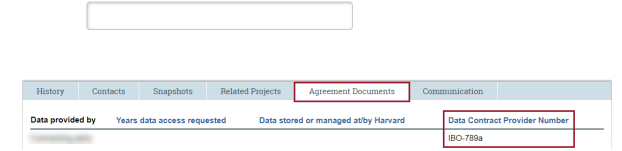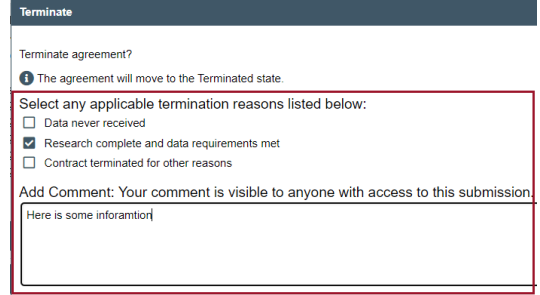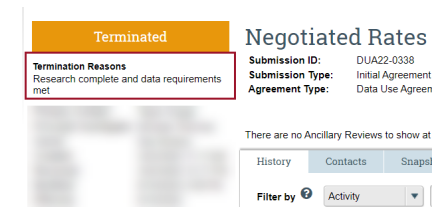| What has changed...	What it means...	How it looks (as applicable) ...
Activate and Track Agreement Elements: (reviewers only) Optional entry of contracting party agreement reference ID	Opportunity for the reviewer to indicate the contracting party's reference number for easier tracking and searching in Agreements. Information also displays on the Agreement Documents tab of the workspace.	**3.** Data provider agreement reference number or ID (if applicable): History / Contacts / Snapshots / Related Projects / Agreement Documents / Communication Data provided by / Years data access requested / Data stored or managed at/by Harvard / Data Contract Provider Number / IBO-789a
Terminate: (reviewers only) Optional entry of termination reasons and comment	Without additional mechanisms for closure, terminate reasons allows for a space to confirm the different types of agreement term end reasons in addition to simple end of period of performance and termination prior to the end of the period. Selected reasons appear under the terminated status on the workspace.	**Terminate** Terminate agreement? ⓘ The agreement will move to the Terminated state. Select any applicable termination reasons listed below: ☐ Data never received ☑ Research complete and data requirements met ☐ Contract terminated for other reasons Add Comment: Your comment is visible to anyone with access to this submission. Here is some inforamtion **Terminated** — Negotiated Rates Termination Reasons: Research complete and data requirements met Submission ID: DUA22-0338 Submission Type: Initial Agreement Agreement Type: Data Use Agreen There are no Ancillary Reviews to show at History / Contacts / Snaps Filter by ⓘ Activity

Miscellaneous

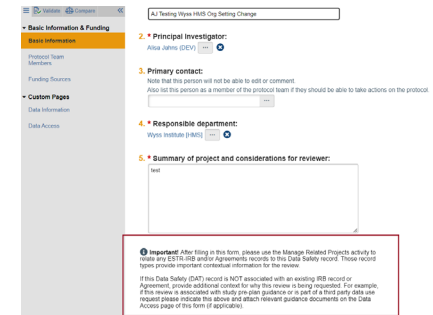|		
Common agreement type background setup	The application is now technically prepared to allow for management of additional agreement types. Further discussion is required prior to availability.	
Use person primary affiliation to drive reviewer view	Agreements tabbed views are now driven by information about a person's affiliation. For reviewers, the application had previously used "research experience" as a workaround. The workaround is removed.	

Data Safety Enhancements 🔒

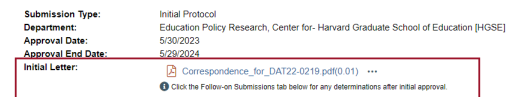| What has changed...	What it means...	How it looks (as applicable) ...
SmartForm		
Basic Information: Additional instruction for initial submissions if there are no defined project relationships	The instructions are meant to support awareness of review dependencies at the time of initial record creation/ completion.	
Study Team: Allow for selection of additional role	To facilitate identification of individuals on the team with special roles on the project, Data Custodian has been added for selection as "role in research"	
Workspace		
Main study: Display instruction regarding the location of follow-on determinations	The initial determination appears on the main study workspace. Instruction appears below it regarding where to locate possible additional determinations following initial approval.	
Notification		
Confirmation of submission notice includes reference copy of attestation language	Newly added Principal Investigator attestation language that appears on the submit activity also appears in the confirmation notification for reference.	

What has changed...	What it means...	How it looks (as applicable) ...
Ancillary reviewer assignment notification has additional instruction	An ancillary reviewer message is now available on the Data Info & Reviews tab. Information about the location of this possible review context is in the notice.	
Continuing review reminder notice includes clarified instruction regarding who can complete which actions to renew	Different members of the research team can take different actions to request an extension of the approval period. This is described in the instruction of the notice.	
Continuing review deadline passed notice includes language related to data management responsibility at the end of data use	Some actions are required when data are no longer needed for active research. A summary of information and resources are available in the notice for researcher reference.	
New notice of relationship addition post approval	When a relationship is added after approval, the researcher is notified of a new relationship. The notice includes a reminder to update all related reviews, as needed.	

What has changed…	What it means…	How it looks (as applicable) …

Activity

What has changed…	What it means…	How it looks (as applicable) …
Submit and Assign PI Proxy: Researcher attestation language visible on activity	Newly added Principal Investigator attestation language that appears on the submit activity to increase awareness of roles and responsibilities.	
Submit: Related project warning notice displays and comment required	If no relationships with other projects are identified on the record at the time of completion of the submit activity, a message will appear along with a required space for researcher note.	
Edit Ancillary Review: Space available to enter message to ancillary reviewer	Ancillary review-specific comments can be added on assignment and now appear on the Data Info & Reviews tab. Instructions regarding the location of any notes have also been added to the ancillary review assignment notice.	
Request Closure: Update question text questions	Question 1 on the activity includes clarified confirmations regarding necessary actions at the time of closure.	

What has changed...	What it means...	How it looks (as applicable) ...
Close Protocol: (reviewer only) Reviewer information is clarified	Question 1 for reviewers corresponds with their actions in the system.	**Close Protocol** You are permanently closing this protocol. 1. ***** I agree to close this Data Safety protocol and discard its follow-on submissions: ○ Yes ○ No _Clear_ 2. **Comments:**
New activity: Track Safety Elements(reviewer only)	Reviewer activity available on main records in all states of review to allow for tracking of specific items of interest that are useful for tracking and reporting. Items tracked can only be tracked by reviewers and are visible to all individuals with access to the project workspace.	✓ Track Safety Elements
Submit response (during closure): increase visibility to display for Principal Investigator and team	The activity is now visible to those who need to respond to questions from reviewer. *Note: There is still a known issue where an error may occur when attempting to complete this activity. Email* rshelp@harvard.edu *if this arises.*	
Miscellaneous		
Safety reviewer permission update	Reviewers can create follow-on submissions to support initiating/ managing submission and review requirements.	
PI access update	Amendment to change Principal Investigator led to some issues with access through the review (until approval). This bug has been fixed, allowing the newly named PI to access the amendment sooner.	
Missing instruction for country selection added back for reference	Informational text added in a prior release was removed in error and has been added back.	
Criteria for reminder of continuing review notice refinement	The original criteria could cause missed notices for projects previously extended via renewal. This is updated so no reminder notices are missed.	

OAIR Enhancements

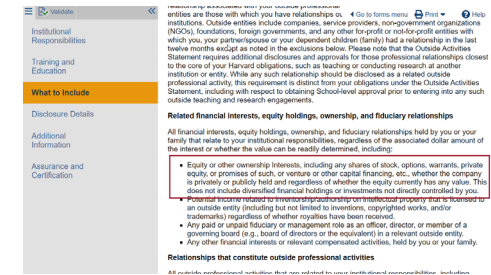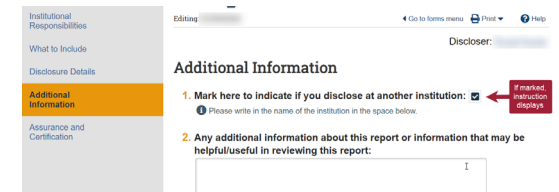| What has changed...	What it means...	How it looks (as applicable) ...
SmartForm		
What to Include and Equity relationship details: clarifications relative to venture capital relationships	Revisions to include National Science Foundation updates to reporting requirements	
Additional Information: Additional option to indicate if the person discloses at another institution	Can only be entered if there are items to disclose and allows the person to indicate that details are provided elsewhere, along with the name of the other institution.	
Disclosure Details: Minor revisions to questions 2 and 4 for individuals with research	Clarified prompts for indicating elements of research. Both questions appear on the Disclosure Details (when a person is filling in information about a specific entity relationship/activity) only if the person is involved in research.	
Assurance and Certification: additional instruction regarding when a person chooses to submit from the form	When navigating away from the last page, the intent to submit from the form does not always complete properly. Additional instruction is intended to support discloser awareness of what to expect next.	
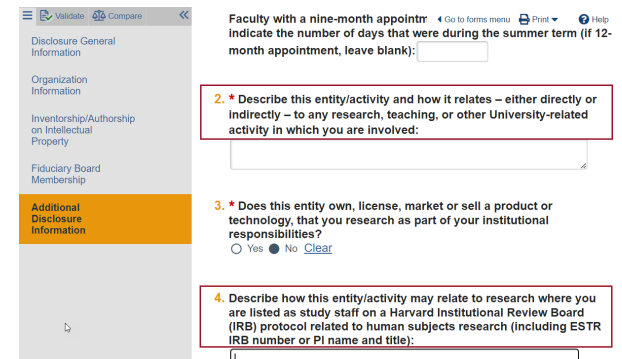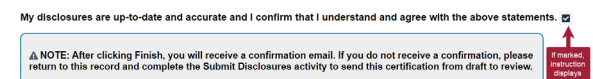
What has changed…	What it means…	How it looks (as applicable) …

Notifications

New reminder notification for disclosers who started their reports and did not finish them	Notice sent when discloser indicates that they have no outside activities and that they inteded to submit from the last page of the form but it did not submit successfully. Email subject: You are almost done! – Submit Your Recently Updated Outside Activity and Interest Report	

Activities

Prepare Correspondence: (reviewer only) Additional template with brief text regarding next steps	New template added for circumstances where the discloser has accepted the management plan through another mechanism and additional actions will be taken by the reviewer.	
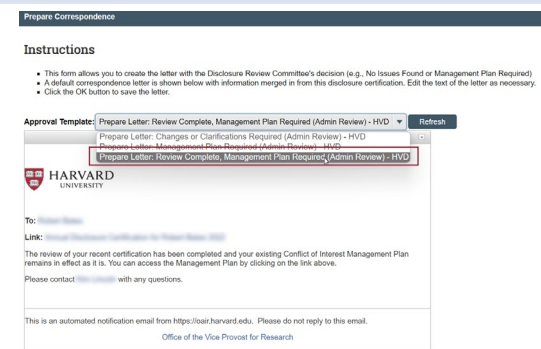
Workspace

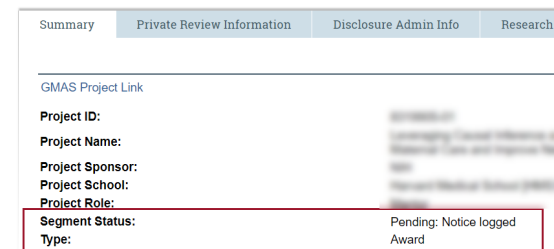|		
Research certification: Additional display of segment/request status and type	Information is visible when visiting the research certification workspace for easier review and prioritization	
Certification (all): (reviewer only) Added GMAS person link on research projects tab	Tab and link visible to reviewers, allowing acces to GMAS details (including portfolio) only if the person already has access to GMAS.	
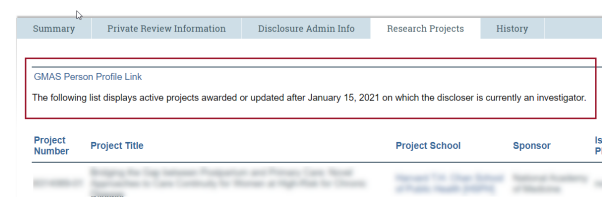
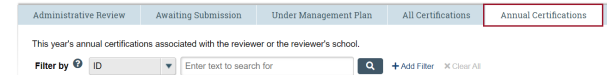| What has changed...	What it means...	How it looks (as applicable) ...
Certification listing: (reviewer only) new annual certification tab	Annual certificaiton tab displays only the current year of annual certifications for a reviewer's primary school and does not also show annual certifications where the reviewer is viewing as a guest.	
Certification listing: tabs display GMAS ID and status	Two new columns appear for easier filtering and sorting of research certifications within a list of many types of certification.	

Miscellaneous

School custom text for annual certification notification	On the organization and by contacting oairhelp@harvard.edu, schools can define a short message to be included in the annual and reminder notices. Note that the text is used for initial annual, and annual plus update draft reminders so it should be removed following the due date of the annual period.	