

1.25.1 Upgrade and Configuration Release Items: October 2020

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IRB Enhancements

What has changed...	What it means...	How it looks (as applicable)...
Activities		
Rationale field added to Track Harvard Determinations when Data Safety review is required	When a study is determined to be “Sensitive,” a new field will prompt the IRB Coordinator to enter a rationale. This property displays on the Reviews tab of the submission workspace and aids School Security Officers with the Safety review.	1. Harvard Research Data Security Level Determination: <input type="text" value="Sensitive"/> Briefly explain why the IRB has classified this data as Sensitive: <div style="border: 1px solid #ccc; height: 100px; width: 100%;"></div>
Manage Related Projects no longer available for RNIs	Users can no longer link RNIs to other submissions using “Manage Related Projects.” Only Initial IRB, Safety, and Agreements submissions should be linked using this activity.	
Reporting		
Reports updated to accommodate data structure changes	Changes in the data structure related to the 9.0 upgrade caused the following reports to fail: <ul style="list-style-type: none">External IRB Studies Lapse and Anniversary ReportExternal IRB Studies Monitoring Report	

- AJ Draft – Submissions Referencing COVID

This has been corrected and reports are now working as expected.

New Report: Person Profile Lookup

A new report has been added which allows IRB staff to easily look up a user profile to view or add training. This report can be found on the Custom Reports tab.

Letters and Notifications

Fixed subject of Submission Confirmation notice

A script for indicating the submission number in the subject of the notification “[ID] has been sent to the IRB for review” was not properly displaying the study ID. This has been fixed.

Document icon in Meeting Agenda notification resized

The icon beside the link to the Agenda document has been resized to appear in line with the text.

People and Organizations

Adding Training via Profile Edits

With the 9.0 upgrade, IRB staff lost the ability to add training information to user profiles using the RMConsole. Now, IRB staff can use the Person Profile Lookup report to access a user profile, and can upload training in the profile SmartForm.

Updates to Person View

The user profile has been updated to display IRB training and additional properties for use with the upcoming OAIR application OAIR.

Little (irbd3), Mary

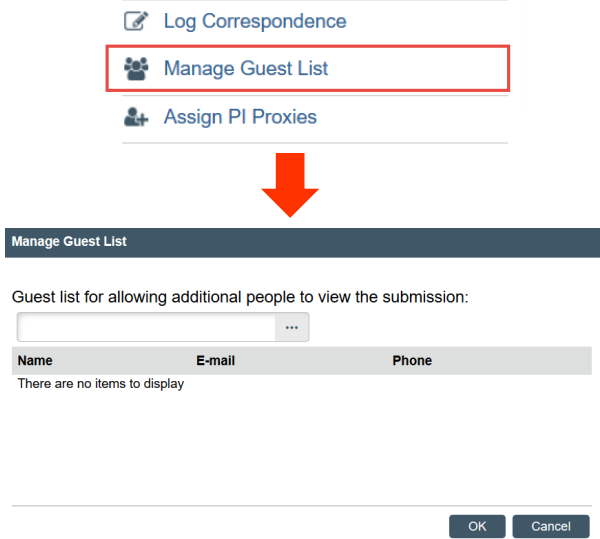
Employer: Harvard University
Phone: 617-555-5555
E-mail: demo@huronconsultinggroup.com
Title: IRB Administrator
School: Harvard Medical School
Department: IRB Office
Job: IRB Administrator 987654
FTE: 1

Harvard Training data (IRB):

To update, click “Edit Details” on the left side of this workspace, then scroll to question 26 (the last question on the page) and upload training documents.

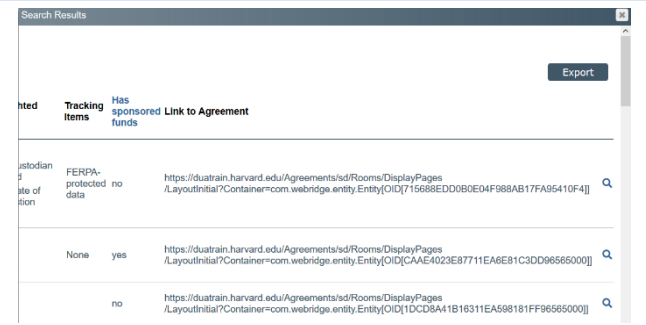
Document	Name	Current?	Training Complete Date	Training Expiration Date
There are no items to display				

Agreements Enhancements

What has changed...	What it means...	How it looks (as applicable)...
SmartForm		
Schools removed from Responsible Department selector	Researchers will no longer be able to select a school as the Responsible Department. This change will ensure submissions are assigned to the appropriate office for review.	
Activities		
New Manage Guest List activity is available	The new Manage Guest List activity allows Agreements Reviewers/Owners, PIs, and Primary Contacts to add additional people as submission viewers. Guests can be added to a submission at any point in the Agreement submission process via the activity,	
Notifications		
Agreement Activated notice updated	The text of the activation noticed has been updated. The new text is, "The agreement is now active. Please click on the link above to view the final documentation (under the Agreement Documents tab), along with a limited list of highlighted terms or requirements associated with this agreement. Before you publish or share this data, check the terms of the agreement."	
Reports		

Link to Agreement Workspace added to Harvard Report: Agreements ad hoc report

A direct link to each Agreement's workspace is now available in the Harvard Report: Agreements ad hoc report. The link will be included in the report export and can be used to quickly access individual submissions from outside the Agreements submission.



The screenshot shows a table titled "Search Results" with an "Export" button in the top right corner. The table has three columns: "Tracking Items", "Has sponsored funds", and "Link to Agreement". The rows contain data for FERPA-protected data, None, and an unlabeled row.

	Tracking Items	Has sponsored funds	Link to Agreement
FERPA-protected data	no		https://duatrain.harvard.edu/Agreements/sd/Rooms/DisplayPages/_Layout/Initial?Container=com.webridge.entity.Entity[OID[715688EDD0B0E04F988AB17FA95410F4]]
None	yes		https://duatrain.harvard.edu/Agreements/sd/Rooms/DisplayPages/_Layout/Initial?Container=com.webridge.entity.Entity[OID[CAAE4023E87711EA6E81C3DD96565000]]
	no		https://duatrain.harvard.edu/Agreements/sd/Rooms/DisplayPages/_Layout/Initial?Container=com.webridge.entity.Entity[OID[1DCD8A41B16311EA598181FF96565000]]

Data Safety Enhancements

What has changed...	What it means...	How it looks (as applicable)...										
SmartForm												
Schools removed from Responsible Department selector	Researchers will no longer be able to select a school as the Responsible Department. This change will ensure reviewers are assigned properly.											
Study Team Member page improvements	A link to the HRDSP course in the Harvard Training Portal was added. Instructions for Managing Related Projects are now included at the top of the page, and any related projects will display to allow for easy reference of linked submissions in instances where the reviewer and study team have agreed to refer to ESTR for study team.	<p>Protocol Team Members</p> <p>In certain instances, reviewers may lock to related Agreements or IRB submissions for information about the study team. To add a related submission, Save and Exit to return to the study workspace, then complete the "Manage Related Projects" activity. For more information, see the section of the Safety Submission Guide on Managing Related Projects.</p> <p>Related Projects: Added on the protocol Workspace.</p> <table border="1"> <thead> <tr> <th>ID</th> <th>Name</th> <th>State</th> <th>Modified Date</th> <th>Project Link</th> </tr> </thead> <tbody> <tr> <td>IRB20-1162</td> <td>Definitely Not Human Subjects Research</td> <td>Not Human Research</td> <td>9/14/2020 9:16 AM</td> <td>IRB20-1162</td> </tr> </tbody> </table>	ID	Name	State	Modified Date	Project Link	IRB20-1162	Definitely Not Human Subjects Research	Not Human Research	9/14/2020 9:16 AM	IRB20-1162
ID	Name	State	Modified Date	Project Link								
IRB20-1162	Definitely Not Human Subjects Research	Not Human Research	9/14/2020 9:16 AM	IRB20-1162								
Funding Questions clarified and expanded in	Wording was revised on this page for clarity, and a new question was added to capture additional information about funding when appropriate.	<p>Funding Sources</p> <p>Many research projects involve additional funding from a sponsor. More information about sponsored funding can be found on the websites for the Office for Sponsored Programs (University Area) and Harvard Chan School Research Administration (Longwood Area).</p> <p>1. Are there costs associated with technology (for example, cloud services, vendors, storage, other service providers)? <input checked="" type="radio"/> Yes <input type="radio"/> No Clear</p> <p>Provide additional information about funding used to cover the cost of technology: <i>Include GMAS number, if applicable.</i></p> <div style="border: 1px solid #ccc; height: 60px; width: 100%;"></div>										
Updated Language on Data Information slide-in	To alleviate confusion, references to “certified” resources were replaced with more descriptive language. Data storage locations are now described as meeting the minimum requirements for storing data up to a particular Data Security Level. This value is referred to as the “maximum DSL” in the summary table.											
Activities												
Assign Specialist activity is now available in the Clarifications Requested state.	Previously, this activity was only available in the Specialist Review state. Now, reviewers can reassign a submission while the study team is working on revisions/clarifications.											
Workspaces												

All Submissions tab displays department and school for amendments

Two new columns on the All Submissions tab display the department and school for amendments.

Department	School	Mod Dept	Mod School	Specialist
African and African American Studies		African and African American Studies	Faculty of Arts and Sciences [FAS]	Mears (ss-rad)
Environmental Health		Environmental Health	Harvard T.H. Chan School of Public Health [HSPH]	Ross
African and African American Studies		African and African American Studies	Faculty of Arts and Sciences [FAS]	Mears (ss-rad)
Health Care Policy		Health Care Policy	Harvard Medical School [HMS]	Wood
Harvard Program in Therapeutic Science [HITS]		Harvard Program in Therapeutic Science [HITS]	Harvard Medical School [HMS]	Zurba

Notifications

Specialist Review Reminder clarified

After receiving feedback that the Specialist Review Reminder was confusing, the wording was revised for clarity.

Reports

Harvard Report – All Study Team Members now displays all names correctly

This report now includes the names of non-Harvard study team members, which previously appeared as blank lines.

Some advanced reports hidden

Some advanced reports caused the site to crash if run. These reports have been hidden from view.