

IRB 8.2.4 Upgrade

What is changing?

Overview

- Primary Changes to External IRB studies
- Workflow Changes
 - External IRB – Single Site Submission
 - External IRB – MultiSite Submission
 - External IRB – Update Study Details
- Smartform Changes
 - Basic Study Information
 - Basic Local Site Information
 - Basic Site Information
 - External IRB
 - Additional Local Funding Source (NEW)
 - Local Study Team
 - Study Scope
 - Local Research Locations (NEW)
 - MOD (Main & Information)
- Workspace Changes
 - IRB Submission Tabs
 - Contacts tab
- Activity Changes
 - Finalize Updates (NEW)
 - Copy Submission (External IRB)
 - Submit Site Materials
 - Create RNI

Primary Changes in IRB 8.2.4

- External IRB Improvements
 - Streamlined submission process
 - Smartform and help text updates to provide clarity
 - **Consolidation of separate Study and Site workspaces into a single workspace**
 - **NOTE: All existing External IRB studies in IRB 8.1.4 will be Discarded, and their data will migrate over to the External IRB SITE Submission.**
 - **After the upgrade to IRB 8.2.4, any NEW External IRB studies will retain the 2019xxxx numbering convention, regardless if they are Single Site or Multi-Site type of study.**
 - **This will NOT affect any studies currently in Velos.**
- New Study Update process to facilitate changes to approved external studies

External IRB User Experience

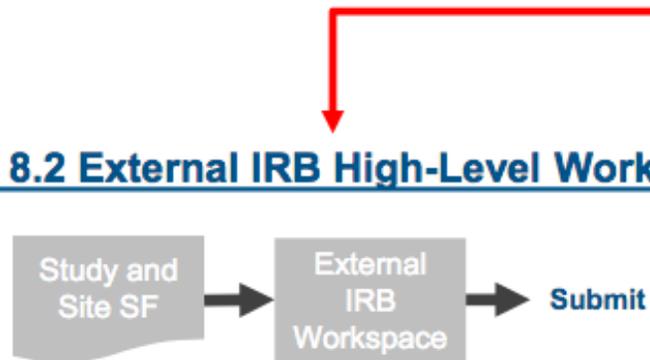
IRB 8.1.x External IRB High-Level Workflow



In **IRB 8.1.x** when submitting an external study, the user had to take multiple steps to complete the process:

1. Study Smartform
2. Study Workspace
3. Site Workspace
4. Site Smartform

IRB 8.2 External IRB High-Level Workflow



In **IRB 8.2**, we have simplified this process to improve the user experience:

1. Study and Site Smartform
2. External IRB Workspace

NOTE: In IRB 8.2.4, any NEW External IRB studies will have a numbering convention of 2019xxxx only. Any EXISTING External IRB studies (pre-IRB 8.2.4) will retain the IRB Site numbering convention.

Workflow Changes

External IRB studies:

Single Site (Initial Study) - External IRB state (DO NOT USE)

MultiSite (IRB Site) - Active state

Workflow Changes – External IRB SSS

Basic Study Information

1. * Title of study:

2. * Short title:

3. * Brief description: ?

4. * What kind of study is this?

Multi-site or Collaborative study

Single-site study

[Clear](#)

5. * Will an IRB other than the University of Miami act as the IRB of record for this study at the UM Site?

Yes No [Clear](#)

6. * Local principal investigator:

UMTest Princ Investigator (pi)

- Questions on the Basic Study Information page have been reorganized to ask the kind of study and external IRB questions **before** we ask about the PI(s).
- In the screenshot on this slide, because we have selected a Single Site **(4)** External Study **(5)**, we are only asking for your Local Principal Investigator **(6)**(who would be the Lead PI) and this question is required to be answered.
- **NOTE: Single Site Studies should NOT go through External IRB process in IRB 8.2.4**

Workflow Changes – External IRB SSS – **DO NOT USE**

- **The External IRB process must be used for Multi-site studies only**

- * **Federally-Funded requiring single IRB**

- * **Industry-funded requiring single IRB as a condition of participation**

Workflow Changes – External IRB MSS

Basic Study Information

1. * Title of study:

test

2. * Short title:

test

3. * Brief description: ?

test

4. * What kind of study is this?

Multi-site or Collaborative study

Single-site study

[Clear](#)

5. * Will an IRB other than the University of Miami act as the IRB of record for this study at the UM Site?

Yes No [Clear](#)

6. Lead principal investigator:

...

7. * Local principal investigator:

UMTest Princ Investigator (pi) ...

- When selecting a **Multi-Site (4)**, **External Study, (5)**, the **Lead Principal Investigator (6)** question will be presented. This is not a required question as often times the user completing the initial submission will not know who the Lead PI is at that time.
- Note that anytime that the External IRB question is answered “Yes” **(5)**, the *Attach Protocol field will be hidden on this page.*
- **Help Text Updates:** the help text for the following questions has been updated:
 - What kind of study is this?
 - Lead Principal Investigator
 - Local Principal Investigator

Workflow Changes – MODs vs Updates

IRB 8.2 includes an option to **Update Study Details** when changes are needed to an approved External IRB study.

This screenshot shows an example of an approved **External Multi-Site Study** where you have an option to **Create Site Modification** in order to make changes to the Site information, or **Update Study Details** in order to edit Study information.

Active

Entered IRB: 9/3/2019 10:51 AM
Initial approval: 10/7/2019
Initial effective: 10/1/2019
Effective: 10/7/2019
Last updated: 10/7/2019 3:23 PM

20190477: Test for Assign IRB fun

Principal investigator: UMTest Princ Investigator (pi)
Submission type: IRB Site
Primary contact: Raquel Zamora Alfonso
PI proxies:
Institution: Western IRB (WIRB)

Next Steps

- View Site
- Printer Version
- View Differences
- Create Site Modification**
- Update Study Details**
- Report New Information

Flowchart: Pre-Submission → Pre-Review → Pending sIRB Review. A feedback loop exists from Pre-Review to Clarification Requested, which then loops back to Pre-Review. Another loop exists from Pending sIRB Review back to Pre-Review.

History: Funding, Contacts, Documents, Follow-up

Filter by: Activity (dropdown) [Enter text to search for]

Activity Log:

- sIRB Decision Edited
- Returned to Post-Review

Workflow Changes – Create Site Modifications

For External IRB MSS Studies Only:

Must be used for UM site modifications

- * Personnel
- * Recruitment Material
- * Consent forms
- * Other UM site documents

To move documents in Velos

Workflow Changes – Update Study details

Do not use Update Study Details to upload any UM site modifications / documents

Workflow Changes – Update Study Details

External, Single Site Studies –the Update Study Details process will allow a user to edit both Study and Site information in the smartform. The screenshot on this slide shows an External, Single Site Study. - **DO NOT USE THIS FEATURE IN IRB 8.2.4**

The screenshot shows a web browser window with the URL 'External IRB Submission - Pre-Review to Active'. The page title is 'Basic Study Information'. The form contains four sections:

- 1. * Title of study:** A text input field containing 'External IRB Submission - Pre-Review to Active'.
- 2. * Short title:** A text input field containing 'External IRB Submission - Pre-Review to Active - SSS'.
- 3. * Brief description:** A text input field containing 'External IRB Submission - Pre-Review to Active'.
- 4. * What kind of study is this?** Radio buttons for 'Multi-site or Collaborative study' (unselected) and 'Single-site study' (selected). A 'Clear' link is below.

A 'Jump To' dropdown menu is open on the right, listing: Basic Study Information, External IRB, Study Funding Sources, Local Study Team Members, Study Scope, Local Research Locations, Local Site Documents, Additional Study Info, and Medical Studies Only.

External, Multi-Site Studies –the Update Study Details process will only allow a user to edit Study information in the Smartform. If changes to the Site are needed, a Site Modification must be created which may have to be routed to the sIRB for review.

The screenshot shows a web browser window with the URL 'Test for Assign IRB functional...'. The page title is 'Basic Study Information'. The form contains four sections:

- 1. * Title of study:** A text input field containing 'Test for Assign IRB functionality'.
- 2. * Short title:** A text input field containing 'Test for Assign IRB functionality'.
- 3. * Brief description:** A text input field containing 'Test for Assign IRB functionality'.
- 4. * What kind of study is this?** Radio buttons for 'Multi-site or Collaborative study' (selected) and 'Single-site study' (unselected). A 'Clear' link is below.

A 'Jump To' dropdown menu is open on the right, listing: Basic Study Information, External IRB, Study Funding Sources, Study Scope, Drugs, Study-Related Documents, Additional Site Info, and Medical Studies Only.

Smartform Changes

Basic Study/Local Site/Site Information

External IRB

Additional Local Funding Sources

Local Study Team

Study Scope/Local Research Locations

MOD/MODCR Main Page / MOD Information

Smartform Changes – Basic Study Information

- Recall that while **IRB 8.1.4** provided the ability to edit the answer to the question: *What kind of study is this?* until the point where participating sites are created, the system still locked the External IRB question after the user proceeded to the next smartform view.
- **IRB 8.2.4** provides flexibility to the External IRB question, allowing users to change the answer to this question up until the point when the **Confirm Reliance** activity has been executed. This gives the user a chance to correct his/her own mistakes when submitting the study, and the IRB office a chance to review the smartform and send it back for changes if the appropriate answer was not selected.

Smartform Changes – Basic Local Site Information

- The **Basic Local Site Information** page has been added to External IRB MSS studies in IRB 8.2. The only question on the Basic Local Site Information page is **(1): Brief Description of activities this site will perform** (enter “ALL” if this site will perform all procedures in the protocol). **The Protocol Attachment field (3) has been moved to this page for External IRB MSS studies only.**

Basic Local Site Information

1. *** Brief description of activities this site will perform:** (enter "ALL" if this site will perform all procedures in the protocol)

2. **Attach the protocol:**

Document	Category	Date Modified	Document History
There are no items to display			

Smartform Changes – Basic Site Information

- On Relying Site (i.e., participating site) submissions, the **Basic Site Information** page has been simplified in IRB 8.2. The Local PI and Local PI financial interest questions have been moved to the initial view of the smartform. The only remaining question on the Basic Site Information page is **(3): Brief Description of activities this site will perform** (enter “ALL” if this site will perform all procedures in the protocol).

Basic Site Information

1. * Short title:

University of Chicago Participating Site for SCRIPT ID: IRB-014.4.0 Co

2. * Local principal investigator: ?

UMTest pSite PI ...

3. * **Brief description of activities this site will perform:** (enter "ALL" if this site will perform all procedures in the protocol) ?

Smartform Changes – External IRB

- IRB 8.2.4 is adding a new question on the External IRB page that will capture the **reason why the study should be reviewed by an External IRB (6)**, to assist with reporting.

External IRB

1. * External IRB:

Schulman IRB

2. External study ID:

3. Approval letter from external IRB:

[None]

4. Initial approval date by external IRB:

5. Last day of approval period:

6. * Specify the reason(s) the study should be reviewed by an external IRB (check all that apply):

- Required by regulation
- Required by sponsor as a condition of conducting the trial
- Other

7. If Other, specify the reason the study should be reviewed by an external IRB:

Smartform Changes – Additional Local Funding Sources

- IRB 8.2.4 is adding a new page for Multi-Site submissions (External IRB and non-External IRB) that will capture **Additional Local Funding Sources**, that will supplement the funding for the study at the local level.

Additional Local Funding Sources

1. Identify each organization supplying funding for the local site:

Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments
There are no items to display			

Smartform Changes – Local Study Team

Local Study Team Members

1. Identify each additional person involved in the design, conduct, or reporting of the research: ?

	Name	Roles	Financial Interest Review Status	COI Expiration Date (CITI)	HSR Expiration Date (CITI)	GCP Expiration Date (CITI)	Involved in Consent	E-mail	Phone
<input type="checkbox"/> Add									
<input checked="" type="checkbox"/> Update	UMTest StudyStaff1 (ss1)	Student or trainee mentor	Pending Creation	Not Found	Not Found	Not Found	no	eproost@med.miami.edu	503.123.4567

- IRB 8.2.4 will bring the following changes to the **Local Study Team** page:
 - **CITI Expiration Dates**
 - **COI Exp Date** displays the most recent CITI training date for “Conflict of Interest” group
 - **GCP Exp Date** displays the most recent CITI training date for “CITI Good Clinical Practice” curriculum
 - **HSR Exp Date** displays the most recent CITI training date for “Human Subjects Research (HSR)” curriculum
 - Dates are not displayed in these columns; instead, the following will appear:
 - **“Account disabled”** displays if there is a disabled eProst account
 - **“Not Found”** displays if there is an active eProst account, but no CITI date for that particular training
 - **No value** displays if there is a disabled eProst account and required account information is not part of the user's profile

Smartform Changes – Local Study Team

2. External team member information:

Name	Description
There are no items to display	

3. * Will any outside agency or organization conduct protocol-required research procedures (i.e. recruitment, survey companies, home health agencies) for this study?

Yes No [Clear](#)

a. If yes, please explain who will be conducting procedures and list the procedures the external agency/organization will conduct.

- IRB 8.2.4 will bring the following changes to the **Local Study Team** page:
 - NEW Question: **Outside Agency procedures**

Smartform Changes – Study Scope

- IRB 8.2.4 will bring the following changes to the **Study Scope** page:
 - **Research Locations/External Sites** question has been removed.

Study Scope ⓘ

1. * Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition? ⓘ

Yes No [Clear](#)

2. * Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?

Yes No [Clear](#)

Smartform Changes – Local Research Location

Local Research Locations ⓘ

1. Identify research locations where research activities will be conducted or overseen by the local investigator:

+ Add				
Location	Contact	Phone	Email	
<input type="checkbox"/> Update	Miami Children's Hospital	MCH Contact		<input type="checkbox"/>

- **IRB 8.2.4** will now include a standing page for **Local Research Location**, which is optional for all submissions
- Identify research locations where research activities will be conducted -they are locations within your institution where institutional leadership would like to track human research activities, or because they are locations outside of the institution where your institution's principal investigators conduct human research
- Research locations are not participating sites in multi-site or collaborative research with separate principal investigators.

Smartform Changes – MOD/MODCR Main Page

Modification / Continuing Review / Study Closure

* What is the purpose of this submission?

- Continuing Review
 - Modification / Update
 - Modification and Continuing Review
- [Clear](#)

i To change the PI, choose 'Other parts of the study/site' scope

For External IRB Submissions only, please select both 'Other parts of the site' AND 'Study team and research location information' options to make any changes to the submission.

Modification scope:

- Study team member information
- Other parts of the study

For Modifications that include 'Other Parts of the study/site' scope:

* This Modification includes changes to: (check all that apply). You will be required to provide more detail on the next page

- | Type of Change for MOD |
|---|
| <input type="checkbox"/> Principal Investigator |
| <input type="checkbox"/> Funding source |
| <input type="checkbox"/> Research locations |
| <input type="checkbox"/> Study protocol (including changes to procedures, study calendar, treatment plan, changes to drug dosage/routing, etc.) |
| <input type="checkbox"/> Drug/Device information (including IND/IDE, investigator brochure) |
| <input type="checkbox"/> Inclusion/exclusion criteria |
| <input type="checkbox"/> Consent/assent documents and/or consent process, translations |
| <input type="checkbox"/> Recruitment materials, surveys, questionnaires |
| <input type="checkbox"/> Risks/benefits |
| <input type="checkbox"/> Data collection or data sharing |
| <input type="checkbox"/> Administrative changes |
| <input type="checkbox"/> Adding Personnel |
| <input type="checkbox"/> Removing Personnel |
| <input type="checkbox"/> Other (please specify in summary on next page) |

- **IRB 8.2.4** will add a new question to capture **Type of Change for Modifications** with scope of Other Parts of Study (or Site), for reporting purposes

Smartform Changes – MOD Information

Modification Information

1. * Study enrollment status:

- No subjects have been enrolled to date
- Subjects are currently enrolled
- Study is permanently closed to enrollment
- All subjects have completed all study-related interventions
- Collection of private identifiable information is complete
- Not Applicable (i.e., chart review, sample collection, etc.)

2. * Notification of subjects: (check all that apply)

- Current subjects will be notified of these changes
- Former subjects will be notified of these changes
- Not Applicable

i Attach files: If notifying subjects, add a description of how they will be notified to the Other attachments section of the Local Site Documents page.

3. * Describe the revisions and the reason for the changes. (Including the items selected for Type of Change for MOD, from the previous page):

changes made.

- **IRB 8.2.4 will require Study Enrollment Status (1) and Notification of Subjects (2).**
- Study Team will also need to elaborate on Type of Change for Modifications within the **Summary Description (3)** field. Provide as much detail as necessary, to avoid delays with processing the MOD.

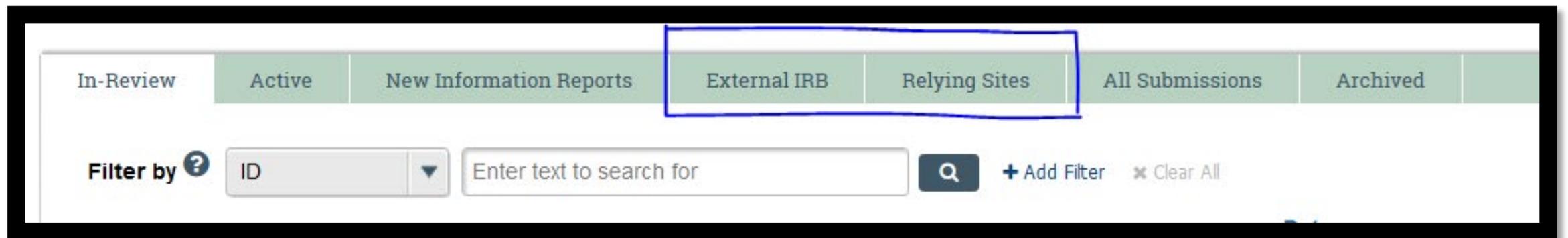
Workspace Changes

IRB Submissions

Contacts Tab

Workspace Changes – IRB Submission Tabs

- In 8.2.4, we incorporated a few changes related to the tabs on the Submissions page.
 - The **External IRB** tab will contain ALL submissions from your institution that are relying on another IRB.
 - The **Relying Sites** tab will contain all submissions from OTHER institutions that are relying on your IRB.



Workspace Changes – Contacts Tab

History	Funding	Contacts	Documents	Reviews	Snapshots				
Principal Investigator									
Name	Financial Interest Review Status	COI Expiration Date (CITI)	HSR Expiration Date (CITI)	GCP Expiration Date (CITI)	E-mail	Phone			
UMTest Princ Investigator (pi)	Pending Creation	Not Found	Not Found	Not Found	eproست@med.miami.edu	503.123.4567			
Study Team									
Name	Roles	Financial Interest Review Status	COI Expiration Date (CITI)	HSR Expiration Date (CITI)	GCP Expiration Date (CITI)	Involved in Consent E-mail	Phone		
UMTest StudyStaff1 (ss1)	Student or trainee mentor	Pending Creation	Not Found	Not Found	Not Found	no	eproست@med.miami.edu	503.123.4567	

- **IRB 8.2.4 will bring the following changes to the Contacts tab:**
 - **CITI Expiration Dates**
 - **COI Exp Date** displays the most recent CITI training date for “Conflict of Interest” group
 - **GCP Exp Date** displays the most recent CITI training date for “CITI Good Clinical Practice” curriculum
 - **HSR Exp Date** displays the most recent CITI training date for “Human Subjects Research (HSR)” curriculum
 - Dates are not displayed in these columns; instead, the following will appear:
 - “**Account disabled**” displays if there is a disabled eProست account
 - “**Not Found**” displays if there is an active eProست account, but no CITI date for that particular training
 - **No value** displays if there is a disabled eProست account and required account information is not part of the user's profile

Activity Changes

Finalize Updates

Copy Submission

Submit Site Materials

Create RNI

Activity Changes: Finalize Updates – *Should not be used for External IRB SSS studies*

- The **Update Study Details** process is like a light-weight modification: the user has to provide a summary of the updates that are being made, and then will be presented with the appropriate smartform views. When the updates are completed, the user is taken to the Study Update workspace.
 - **Note:** PIs and IRB Coordinators are able to execute the Study Update process.
- Once the updates have been made, the **Finalize Updates** activity must be executed to complete the process.
 - Upon execution on the **Finalize Updates Activity**, a notification will be sent to the Assigned IRB Coordinator.
 - **Note:** when an IRB Coordinator executes a Study Update, they will have the ability to **Edit sIRB Decision** before the updates are finalized.
- When the updates are finalized, the changes are synched with the study, a **Snapshot** is recorded, and **View Differences** can be run on the external study in order to see what changed as a part of the study update.

The screenshot displays the IRB system interface for study MOD00029254. On the left, a sidebar lists 'Next Steps' including 'Edit Study Details', 'Printer Version', 'View Differences', 'Finalize Updates' (highlighted), 'Edit sIRB Decision', 'Assign Coordinator', 'Manage Ancillary Reviews', 'Add Comment', and 'Discard'. The main content area shows 'MOD00029254: Update #1' with details for the Principal Investigator (UMTest Princ Investigator (pi)), Submission type (Study Update), and Primary contact (Kanchan Sakhrani). A flow diagram shows 'Updating Study' leading to 'Updates'. Below this are tabs for 'History', 'Documents', 'Reviews', and 'Snapshots', along with a 'Filter by' dropdown set to 'Activity'. An overlay window titled 'Execute "Finalize Updates" on MOD00029254 - Mozilla Firefox' is open, showing a confirmation dialog with the text: 'By clicking on OK below, you are verifying that:'. The dialog lists two main points: 'You have updated the study record only to reflect what the external IRB has approved.' and 'You assure the following:'. The assurance points are: 'That the information submitted in this application is true, complete, and accurate to the best of your knowledge, and', 'That you (as Principal Investigator) agree to conduct and to report this study in a responsible manner, free from fabrication, falsification, and/or plagiarism.', and 'That you have taken into account appropriate security measures to protect data.'. 'OK' and 'Cancel' buttons are at the bottom of the dialog.

Activity Changes: Copy Submission

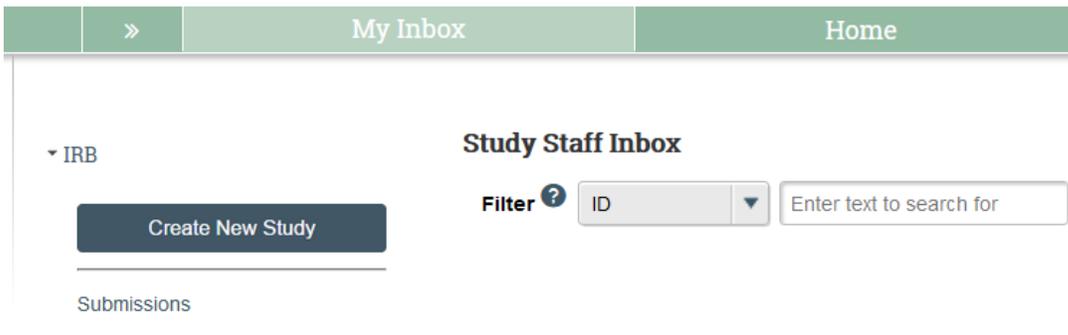
- In **IRB 8.1.4**, the Copy Submission activity could not be used for External IRB studies because it would not allow changes to be made to some of the values on the smartform. In addition, it would copy the Site submission's workspace, and not allow the study team to make changes to that Site submission. This would mean the study team would have to create another External IRB study submission from scratch.
- In **IRB 8.2.4**, the **Copy Submission** activity has been updated, and is available in all states of External Studies. This is particularly helpful if a study is past the point of confirming reliance and you do not want to start from scratch on another submission.

Activity Changes: Submit Site Materials

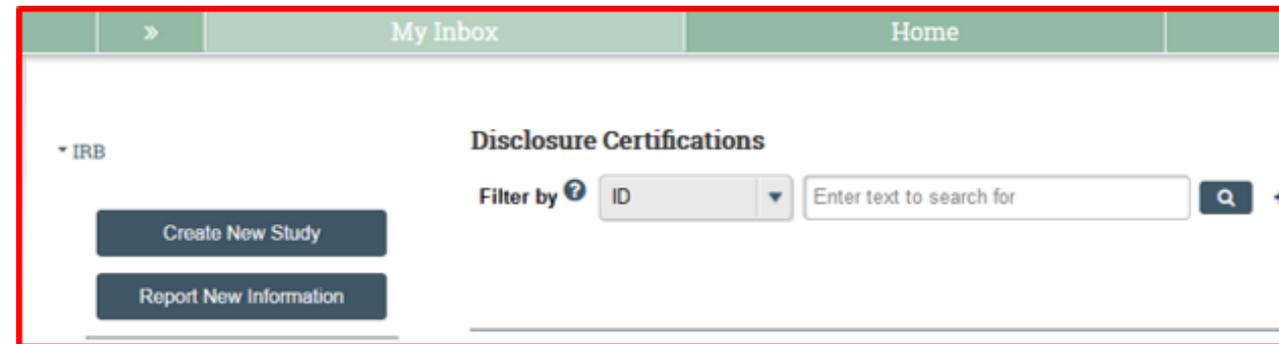
- For Relying Sites (participating sites) - In 8.1.4, the IRB Coordinator had to execute “**Site Materials Received**” activity on the Site record of a Multi-Site Study.
- In IRB 8.2.4 this activity has been changed to “**Submit Site Materials**” and the Lead PI, Proxy, and Reliance Coordinator are now able to execute it in addition to the IRB Coordinator.
 - ***NOTE: This will be applicable for a very small set of users in the system. Most Lead PIs for participating sites do not have active accounts, and we are not using the Reliance Coordinator role in the system at this time. Therefore, only the pSite Proxy and the IRB Coordinator of the pSite will be able to execute this activity.***

Create RNI Button: My Inbox

In 8.1.4, **Create RNI** button only available on the Approved Study workspace

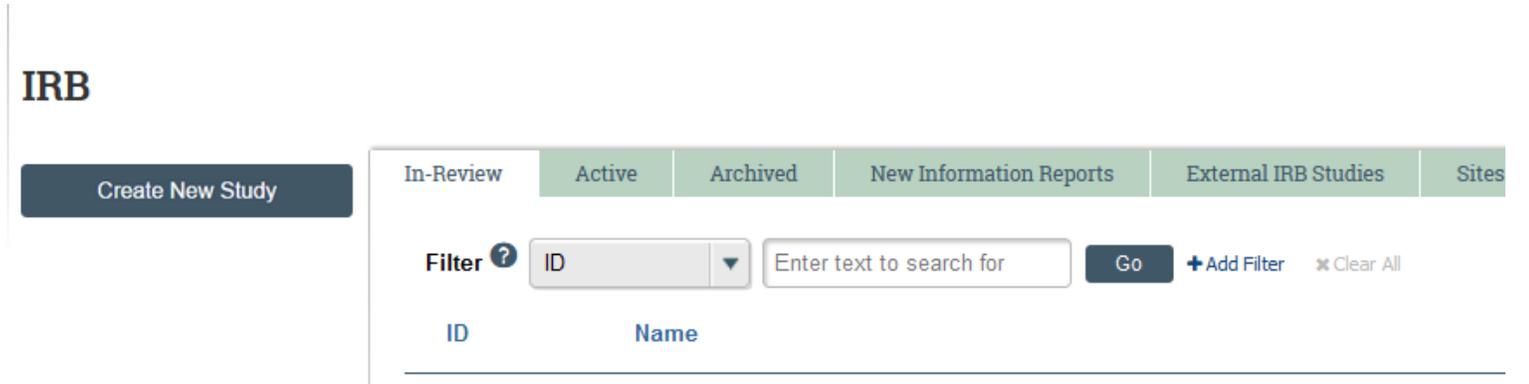


In 8.2.4, **Create RNI** button is now available on My Inbox pages, to allow RNI to be created outside of a study workspace:



Create RNI Button: IRB and Submissions

In 8.1.4, **Create RNI** button only available on the Approved Study workspace



In 8.2.4, **Create RNI** button is now available on IRB & Submissions pages:

