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

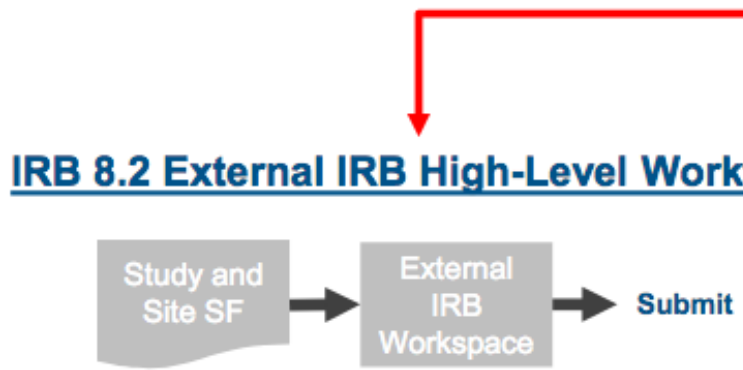
Primary Changes in IRB 8.2.4

- 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

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



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 IRBSite numbering convention.

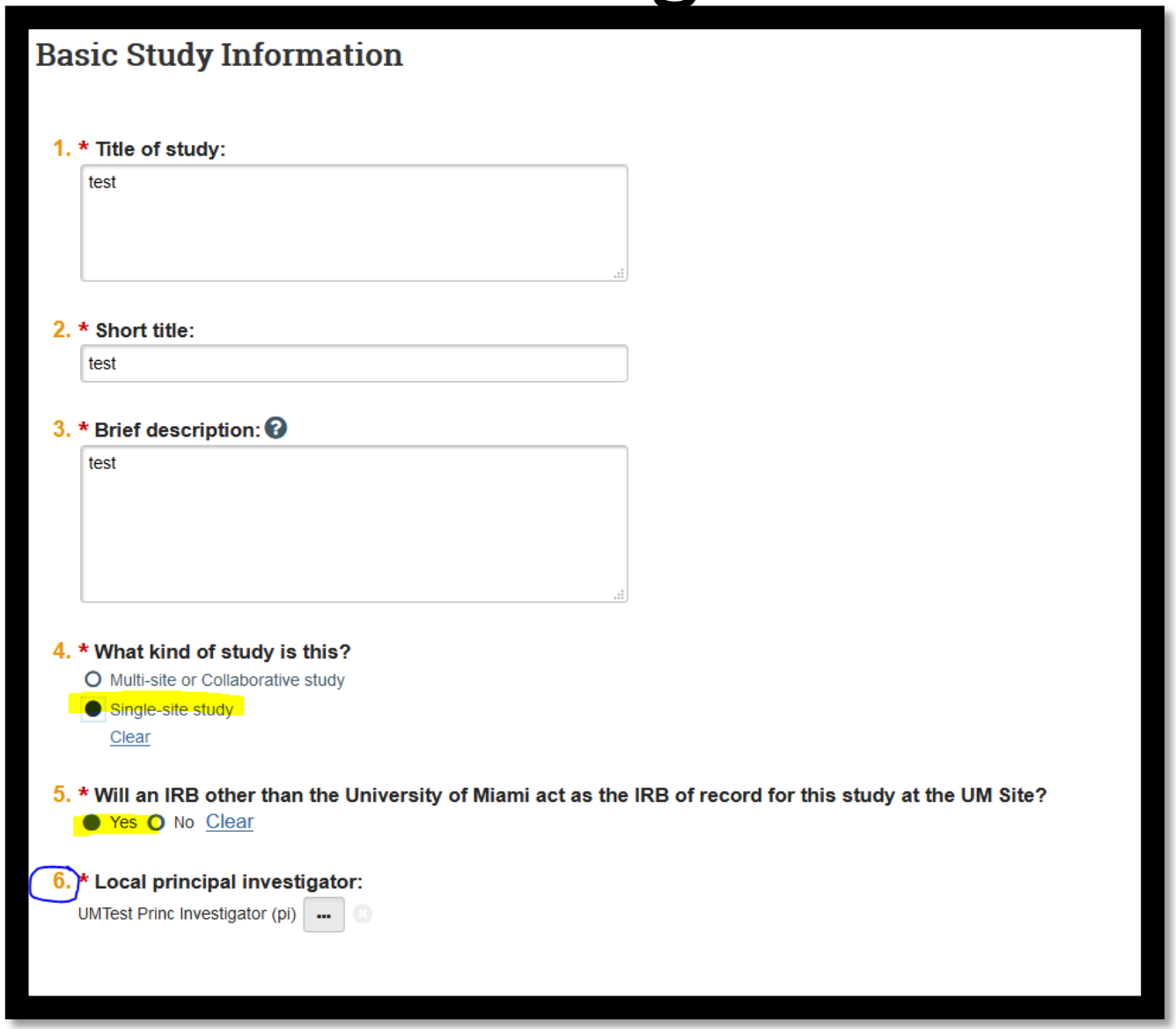
Workflow Changes

External IRB studies:

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

MultiSite (IRB Site) - Active state

Workflow Changes – External IRB SSS

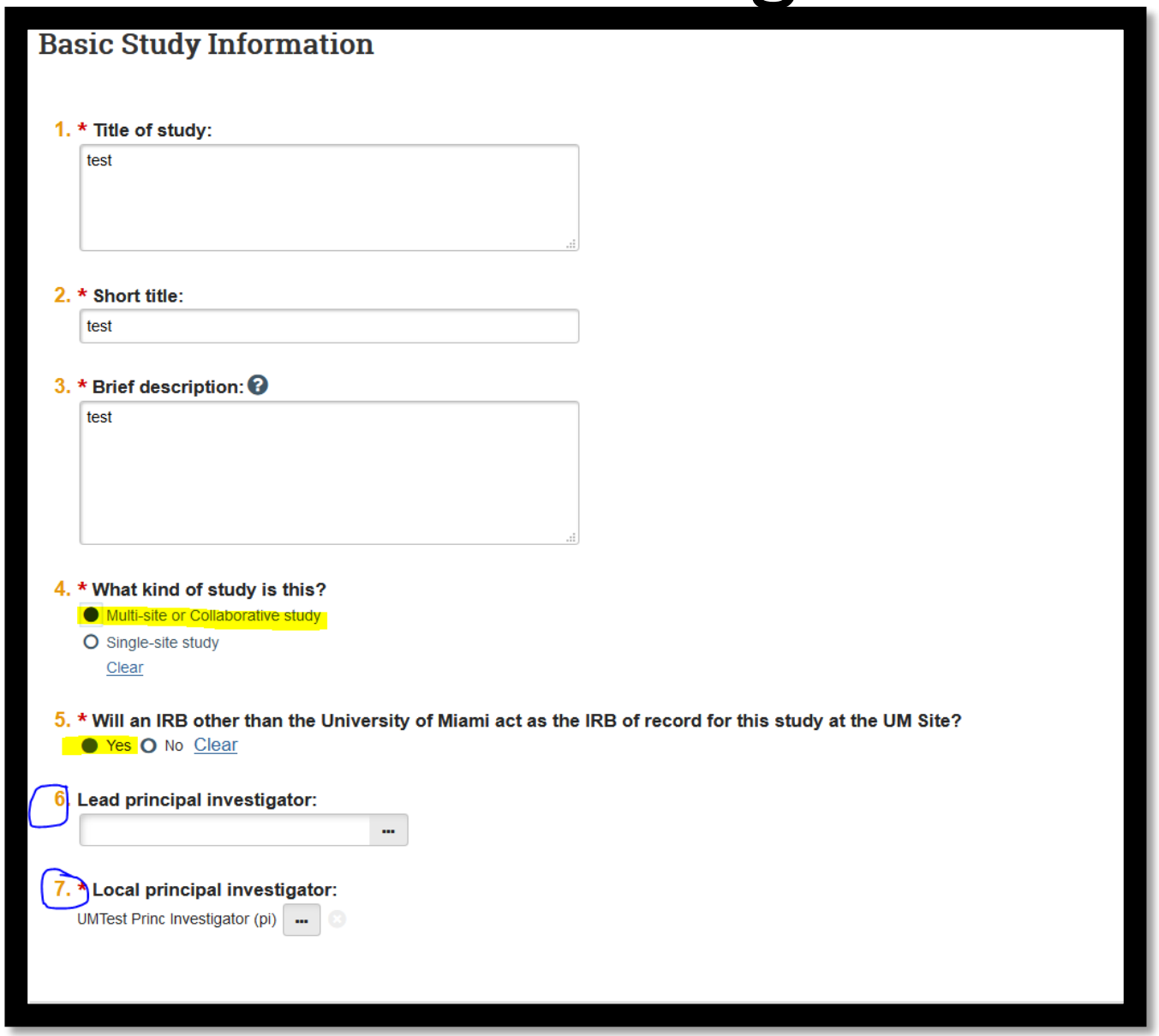


- Questions on the Basic Study Information page have been reorganized to ask the kind of study and external IRB questions **before** we ask about the PI(s).
- In the screenshot on this slide, because we have selected a Single Site **(4)** External Study **(5)**, we are only asking for your Local Principal 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

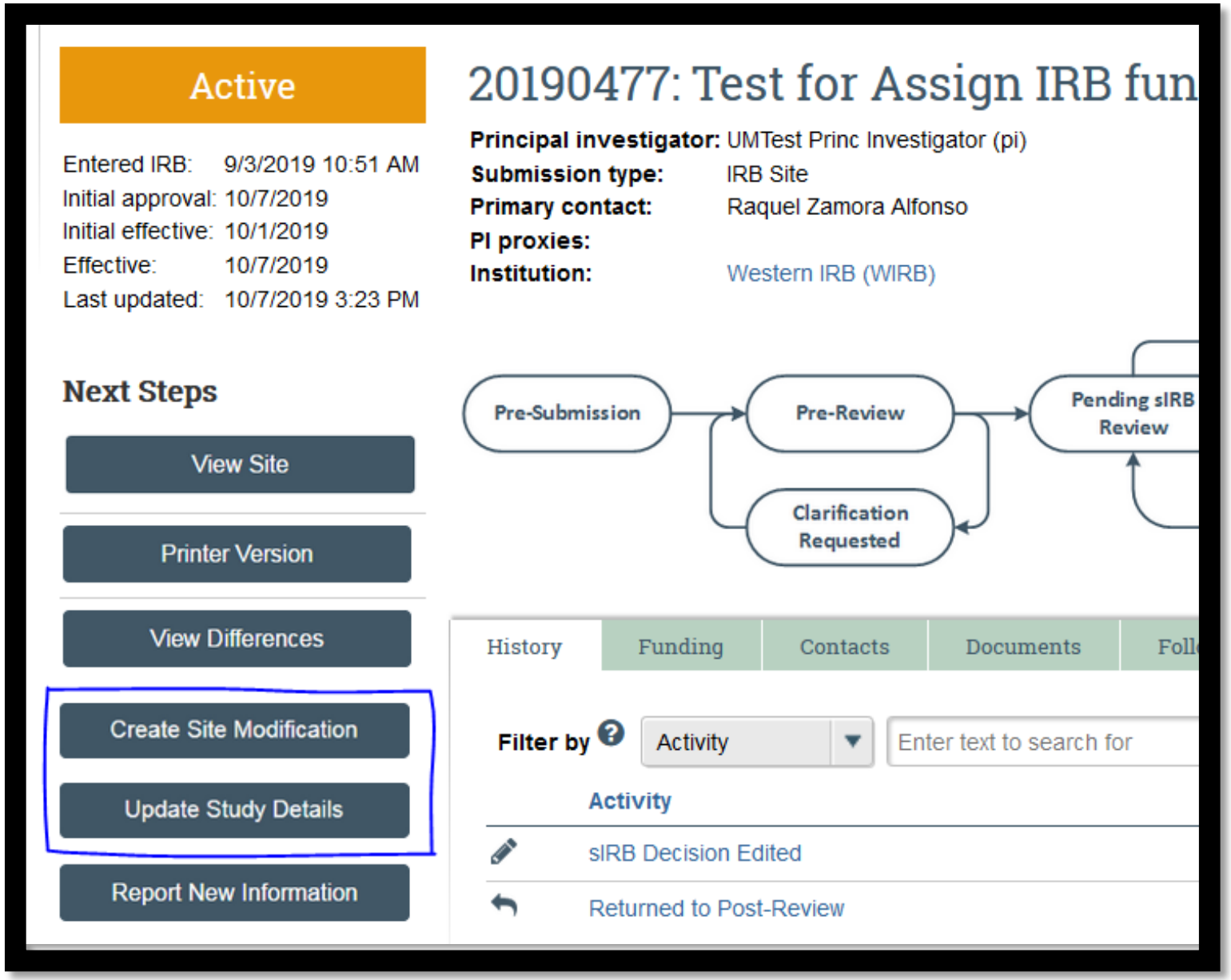


- When selecting a **Multi-Site (4), External Study, (5),** the **Lead Principal Investigator (6)** question will be presented. This is not a required question as often times the user completing the initial submission will not know who the Lead PI is at that time.
- Note that anytime that the External 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.



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

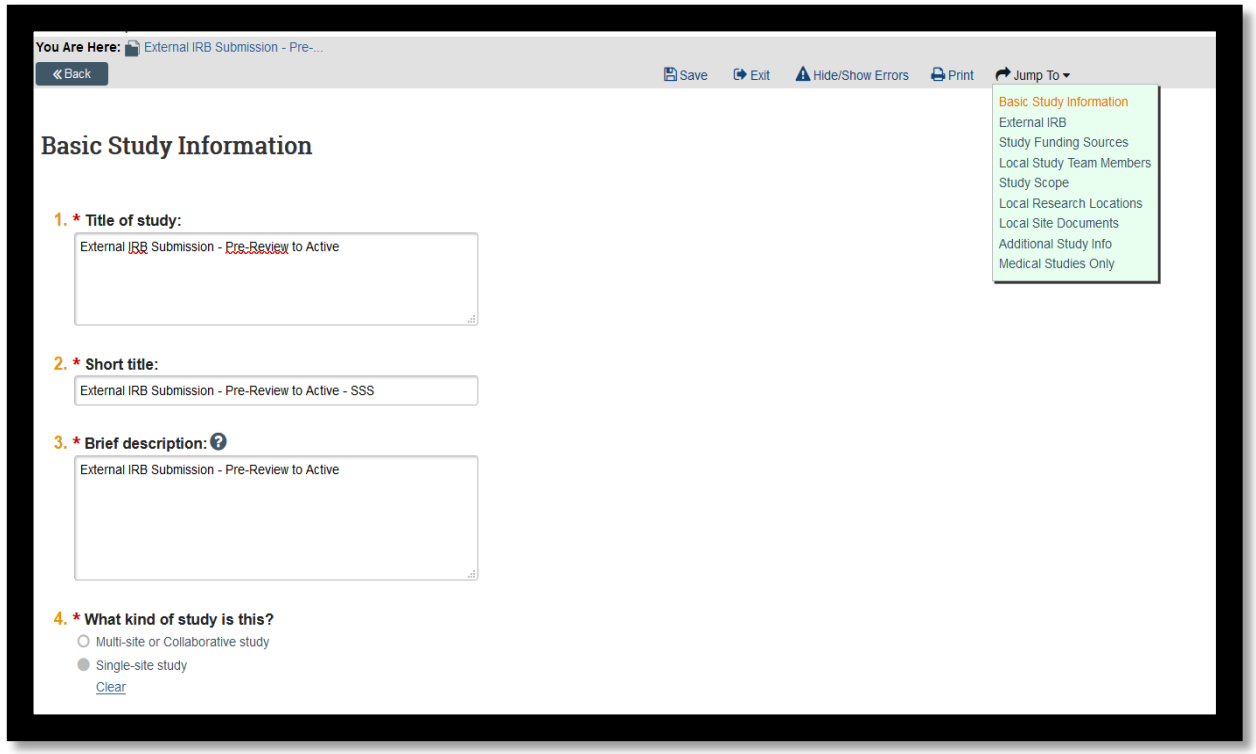
To move documents in Velos

Workflow Changes – Update Study details

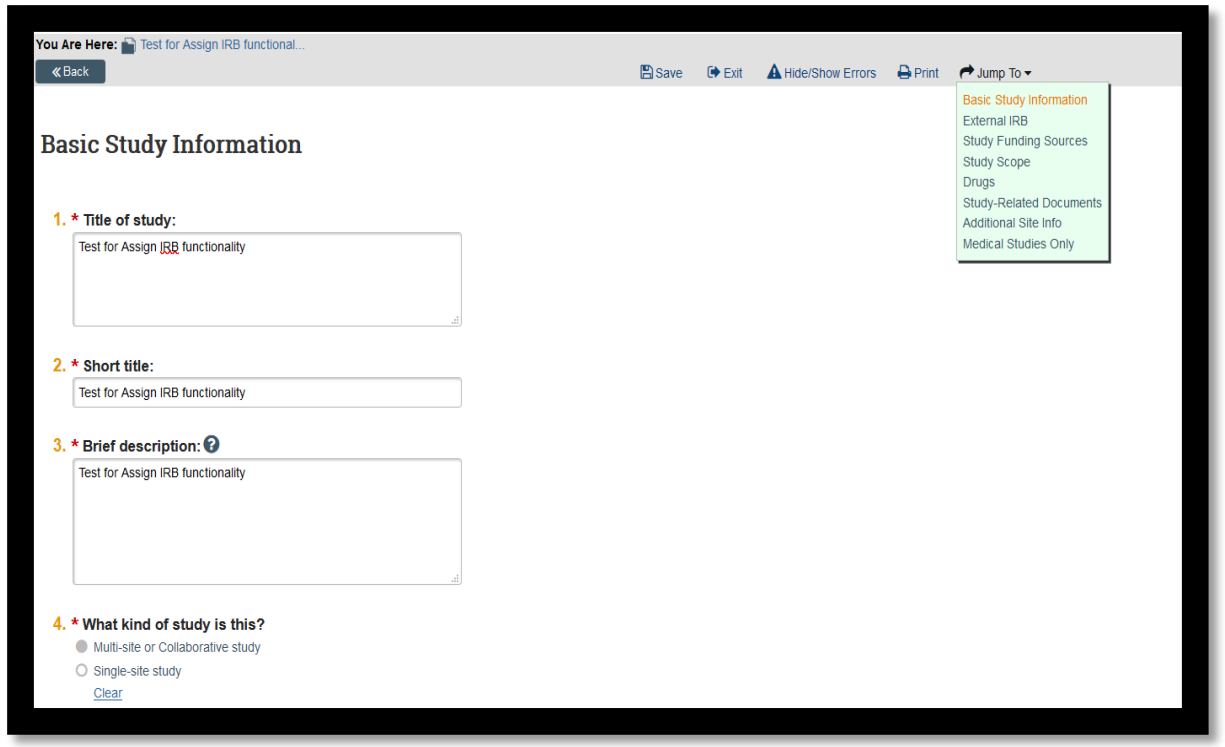
Do not use Update Study Details to upload any UM site modifications / documents

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**



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.



Smartform Changes

Basic Study/Local Site/Site Information

External IRB

Additional Local Funding Sources

Local Study Team

Study Scope/Local Research Locations

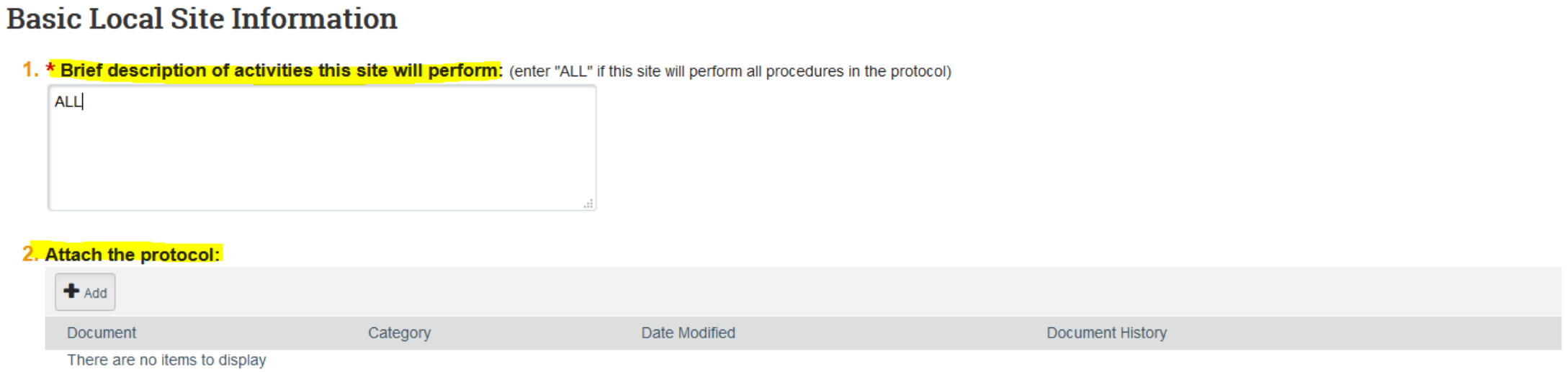
MOD/MODCR Main Page / MOD Information

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.

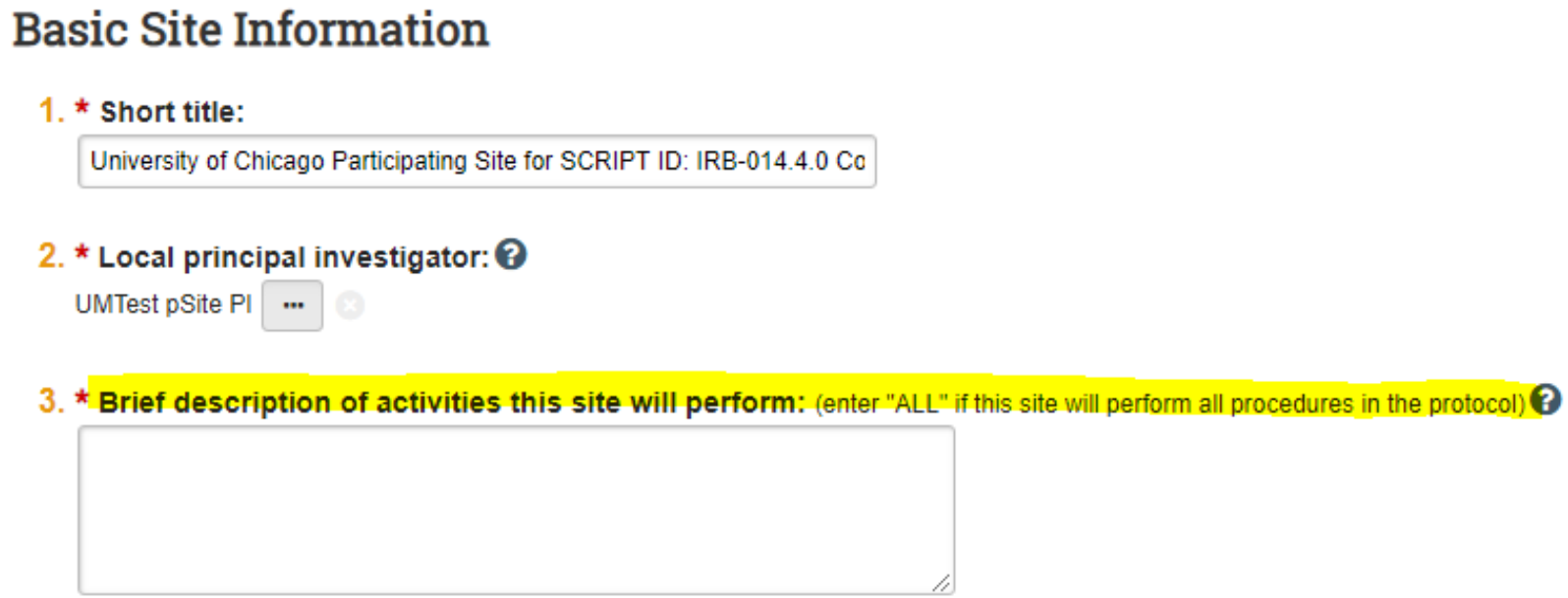
Smartform Changes – Basic Local Site Information

- 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.



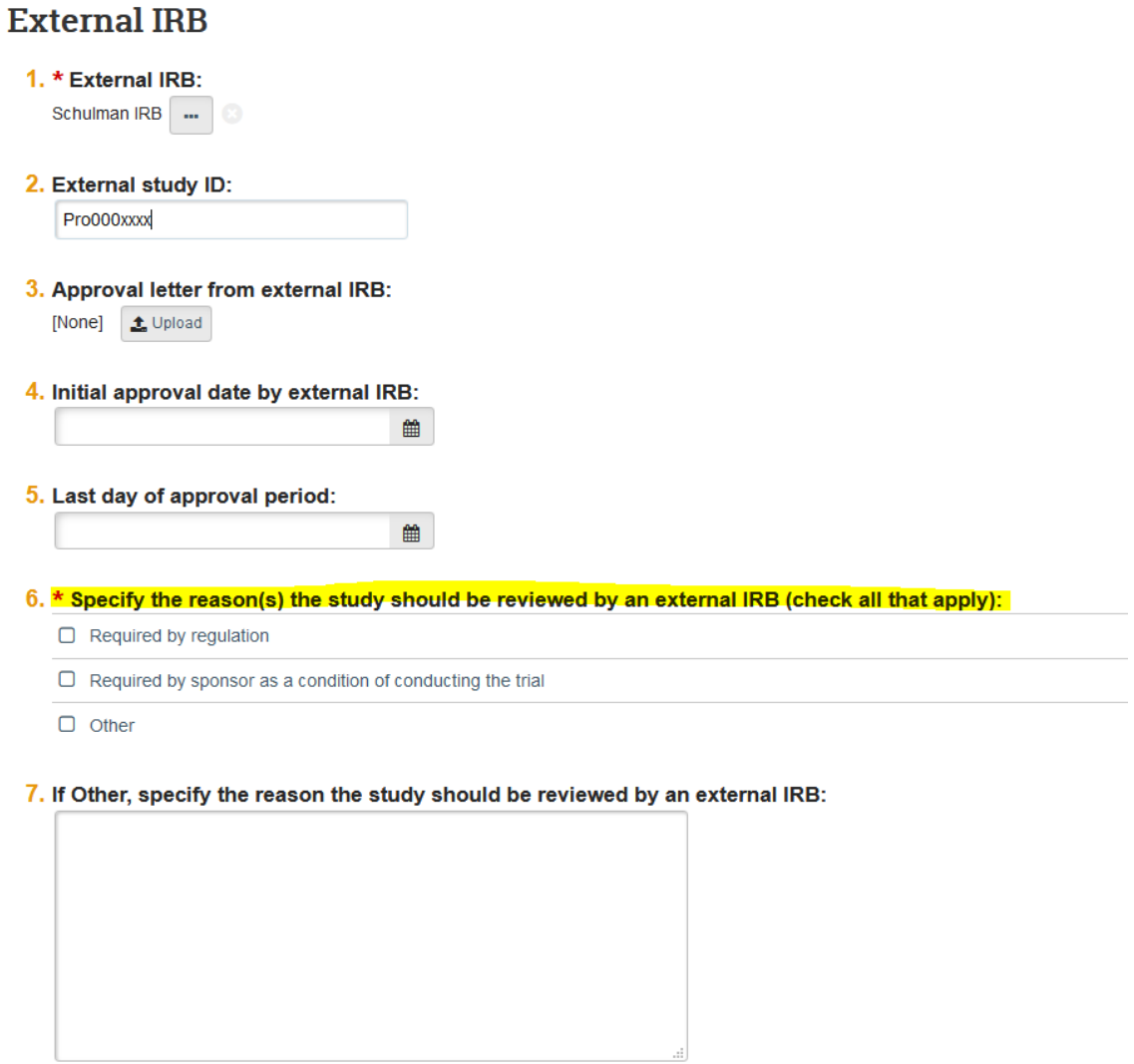
Smartform Changes – Basic Site Information

- 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).



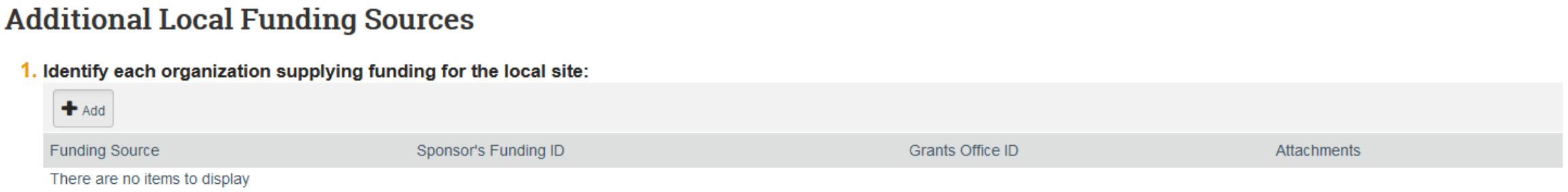
Smartform Changes – External IRB

- 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.



Smartform Changes – Additional Local Funding Sources

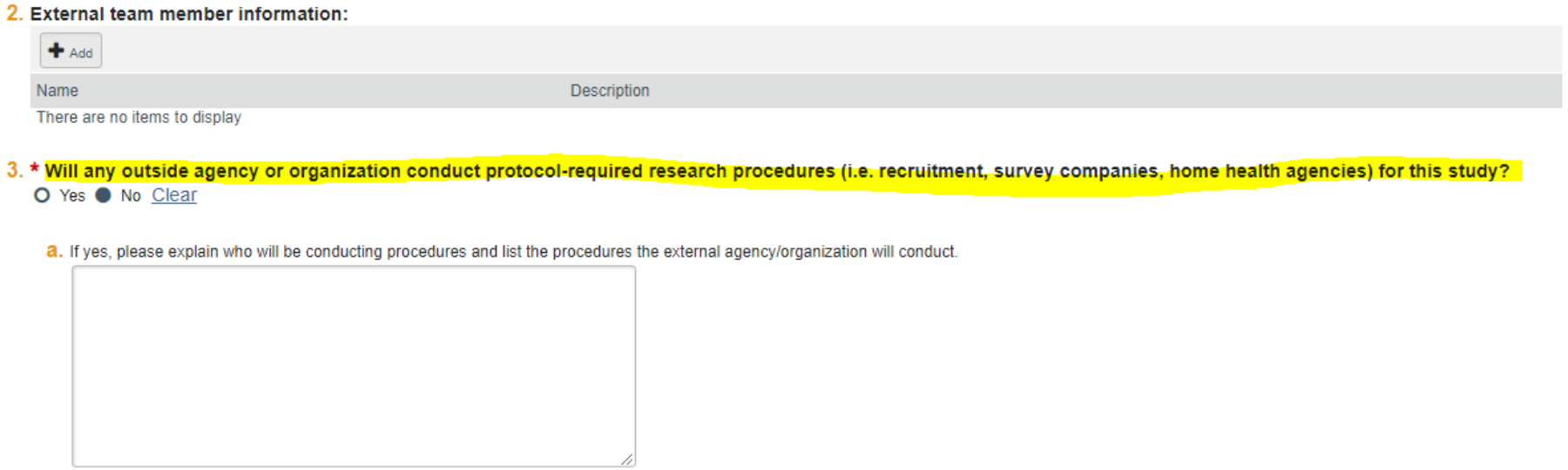
- IRB 8.2.4 is adding a new page for Multi-Site submissions (External IRB and non-External IRB) that will capture **Additional Local Funding Sources**, that will supplement the funding for the study at the local level.



Smartform Changes – Local Study Team

- 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

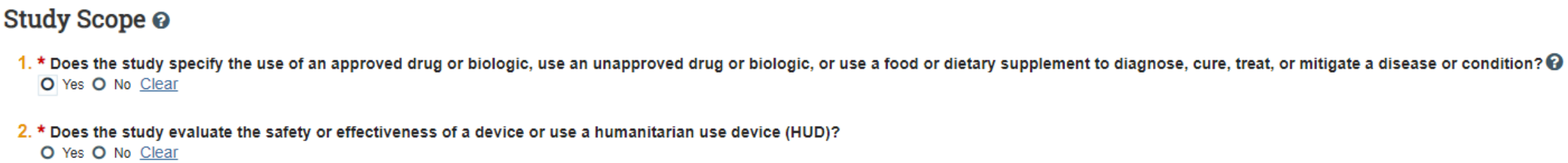
Smartform Changes – Local Study Team



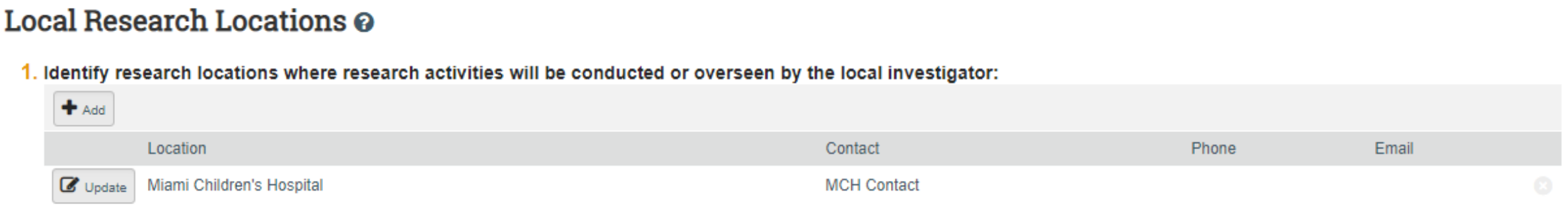
- IRB 8.2.4 will bring the following changes to the **Local Study Team** page:
  - NEW Question: **Outside Agency procedures**

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.

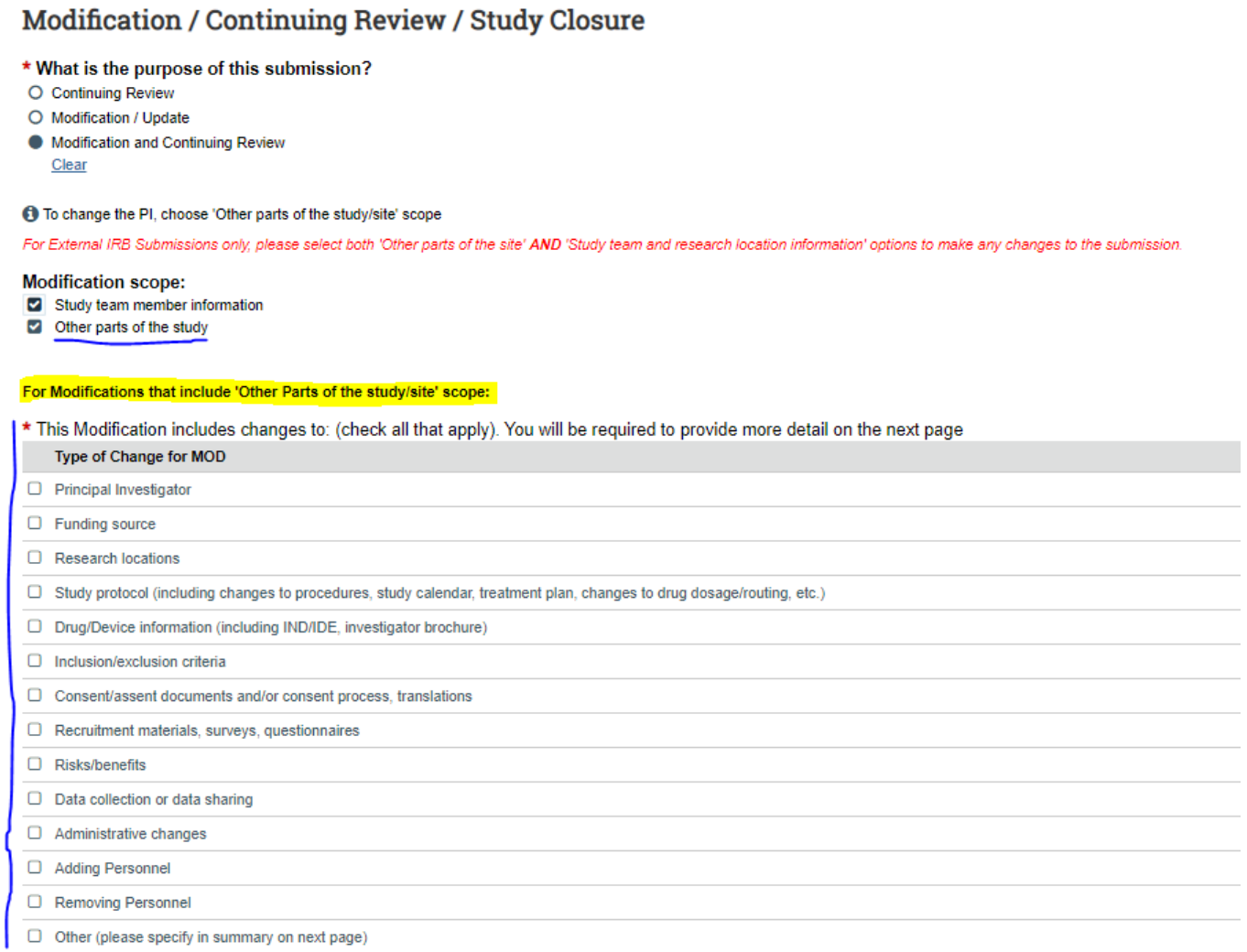


Smartform Changes – Local Research Location



- **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

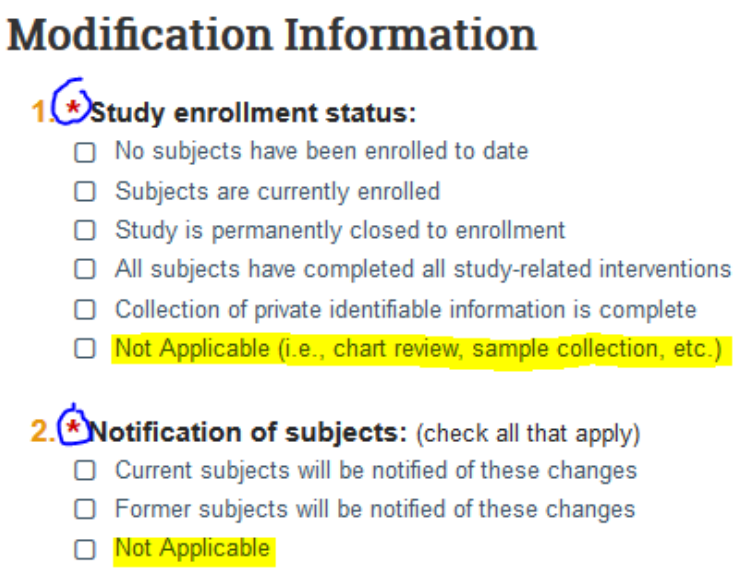
For Modifications that include 'Other Parts of the study/site' scope:

* 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
☐ Principal Investigator
☐ Funding source
☐ Research locations
☐ Study protocol (including changes to procedures, study calendar, treatment plan, changes to drug dosage/routing, etc.)
☐ Drug/Device information (including IND/IDE, investigator brochure)
☐ Inclusion/exclusion criteria
☐ Consent/assent documents and/or consent process, translations
☐ Recruitment materials, surveys, questionnaires
☐ Risks/benefits
☐ Data collection or data sharing
☐ Administrative changes
☐ Adding Personnel
☐ Removing Personnel
☐ 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



- **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.

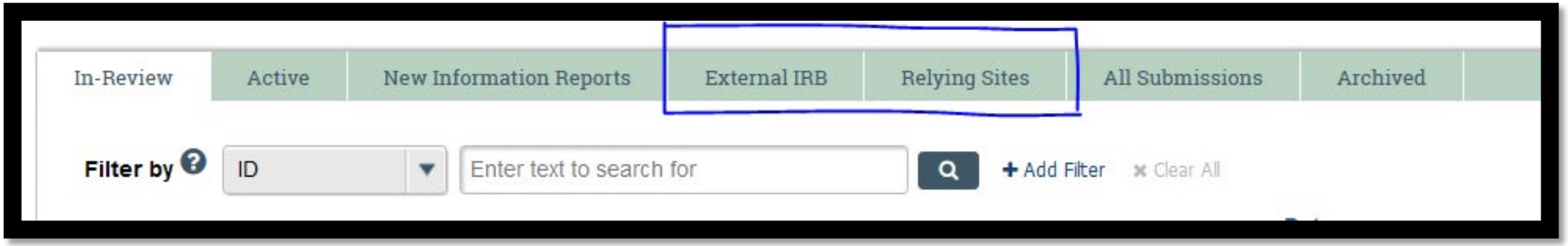
Workspace Changes

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

- **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 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

Activity Changes

Finalize Updates

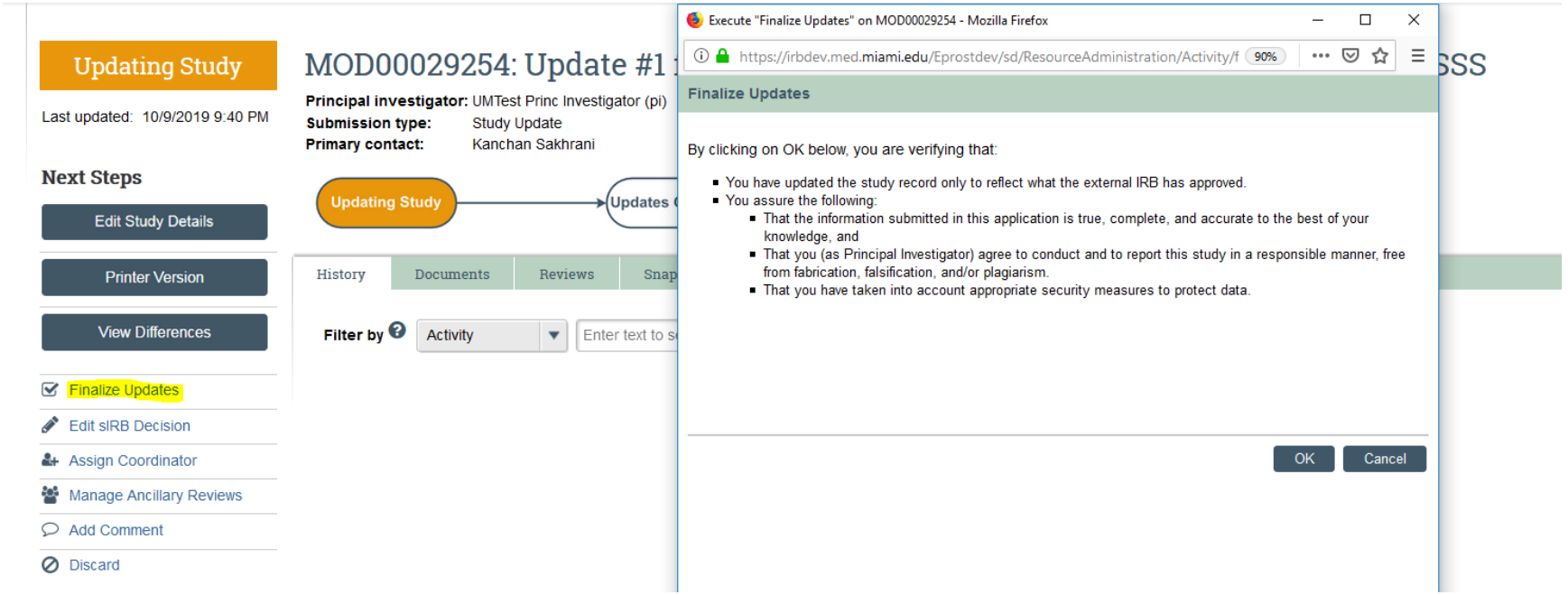
Copy Submission

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.



Activity Changes: Copy Submission

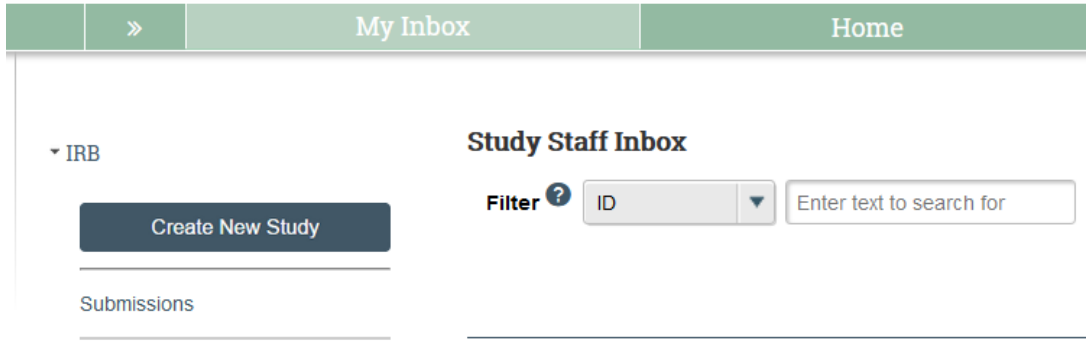
- In **IRB 8.1.4**, the Copy Submission activity could not be used for External IRB studies because it would not allow changes to be made to some of the values on the smartform. In addition, it would copy the Site submission's workspace, and not allow the study team to make changes to that Site submission. 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

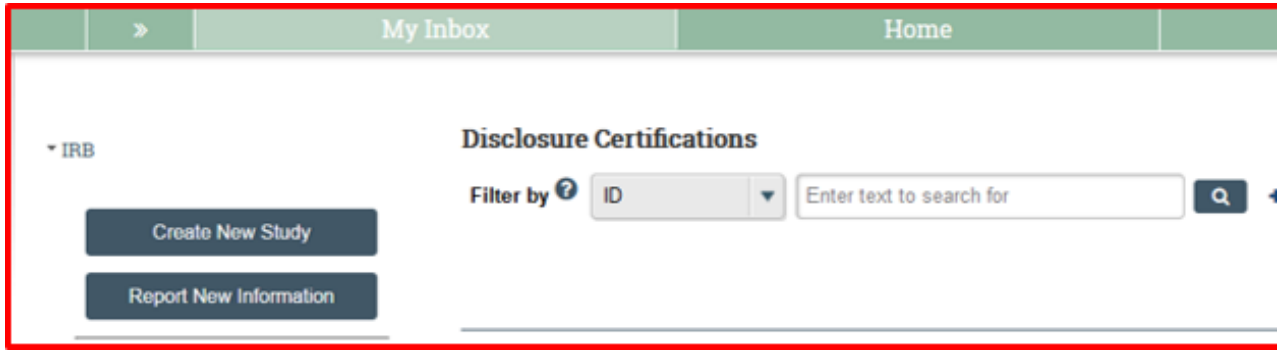
- For Relying Sites (participating sites) - In 8.1.4, the IRB Coordinator had to execute **“Site Materials Received”** activity on the Site record of a Multi-Site Study.
- In IRB 8.2.4 this activity has been changed to **“Submit Site Materials”** and the Lead PI, Proxy, and Reliance Coordinator are now 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

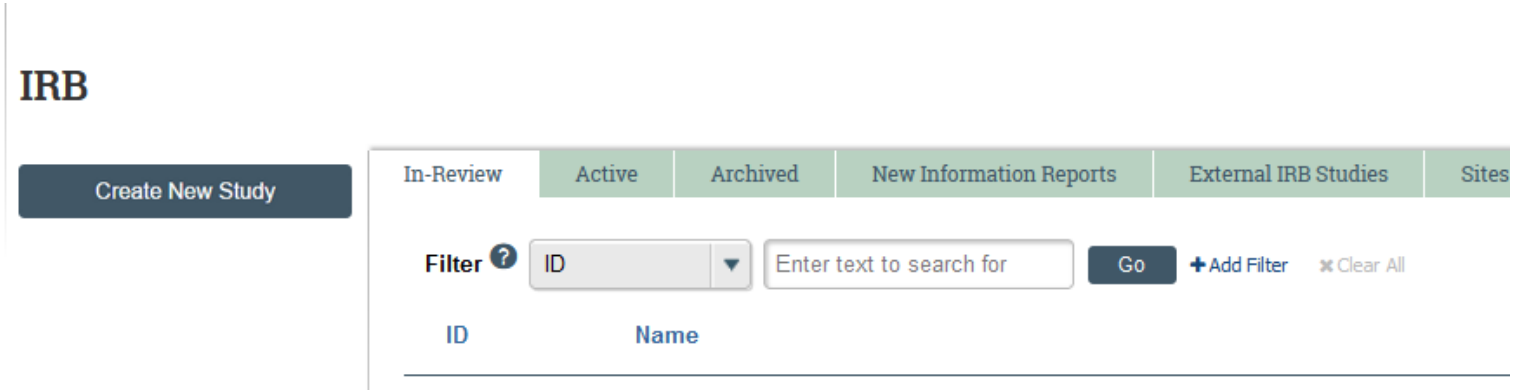


In 8.2.4, **Create RNI** button is now available on My Inbox pages, to allow RNI to be created outside of a study workspace:



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: