

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


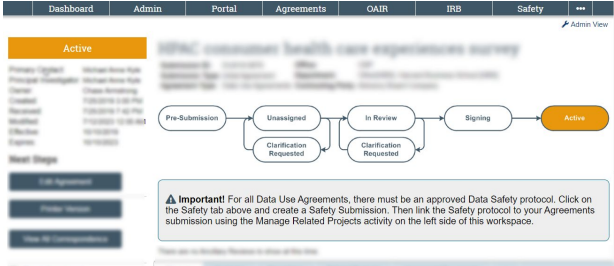

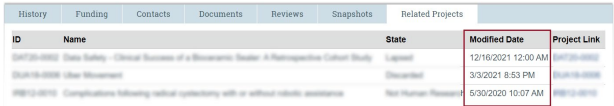


Data Safety



OAIR

Cross-Suite Enhancements

What has changed...	What it means...	How it looks (as applicable) ...
<p>Workspace</p> <p>Main study: New instruction when there is a missing relationship</p> 	<p>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:</p> <ul style="list-style-type: none"> • <i>ESTR-IRB: When use of sensitive data is confirmed by a reviewer or by the committee and no Data Safety record is linked.</i> • <i>Agreements-DUA: If no Data Safety record is linked.</i> • <i>Data Safety: If no relationship exists.</i> 	
<p>Main study: Related projects listing display by date modified</p> 	<p>Projects will automatically display with most recently changed or updated items at the top.</p>	

What has changed...

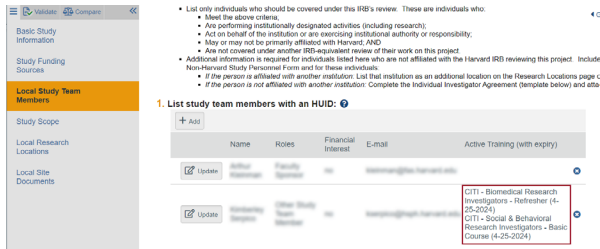
SmartForm

Study Team Members: Active Human Subjects Training displays on list of team members

What it means...

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.

How it looks (as applicable) ...






• List only individuals who should be covered under this IRB's review. These are individuals who:

- Meet the above criteria.
- Are performing institutionally designated activities (including research).
- Act on behalf of the institution or are exercising institutional authority or responsibility.
- May or may not be primarily affiliated with Harvard, AND
- Are not covered under another IRB-equivalent review of their work on this project.

• Additional information is required for individuals listed here who are not affiliated with the Harvard IRB reviewing this project. Include Non-Harvard Study Personnel Form and for these individuals:

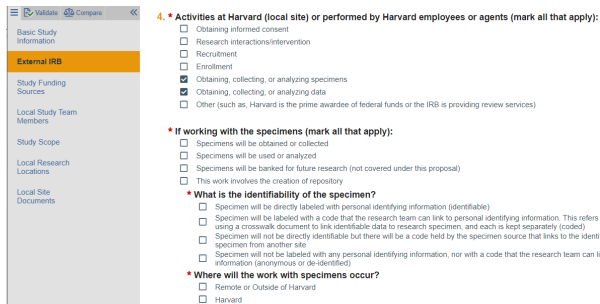
- If the person is affiliated with another institution: List that institution as an additional location on the Research Locations page.
- If the person is not affiliated with another institution: Complete the Individual Investigator Agreement (describe below) and state:

1. List study team members with an HUID: 

Name	Roles	Financial Interest	E-mail	Active Training (with expiry)
	Principal Investigator	Yes	xxxxxx@harvard.edu	CITI - Biomedical Research Investigators - Refresher (4-25-2024)
	Research Assistant	No	xxxxxx@harvard.edu	CITI - Social & Behavioral Research Investigators - Basic Course (4-25-2024)

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.



4. * Activities at Harvard (local site) or performed by Harvard employees or agents (mark all that apply):

- Obtaining informed consent
- Research interactions/intervention
- Recruitment
- Enrollment
- Obtaining, collecting, or analyzing specimens
- Obtaining, collecting, or analyzing data
- Other (such as, Harvard is the prime awardee of federal funds or the IRB is providing review services)

* If working with the specimens (mark all that apply):

- Specimens will be obtained or collected
- Specimens will be used or analyzed
- Specimens will be banked for future research (not covered under this proposal)

* What is the identifiability of the specimen?

- Specimen will be directly labeled with personal identifying information (identifiable)
- Specimen will be labeled with a code that the research team can link to personal identifying information. This refers using a crosswalk document to link identifiable data to research specimens, and each is kept separately (coded)
- Specimen will not be directly identifiable but there will be a code held by the specimen source that links to the ident specimen from another site
- Specimen will not be labeled with any personal identifying information, nor with a code that the research team can link to information (anonymous or de-identified)

* Where will the work with specimens occur?

- Remote / Outside of Harvard
- Harvard

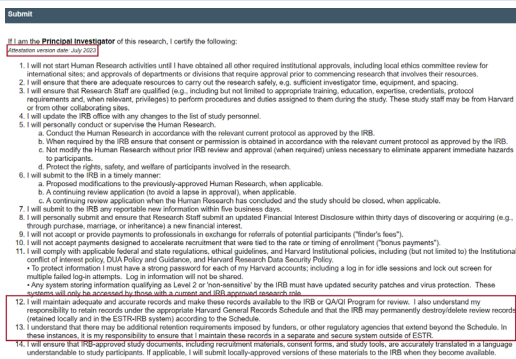
* New required questions additionally impact records which are not yet submitted or are in review.

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.



Submit

If I am the Principal Investigator of this research, I certify the following:

1. I will not start Human Research activities until I have obtained all other required institutional approvals, including local ethics committee review for international sites, and approvals of departments or divisions that require approval prior to commencing research that involves their resources.
2. I will ensure that there are adequate resources to carry out the research safely, e.g., sufficient investigator time, equipment, and spacing.
3. I will ensure that Research Staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study. These study staff may be from Harvard or from other collaborating sites.
4. I will update the IRB office with any changes to the list of study personnel.
5. I will personally conduct or supervise the Human Research.
 - a. Conduct the Human Research in accordance with the relevant current protocol as approved by the IRB.
 - b. When required by the IRB ensure that consent or permission is obtained in accordance with the relevant current protocol as approved by the IRB.
 - c. Not modify the Human Research without prior IRB review and approval (when required) unless necessary to eliminate apparent immediate hazards to participants.
 - d. Protect the rights, safety, and welfare of participants involved in the research.
6. I will submit to the IRB in a timely manner:
 - a. Proposed modifications to the previously-approved Human Research, when applicable.
 - b. A continuing review application (to avoid a lapse in approval), when applicable.
 - c. A continuing review application when the Human Research has concluded and the study should be closed, when applicable.
7. I will submit to the IRB any reportable new information within five business days.
8. I will personally submit and ensure that Research Staff submit an updated Financial Interest Disclosure within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.
9. I will not accept or provide payments to professionals in exchange for referrals of potential participants ("finder's fees").
10. I will not accept payments designed to accelerate payment that were tied to the rate or timing of enrollment ("bonus payments").
11. I will comply with applicable federal and state regulations, ethical guidelines, and Harvard institutional policies, including (but not limited to) the Institutional conflict of interest policy, OIA Policy and Guidance, and Harvard Research Data Security Policy.
 - To protect information I must have a strong password for each of my Harvard accounts, including a log in for site sessions and lock out screen for multiple failed login attempts. Log in information will not be shared.
 - Any system storing information qualifying as Level 2 or "non-sensitive" by the IRB must have updated security patches and virus protection. These systems will only be accessible by those with current and IRB approved research roles.
12. I will maintain adequate and accurate records and make these records available to the IRB or OACI Program for review. I also understand my responsibility to retain records under the appropriate Harvard General Records Schedule and that the IRB may permanently destroy/delete review records (created locally and in the ESTR-IRB system) according to the Schedule.
13. I understand that there may be additional retention requirements imposed by funders, or other regulatory agencies that extend beyond the Schedule. In these instances, it is my responsibility to ensure that I maintain these records in a separate and secure system outside of ESTR.
14. I will ensure that IRB-approved study documents, including recruitment materials, consent forms, and study tools, are accurately translated in a language understandable to study participants. If applicable, I will submit locally-approved versions of these materials to the IRB when they become available.

What has changed...

Discard: Display instruction regarding the scope of the discard

What it means...

Information about discarding a follow-on submission displays on the discard activity pop-up when discarding a follow on.

How it looks (as applicable) ...

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).

Name	Location	State	Tin
2024-2025 IRB Meeting	https://meetings.zoom.us/j/929776227	Schedule/02	02/20/2024
2024-2025 IRB Meeting	6648 Boulder St, Suite 200 - Zoom	Schedule/03	02/20/2024
Harvard Chan School IRB meeting	https://meetings.zoom.us/j/929776227	Schedule/07	02/20/2024
2024-2025 IRB Meeting	https://meetings.zoom.us/j/929776227	Schedule/08	02/20/2024
2024-2025 IRB Meeting	6648 Boulder St, Suite 200 - Zoom	Schedule/09	02/20/2024

Name	Description
Report by Agenda Item	List of all submissions assigned to meetings.

1 Items

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.

ID	Name	Coordinator	Assigned Reviewer Role	Submitted Date
2024-2025 IRB Meeting	2024-2025 IRB Meeting	Kara Thrope	Secondary Reviewer	02/20/2024
		Marty McFly	Primary Reviewer	02/20/2024
2024-2025 IRB Meeting	2024-2025 IRB Meeting	Kara Thrope	Secondary Reviewer	02/20/2024
		Marty McFly	Primary Reviewer	02/20/2024

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.

2. * Is this expected to include international data? Yes No [Clear](#)

Select country/countries if known. (Note: Multiple countries can be selected)

Name
Italy
France
Sweden

Write in any other countries or states if known:

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.

Notification of Agreement Activated

To:
Link:
P.I.:
Title:

Description:

The agreement is now active. Click on the link above to view the final documentation (under the Agreement Documents tab) which includes the full terms and conditions of the agreement. For easy reference, below is a limited list of highlighted terms or requirements associated with this agreement (as applicable). However, before you publish or share the data, check the terms of the full agreement.

Highlighted Terms of Agreement:

Specific restrictions on naming data provider in publication
Notification of breach to data provider less than 48 hours
Unilateral actions required of Harvard beyond provider notification in event of breach
Archival copy authorized
Destruction required

Other Agreement Attributes Noted by the Reviewer:

HIPAA-protected data: Limited Data Set
Personally Identifiable Data (other than HIPAA/FERPA-covered)
Subject to GDPR
State specific regulation applies per the terms of the DUA
Non-custodial agreement (the data will not be stored at Harvard)

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)

1. Agreement Tracking Elements (mark all that apply):

- Export-controlled data (ITAR/EAR)
- FERPA-protected data
- HIPAA-protected data: Limited Data Set
- HIPAA-protected data: PHI (i.e. more than a Limited Data Set)
- Master Agreement
- Personally Identifiable Data (other than HIPAA/FERPA-covered)
- Subject to DOD requirements (e.g. Covered Defense Information)
- Subject to NIST/FISMA requirements
- Subject to GDPR
- Subject to banking/financial regulations
- Subject to China PIPL requirements
- State specific regulation applies per the terms of the DUA
- Non-custodial agreement (the data will not be stored at Harvard)
- None

What has changed...

Activate and Track Agreement Elements: (reviewers only) Optional entry of contracting party agreement reference ID

Terminate: (reviewers only) Optional entry of termination reasons and comment

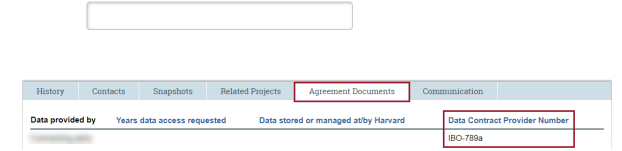
What it means...

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.

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.

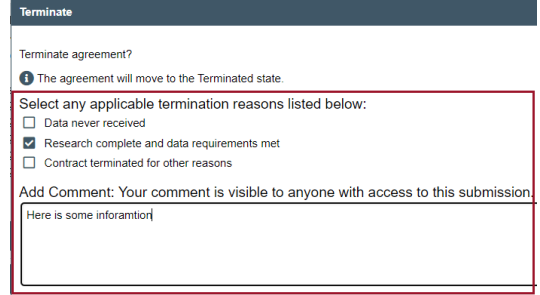
How it looks (as applicable) ...

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

Terminate agreement?

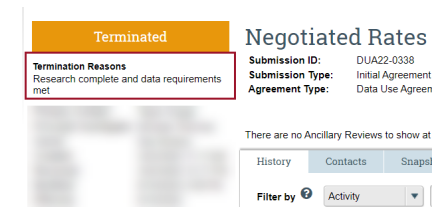
The agreement will move to the Terminated state.

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 information:



Terminated

Termination Reasons
Research complete and data requirements met

Submission ID: DUJ22-0338
Submission Type: Initial Agreement
Agreement Type: Data Use Agreeen

There are no Ancillary Reviews to show at

History | Contacts | Snapshots

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.

What has changed...

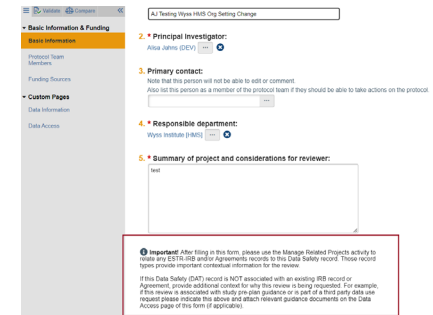
What it means...

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.



2. * Principal investigator:
Alexa Johns (DEV) ...

3. Primary contact:
Note that this person will not be able to edit or comment. Also list this person as a member of the project team if they should be able to take actions on the protocol.

4. * Responsible department:
WVU Institute (HMS) ...

5. * Summary of project and considerations for review:
Text

Required: After filling in this form, please use the Storage Based Project which is listed in ETR, IRB and/or Agreements records in the Data Safety record. Those records then provide important contextual information to the review.
If this review is associated with both a protocol submission or a set of data then both data and protocol should include the above and attach relevant guidance documents on the Data Access page of this form if applicable.

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”

Add Study Team Member

1. Harvard study team member:

Individuals with an HUID can be chosen here.

Mary McFly (sat-rev) ...

If not listed, external team member:

First Name:

Last Name:

Affiliation:

2. Role in research: (check all that apply)

Can access data

Study support (does not imply

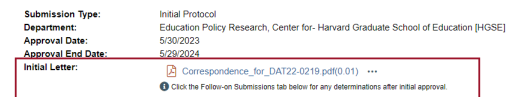
data access)

Data Custodian

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.



Submission Type: Initial Protocol
Department: Education Policy Research, Center for - Harvard Graduate School of Education (HGSE)
Approval Date: 5/30/2023
Approval End Date: 5/28/2024

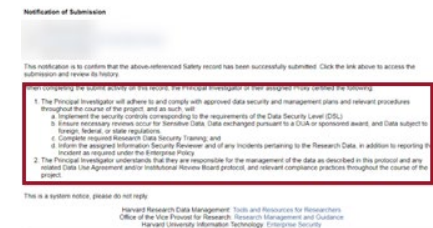
Initial Letter: Correspondence_for_DAT22-0219.pdf(0.01) ...

Click the Follow-on Submissions tab below for any determinations after 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.



Notification of Submission

This notification is to confirm that the above-referenced Safety record has been successfully submitted. Click the link above to access the submission and review its history.

Implementing the review process on this record, the Principal Investigator or their designated proxy must follow the following:

- The Principal Investigator will adhere to and comply with approved data security and management plans and relevant procedures throughout the course of the project, and as such:
 - implement the security controls corresponding to the requirements of the Data Security Level (DSL)
 - ensure necessary review prior to Sensitive Data, Data exchanged pursuant to a DUA or sponsored award, and Data subject to Transfer, Retention, or Data Repatriation.
 - Complete required Research Data Security Training, and
 - submit the assigned Information Security Reviewer and if any incidents pertaining to the Research Data, in addition to reporting it incident as required under the Information Policy.
- The Principal Investigator understands that they are responsible for the management of the data as described in this protocol and any related Data Use Agreement and/or Institutional Review Board protocol, and relevant compliance practices throughout the course of the project.

This is a system notice, please do not reply.

Harvard Research Data Management | Tools and Resources for Researchers
Office of the Vice Provost for Research | Research Management and Guidance
Harvard University Information Technology | Enterprise Security

What has changed...

Ancillary reviewer assignment notification has additional instruction

What it means...

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.

How it looks (as applicable) ...

Notification of Ancillary Review

To: Alisha Jahns (DEV)

Link: [redacted]

PI: [redacted]

A Safety submission has been assigned to you for ancillary review. Click the link above to access and review the submission. View the History tab or Ancillary Reviews section of the Data Info & Reviews tab for any notes from the reviewer.

This is a system notice, please do not reply.

Harvard Research Data Management: Tools and Resources for Researchers
Office of the Vice Provost for Research, Research Management and Guidance
Harvard University Information Technology: Enterprise Security

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.

ACTION REQUIRED - Notification of Approaching Deadline for Continuing Review

To: Alisha Jahns (DEV)

Link: [redacted]

PI: [redacted]

The Harvard Research Data Security Policy requires that you provide an update for your Data Safety submission prior to the expiration date.

A renewal or continuing review for this record is due prior to 10/28/2022.

- If there are no changes to propose and no incidents to report, the PI or Proxy can click the link above and complete the Renew activity on the left of the workspace. OR
- If there are changes to propose, incidents, or other items requiring review by a specialist, click the link above and the PI, Proxy, or other member of the team can "Create Amendment/CR". As part of the process, choose at least Continuing Review or Amendment/CR and complete the SmartForm.

Please see the Safety Submission Guide for detailed instructions on Renew or Submitting a Continuing Review.

If you need to make changes to your approved Safety submission, such as changes to the study team or data storage location/resources, submit an amendment to ensure your Safety study is up-to-date. Additional instructions for submitting an amendment can be found in the Safety Submission Guide: Submitting an Amendment to an Active Protocol.

Failure to submit your renewal or continuing review will cause this approval to lapse.

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.

Continuing Review Deadline Passed

To: Alisha Jahns (DEV)

Link: Improving Feasibility and Efficiency of Quality Measurement in Oncology Practices (ASCO QOPI data)

PI: Nancy Keating

The approval for this data safety and security plan ended on 9/9/2022.

Click the link above to access the submission and "Create Amendment/CR" to create a continuing review to extend approved data use and management, if appropriate.

Note that if this project involves the use of data under a Data Use Agreement or Human Subjects Research project, you may be required to destroy the data, or carry out other data management requirements. Visit any related submissions to ensure those requirements are identified and addressed. For reference materials about data retention or disposition at the end of a study, please visit: <https://research.harvard.edu/research-data-management/retention>.

This is a system notice, please do not reply.

Harvard Research Data Management: Tools and Resources for Researchers
Office of the Vice Provost for Research, Research Management and Guidance

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.



To: [redacted]

Link: [redacted]

ID / Status: [redacted]

PI: [redacted]

This email is being sent to remind you that any changes in data, data management or team must also be reflected in the Data Safety Protocol. Per the table below, if this new update represents a change that has not been submitted for review in Safety, please submit an Safety Amendment.

This notice is only sent to the study team members listed on the Safety Submission.

Related Projects Status Summary

ID	Name	State	Modified Date
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

What has changed...

What it means...

How it looks (as applicable) ...

Activity

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

Confirmation
Version date: July 2022

- All information provided is accurate and filled out to the best of my knowledge.
- Everything related to this submission has been included.
- I certify the following:
 - If I am the Principal Investigator on this protocol:**
 - I will adhere to and comply with approved data security and management plans and relevant procedures throughout the course of the project, and as such, I will:
 - Implement the security controls corresponding to the requirements of the Data Security Level (DSL).
 - Ensure necessary reviews occur for Sensitive Data, Data exchanged pursuant to a DUA or sponsored award, and Data subject to foreign, federal, or state regulations.
 - Complete required Research Data Security Training, and
 - Inform the assigned Information Security Reviewer and of any incidents pertaining to the Research Data, in addition to reporting the incident as required under the Enterprise Policy.
 - I understand that I am responsible for the management of the data as described in this protocol and any related Data Use Agreement and/or Institutional Review Board protocol, and relevant compliance practices throughout the course of the project.

If I am completing this activity and I am not the Principal Investigator: I confirm that the Principal Investigator has approved these proposed activities. Note that the Principal Investigator will be provided a copy of this attestation as part of the system notification of this activity.

*** I agree with the above confirmation:**

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.

Submit

Confirmation
Version date: July 2022

- All information provided is accurate and filled out to the best of my knowledge.
- Everything related to this submission has been included.
- I certify the following:
 - If I am the Principal Investigator on this protocol:**
 - I will adhere to and comply with approved data security and management plans and relevant procedures throughout the course of the project, and as such, I will:
 - Implement the security controls corresponding to the requirements of the Data Security Level (DSL).
 - Ensure necessary reviews occur for Sensitive Data, Data exchanged pursuant to a DUA or sponsored award, and Data subject to foreign, federal, or state regulations.
 - Complete required Research Data Security Training, and
 - Inform the assigned Information Security Reviewer and of any incidents pertaining to the Research Data, in addition to reporting the incident as required under the Enterprise Policy.
 - I understand that I am responsible for the management of the data as described in this protocol and any related Data Use Agreement and/or Institutional Review Board protocol, and relevant compliance practices throughout the course of the project.

If I am completing this activity and I am not the Principal Investigator: I confirm that the Principal Investigator has approved these proposed activities. Note that the Principal Investigator will be provided a copy of this attestation as part of the system notification of this activity.

*** I agree with the above confirmation:**

Important: Additional information may be required. After completing this activity, use the Manage Related Projects activity to create any ESI/IRB and/or agreements records to the Data Safety record. Those record types provide important contextual information for the reviewer. If this Data Safety (DS) record is NOT associated with an existing ESI/IRB record or Agreement, please establish contact rationale for review in the space provided here.

*** Note for reviewer:**

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.

Edit Ancillary Review

1. * Select either an organization or a person as reviewer:
Organization:

2. Review type:

3. * Is a response required?
 Yes No

4. Comments for ancillary reviewer (appears on Data Info & Reviews tab):

History	Documents	Contacts	Subgrants	Follow-up Submissions	Data Info & Review
Data Information Click on data name below to view details that are entered on the SmartForm.					
Date Name	Set DSL	Storage Locations			
ASCO QOPM Data	3	Other Resource HMS HCP (180 Longwood)_4			
Ancillary Reviews					
Ancillary Person	Organization	Type	Required	Comments for Ancillary	
Mary McFly (saf-rev)	Other	re		Can you look at the status of this?	

Request Closure: Update question text questions

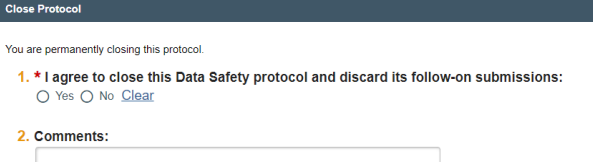

Question 1 on the activity includes clarified confirmations regarding necessary actions at the time of closure.

Request Closure

You are formally requesting closure of this protocol.

1. * I will discontinue working with the data managed under this protocol and I confirm that the data have been destroyed, returned, or anonymized according to this (i) plan, (ii) any associated data use agreement (DUA), and/or (iii) any Human Subjects Research project requirements. I will update my other associated research protocols and records as appropriate, and I also agree to close this protocol and discard the follow-on submissions:
 Yes No

2. * Reason for requesting 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.	
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.	
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. <i>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.</i>	
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.	

What has changed...

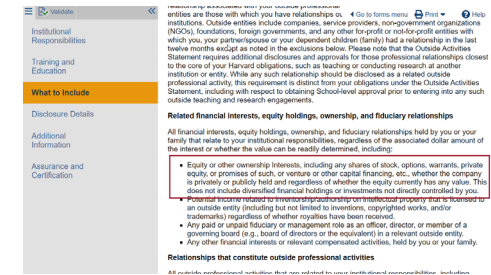
What it means...

How it looks (as applicable) ...

SmartForm

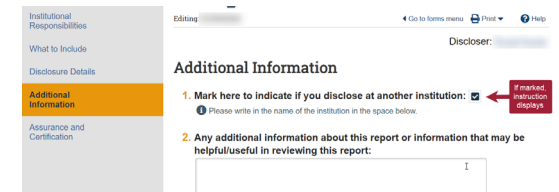
What to Include and Equity relationship details: clarifications relative to venture capital relationships

Revisions to include National Science Foundation updates to reporting requirements



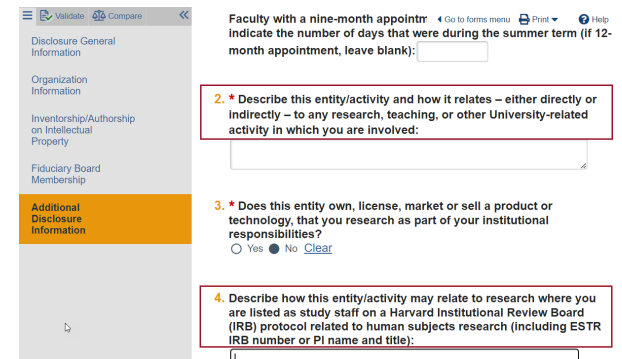
Additional Information: Additional option to indicate if the person discloses at another institution

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.



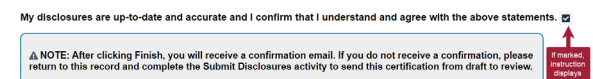
Disclosure Details: Minor revisions to questions 2 and 4 for individuals with research

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) ...
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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 intended 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

To: [redacted]
 Link: [redacted]
Action Required: Please complete the submit activity on your Outside Activity and Interest Report

The system indicates that updates were made but you have not yet submitted this certification. **One more step is needed to complete the requirement.**

To complete this report:
 - Click on the link above
 - Click the "Submit Disclosures" activity on the left side of the screen

When this action is successfully completed, you will receive a confirmation email from oair@harvard.edu

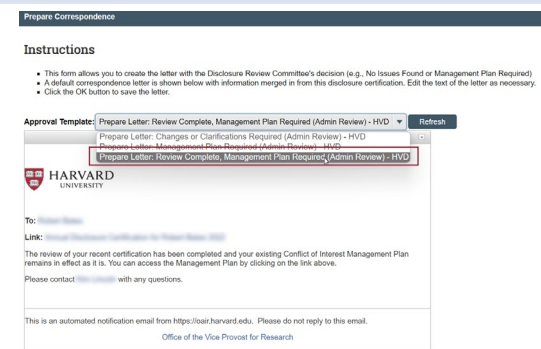
If you think that you have received this reminder in error, please contact oairhelp@harvard.edu.

This is a system notice from https://oair.harvard.edu, please do not reply.
 Office of the Vice Provost for Research

Activities

Prepare Correspondence: (reviewer only)
 Additional template with brief text regarding next steps

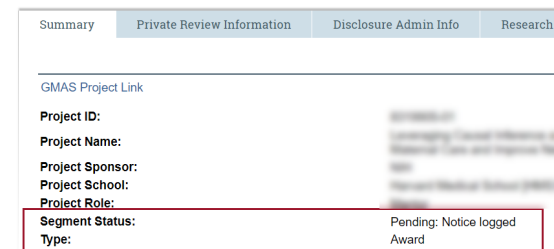
New template added for circumstances where the discloser has accepted the management plan through another mechanism and additional actions will be taken by the reviewer.



Workspace

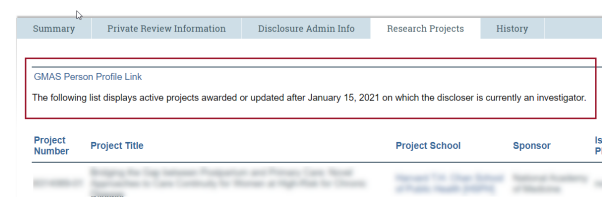
Research certification: Additional display of segment/request status and type

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 access to GMAS details (including portfolio) only if the person already has access to GMAS.



What has changed...

Certification listing: (reviewer only) new annual certification tab

Certification listing: tabs display GMAS ID and status

Miscellaneous

School custom text for annual certification notification

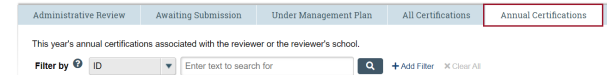
What it means...

Annual certification 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.

Two new columns appear for easier filtering and sorting of research certifications within a list of many types of certification.

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.

How it looks (as applicable) ...



This screenshot shows a table of certifications. The table has columns for ID, Name, Last Name, First Name, Department Name, Certification Type, Status, Date Created, Date Modified, Reviewed Office Contact, GMAS ID, and GMAS Status. The GMAS ID and GMAS Status columns are highlighted with a red box. The GMAS ID column contains values like 'S-01' and the GMAS Status column contains 'Pending'. There is an 'Export' button in the top right corner of the table area.

ID	Name	Last Name	First Name	Department Name	Certification Type	Status	Date Created	Date Modified	Reviewed Office Contact	GMAS ID	GMAS Status
										S-01	Pending
										S-01	Pending