

1.27.1 Minor Configuration Release Items: January 2025

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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...

There are no cross-suite enhancements with Minor Configuration Release 1.27.1.

ESTR-IRB Enhancements

What has changed...

SmartForm

Basic Study Information, Question 4. What Kind of Study is This? includes updated help text defining multi-site and single-site studies. The help text also reminds the user to ensure documents are attached if the study has been changed from multi-site to single-site or vice versa.

What it means...

When answering the question “What kind of study is this?” users see an updated, concise definition of whether to choose a multi-site study or a single-site study.

A reminder to check for successful attachment of documents provides the user with an opportunity to ensure the protocol draft is complete before continuing to the next smart form.

How it looks (as applicable) ...


Basic Study Information

Visit the [ESTR Support Site](#) for guidance on using this system and completing this form.

1. * Title of study:

2. Short title:


3. Brief description or abstract:

4. * What kind of study is this? 

Multi-site or Collaborative study

Single-site study

Clear

 Choose "multi-site or collaborative" where there is more than one site conducting the study, if there is possible collaboration with non-Harvard researchers, or if it is unclear if there will be additional sites.

What kind of study is this?

- Choose **Single-site study** when only Harvard investigators are involved in the research. Note that a single-site study can have multiple research locations, but only Harvard investigators are involved.
- Choose **Multi-site or Collaborative study** when there are both Harvard and non-Harvard researchers involved in the research.

If study is changed from Multi-site to Single Site (or vice versa) before submission, please ensure all attachments have been successfully uploaded after the change is made.

What has changed...

Center for Race, Inequality and Social Equity Studies [CRISES] appears as an organization with type: department under parent organization Faculty of Arts and Sciences.

What it means...

Users can choose Center for Race, Inequality and Social Equity Studies [CRISES] for a study's department.

This department appears in reports that display department-level data.

How it looks (as applicable) ...

8. * Study's Department ?

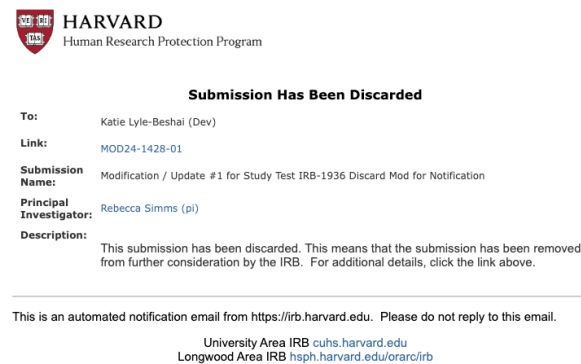
Center for Race, Inequality and Social Equity Studies [CRISES] ... ✕

Notifications

Discard notice uses Harvard-specific language and Harvard-specific format.

Upon IRB submission discard, users receive a notification that displays Harvard-specific formatting and includes Harvard-specific language.

Previously, post-upgrade to 10.5, users saw a default notice without Harvard-specific language or formatting. This change ensures consistency across notification templates.



HARVARD
Human Research Protection Program

Submission Has Been Discarded

To: Katie Lyle-Beshai (Dev)

Link: [MOD24-1428-01](#)

Submission Name: Modification / Update #1 for Study Test IRB-1936 Discard Mod for Notification

Principal Investigator: Rebecca Simms (pi)

Description: This submission has been discarded. This means that the submission has been removed from further consideration by the IRB. For additional details, click the link above.

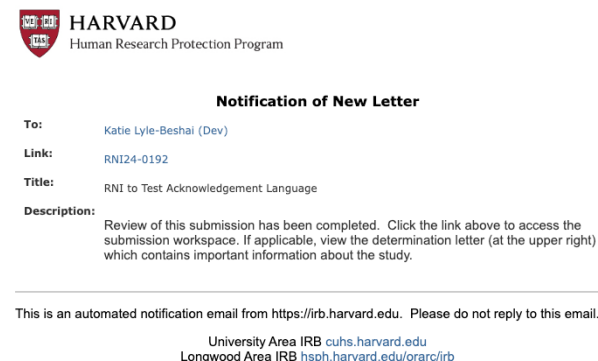
This is an automated notification email from <https://irb.harvard.edu>. Please do not reply to this email.

University Area IRB cuhs.harvard.edu
Longwood Area IRB hsph.harvard.edu/orarc/irb

RNI acknowledgement notice uses updated language, referring user to view letter only if applicable.

Upon RNI acknowledgement, the user receives a notification alerting them to determination status. This notification specifies that a letter can be viewed if applicable.

Previously, users received a notice referencing a letter regardless of whether the user indeed received a letter. This distinction clarifies that users only see a determination letter if it is applicable to their submission decision.



HARVARD
Human Research Protection Program

Notification of New Letter

To: Katie Lyle-Beshai (Dev)

Link: [RNI24-0192](#)

Title: RNI to Test Acknowledgement Language

Description: Review of this submission has been completed. Click the link above to access the submission workspace. If applicable, view the determination letter (at the upper right) which contains important information about the study.

This is an automated notification email from <https://irb.harvard.edu>. Please do not reply to this email.

University Area IRB cuhs.harvard.edu
Longwood Area IRB hsph.harvard.edu/orarc/irb

Guidance updates

The IRB Submission guide language was updated to clarify that large files should be in .zip format.

Users will see language indicating large files must be compressed as a .zip file.

Agreements-DUA Enhancements

What has changed...

What it means...

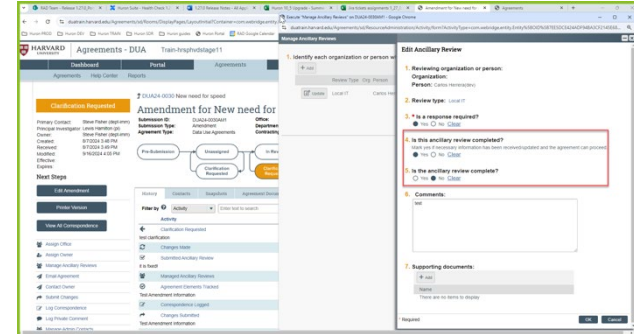
How it looks (as applicable) ...

SmartForm

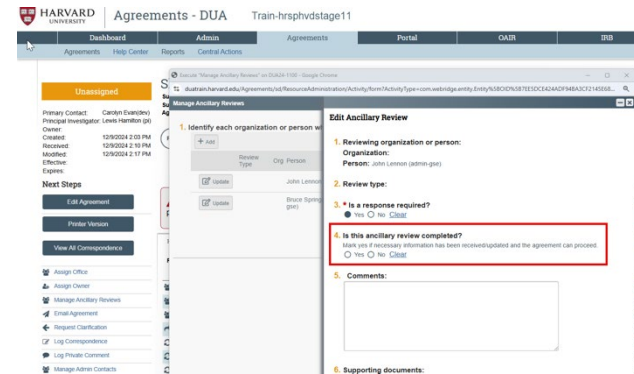
Removed duplicate question on Edit Ancillary Review form.

When one created an ancillary review and then returned to Manage Ancillary Review and clicked "Update" next to the ancillary review it was still showing a duplicate question asking if the review was complete. We removed that duplicate question from this SmartForm.

Previous View:



Updated View:



What has changed...

What it means...

How it looks (as applicable) ...

Workspaces/Reporting

We updated several reports and workspaces in DUA to use the updated State Name (Internal Signature and External Signature) from the fall release.

For the reports and workspaces listed on the right we changed the reports to look at Project.State.Name instead of Project.State.ID, so you will no longer see the old "Routing for Signature" and "Out for Signature" states in these reports.

Workspaces:

Agreements: Display Office Work HVD-All
Agreements: Display Office Work HVD-Progress
Agreements: Display Office Work ORA HVD
Agreements: Display Office Work OSP HVD
Agreements: Display Office Work SPA HVD

Reports:

Harvard Report: Incomplete review (over six months)
Harvard Report: Agreements CMS report
Harvard Report: Agreements with Contacts
Harvard Report: School Agreements in Review – HBS
Harvard Report: Agreements ad hoc report with Data Owner

The Ancillary Reviews workspace tab was not appearing correctly. The tab was hidden, included extra fields, and the reporting needed to be adjusted to correctly display the "Is Completed" information.

The Ancillary Reviews tab now appears and, when opened, it no longer includes extra unnecessary fields. In addition, there is the following note at the bottom of the page, informing users about use of the Accepted and Completed columns on the table:
"The 'Completed' column now supersedes the 'Accepted' column. For older records, 'Completed' may be blank. For new records, only 'Completed' will indicate whether ancillary reviews are finished ('Yes' or 'No')."

Previous View:

Review Type	Person	Organization	Required	Requestor Comments	Requestor Documents	Accepted	Completed	Reviewer Comments	Reviewer Documents	Date Review Created	Date Review Submitted
Agreement Manager/Principal Investigator			yes			yes	no				
Agreement Creator/Primary Contact	Need Shah	shah@hgh.harvard.edu									Active
Agreement Owner/Assigned Reviewer	Janice Little	janicelittle@hgh.harvard.edu									Active
Contracting Party	Wendy Chan	wchan@hgh.harvard.edu								617-432-4135	
Agreement Collaborators	Dr. John Evins	John.Evins@chbcu.edu								919-860-8330	
Guests Who Can View This Submission											

Updated View:

Review Type	Person	Organization	Required	Requestor Comments	Requestor Documents	Accepted	Completed	Reviewer Comments	Reviewer Documents	Date Review Created	Date Review Submitted
OSM	Carla Herrera (S&C)	HBS Information Security	yes	info@hbs.com	no	yes	no	info@hbs.com	no	11/22/2024	11/22/2024
Local IT	Carla Herrera (S&C)	HBS Information Security	yes	info@hbs.com	no	yes	no	info@hbs.com	no	11/22/2024	11/22/2024
Department	Martin Raskley		no			yes	no				

Note:
The "Completed" column now supersedes the "Accepted" column. For older records, "Completed" may be blank. For new records, only "Completed" will indicate whether ancillary reviews are finished ("Yes" or "No").

What has changed...

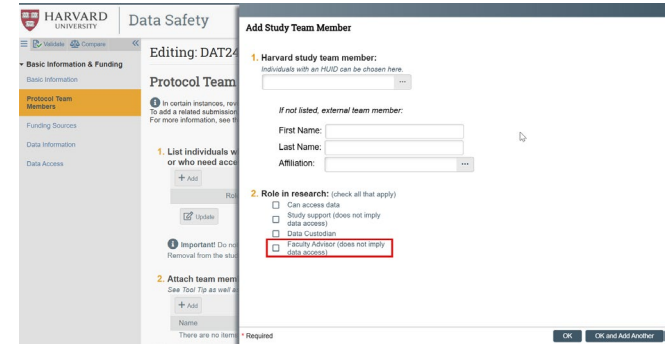
What it means...

How it looks (as applicable) ...

SmartForms

Changed settings of Protocol Team Member SmartForm to include an option for “Faculty Advisor (does not imply data access.)”

When you are creating/editing a Data Safety project and click Add (Study Team Member) on the Protocol Team Member SmartForm, you will see a 4th checkbox under Role in Research for Faculty Advisor.
More than one role can still be selected-that has not changed.



Language for Item # 2 on the Protocol Team Member SmartForm has changed to be clearer.

When you are creating/editing a Data Safety project and open the Protocol Team Member SmartForm, you will notice new language for Item # 2. We updated the language to now say “Attach team member specific documents such as security or privacy training information.”

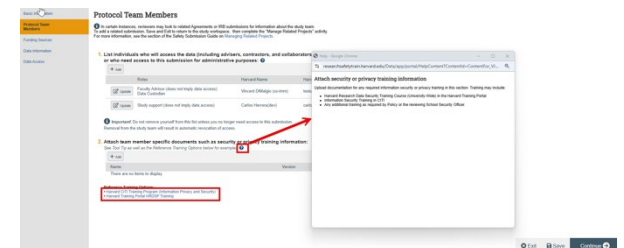
Previous View:

2. Attach security or privacy training information as applicable:
For example: CITI Informatic Security, required training information, or privacy training

Updated View:

2. Attach team member specific documents such as security or privacy training information:
See Tool Tip as well as the Reference Training Options below for examples

We added a Tool Tip for additional guidance and updated the hyperlinks found at the bottom of the SmartForm.



OAIR Enhancements

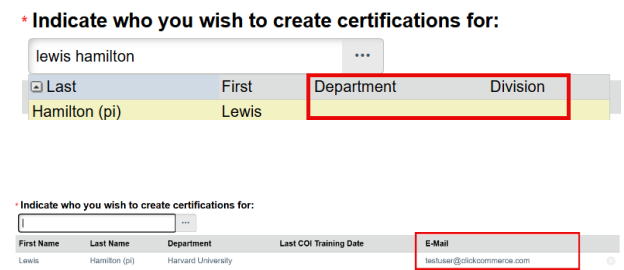
What has changed... What it means... How it looks (as applicable) ...

Activity

When creating a certification for someone you will now have additional information displayed to ensure you are selecting the correct person.

When you click the Create Certifications button, and type in the name of someone, there are now 2 additional columns (Department and Division) that are displayed in addition to Last and First Name.

Then when you select the person for whom you would like to create a cert, you will see their E-mail address appear next to the person's name, department, and last COI training date.

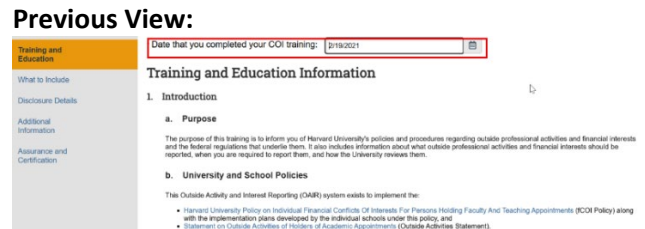


SmartForm

The Training and Education SmartForm no longer has a date of COI training completion field at the top of the page, as it was causing unnecessary confusion for users.

When creating a brand new certification for a new researcher or when it has been 3+ years since a researcher's last COI Training, the Training and Education SmartForm will appear for the user when they click Edit Disclosures.

The date of COI training completion field at the top of the page has been removed and now the system stores the date of completion using the date when the user clicks Yes to the attestation at the bottom of the page.



What has changed...

What it means...

How it looks (as applicable) ...

Updated View (top of page):

The screenshot shows a web interface with a left-hand navigation menu. The menu items are: 'What to Include', 'Assurance and Certification', and 'Research Information'. The 'Training and Education Information' section is highlighted in orange. The main content area displays the following text:

Training and Education Information

1. Introduction

a. Purpose

The purpose of this training is to inform you of Harvard University's policies and procedures, regarding outside professional activities and financial interests and the federal regulations that underlie them. It also provides information about what outside professional activities and financial interests should be reported, when you are required to report them, and how the University manages them.

b. University and School Policies

This Outside Activity and Interest Reporting (OAIR) system exists to implement the:

- Harvard University Policy on Individual Financial Conflicts of Interest For Persons Holding Faculty And Teaching Appointments (ECOI Policy) along with the implementation plan developed by the Individual Schools under this policy, and
- Statement on Outside Activities of Members of Academic Appointments (Outside Activities Statement).

Together, these documents outline the obligations of holders of academic and research appointments at Harvard to disclose their outside professional activities and financial interests to the University.

Updated View (bottom of page):

The screenshot shows the bottom portion of the web interface. The left-hand navigation menu includes: 'What to Include', 'Assurance and Certification', 'Research Information', 'Additional Information', and 'Assurance and Certification'. The 'Research Information' section is highlighted in orange. The main content area displays the following text:

Research Information

1. I certify that I have read and understand the education materials presented to me.

For approval, the Training and Education Information has to be submitted every year for the top end of the career spectrum of the holder of the position of the Harvard Medical School.

Exit Save Continue

For Research Initiated Certs, the language has changed on the Research Initiated Certification Information SmartForm to include projects that are not considered “research.”

When a user clicks “Edit Disclosures” for a Research Initiated cert, and then opens the Research Initiated Certification Information SmartForm on the left-hand menu, the language on that page has changed. It now shows the “Research Information” heading as “Project Information” and “Research Projects” has been changed to “Sponsored Projects.”

Previous View:

The screenshot shows the previous version of the web interface. The left-hand navigation menu includes: 'What to Include', 'Assurance and Certification', 'Research Information', 'Additional Information', and 'Assurance and Certification'. The 'Research Information' section is highlighted in orange. The main content area displays the following text:

Research Information

Project Information

Project Number: [input field]

Project Title: [input field]

Project School: [input field]

Sponsor: [input field]

Is PHS Plus: [input field]

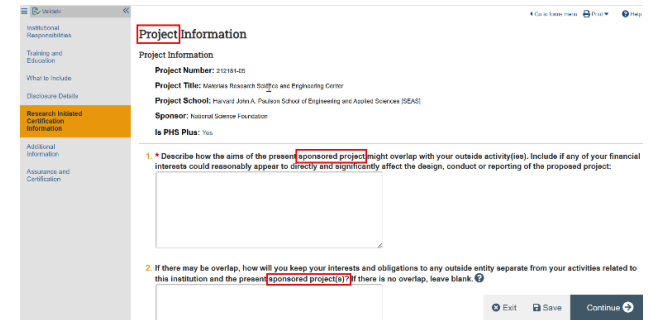
1. * Describe how the aims of the present research project might overlap with your outside activity(ies). Include if any of your financial interests could reasonably appear to directly and significantly affect the design, conduct or reporting of the proposed research:

[input field]

2. If there may be overlap, how will you keep your interests and obligation activities related to this institution and the present research project(s)?

Exit Save Continue

Updated View:



The language in the "What to include" SmartForm within a certification for reporting has been updated.

When a user clicks the Edit Disclosures button, they will see the What to Include SmartForm on the left-hand menu. Once clicked, it will open a page with this [updated language](#).