*my*IRB

Electronic Submission

Researcher Manual

UF | UNIVERSITY of FLORIDA

The Foundation for The Gator Nation

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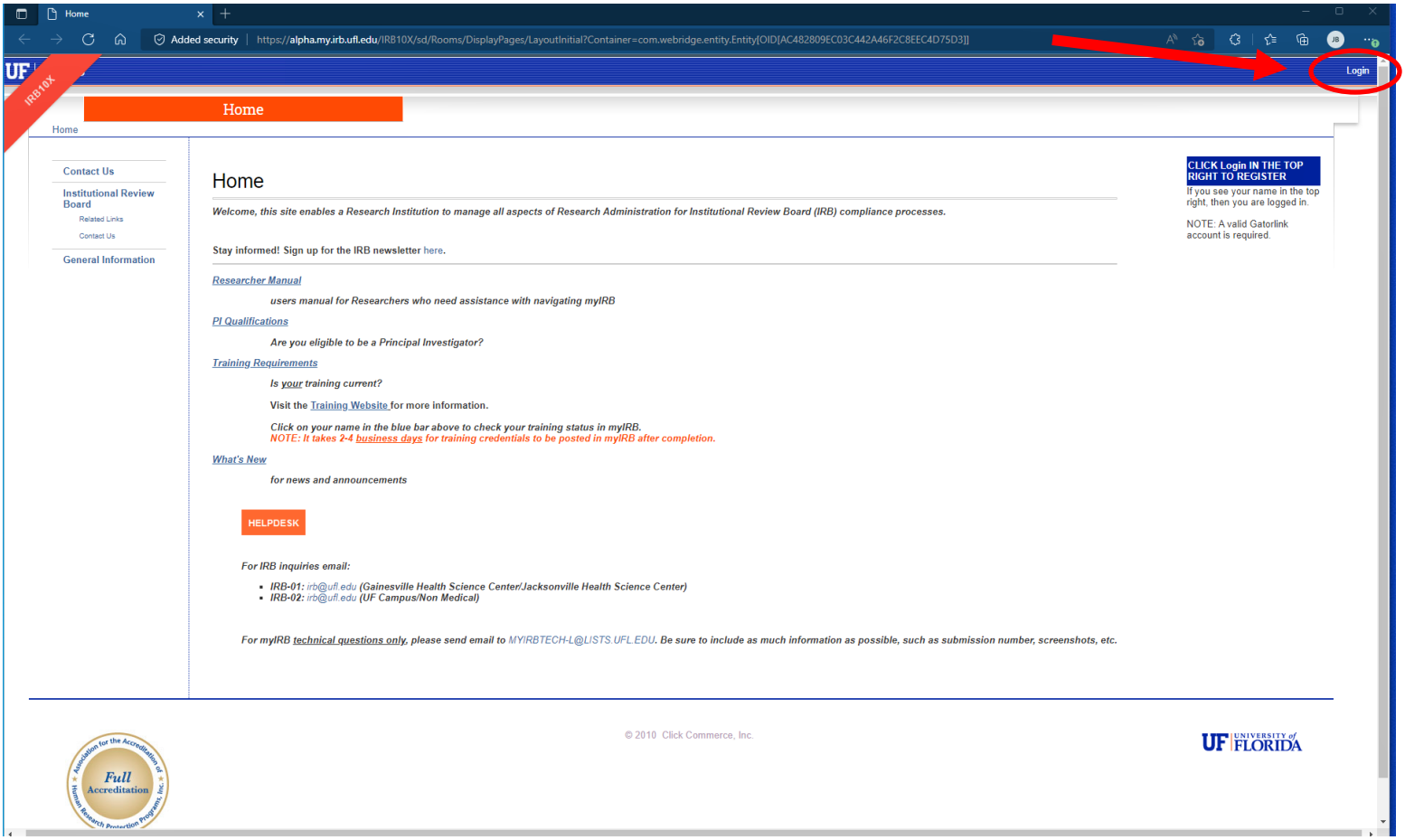
Each chapter is hyperlinked. Click on the name of the chapter to automatically navigate to that page in the manual.

Introduction

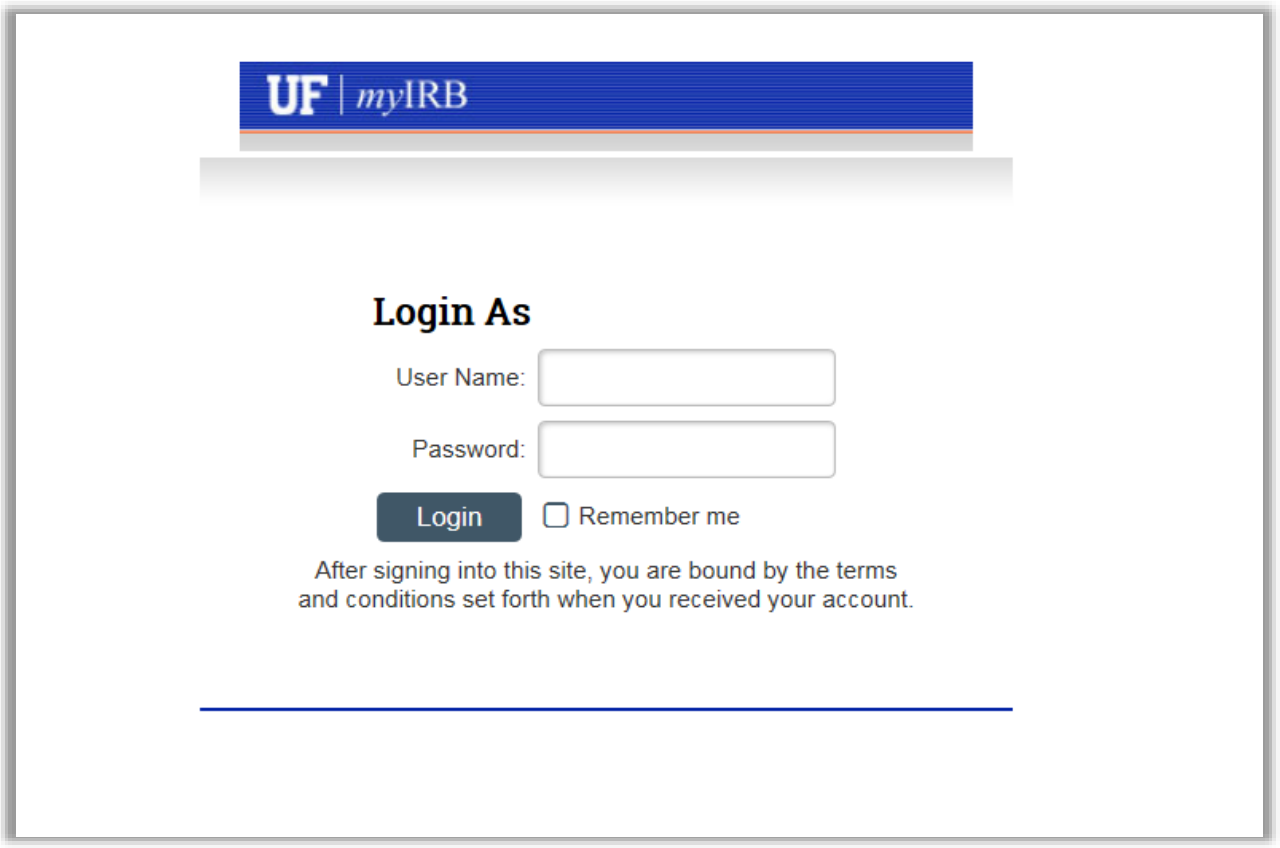
1. Go to the myIRB website: https://my.irb.ufl.edu

2. Click the "**Login**" link located on the right side of Home page:



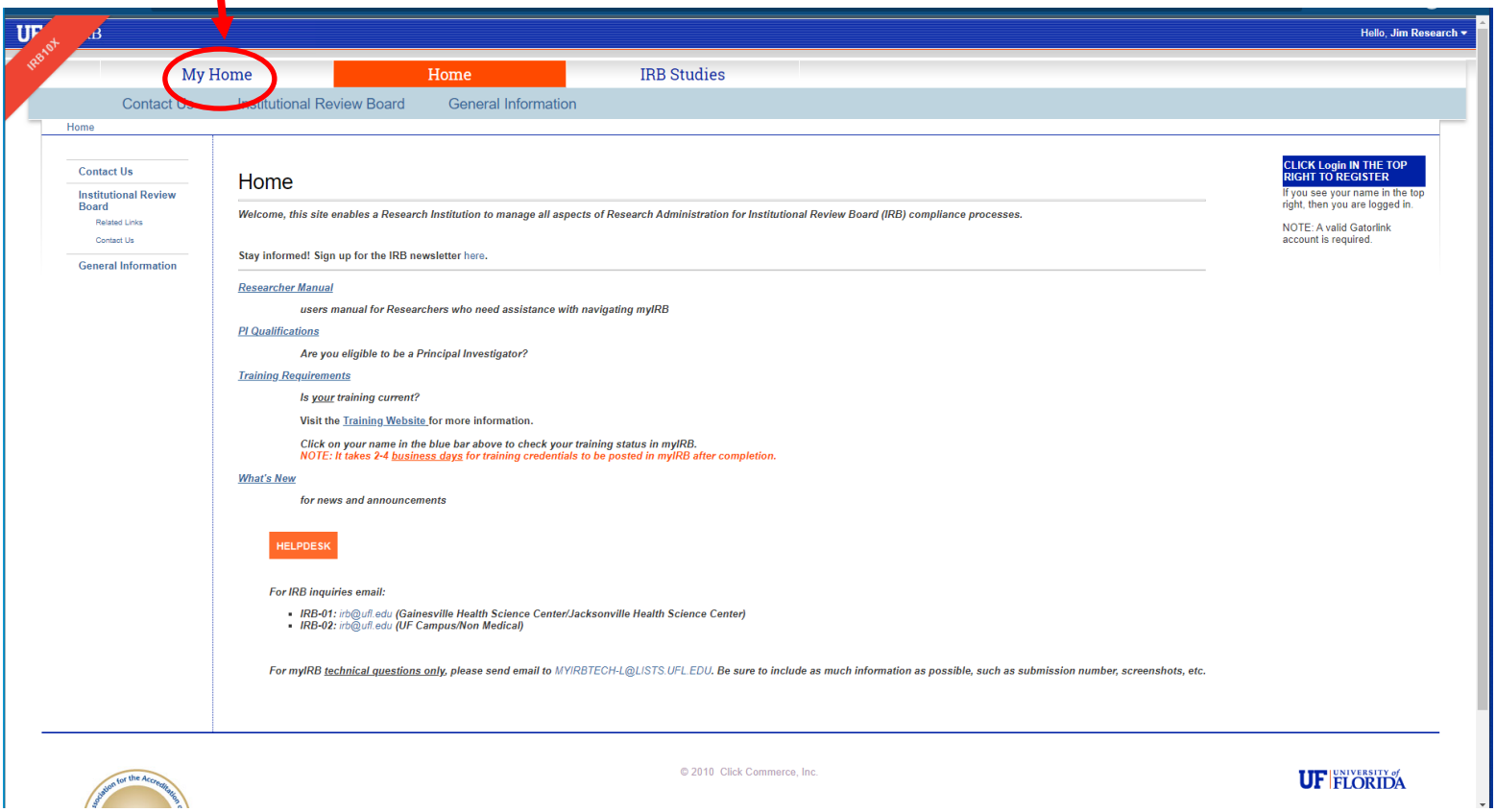
TIP: If you have not previously registered for a myIRB account, when you click the **Login** link, the myIRB registration page will appear. The registration page will be pre-populated with information obtained from your Gatorlink account. Please update/complete all mandatory and editable fields and submit. Registrations will take approximately 48hrs to be finalized.

3. Next, login using your Gatorlink username and password. This step will only appear the **first time** you register for a myIRB account. Once your myIRB account is established, click the **Login** link in the upper right corner of the previous screen. The screen below will appear after clicking on the login link. Once there, enter your Gatorlink username and password. Then, you will be redirected to **myIRB home**.

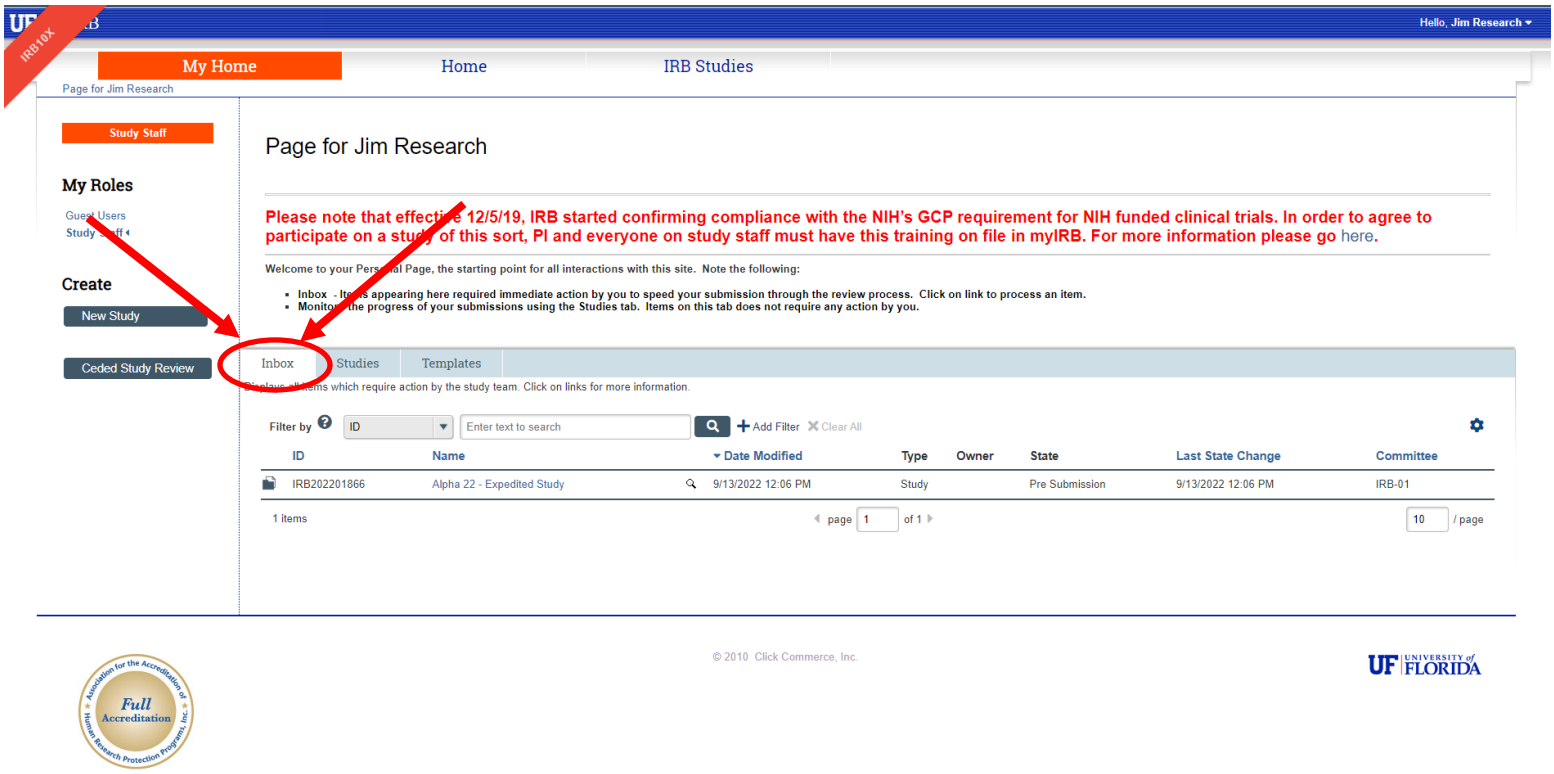


"My Home" Personal Folder

After logging in to the IRB site, you will be redirected to the **myIRB Home Page**. From here, click the "**My Home**" tab. This is where you can access and edit your studies.



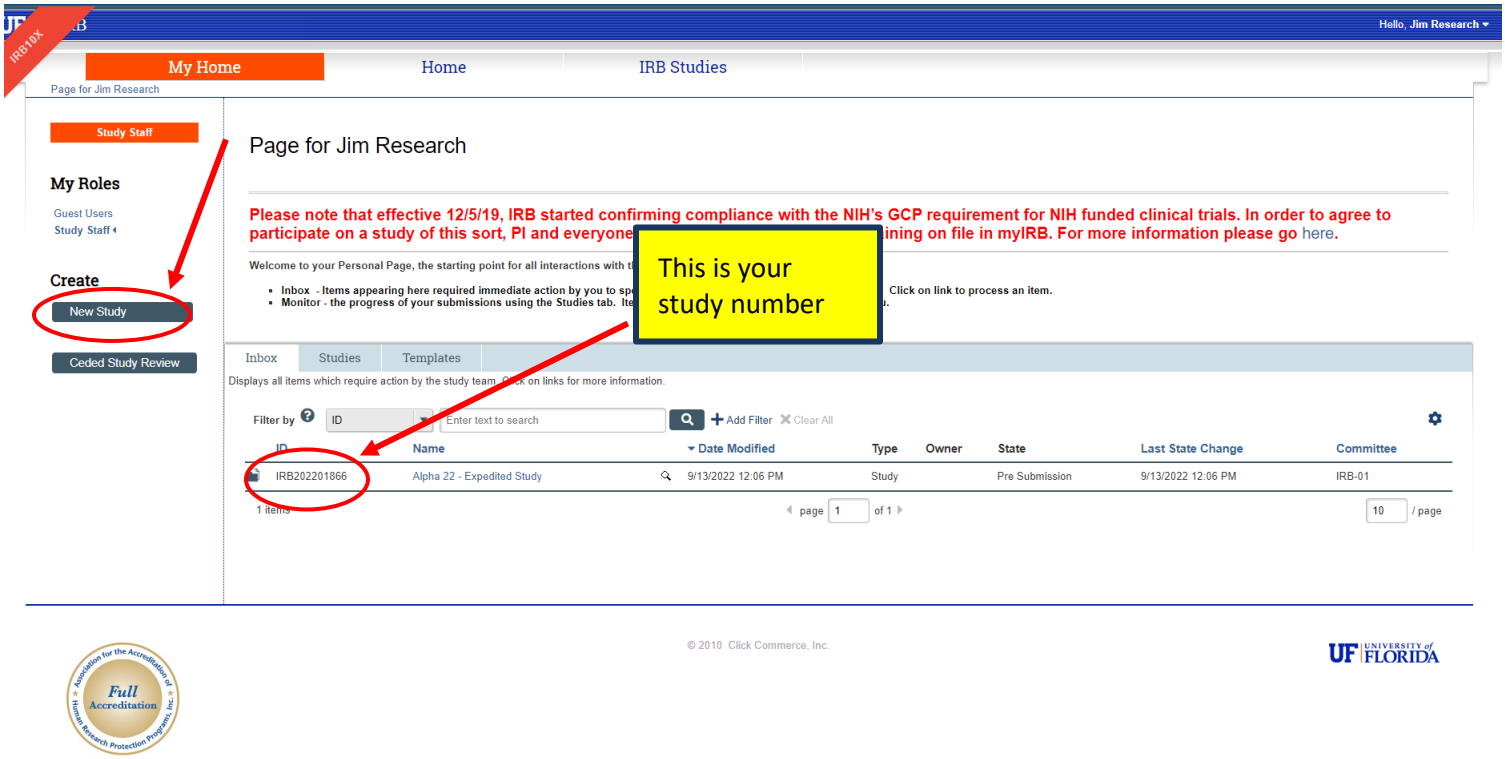
The default tab will always be your **Inbox**, which includes all submissions that require some action by you (e.g., new studies, reportable events, continuing reviews, or revisions). The **Studies** tab (located to the right of the Inbox tab) will list all studies to which you have access.



Create New Study

In the role of PI or Study Staff, you can create a new study by clicking the **New Study** button in the column on the left side of the page.

The **IRB Study Number** is assigned automatically the first time you save the study **or** after you complete the first page of the SmartForm and click **Continue**.



TIP: While accessing the *my*IRB website, ensure your web browser is configured to allow pop-ups.

Working with SmartForms

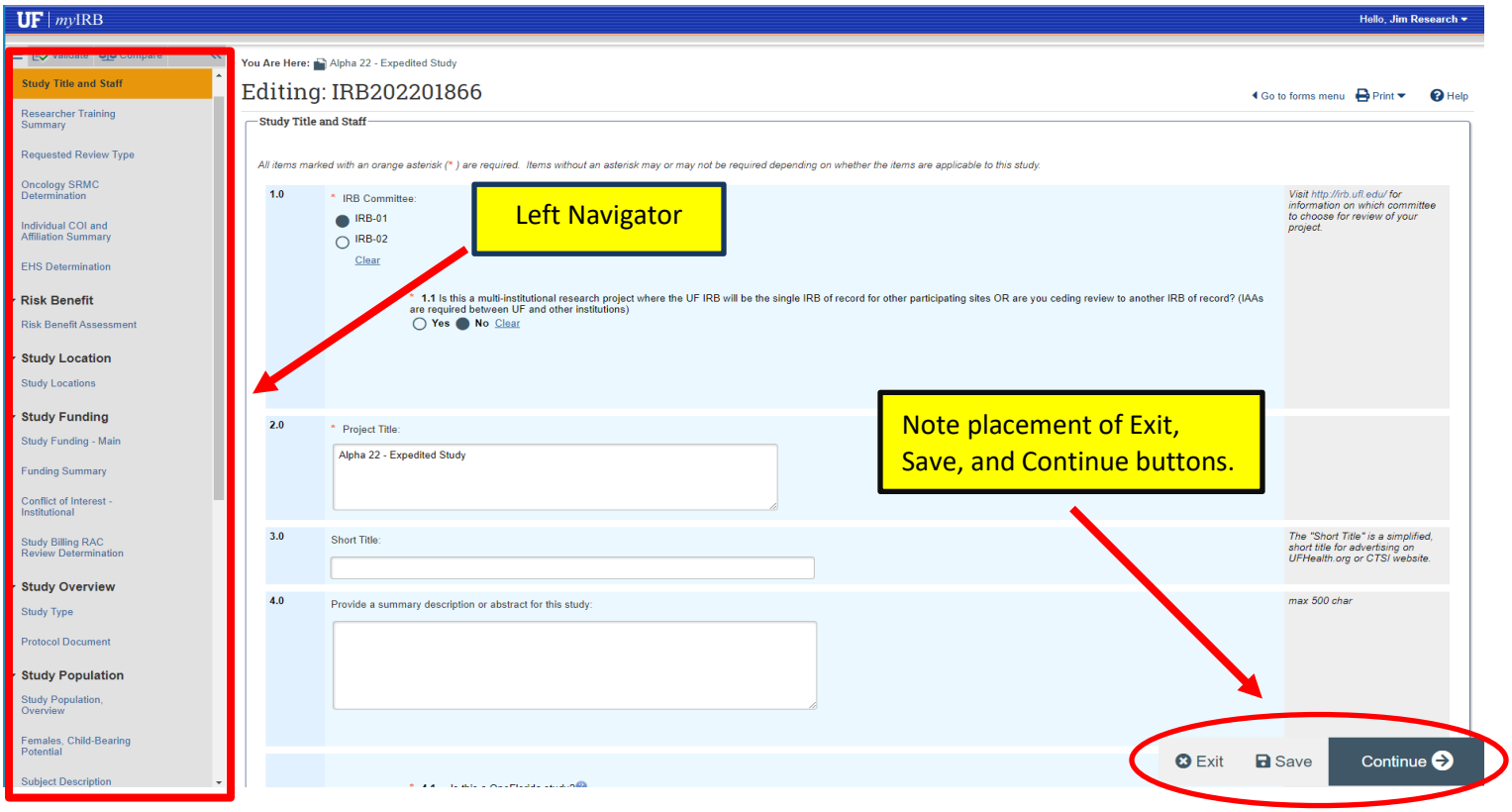
The *myIRB* system uses **SmartForms** to guide you through your project submission. The system will present only those SmartForms and questions which are relevant to your study based upon your previous responses.

While completing each SmartForm, you can provide information by:
a) typing directly into text boxes; or
b) copying text from another document and pasting that text into the appropriate box.

Relevant documents can be uploaded where indicated throughout the submission.

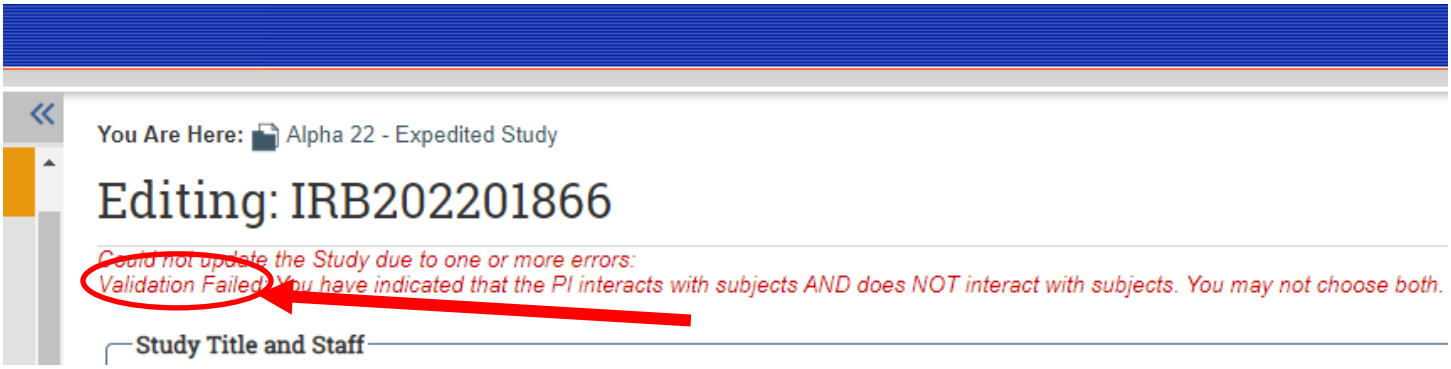
TIP: Throughout the SmartForms, required fields are marked with an orange asterisk *.

Researchers can navigate to SmartForm pages by **clicking the desired SmartForm title** in the **Left Navigator**. This navigator simplifies the process of searching for a particular SmartForm. This feature also provides an overview of remaining SmartForms to be completed. Study teams can **Exit, Save,** or **Continue** by clicking on the appropriate button in the lower right corner of the screen. See screenshot below:

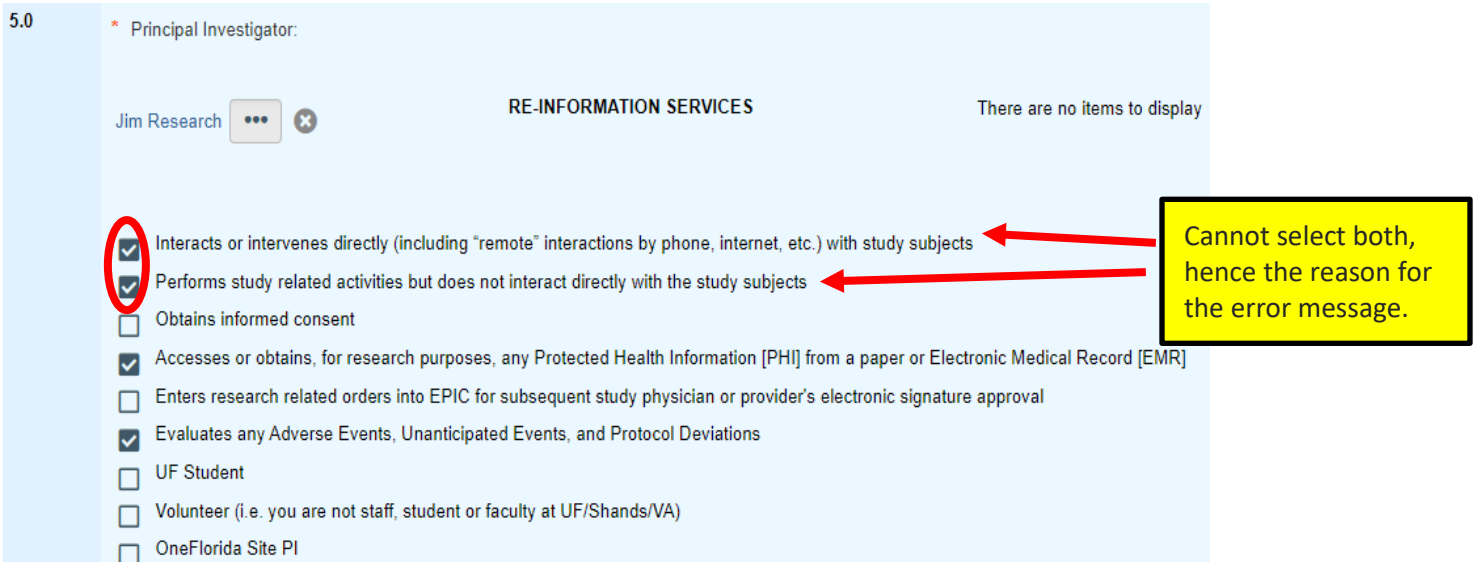


As you advance through the SmartForms, the system will notify you of submission errors. If you make an obvious error on a SmartForm and attempt to advance to a new page by clicking Continue, the original page will reload and you will receive a **Validation Failed** message. See screenshots below for an example of an error message as well as the source of the error:

Error message on reloaded SmartForm:



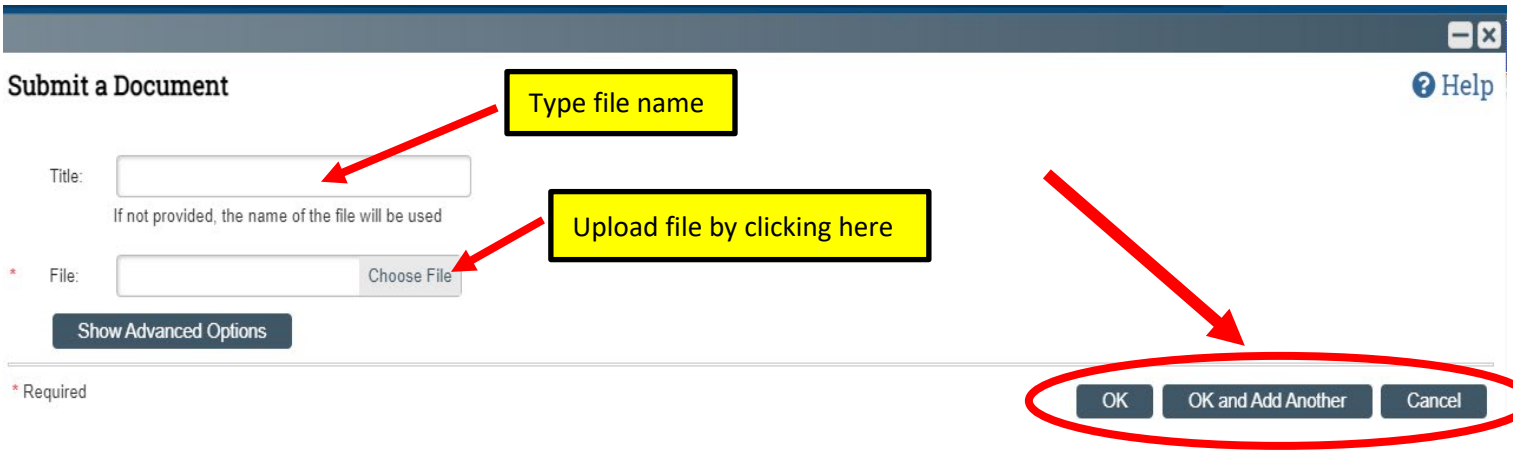
Source of error on SmartForm:



Some screens will also have an **Add** button (see screenshot 1 below). This button opens a new window with additional, item-specific questions (see screenshot 2 below). On the sub-page, you can upload documents and add document-specific information. The system will also present you with the options of **OK**, **OK and Add Another**, and **Cancel.** If your study requires the submission of multiple documents, submit each document separately here. For each document, remember to provide additional information as required.

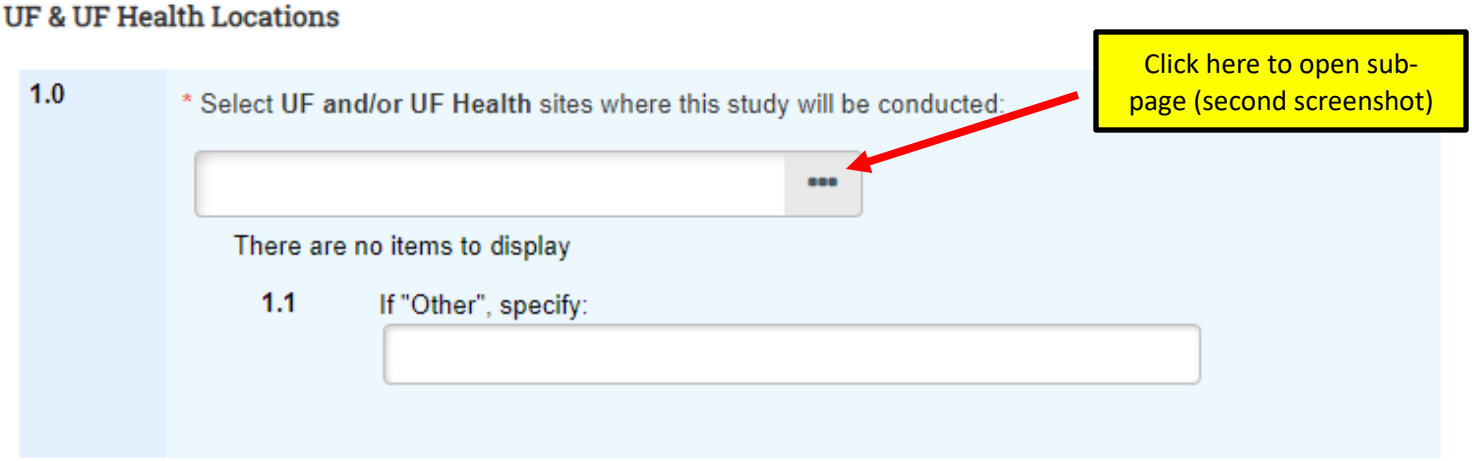
Screenshot 1:

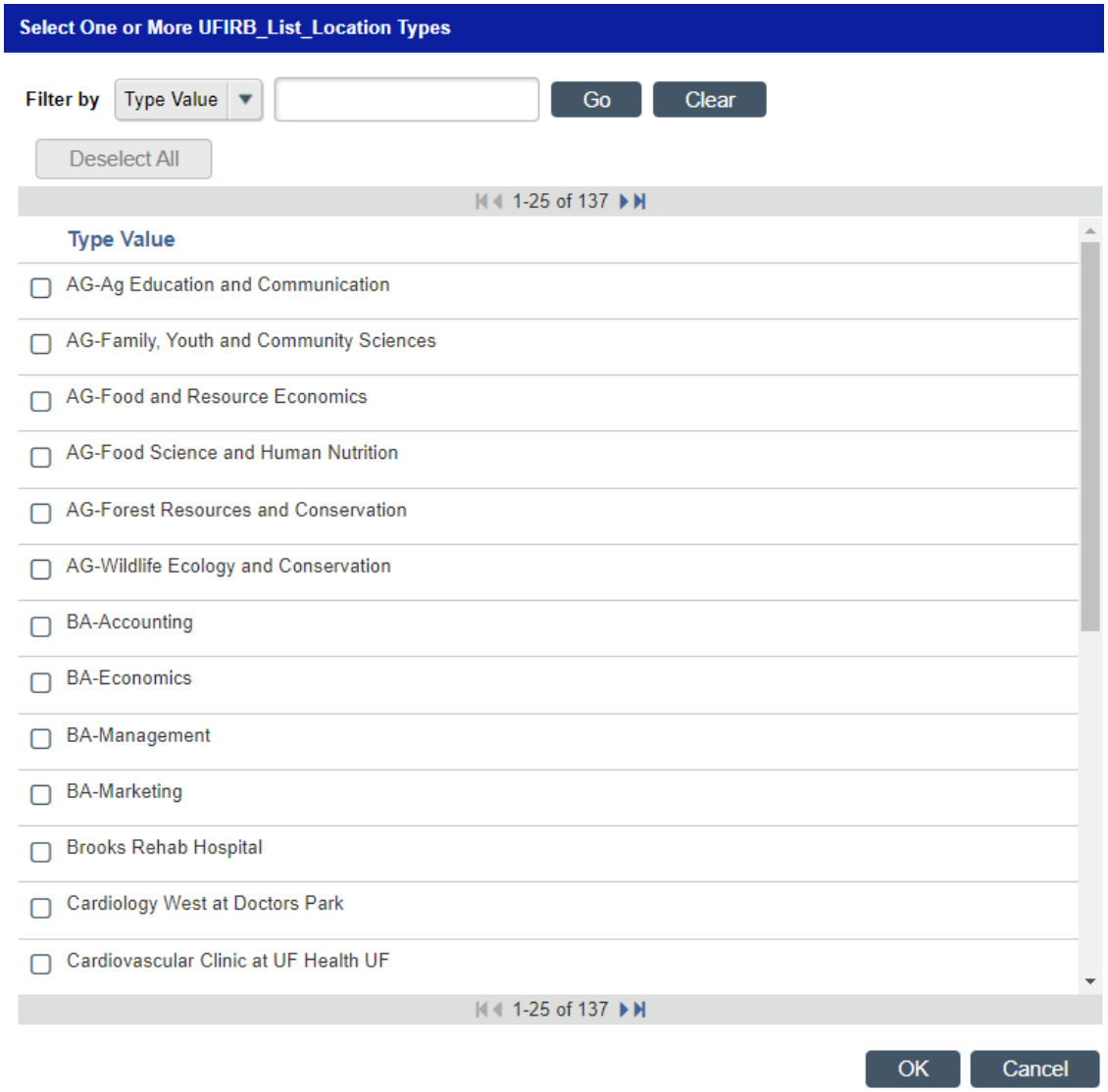
Screenshot 2:



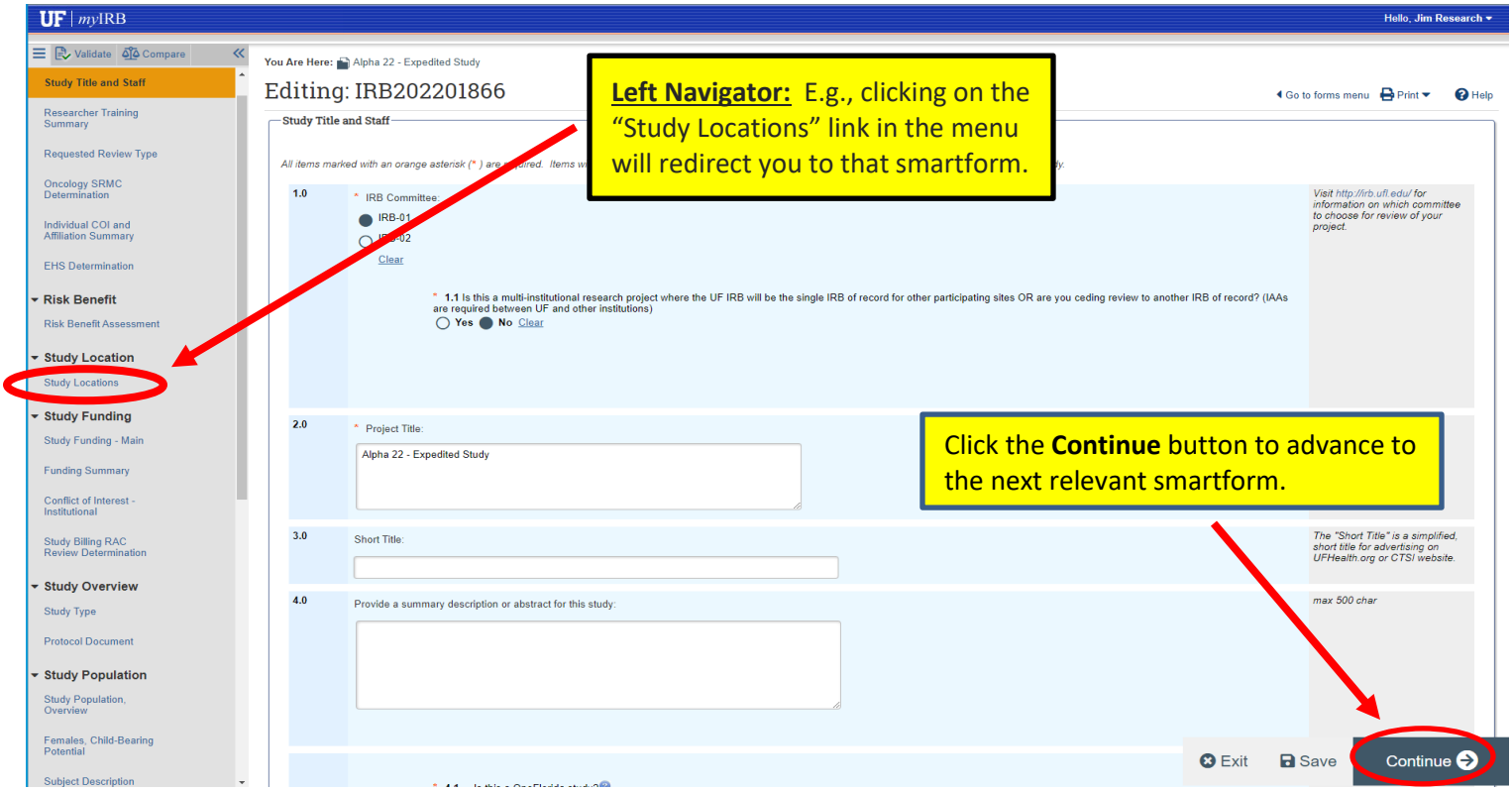
Some questions will allow you to select from a drop down list by clicking on the ellipses (e.g., UF site locations). On the next screen, you will be prompted to select specific site(s). You can do so by typing the information into the search bar preceded by the '**%**'sign. See screenshots below:

UF & UF Health Locations





TIP: To progress through SmartForms, use the **Continue** button at the bottom of each SmartForm.

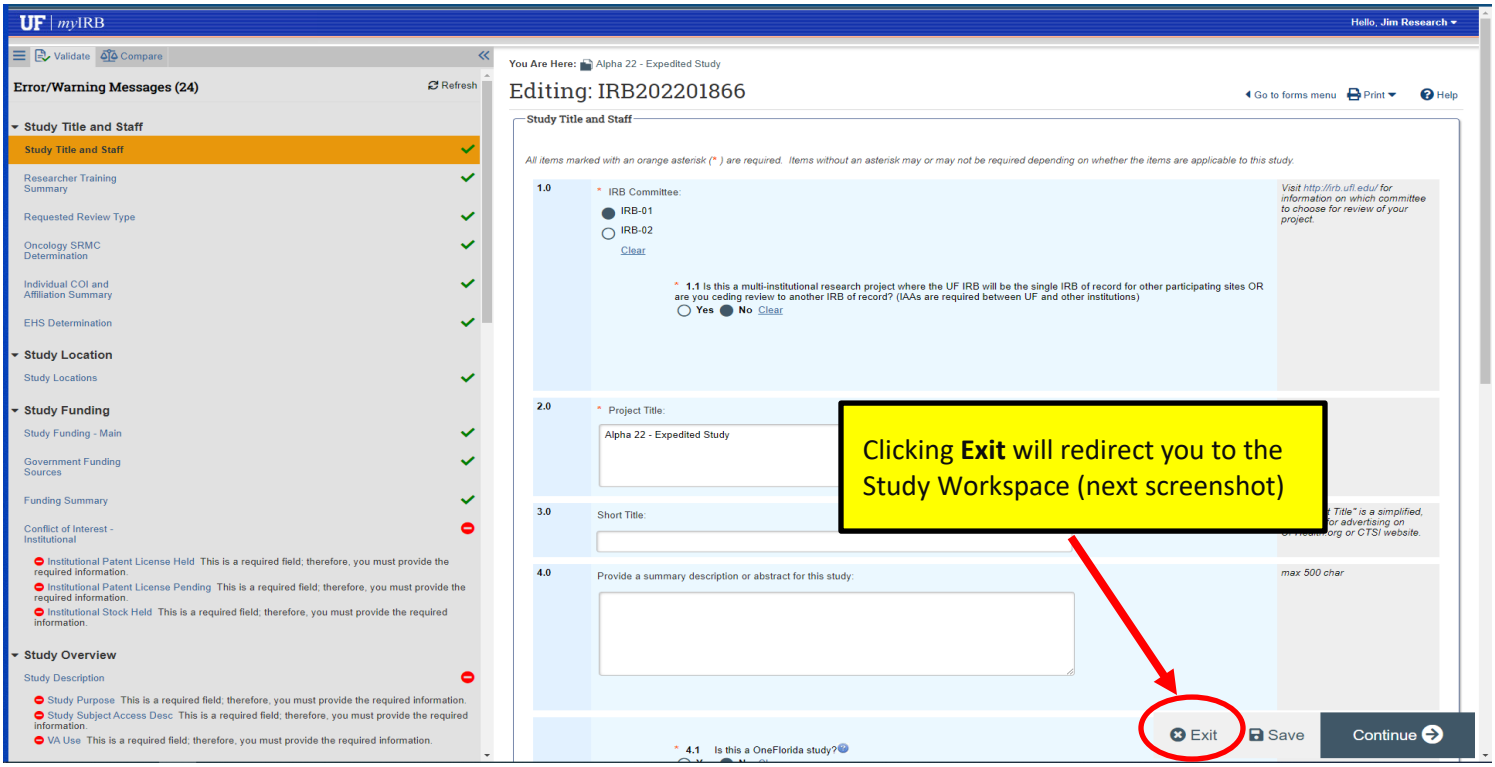


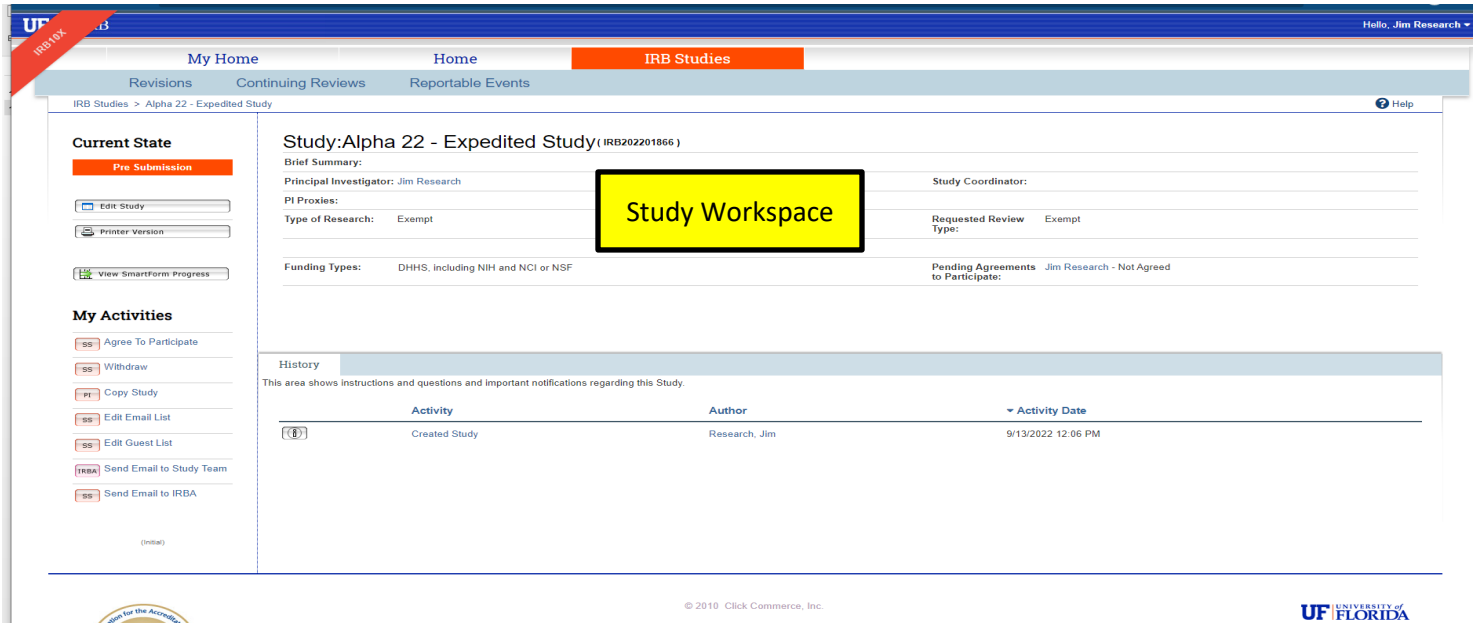
TIP: During your initial pass through the SmartForms, use the **Continue** button to advance to the next page. **Using Continue for the initial submission is essential.** By doing so, you will be prompted to complete all appropriate SmartForms for your type of submission.

> ***Remember***: The branching logic (i.e., the pages you see throughout your submission) is predicated on the consecutive completion of smartforms and questions during your initial project submission.

After editing a SmartForm, click **Save** or **Continue** to save your progress. Note that some pages require you to upload documents (e.g., The *Questionnaires, Surveys, and Tests* page). On those SmartForms, save the page **before clicking Continue** to ensure uploaded documents are saved.

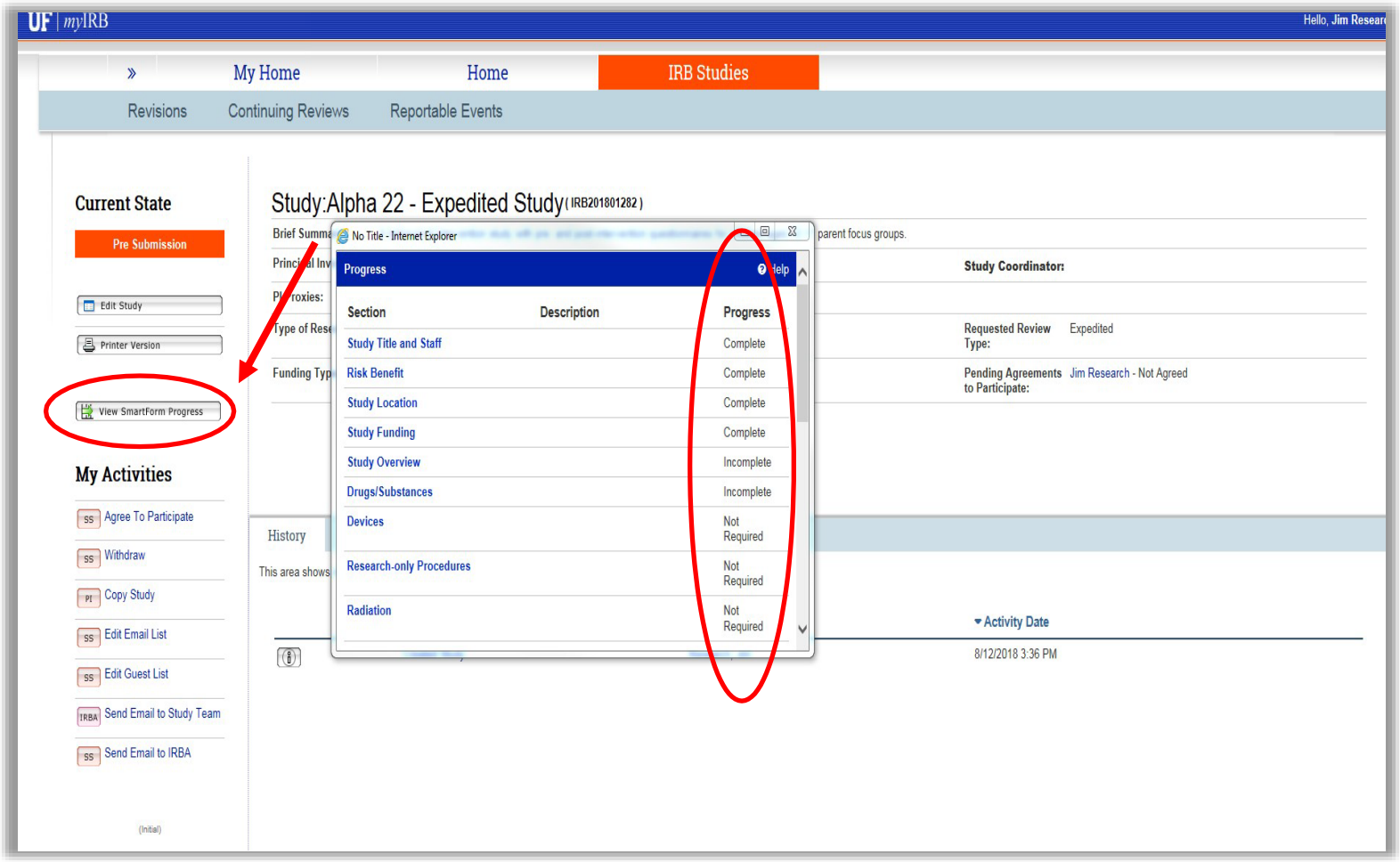
To exit a SmartForm and return to the **Study Workspace,** click **Exit**.





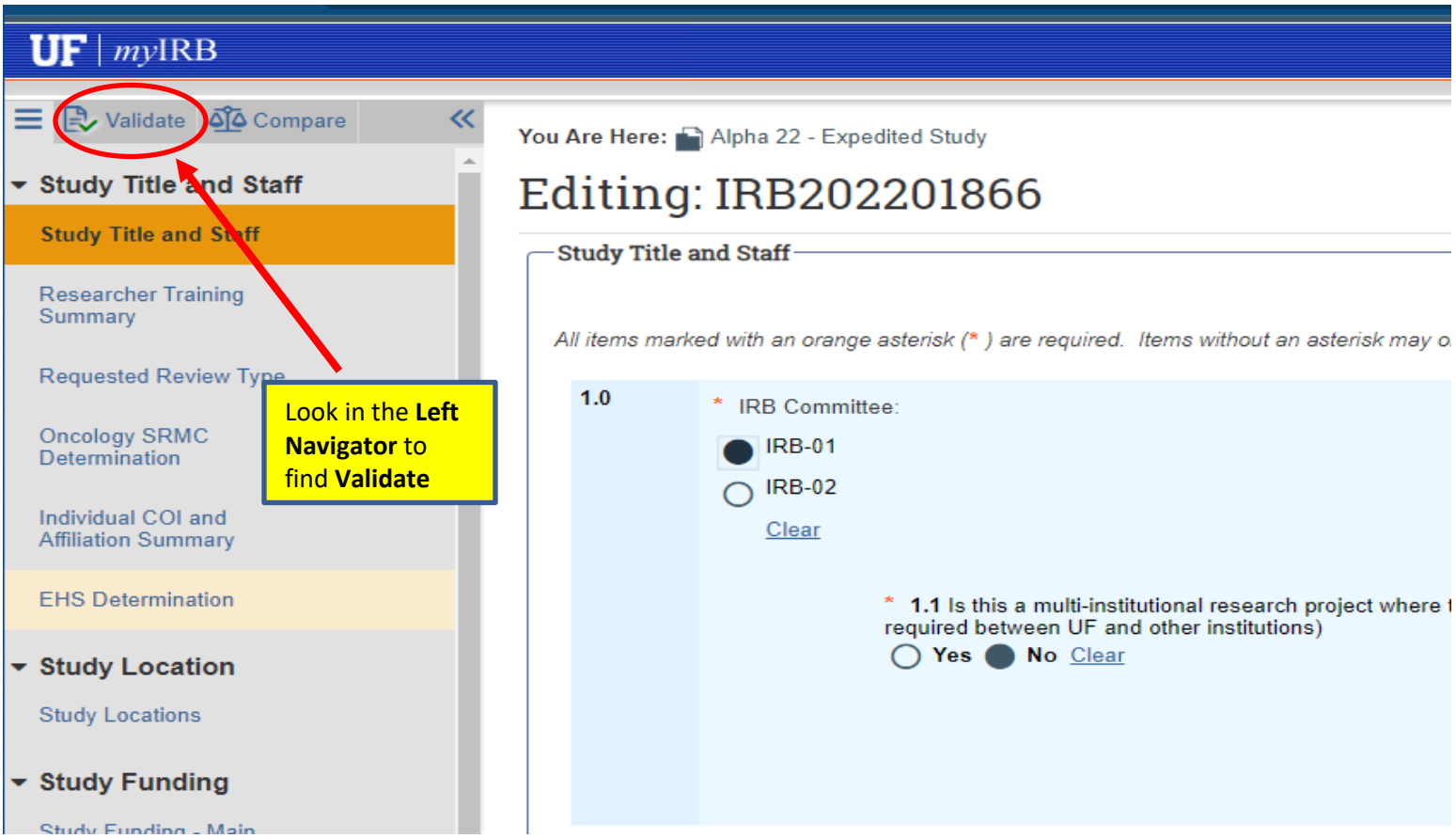
TIP: Save often, but remember that you **do not** need to complete your submission at one time.

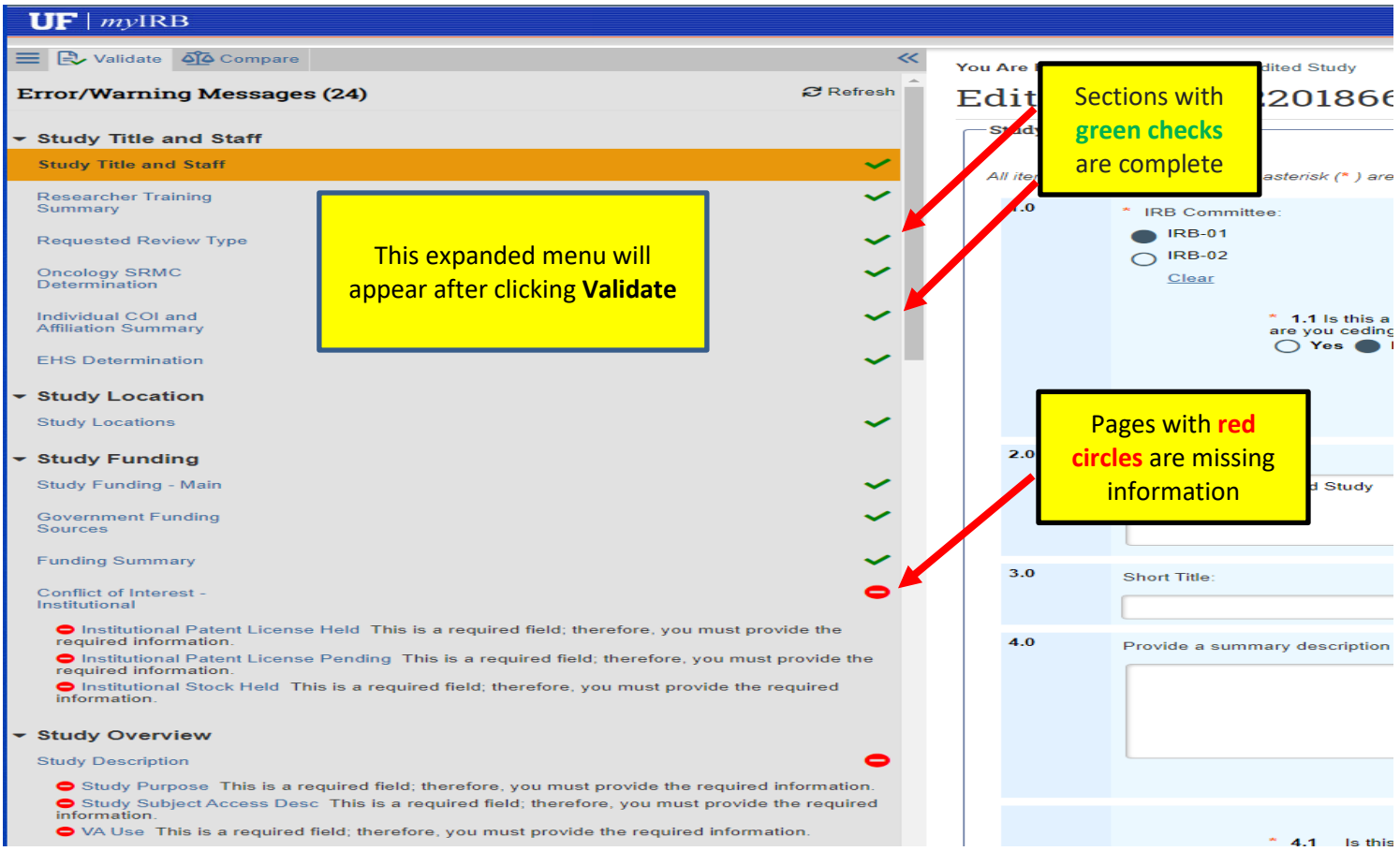
To check the progress of your submission, visit the **Study Workspace** (screenshot above). From there, click **View SmartForm Progress** on the left side of the page to open a window which will provide a status report on the SmartForms. Each will be listed as **Complete, Incomplete,** or **Not Required** (see screenshot below).



Validate

To receive a system-generated report of missing information **while within a SmartForm**, click the **Validate** button in the upper left corner of any SmartForm. Doing so will expand the menu and provide information about incomplete SmartForms (see screenshots below).

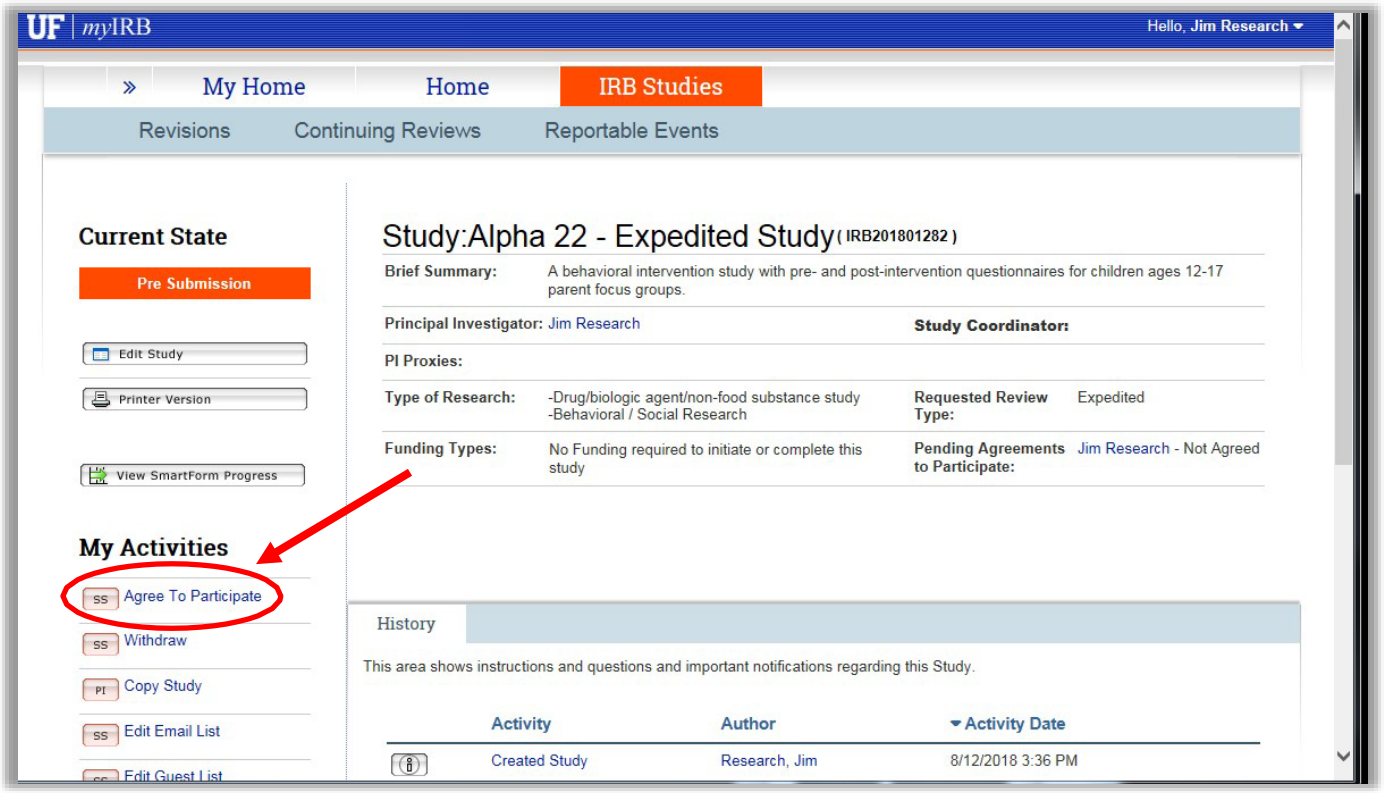




TIP: A study cannot be submitted for IRB review until all errors have been addressed and study personnel have completed all required trainings.

Agree to Participate

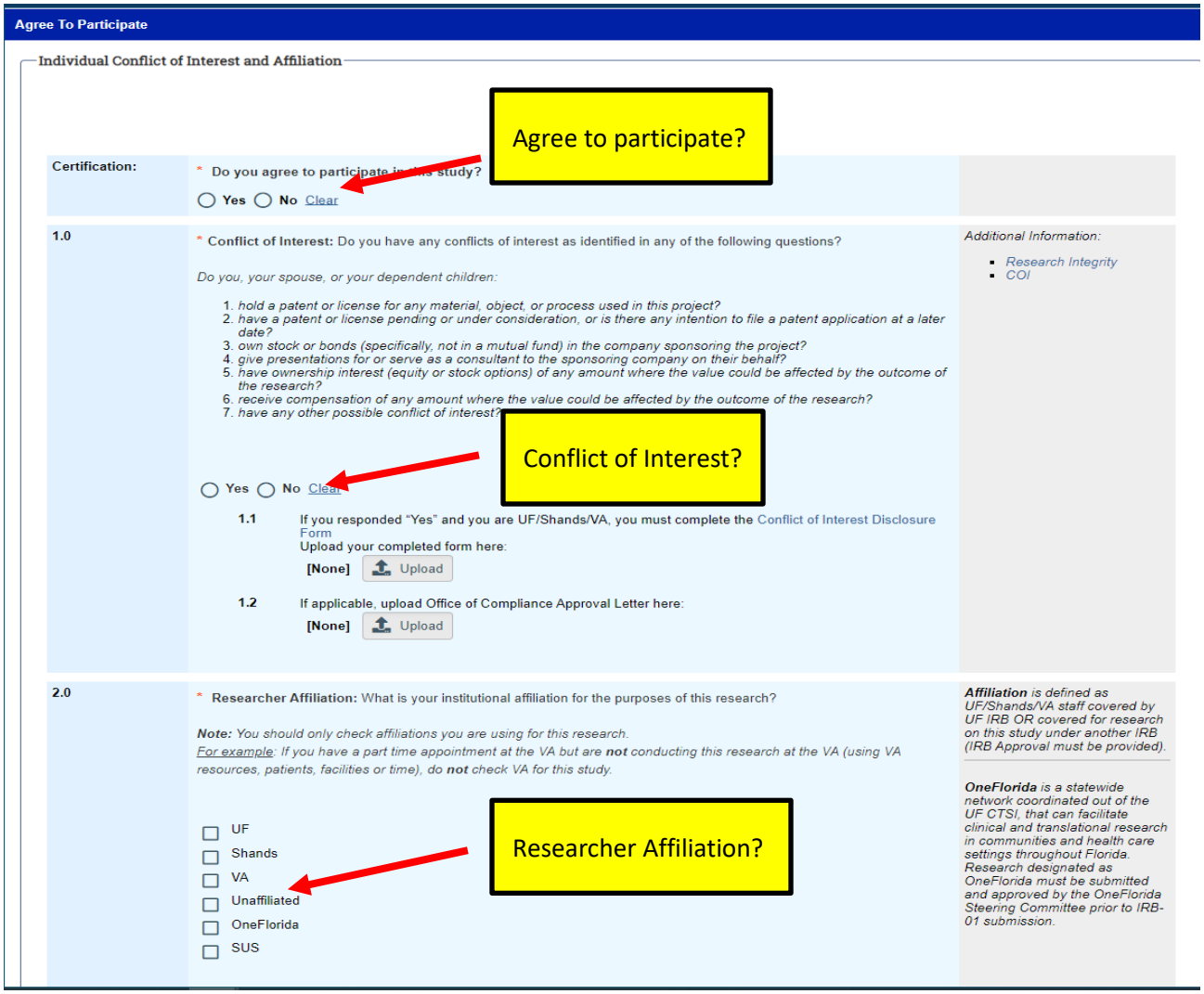
Before an application can be submitted, each person identified as part of the study team must **Agree to Participate**. To complete this task, open the **Study Workspace** and click **Agree To Participate** under the **My Activities** sub-heading. See screenshot below:

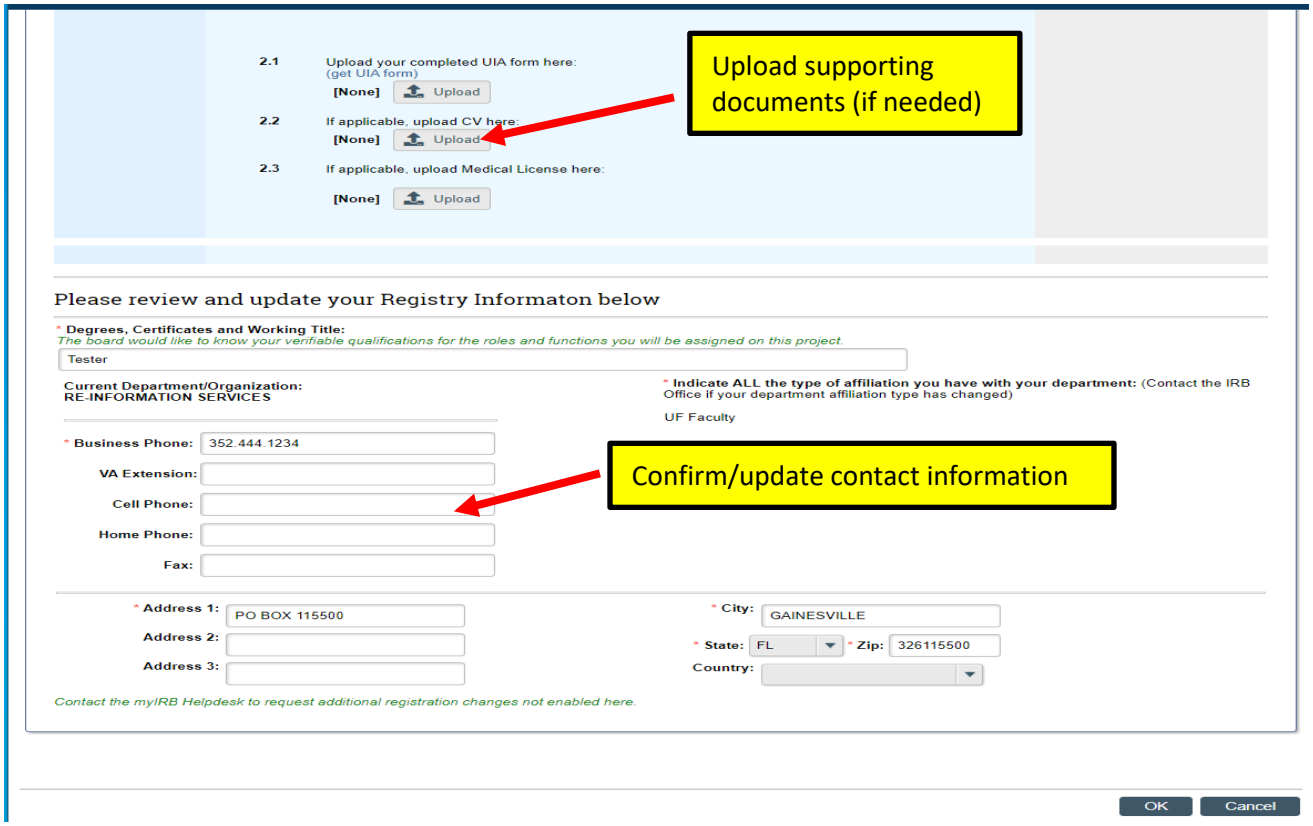


Each person listed on the **Study Title and Staff** SmartForm is considered part of the research team and must Agree to Participate in the project. To confirm participation, study staff must:

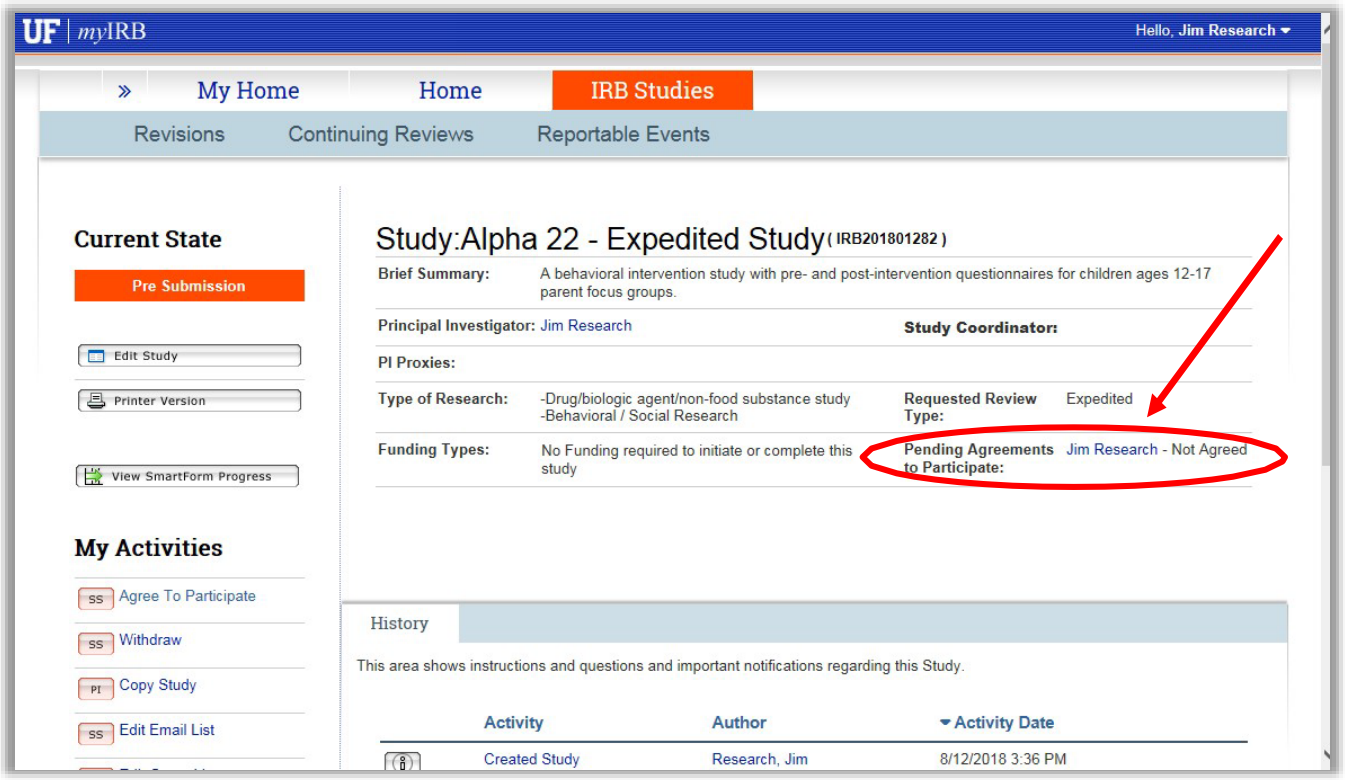
1). **Agree** to take part in the research
2). Declare any **Conflicts of Interest**
3). Confirm their **Researcher Affiliation**
4). Review/update their **contact information** (see screenshots below)

NOTE: All study staff, **including the Principal Investigator**, must Agree to Participate.

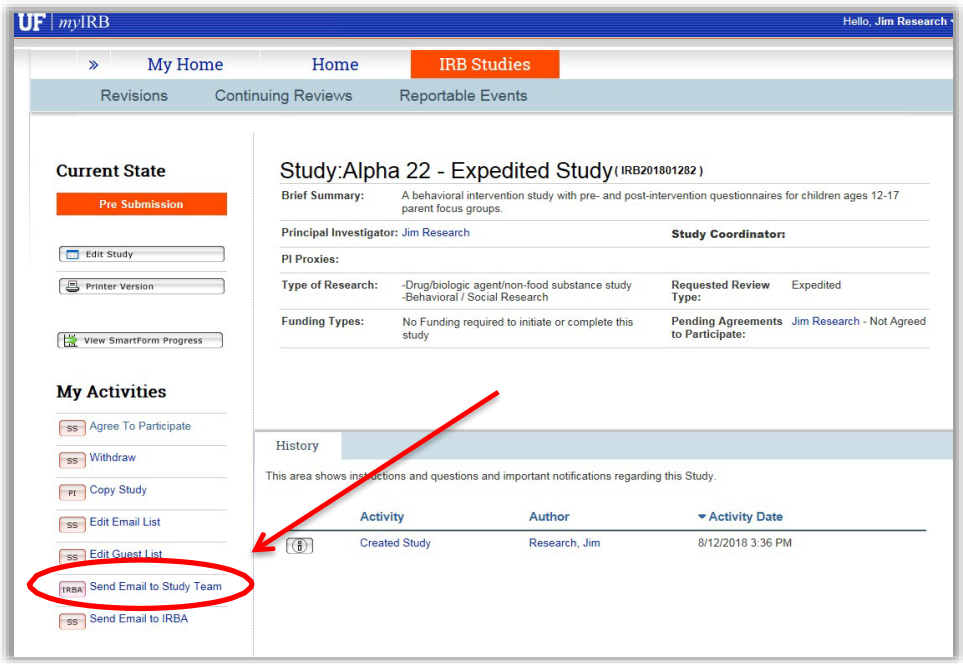

Agree To Participate
Individual Conflict of Interest and Affiliation
Agree to participate?
Certification:
* Do you agree to participate in this study?
Yes No Clear
1.0
* Conflict of Interest: Do you have any conflicts of interest as identified in any of the following questions?
Do you, your spouse, or your dependent children:
1. hold a patent or license for any material, object, or process used in this project?
2. have a patent or license pending or under consideration, or is there any intention to file a patent application at a later date?
3. own stock or bonds (specifically, not in a mutual fund) in the company sponsoring the project?
4. give presentations for or serve as a consultant to the sponsoring company on their behalf?
5. have ownership interest (equity or stock options) of any amount where the value could be affected by the outcome of the research?
6. receive compensation of any amount where the value could be affected by the outcome of the research?
7. have any other possible conflict of interest?
Conflict of Interest?
Yes No Clear
1.1 If you responded "Yes" and you are UF/Shands/VA, you must complete the Conflict of Interest Disclosure Form
Upload your completed form here:
[None] Upload
1.2 If applicable, upload Office of Compliance Approval Letter here:
[None] Upload
Additional Information:
Research Integrity
COI
2.0
* Researcher Affiliation: What is your institutional affiliation for the purposes of this research?
Note: You should only check affiliations you are using for this research.
For example: If you have a part time appointment at the VA but are not conducting this research at the VA (using VA resources, patients, facilities or time), do not check VA for this study.
Researcher Affiliation?
UF
Shands
VA
Unaffiliated
OneFlorida
SUS
Affiliation is defined as UF/Shands/VA staff covered by UF IRB OR covered for research on this study under another IRB (IRB Approval must be provided).
OneFlorida is a statewide network coordinated out of the UF CTSI, that can facilitate clinical and translational research in communities and health care settings throughout Florida. Research designated as OneFlorida must be submitted and approved by the OneFlorida Steering Committee prior to IRB-01 submission.


2.1 Upload your completed UIA form here:
(get UIA form)
[None] Upload
2.2 If applicable, upload CV here:
[None] Upload
2.3 If applicable, upload Medical License here:
[None] Upload
Upload supporting documents (if needed)
Please review and update your Registry Informaton below
* Degrees, Certificates and Working Title:
The board would like to know your verifiable qualifications for the roles and functions you will be assigned on this project.
Tester
Current Department/Organization:
RE-INFORMATION SERVICES
* Indicate ALL the type of affiliation you have with your department: (Contact the IRB Office if your department affiliation type has changed)
UF Faculty
* Business Phone: 352.444.1234
VA Extension:
Cell Phone:
Home Phone:
Fax:
Confirm/update contact information
* Address 1: PO BOX 115500
Address 2:
Address 3:
* City: GAINESVILLE
* State: FL * Zip: 326115500
Country:
Contact the myIRB Helpdesk to request additional registration changes not enabled here.
OK Cancel

In addition, study teams can see who has agreed to participate on the **Study Workspace**.



Researchers can also click **Send Email to Study Team** to notify the study team that they need to Agree to Participate (see screenshot below).



TIP: If a team member does not Agree to Participate in a timely manner, you can remove them from the study during your initial submission and add them later via a **Revision**.

PI Proxy

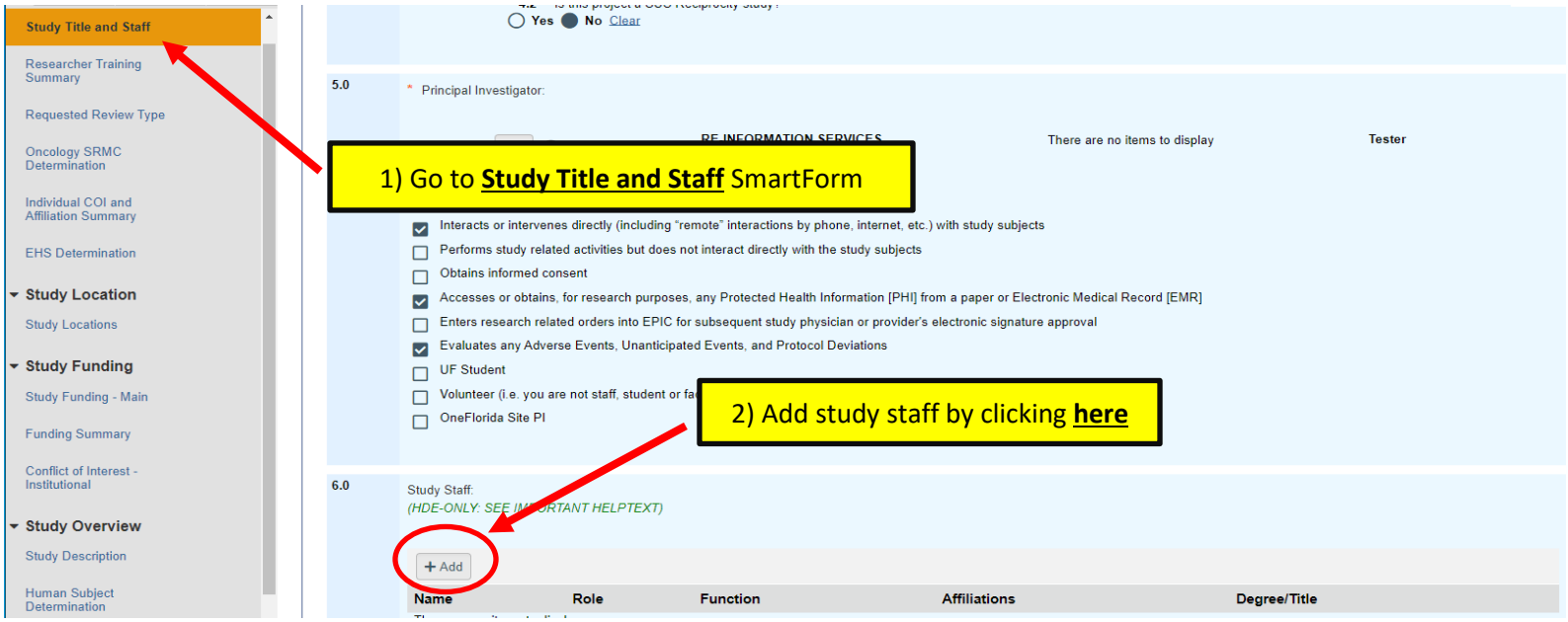
PIs can designate one Co-Investigator on the study team to serve as **PI Proxy**. This person can submit revisions, reportable events, and continuing reviews if the PI is unavailable to do so. The PI Proxy is a "function" that can be assigned to **only one** Co-Investigator per study.

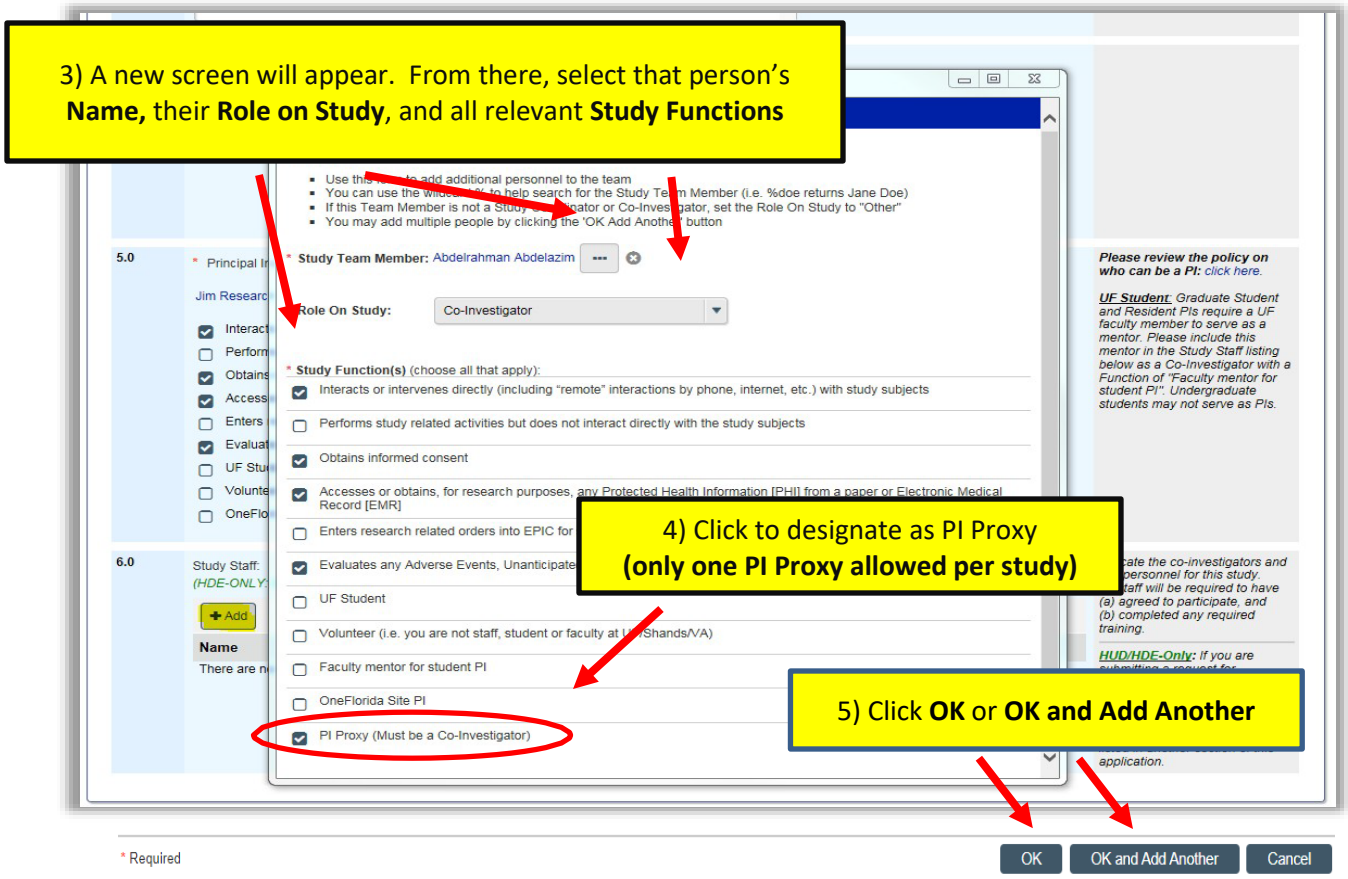
Adding a PI Proxy can be done during the initial project submission **or** after the fact with a Revision (which will require IRB approval). The PI Proxy, once approved, is afforded all the same functions as the PI.

When a PI Proxy is added to a study, that person must agree to participate in order to accept the function. If a PI Proxy is **not** designated prior to initial study approval, the PI would need to submit a revision to add a PI Proxy. A Revision is also required to **delete a PI Proxy** (see p. 23).

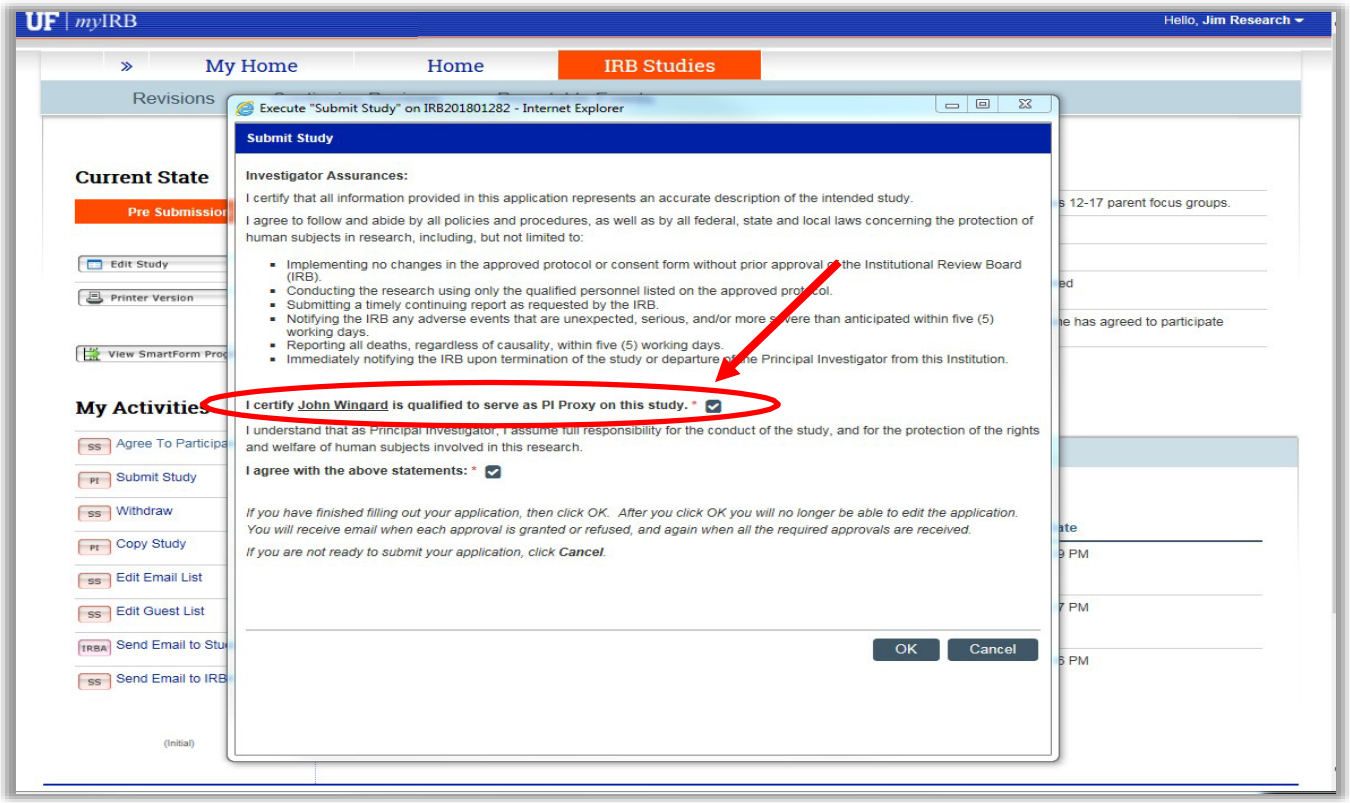
TIP: It is best practice for a PI to designate a PI Proxy when first submitting a study.

To designate a PI proxy, follow the instructions in the screenshots below:





If a PI Proxy is added when the study is initially submitted, the PI must certify that the individual they designated as PI Proxy is qualified to serve in that role. See screenshot below:



Deleting a PI Proxy

A PI must submit a revision when **deleting the function** of PI Proxy from a co-investigator.

A reminder that the PI Proxy has the same rights as the PI, including the ability to:

- Submit **or** withdraw revisions, adverse events, continuing reviews, etc.
- Withdraw a study entirely.

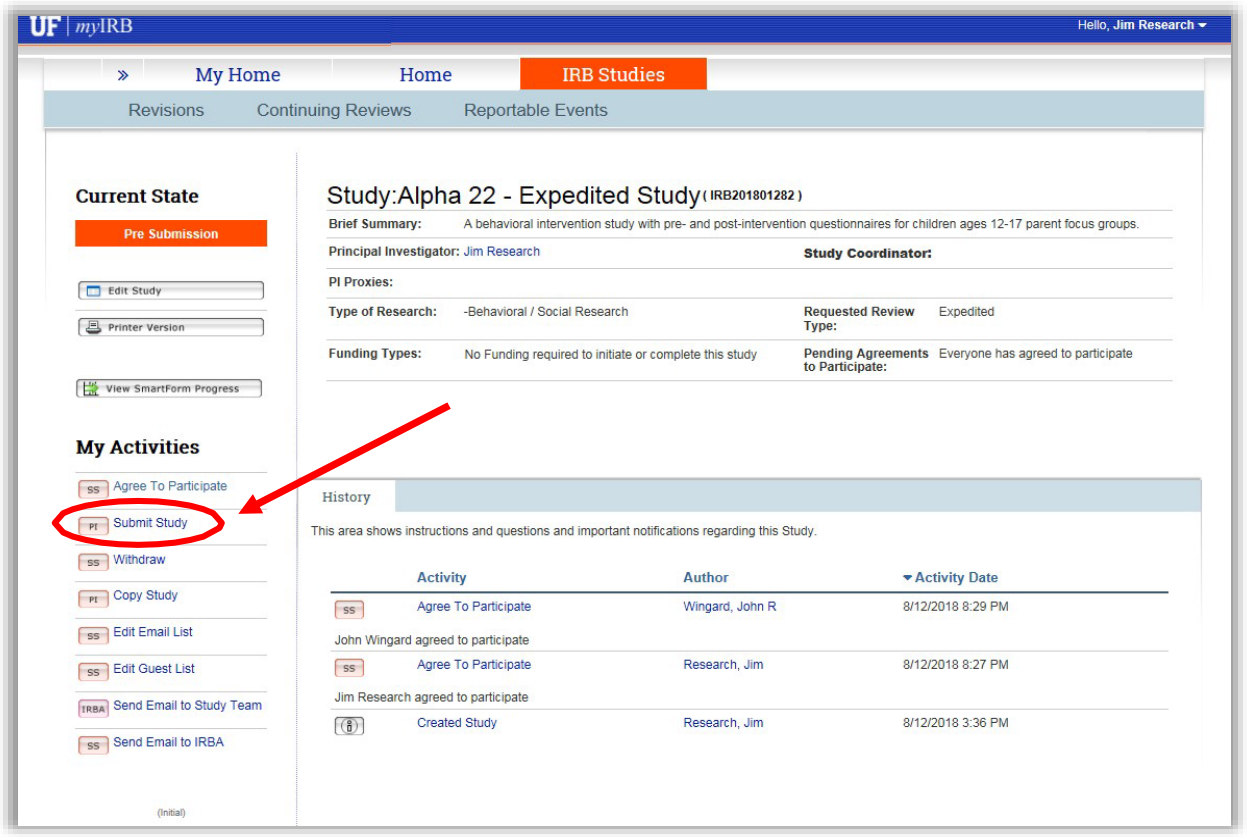
The **only** time the PI is notified of study changes is if the PI Proxy attempts to delete the PI from the study. Otherwise, the PI receives **no notifications** about study activities carried out by the PI Proxy.

When selecting a PI Proxy, it is the PI's responsibility to confirm that the co-investigator:

- Is qualified to fulfill the role of proxy (i.e., a research coordinator cannot perform duties that are best completed by an MD)
- Has the appropriate roles assigned to them to intervene as necessary (i.e., a lab manager should not consent subjects if their role states that they will not have any interaction with participants)

Application Submission

Only the Principal Investigator can submit a study for IRB review. To submit a study, open the **Study Workspace** and click **Submit Study** under **My Activities** on the left side of the page:

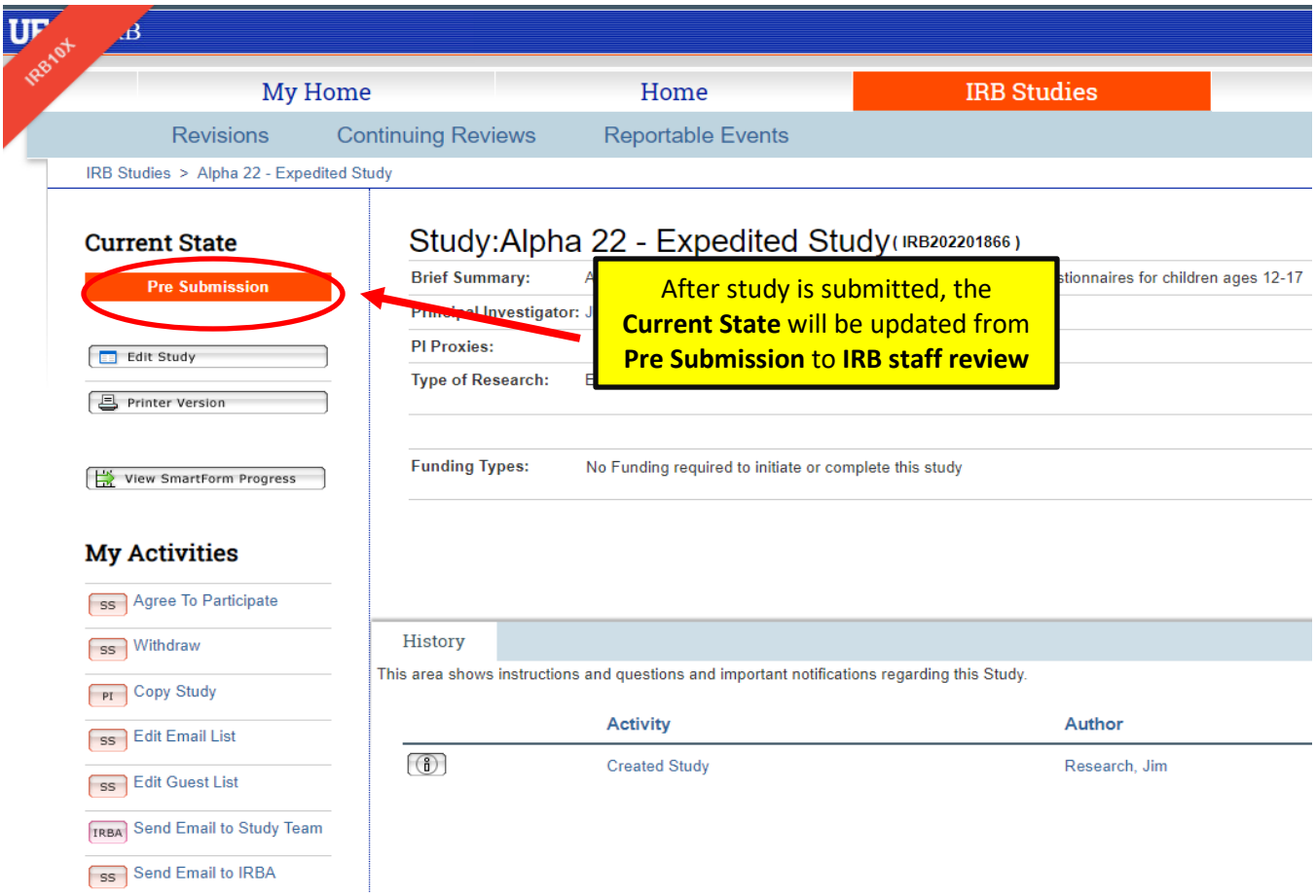


The system will run a final validation check on the full application before submission. If errors exist, they will be displayed. Your application **cannot be submitted** until all errors are resolved**.**

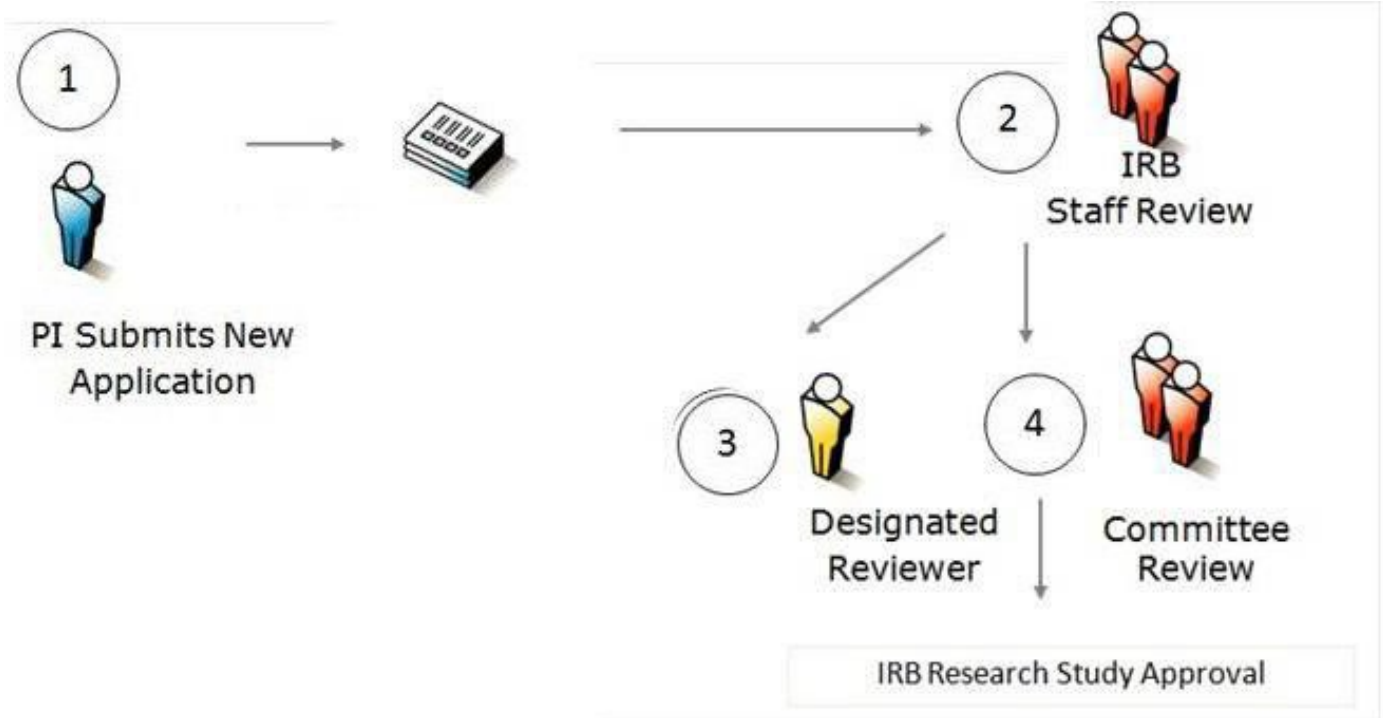
> **TIP**: As discussed on pages 16-17, the person who creates the study can use the **Validate** function in the Left Navigator to see errors before asking the PI to submit.

> **TIP**: Clicking **Finish** in the final SmartForm page **does not** submit the study to IRB.

Once all study team members agree to participate and the application is submitted, the study will automatically be routed to the required persons in the review process. Also, after the PI submits a study, the **Current State** of that study will be updated from **Pre-Submission** to **IRB Staff Review.** See screenshots below.



Routing process for study submissions:



Progress Notifications

myIRB automatically sends email notifications to the study team when significant events occur in the review process. Be sure to keep your email address current in the *myIRB* system!

The study team will **receive notifications** at the following times:

- When IRB is asking the study team to **provide more information**
- When IRB is asking the study team to **make changes** to the project submission
- When IRB has **official actions/updates** for the study team (e.g., when the application is scheduled for a full board meeting, if an application is approved/disapproved, etc.)

Study teams can also check the progress of their application at any time by opening the **Study Workspace** from your Personal Folder and reviewing the **History** tab to display a list of the actions you have permission to view.

Tracking Your Study Through Review

Once your study has been submitted to the IRB office, the review process will begin.

Depending on your submission, your study could be in any of the following **States:**

IRB Staff Review – IRB staff pre-review process. You may receive questions you need to respond to before the study can advance past this state. No further action is required by you when the study is in this state.

In Exempt Review – Study has been assigned to an exempt reviewer. No further action is required by you when the study is in this state.

In Expedited Review – Study has been assigned to an expedited reviewer. No further action is required by you when the study is in this state.

Assigned to IRB meeting – Study has been assigned to an **IRB Full Board Meeting*** and appropriate reviewers. In this stage, you may receive study-related questions from reviewers. To make changes while a study is in this stage, contact the IRB office to request **Removal From Agenda**. Once complete, the IRB office will send the study back to you in a state where you can edit your submission.

TIP: **Remove From Agenda with caution**. Your study may not be reassigned to the same meeting depending on your response time and the deadline(s) for that meeting. If changes are needed, it may be preferable to respond to all reviewers after the meeting.

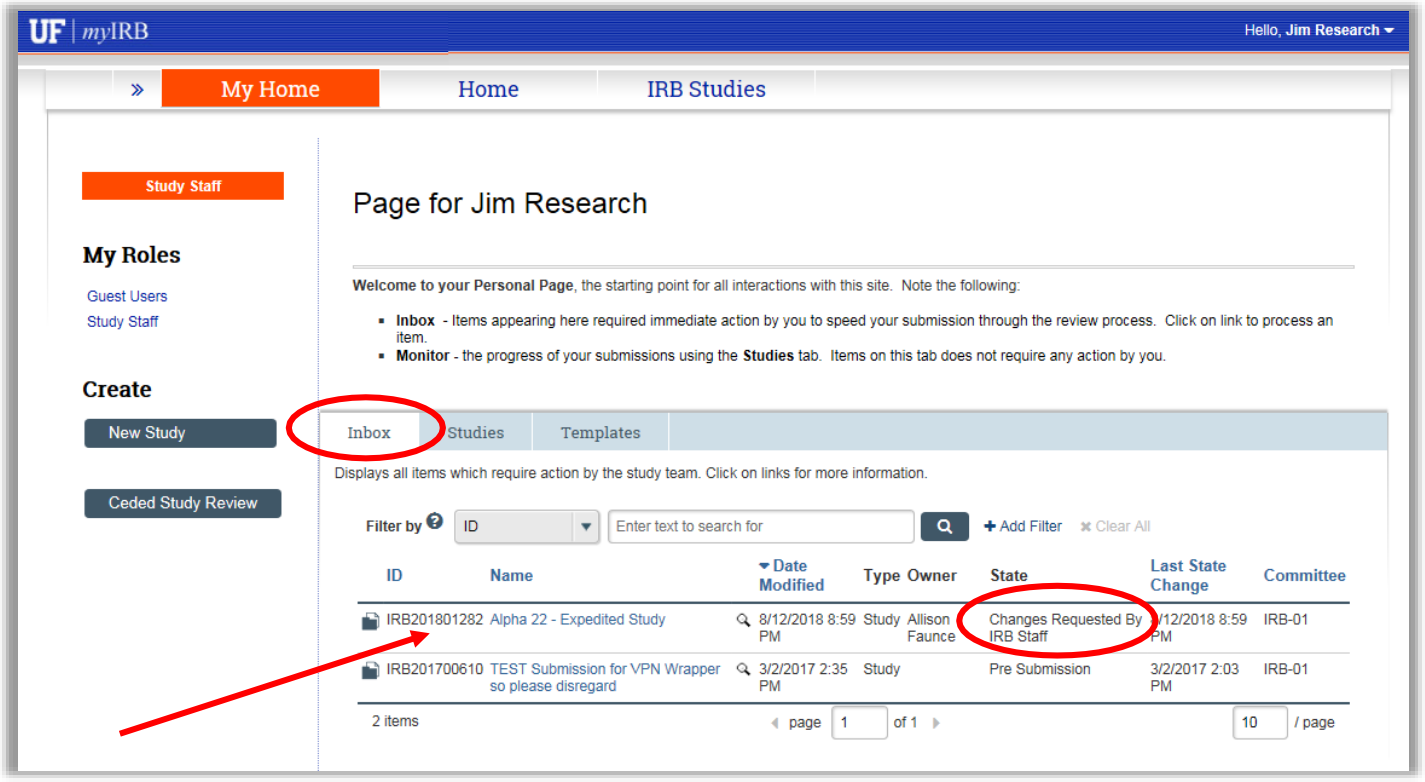
**IRB Full Board Meetings are scheduled for the 1st and 3rd Wednesday of each month.*

For a schedule of meetings and submission deadlines, click this link:

https://irb.ufl.edu/irb01/irb-01/deadlines.html

Responding to Reviewer Notes

When the IRB staff or reviewers have questions or request changes, studies will be returned to the PI/study staff inboxes. The State of the study will be updated to **Changes Requested by… IRB Staff or by Exempt/Expedited Reviewer**.



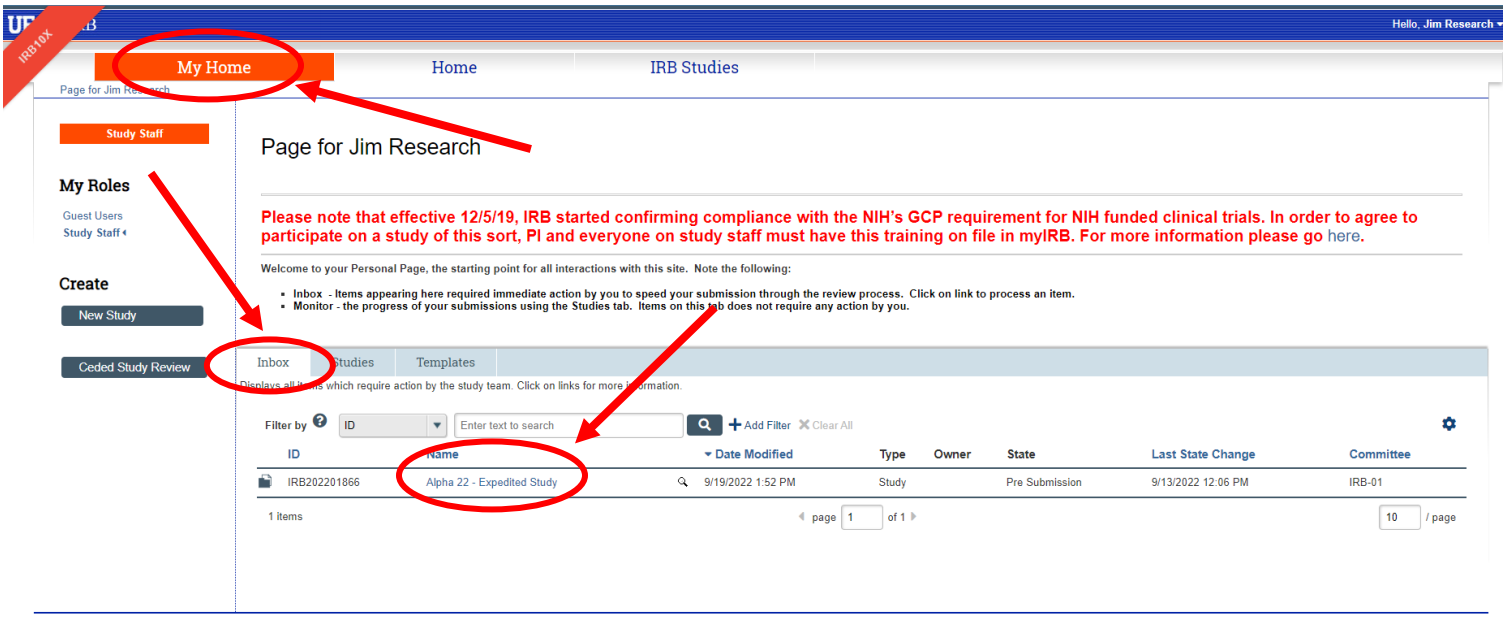
TIP: The study will show up in the *myIRB* inboxes of all study staff who have agreed to participate, so your team should establish a plan for who will respond to change requests.

To open the study workspace and respond to questions or changes, follow these steps:

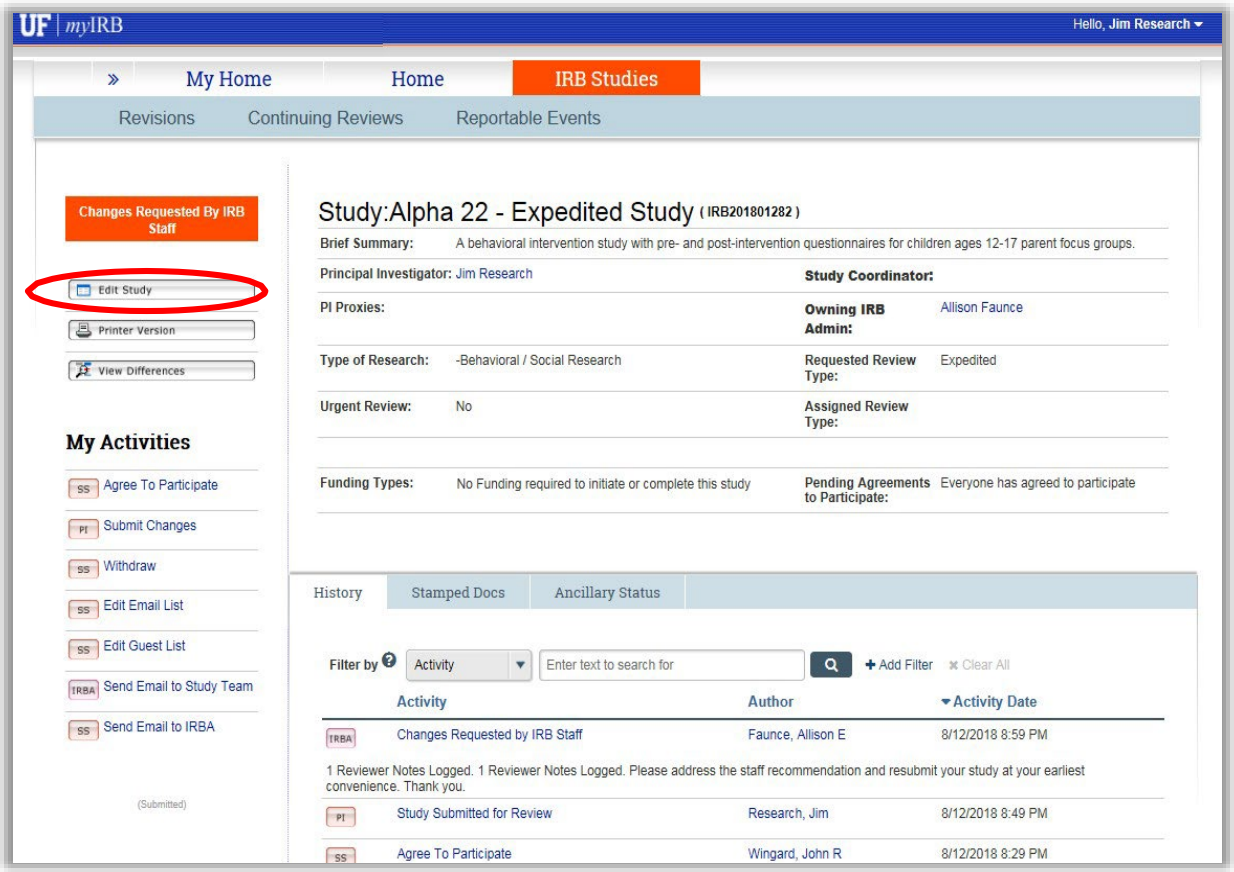
1). Log-in to the *myIRB* website*:* https://my.irb.ufl.edu

2). Select the **My Home** tab (top of screen) and the **Inbox** tab (middle of screen).

3). Next, look for the study in your Inbox and click the **Hyperlinked Study Title**.

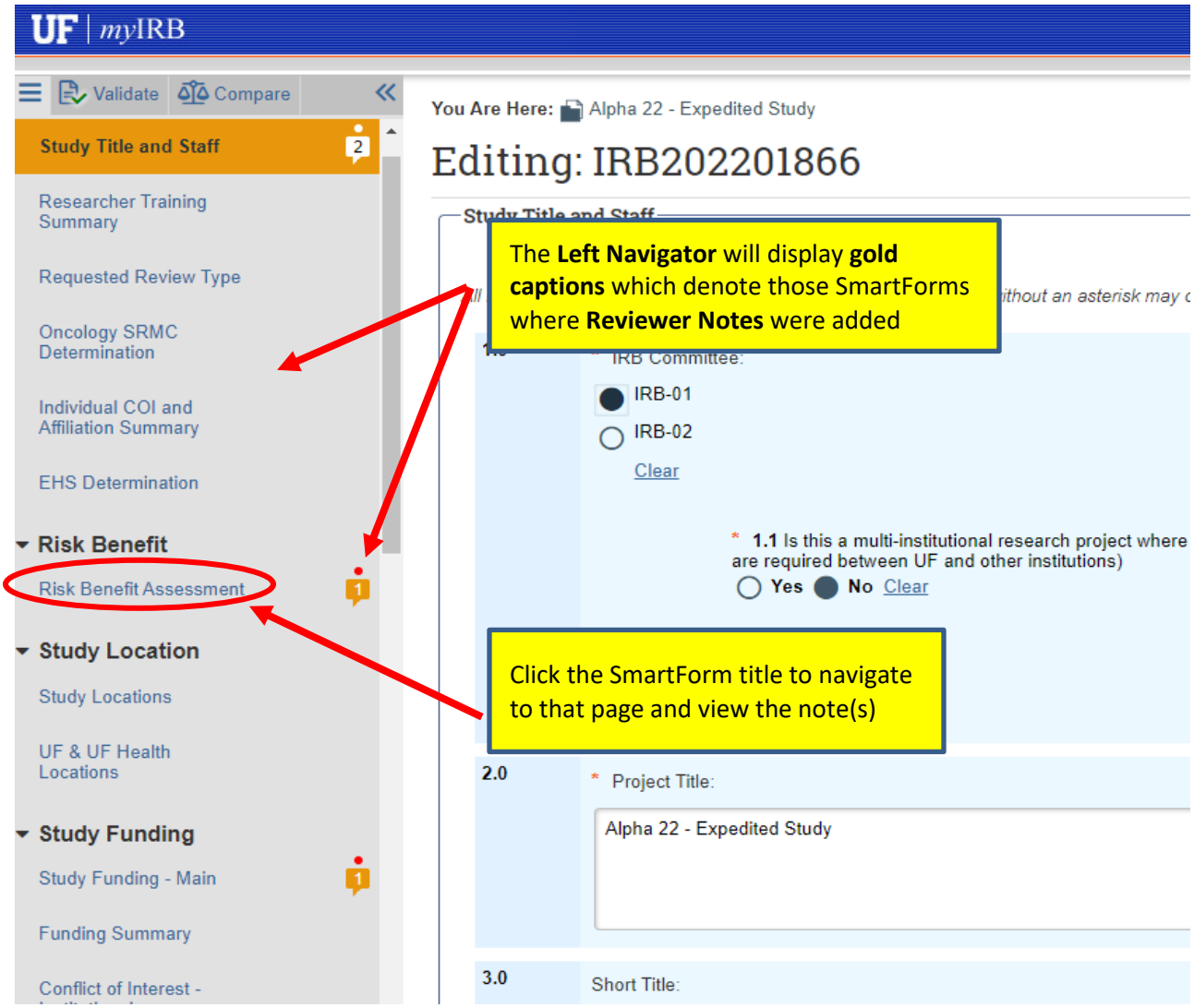


4). You will then be redirected to the Study Workspace. From here, click **Edit Study.**

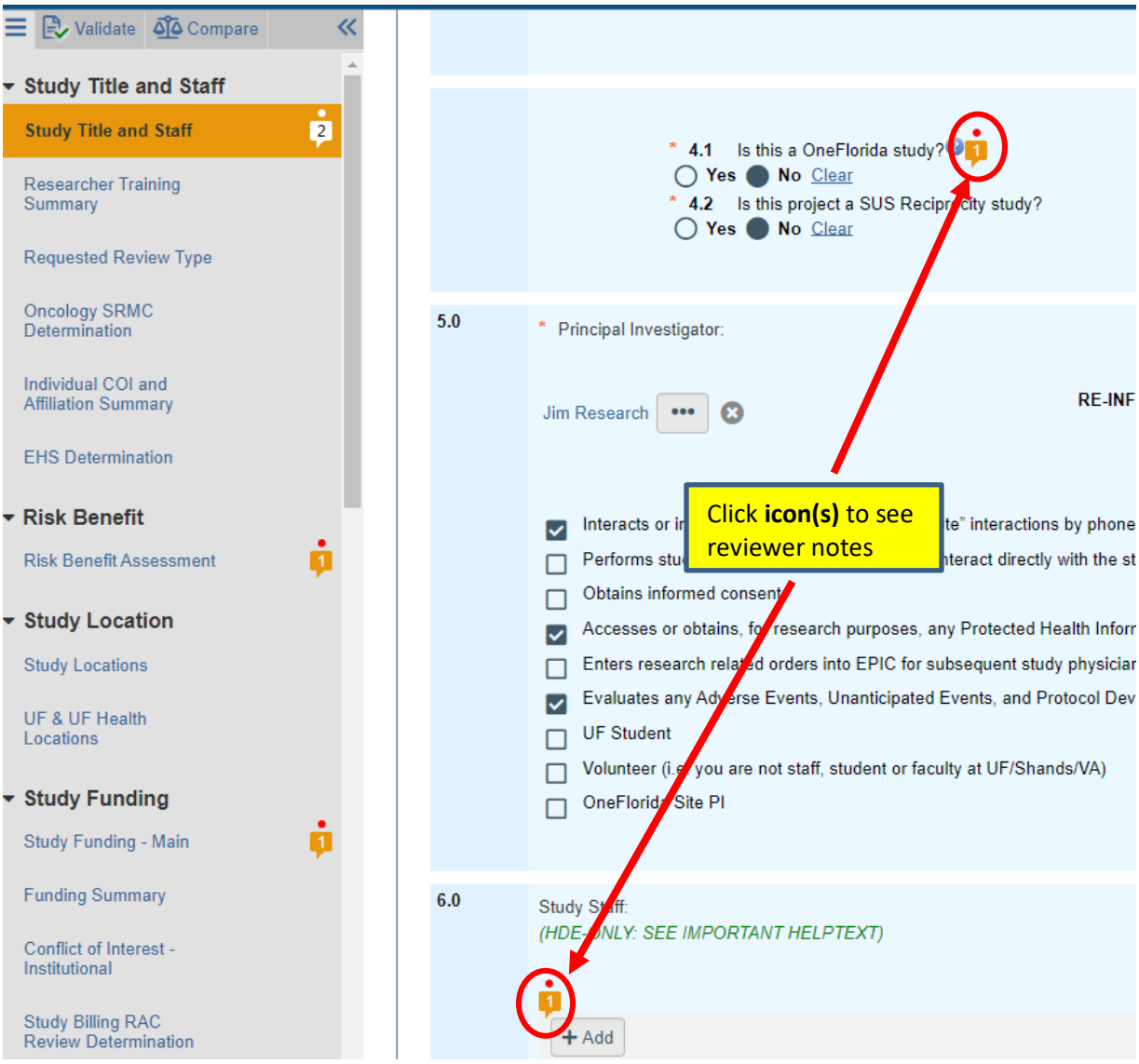


From here, the PI can view all **Reviewer Notes**. To locate reviewer notes, look at the **Left Navigator**. In that menu, you will see **gold caption** with numbers inside. Each SmartForm that has this box next to its name has a reviewer note enclosed. The number in the boxes corresponds with the number of reviewer notes left on that SmartForm.

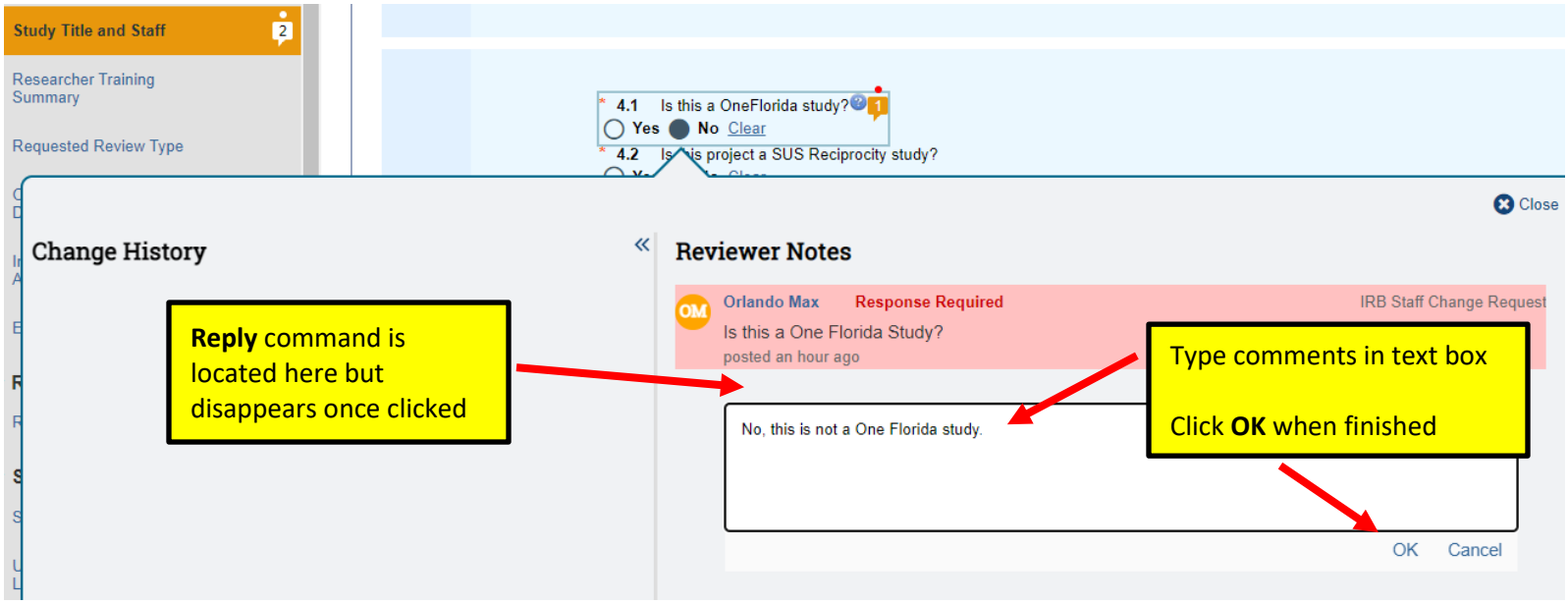
To view notes, first click on the relevant SmartForm in the Left Navigator:



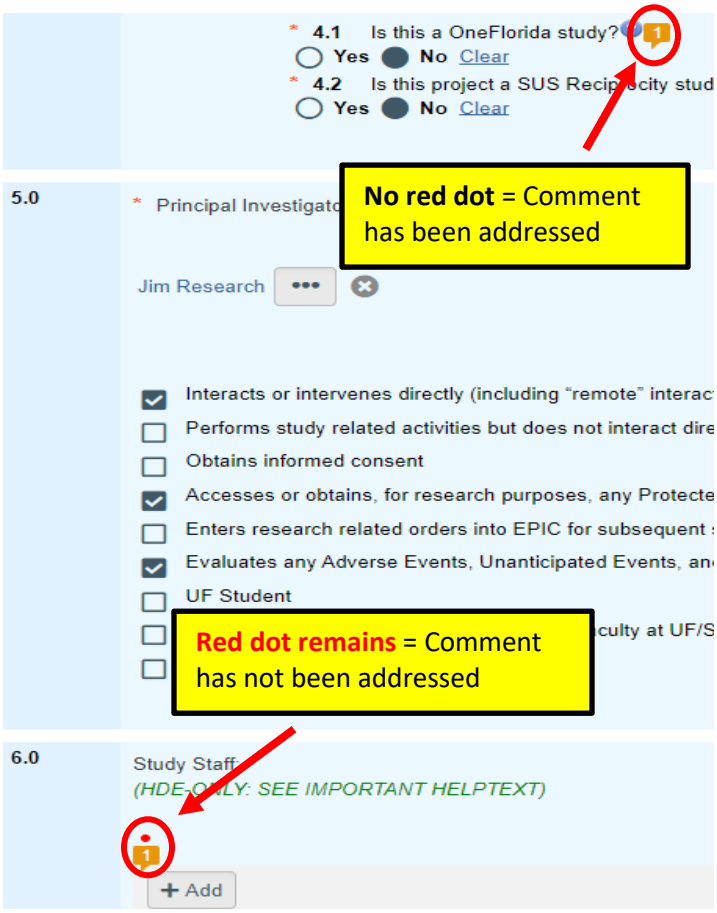
Once you have navigated to a SmartForm with a reviewer note added, click the icon(s) of the gold caption to open the comment(s).



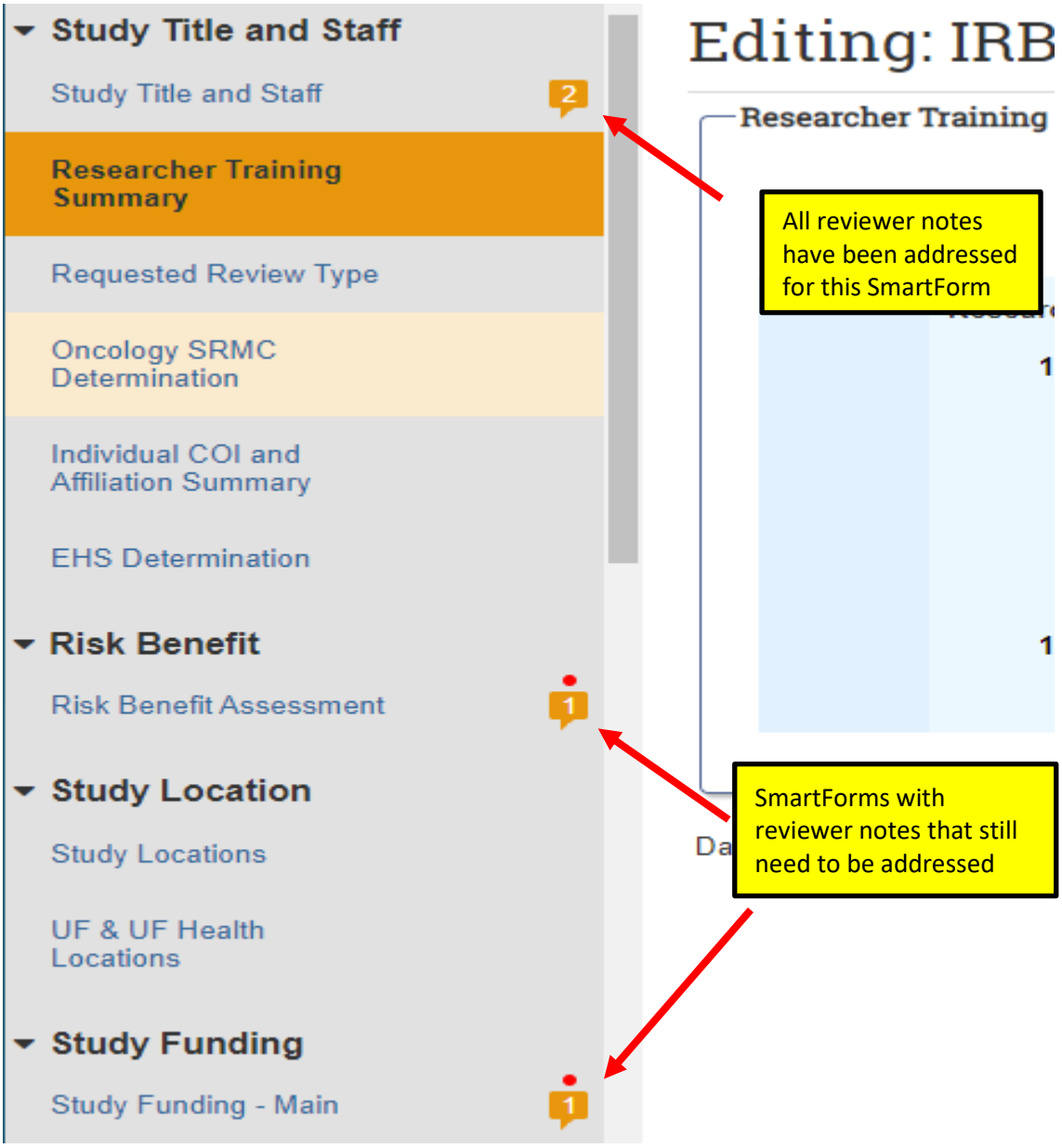
Clicking the icon will open a new screen with the comment enclosed. From here, click **Reply**, and then enter your comment/response. When complete, click **OK:**



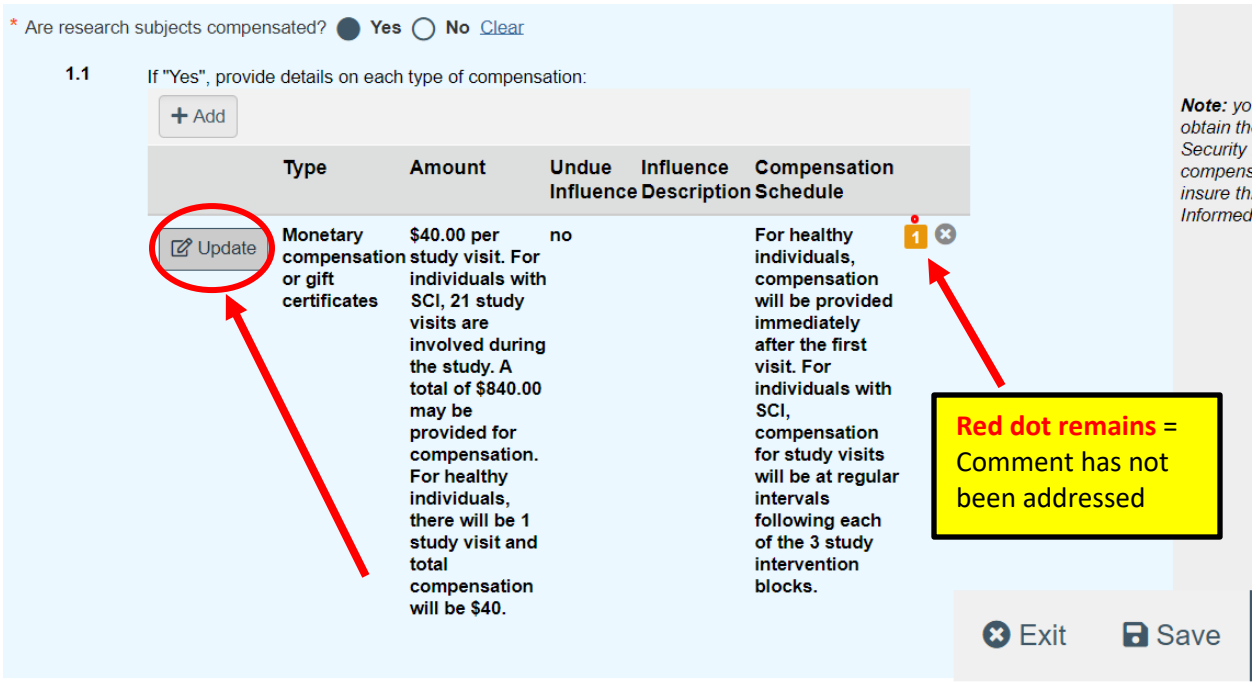
The system will track which comments have been reviewed and addressed by the presence or absence of a **red dot** on top of the gold caption:

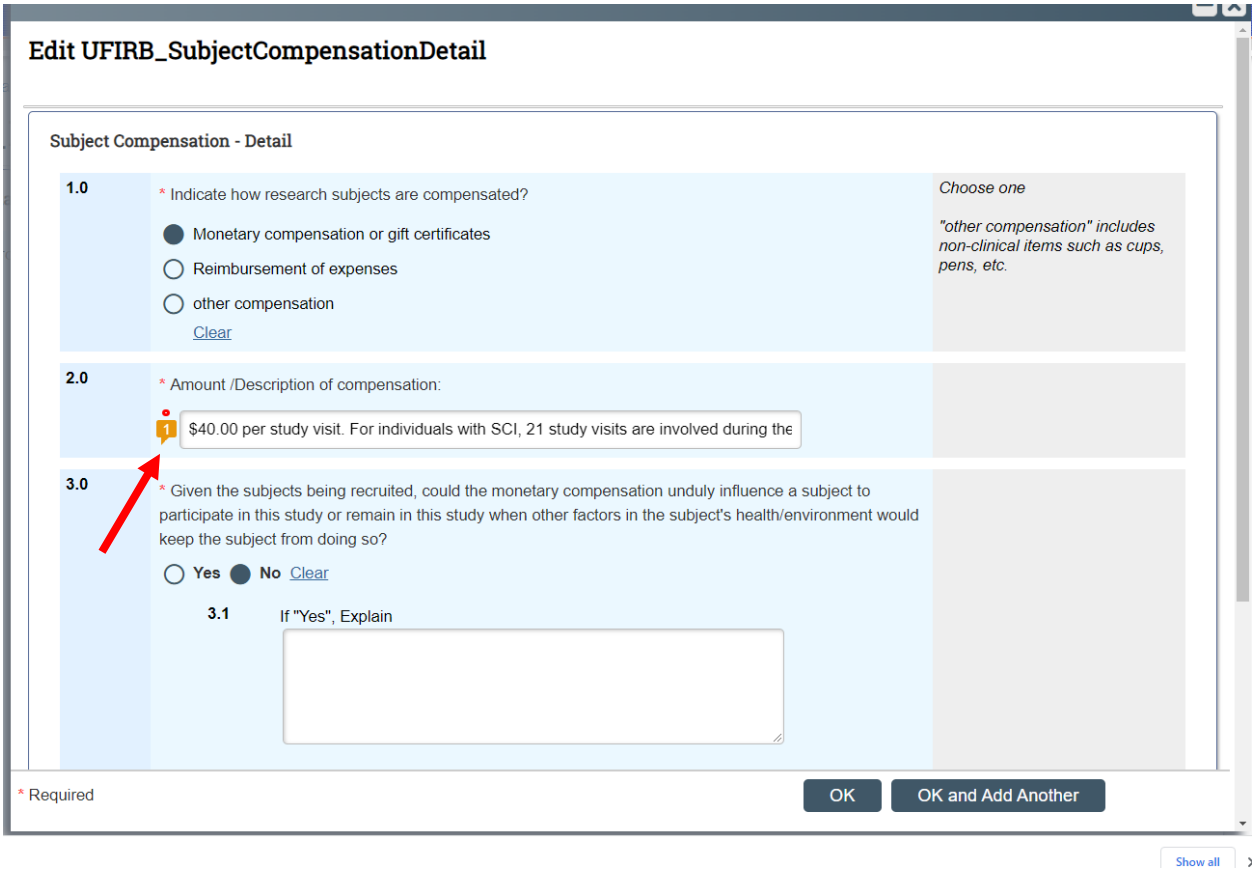


Repeat this process for all other reviewer notes on that SmartForm **and** all other reviewer notes throughout the submission. You can see the SmartForms which have reviewer notes that still need to be addressed by scrolling through the **Left Navigator.**



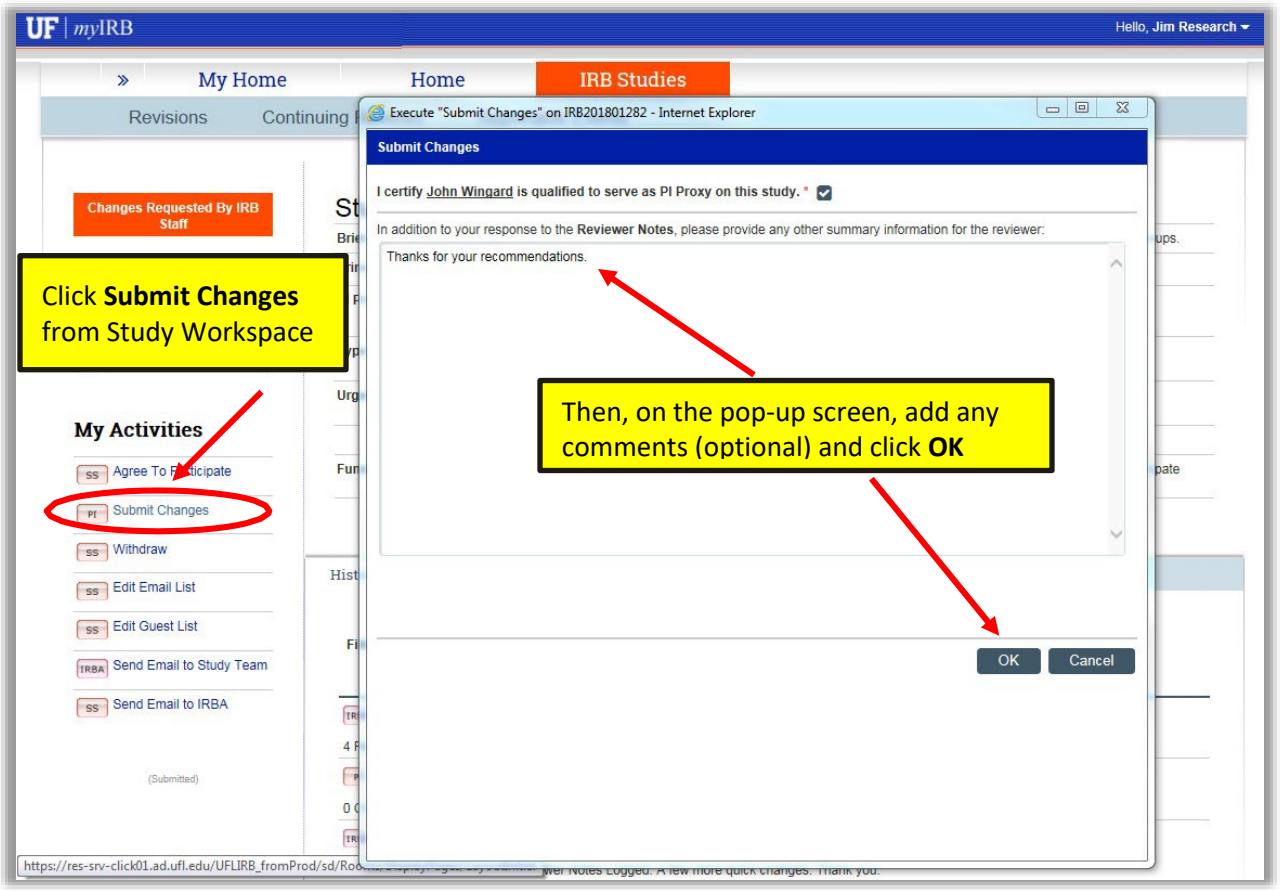
To access reviewer note(s) embedded in tables, click **Update**. Doing so will open a second page which will allow the study team to view and respond to the reviewer's comment(s). See screenshots below:





When the PI has responded to all Reviewer Notes, the next step is to **submit changes**. This will return the study to IRB for further review.

To submit changes, the PI should first access the **Study Workspace.** From there, look for the **My Activities** menu on the left side of the page, and then click **Submit Changes.** Clicking that button will cause a pop-up window to appear. In that screen, the PI can make additional comments (this is optional). When ready to submit all changes, click **OK**.

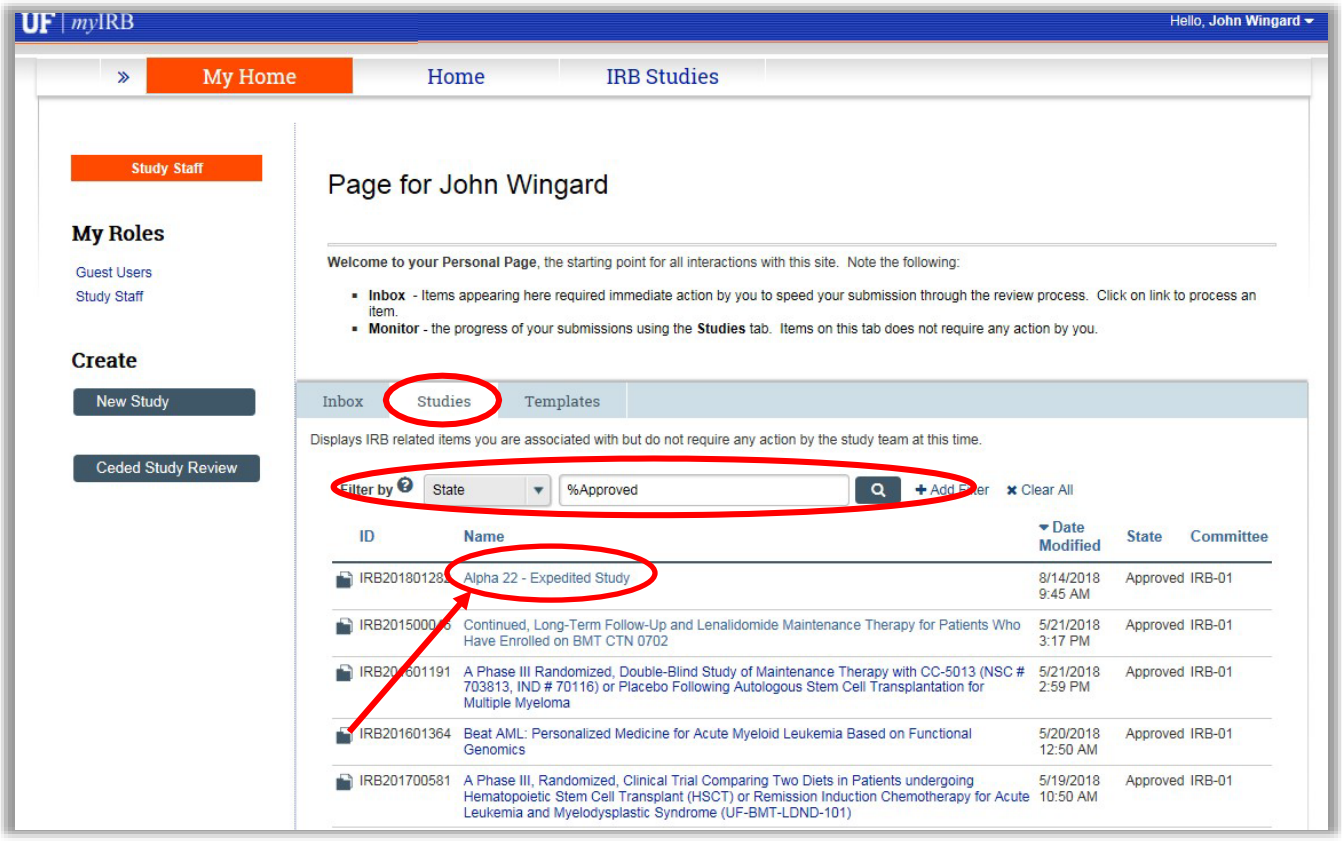


Full Board studies that are tabled will require response in the same way. The PI will receive a letter in their *myIRB* inbox that also has links to Reviewer Notes.

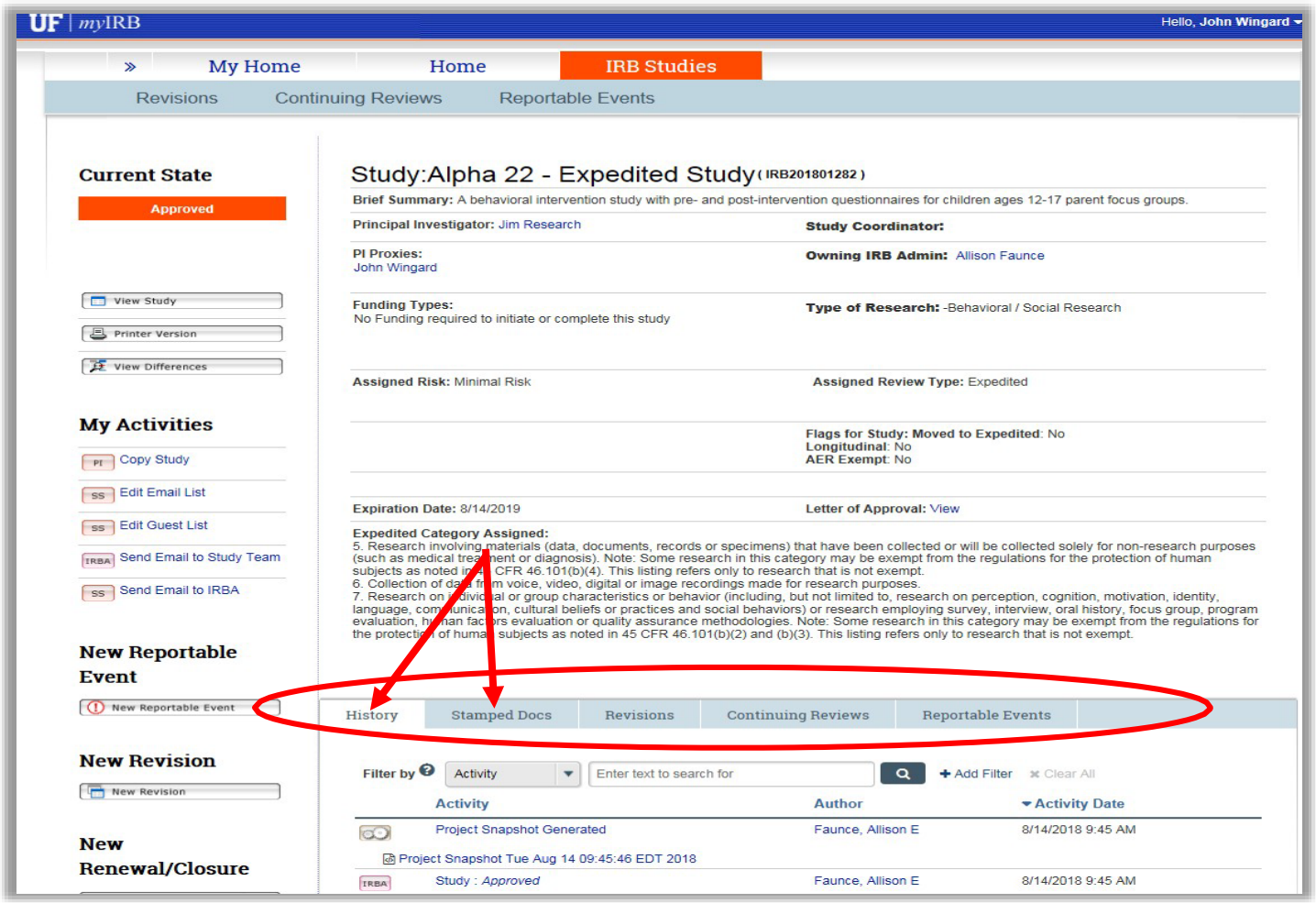
If the changes requested are to an uploaded attachment (e.g., protocol, ICF, advertisements), the research team must **download** the document from the appropriate SmartForm, **track changes** on that document, and **re-upload** the revised document to the appropriate SmartForm. For a visual explanation of this process, see pages 66-71 of this manual.

Accessing Letters and Attachments

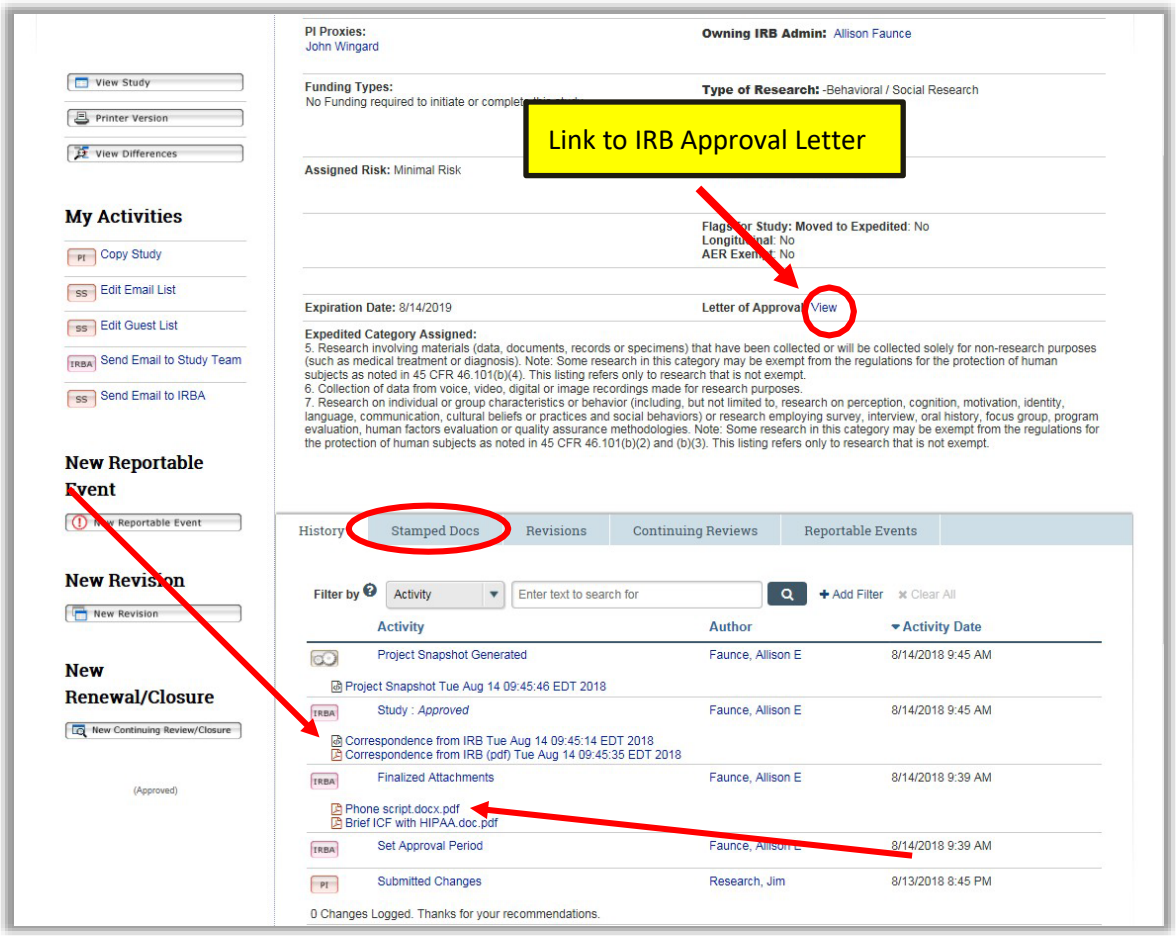
Once your study is approved, you will receive a status change notification in your *myIRB* inbox. You can access all your approved studies under the **Studies** tab. Then, to filter by state, select **State** from the **Filter by** dropdown menu. Next, type the command **%Approved** into the search box to see a list of your approved studies.



From here, click the **Name** of the study to access the study workspace. Doing so will open the **History** tab where all past events related to your submission are recorded. Note that **Stamped Documents** (i.e., project documents that have been reviewed and revised by IRB) can be found in the neighboring tab on this menu (see screenshot below).


UF myIRB
Hello, John Wingard
My Home
Home
IRB Studies
Revisions
Continuing Reviews
Reportable Events
Current State
Approved
View Study
Printer Version
View Differences
My Activities
Copy Study
Edit Email List
Edit Guest List
Send Email to Study Team
Send Email to IRBA
New Reportable Event
New Reportable Event
New Revision
New Revision
New Renewal/Closure
Study:Alpha 22 - Expedited Study (IRB201801282)
Brief Summary: A behavioral intervention study with pre- and post-intervention questionnaires for children ages 12-17 parent focus groups.
Principal Investigator: Jim Research
Study Coordinator:
PI Proxies:
John Wingard
Owning IRB Admin: Allison Faunce
Funding Types:
No Funding required to initiate or complete this study
Type of Research: -Behavioral / Social Research
Assigned Risk: Minimal Risk
Assigned Review Type: Expedited
Flags for Study: Moved to Expedited: No
Longitudinal: No
AER Exempt: No
Expiration Date: 8/14/2019
Letter of Approval: View
Expedited Category Assigned:
5. Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). Note: Some research in this category may be exempt from the regulations for the protection of human subjects as noted in 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.
6. Collection of data from voice, video, digital or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behaviors) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies. Note: Some research in this category may be exempt from the regulations for the protection of human subjects as noted in 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.
History
Stamped Docs
Revisions
Continuing Reviews
Reportable Events
Filter by
Activity
Enter text to search for
Add Filter
Clear All
Activity
Author
Activity Date
Project Snapshot Generated
Faunce, Allison E
8/14/2018 9:45 AM
Project Snapshot Tue Aug 14 09:45:46 EDT 2018
Study : Approved
Faunce, Allison E
8/14/2018 9:45 AM

To access correspondence, click the links next to the paperclips. You can also view the **IRB Approval Letter** at the top of the screen.



You can access your approved attachments, such as the stamped informed consent, by clicking the link next to the paperclip under **Finalized Attachments**. The informed consent and other stamped documents also can be found under the **Stamped Documents** tab.

TIP: **Do not** print any stamped documents, including the consent form for enrollment, from the individual SmartForm page. It is not a finalized, stamped version. Instead, print these documents from the **Study Workspace** (screenshot above).

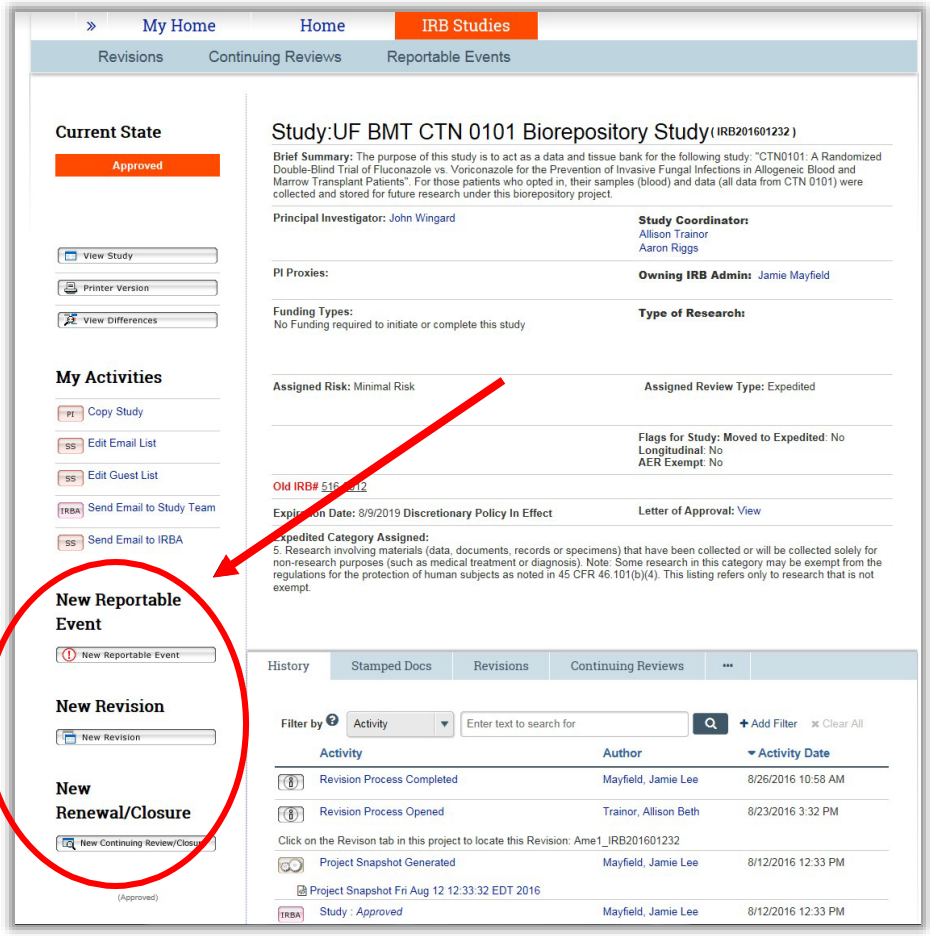
OTHER SUBMISSION TYPES

In addition to the initial study submission, other events may occur during your research study which require the study team to inform UF IRB of these developments.

Such submissions and events include:

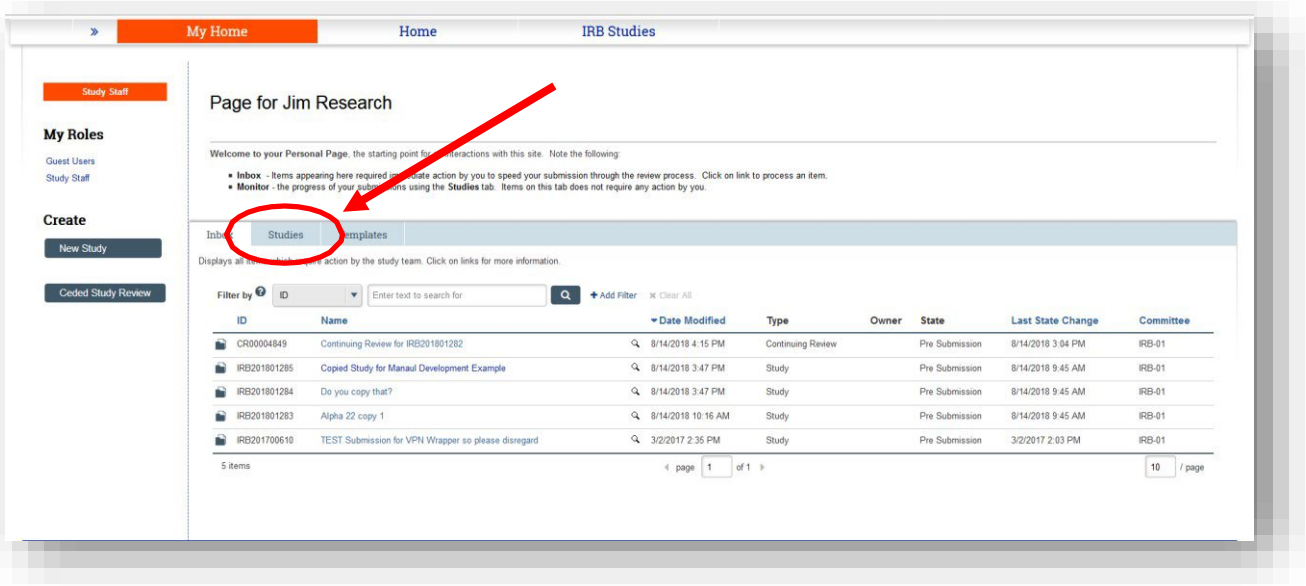
a) Serious Adverse Events (local and non-local)
b) Non-Reportable Event
c) Deviations (regulatory or subject related)
d) Unanticipated Problem(s)
e) Miscellaneous
f) New Continuing Review(s)/Study Closures Status Report(s)
g) New Revision(s)

The link for each of these submission types is in the lower left corner of the **Study Workspace.**

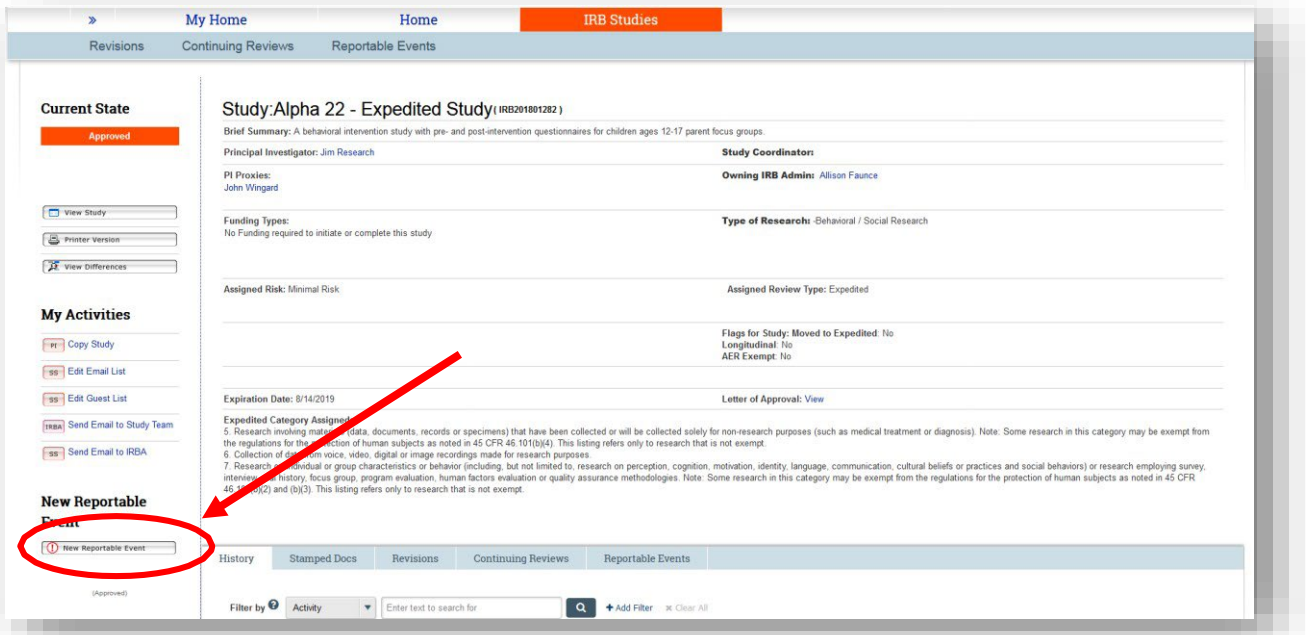


Submitting a New Reportable Event

When logging in to *myIRB*, **Inbox** will be the default tab. To locate a study and submit a new reportable event, begin by clicking the **Studies** tab. Then, search for the study for which you need to submit a reportable event. See screenshot below:

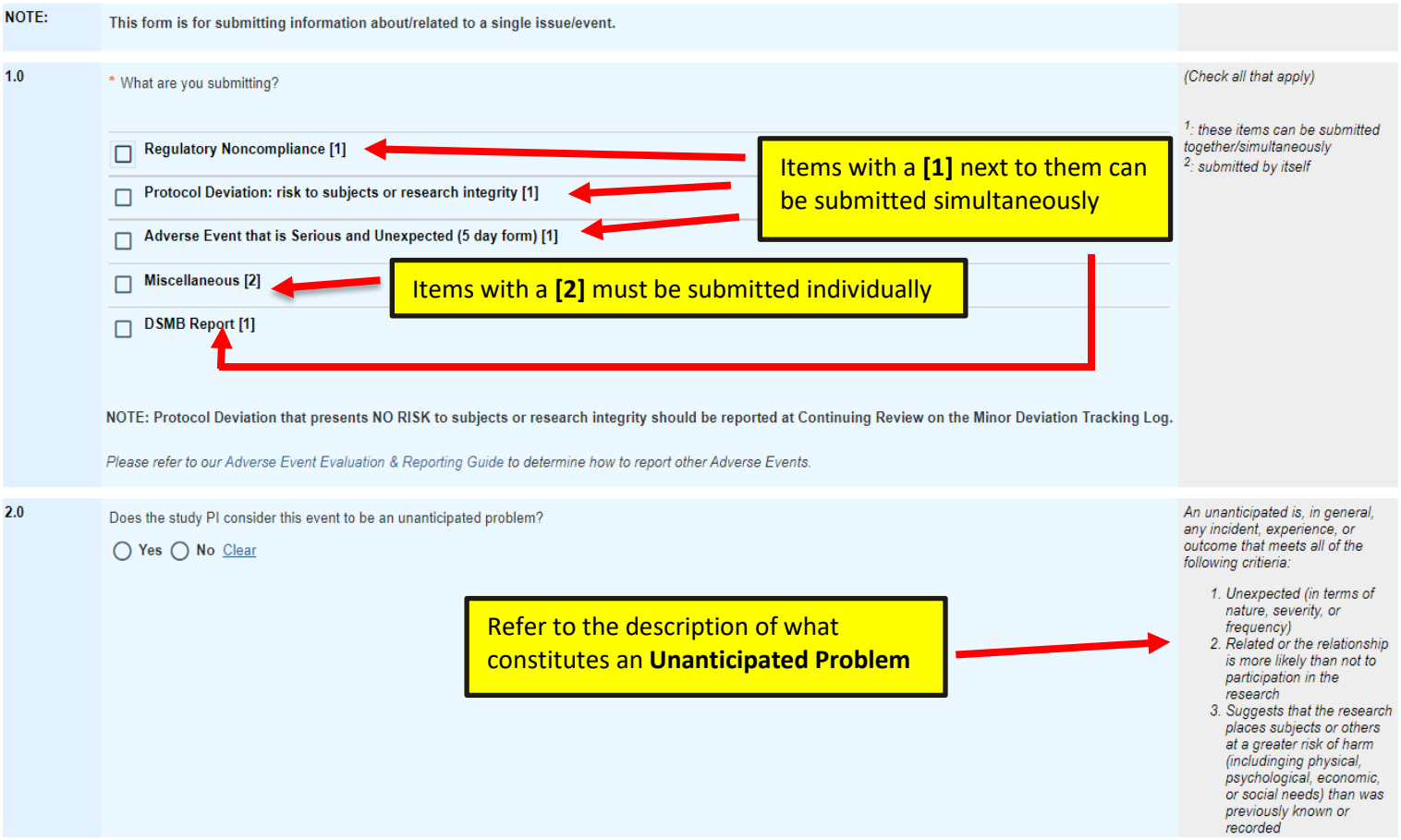


After clicking on the specific study, look in the column on the left side of the page. There, you will see all available submission types. From here, click **New Reportable Event.**

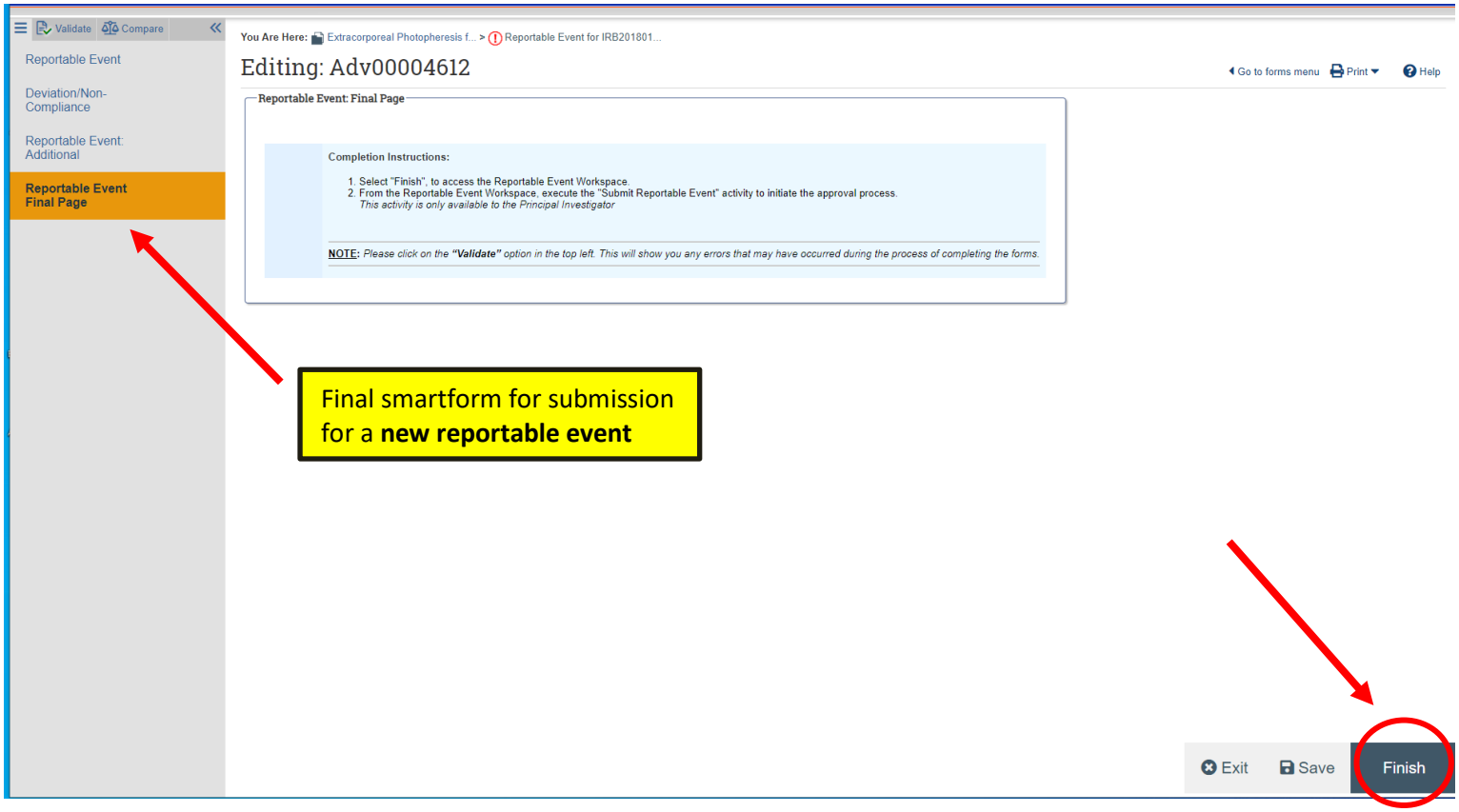


TIP: Please pay attention to the numeric subscripts next to each type of Reportable Event in Question 1.0. Some reportable events can be submitted **simultaneously**, while others require the submission of a **separate reportable event.**

From here, provide all relevant information on the initial page:



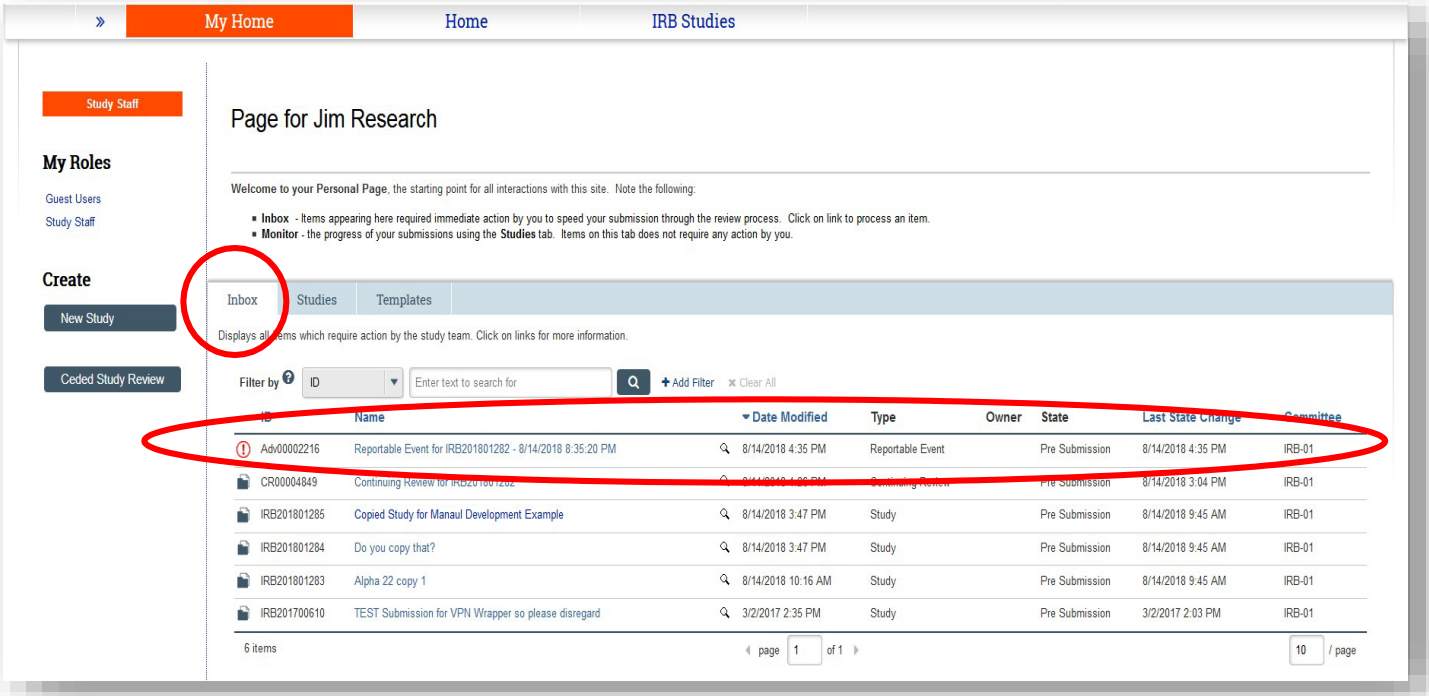
Depending on how the PI answers the page above, the system will present different SmartForms relevant to the details of the reportable event. Regardless of the nature of the event, the PI will be required to answer questions and provide additional background. And irrespective of the specifics of the event, the final SmartForm will be the **Reportable Event Final Page**. From here, click **Finish** to finalize the application.



TIP: Clicking **Finish** does not submit the event to IRB. Additional steps are required.

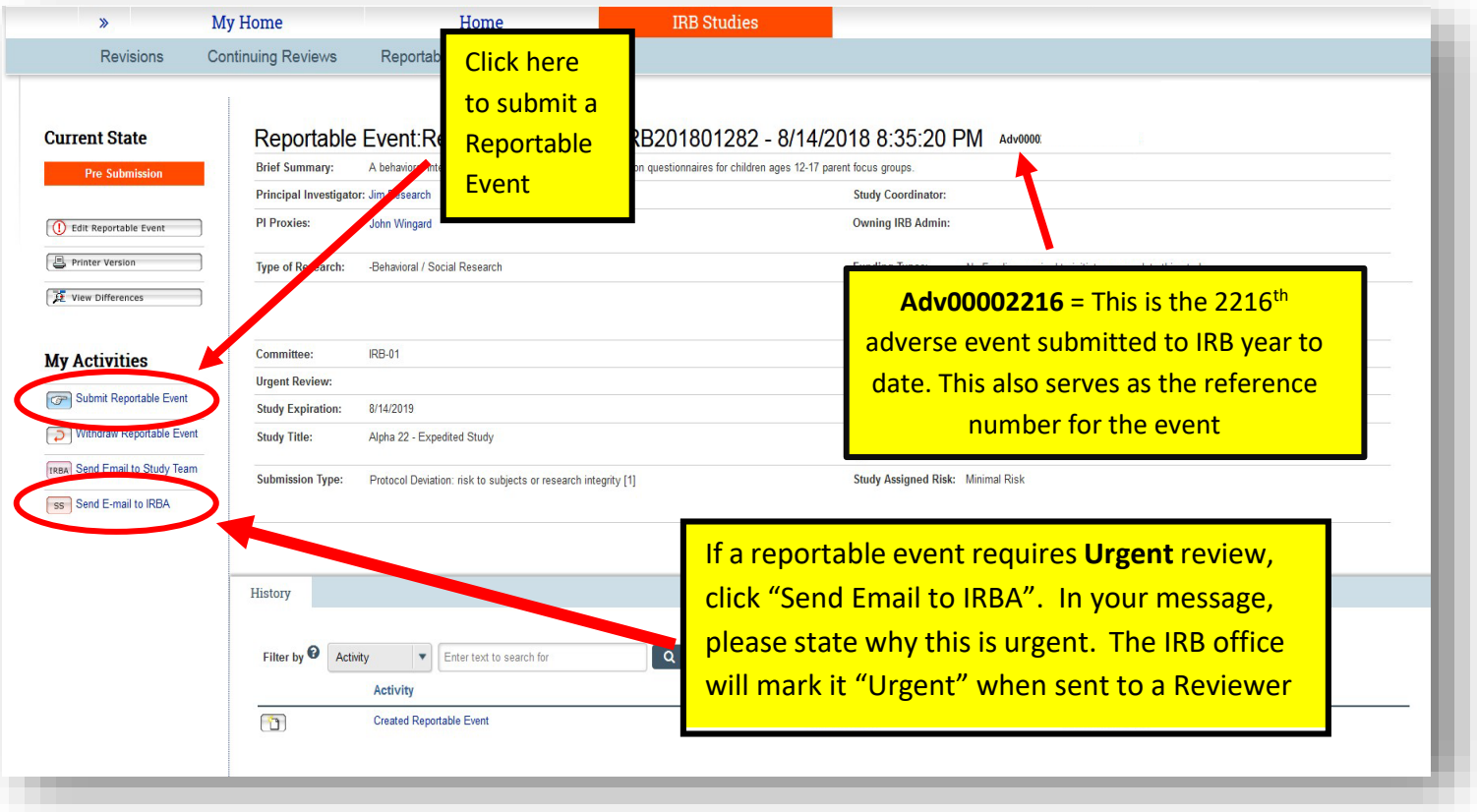
From here, return to the Study Summary Page and look in the **Inbox** for the Reportable Event you created. A red exclamation point denotes Reportable Events. Then, click the Reportable Event you need to submit to IRB.

TIP: Items in the **State** column labeled Pre-Submission **have not** been submitted to IRB.

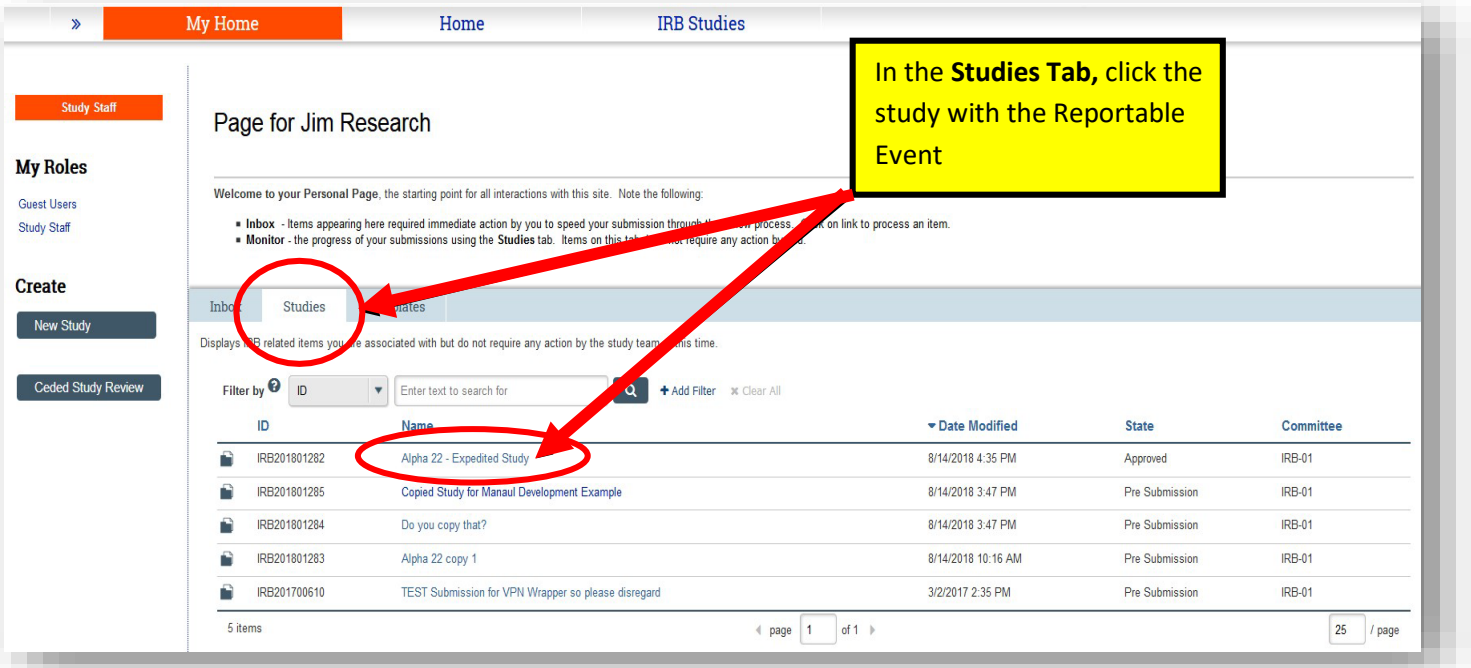


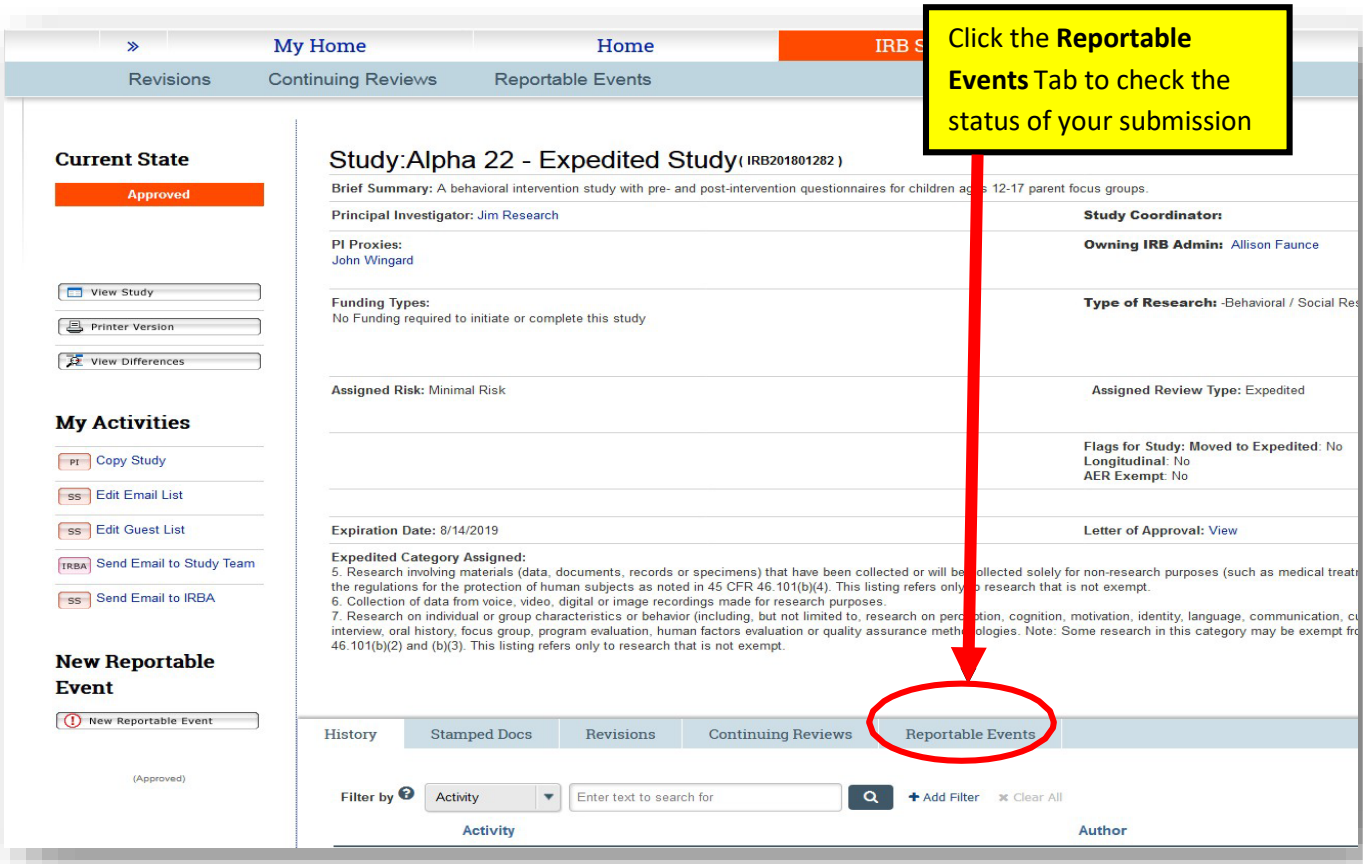
Once the Reportable Event is open, look for **My Activities** on the left-hand side of the page.

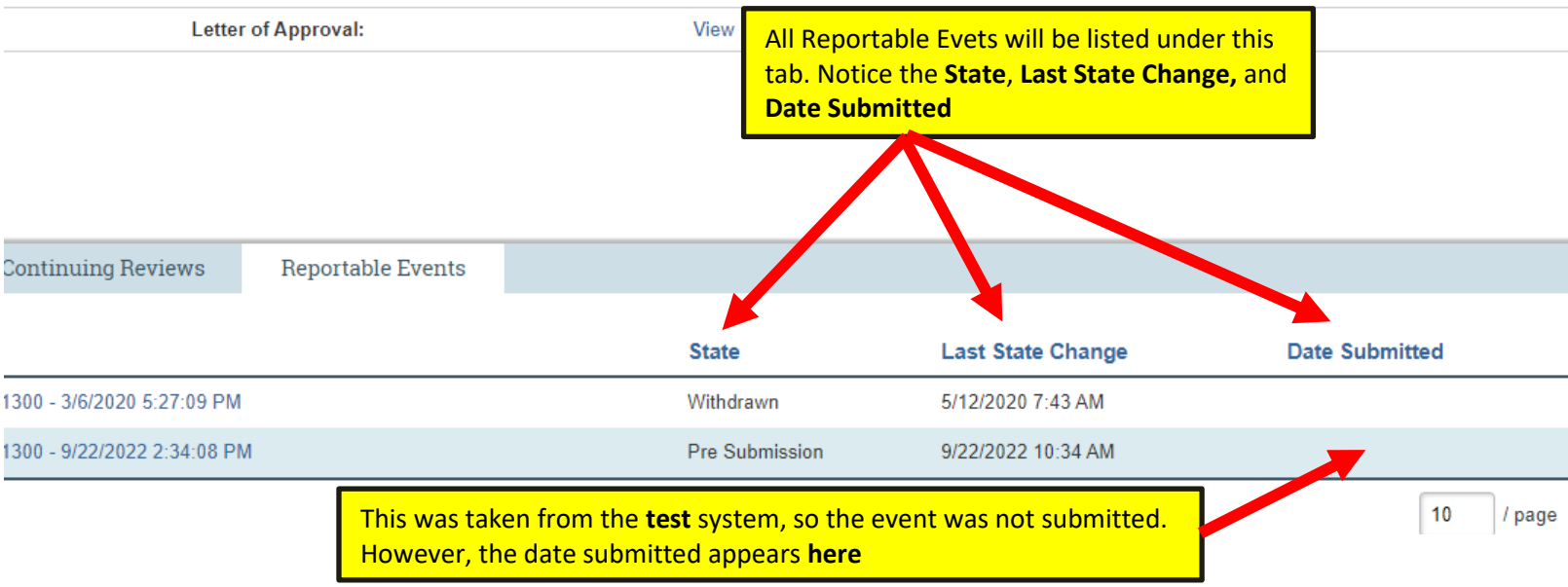
Under that heading, click **Submit Reportable Event**.



To check the status of the Reportable Event, go to the **Studies** tab. From here, click the study for which the reportable event was submitted. Next, click the **Reportable Events** tab. Then, look at the **State** column to see the status of the study in the IRB review process.

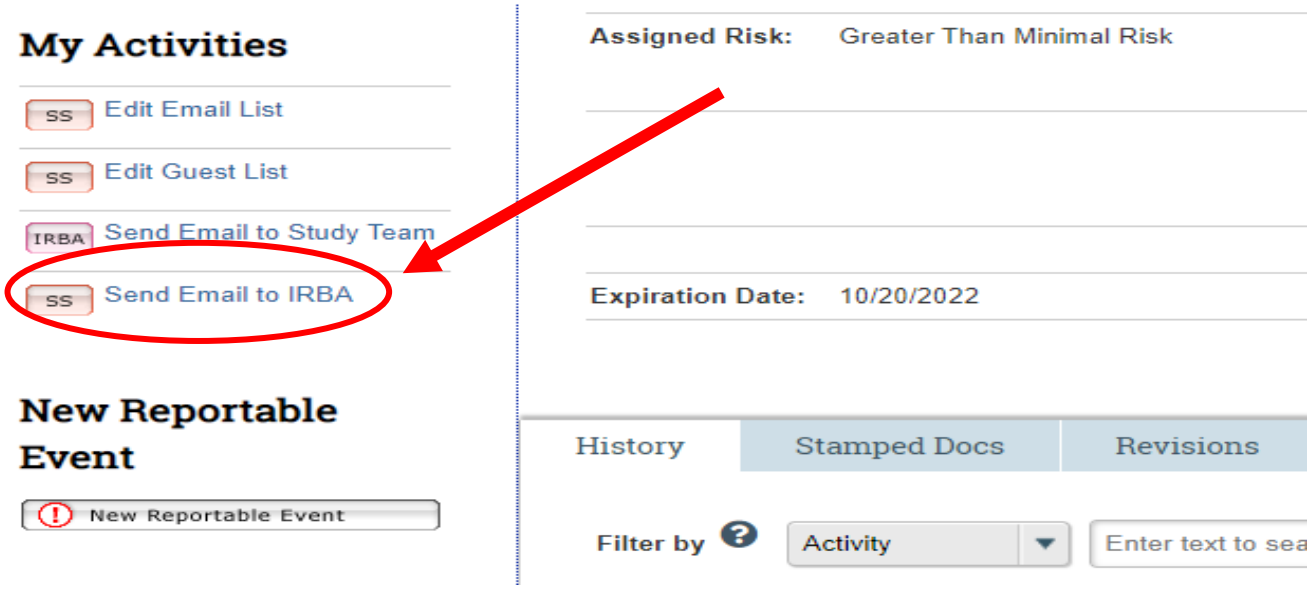






Once a reportable event is in the **IRB Staff Review** state, the only way to withdraw the submission is to contact the IRB office and ask that the submission be returned to the PI.

To do so, contact IRB via the **Send Email to IRBA** link under the **My Activities** heading on the main **Study Workspace**. This will ensure the request is added to the study history log.



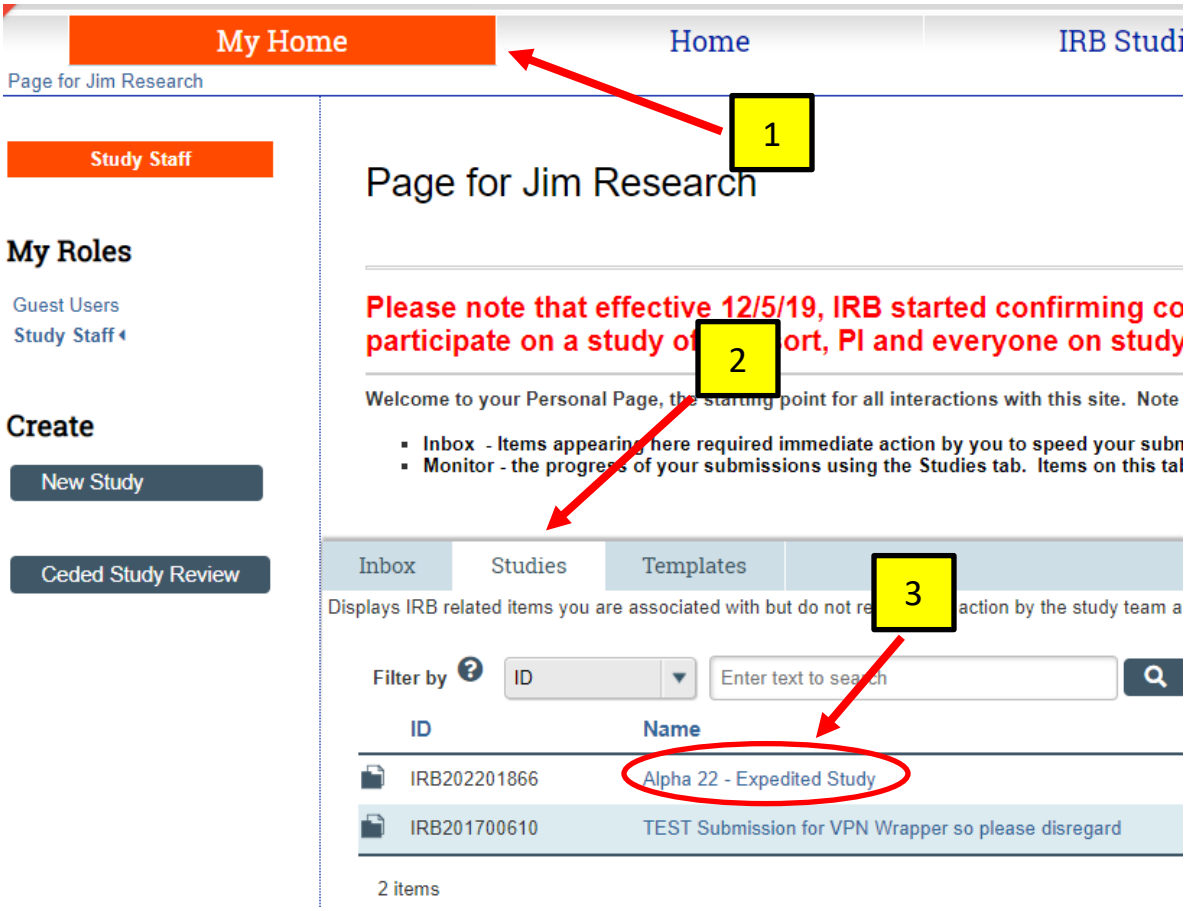
TIP: Once a submission has been withdrawn by the PI or study staff, it is non-recoverable. The **only way** to resubmit the reportable event is to re-create the entire submission.

Submitting a New Continuing Review or Study Closure

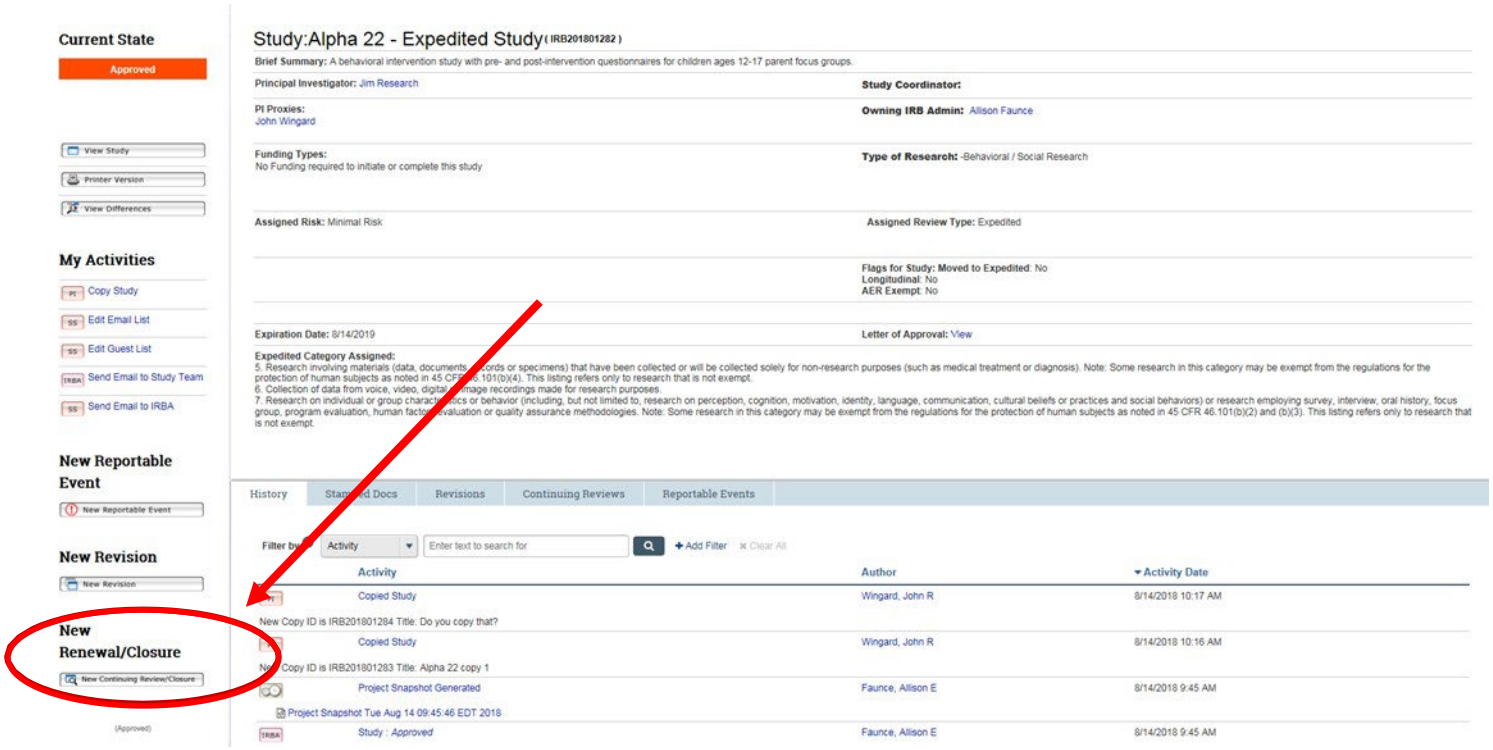
Note: If your study is **Expedited**, you may not have the option of a Continuing Review. Expedited studies will have a **Status Report** option unless IRB has determined that a Continuing Review is required.

To submit a New Continuing Review, follow these steps:

1. First, log-in to *myIRB.* You will automatically begin in the **My Home** tab.
2. Next, click the **Studies** tab located in the middle of the page.
3. Then, look for and click on the desired study name to open the **Study Workspace.**

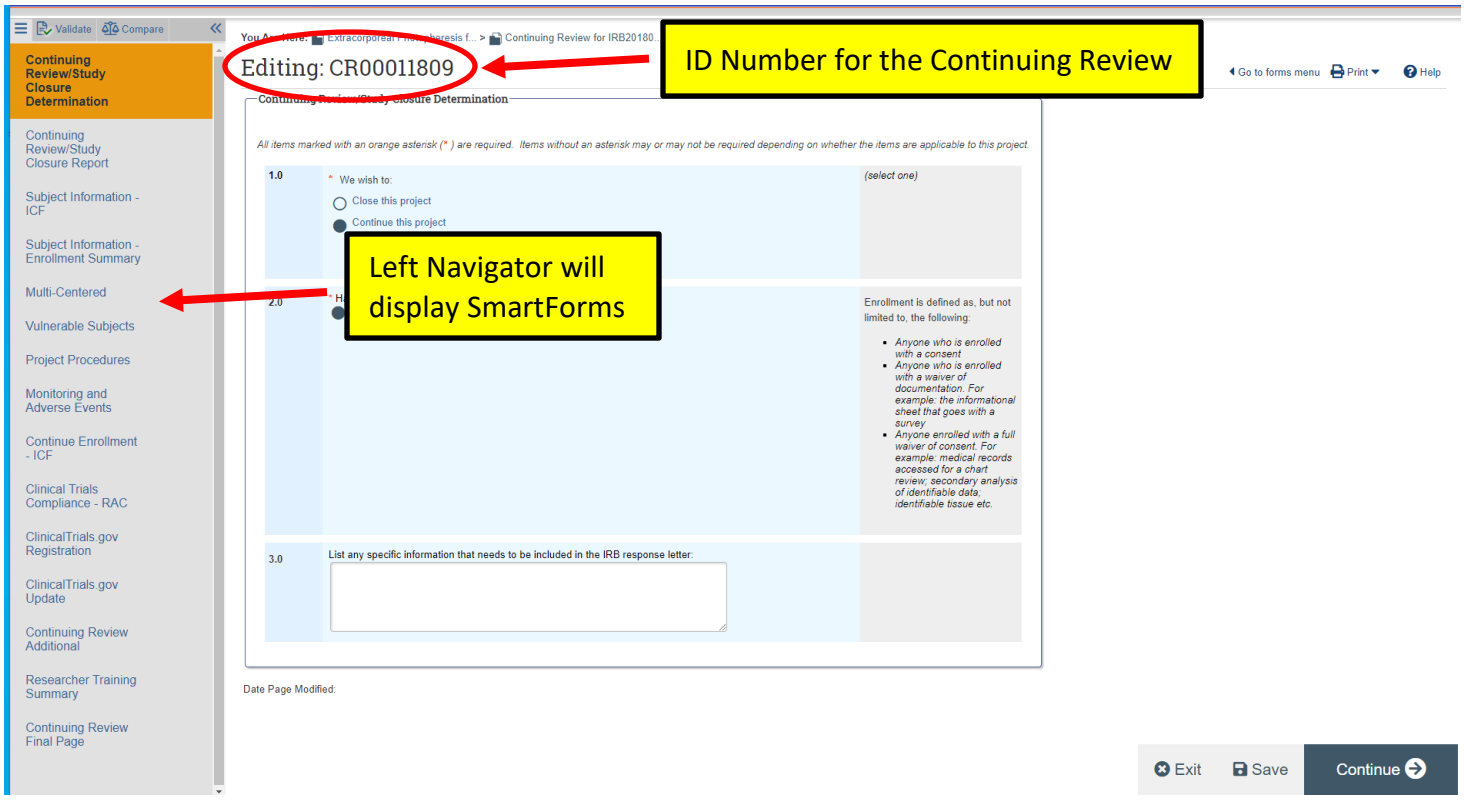


4. From here, on the Main **Study Workspace** (next screenshot), look in the column on the left-hand side of the page. There, you will see 3 bolded categories:
    - **New Reportable Event**
    - **New Revision**
    - **New Renewal/Closure** ← Select this option



Next, you will be directed to a series of SmartForms where you can input the relevant information for your Continuing Review.

TIP: The Continuing Review Number displayed in the SmartForms is the ID# for your CR.



Then, follow the system-generated progression of SmartForms until all are complete.

TIP: Continuing Reviews (CR) and Revisions **cannot** be in process simultaneously. Therefore, if a CR or Revision is pending approval and a new CR or Revision must be submitted, the PI must choose **one** of the following options:

- **Withdraw** the pending submission and **submit** the more urgent CR/Revision.
- **Wait** for the pending submission to be approved, and then **submit** another revision with the additional changes or the CR. In the interim, when a CR is approved, *my*IRB will automatically renew the most current IRB approved ICF for the new CR year.

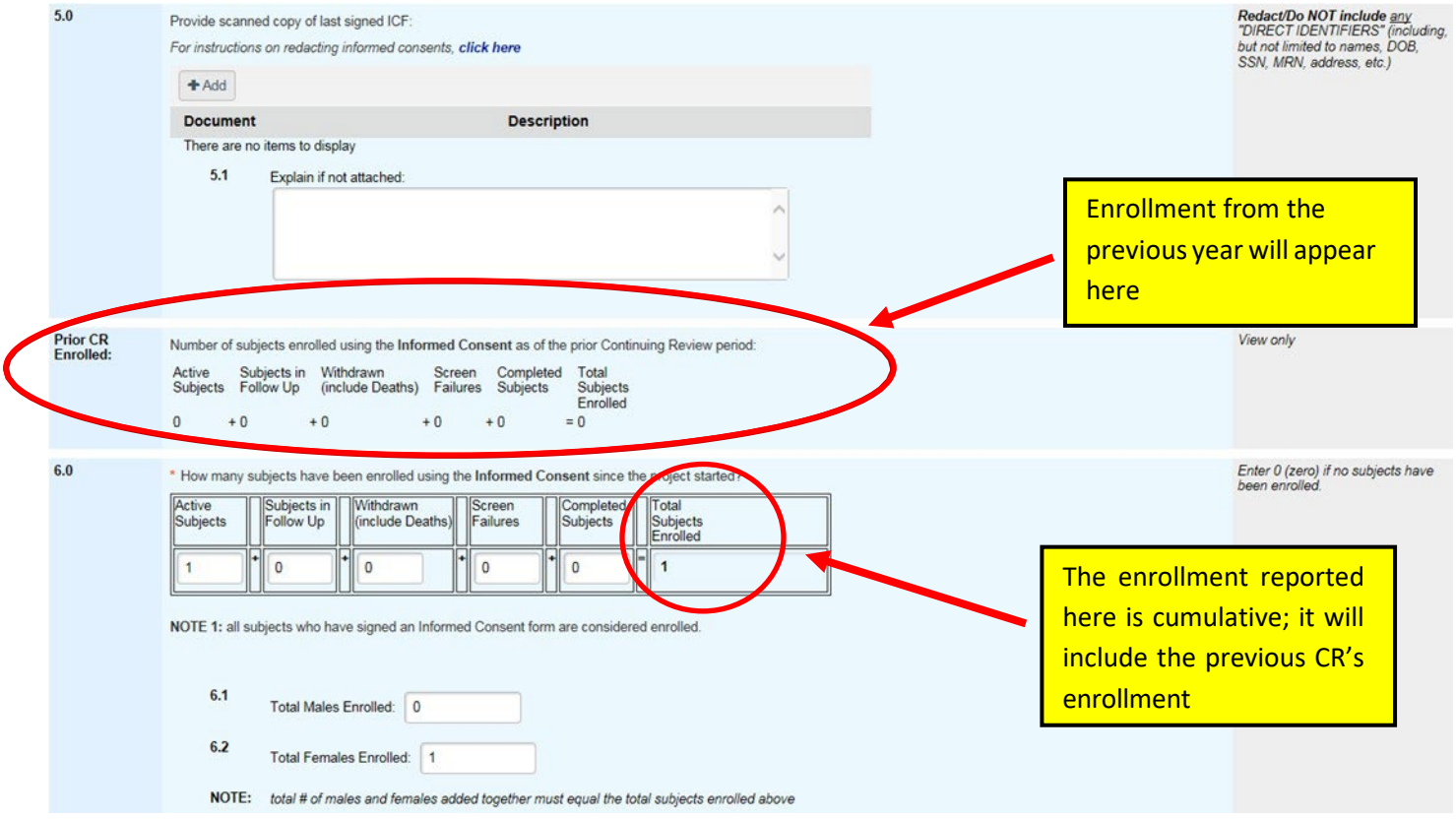
The system will automatically pull responses from the initial study submission and add them to these smart forms to remind the PI and study team what they originally submitted. This also helps the study team determine if the study is still following the same procedures.

Specifically, on the **Continuing Review/Study Closure Report** SmartForm, the system will pre-populate the **Recruitment Methods** that were identified by the study team during initial study submission and later approved by IRB.

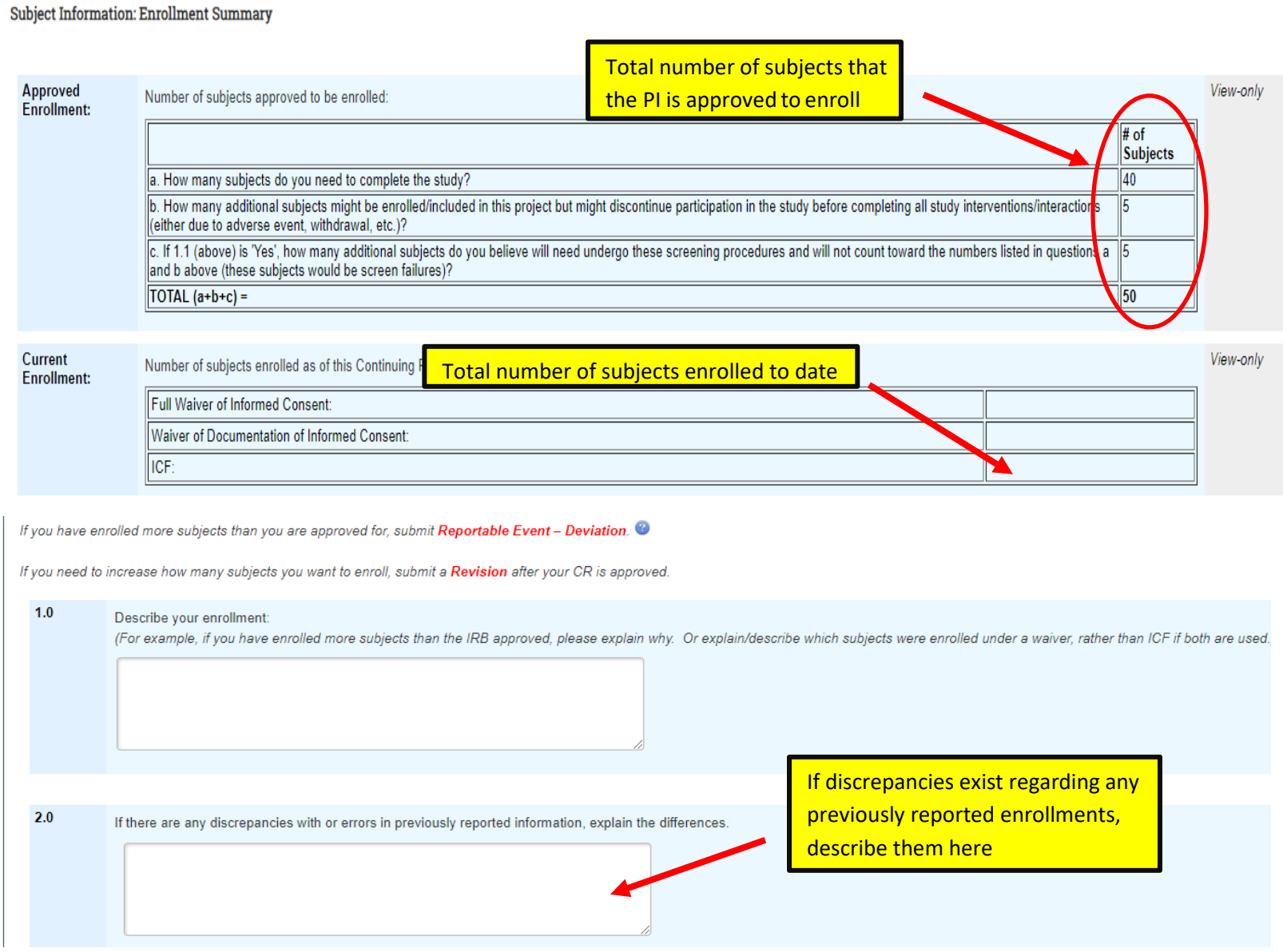
If any recruitment methods have changed, you must submit a **Revision**.

Responses from previous CRs will appear on the **Subject Information – ICF – Enrolled** SmartForm, including the dates of the first/last signed ICF (as reported by the study team).

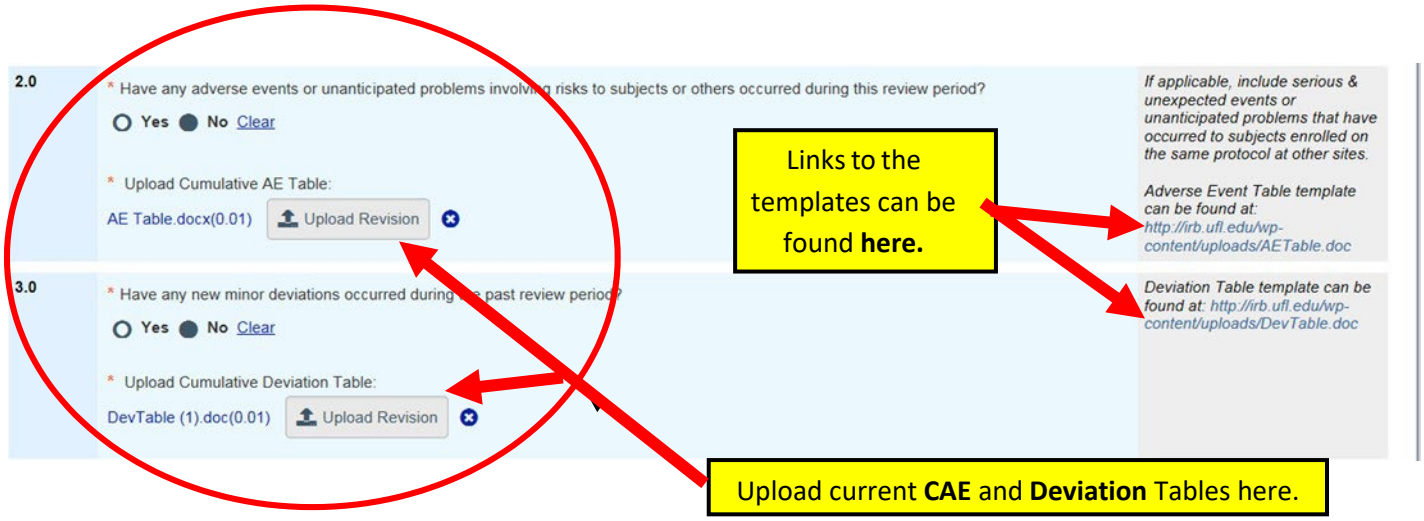
Later in the same SmartForm, information will appear regarding the number of subjects who have signed an Informed Consent and the total number of subjects who have enrolled on study:



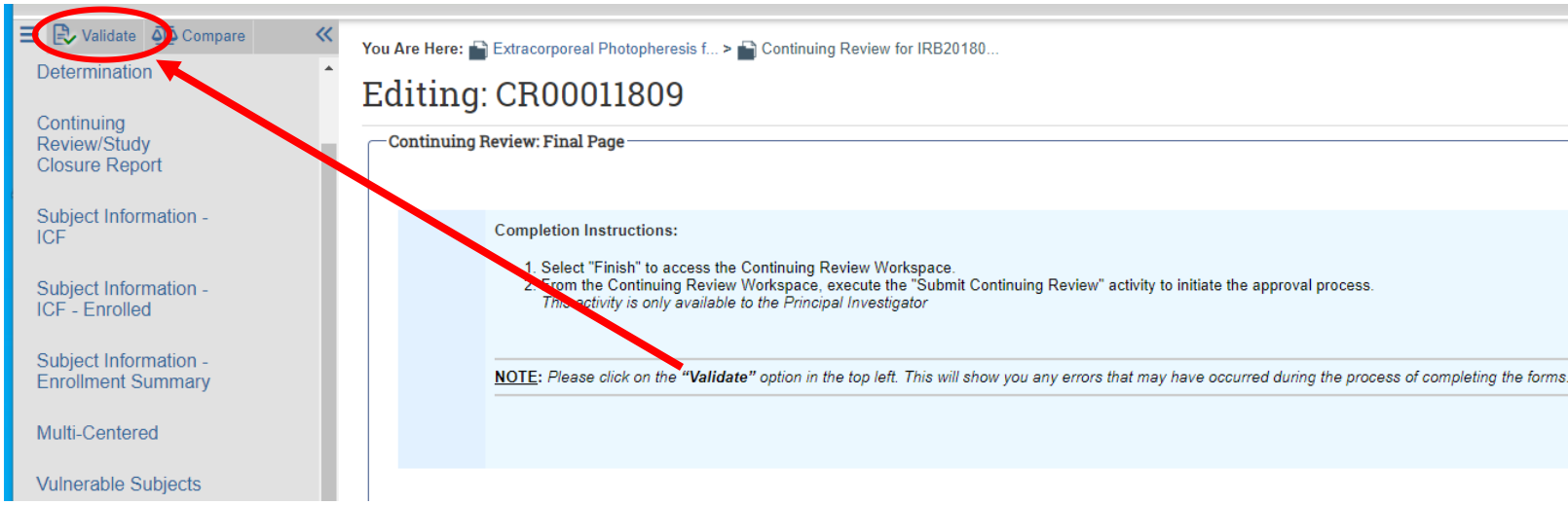
The **Subject Information – Enrollment Summary** SmartForm will provide information regarding the Total Number of Subjects the PI has been **approved to enroll**, as well as the total number of subjects **enrolled to date**:



Later, on the **Monitoring and Adverse Events** SmartForm, remember to upload the current **Cumulative Adverse Events** (CAE) table and **Deviation Tracking Log** table:

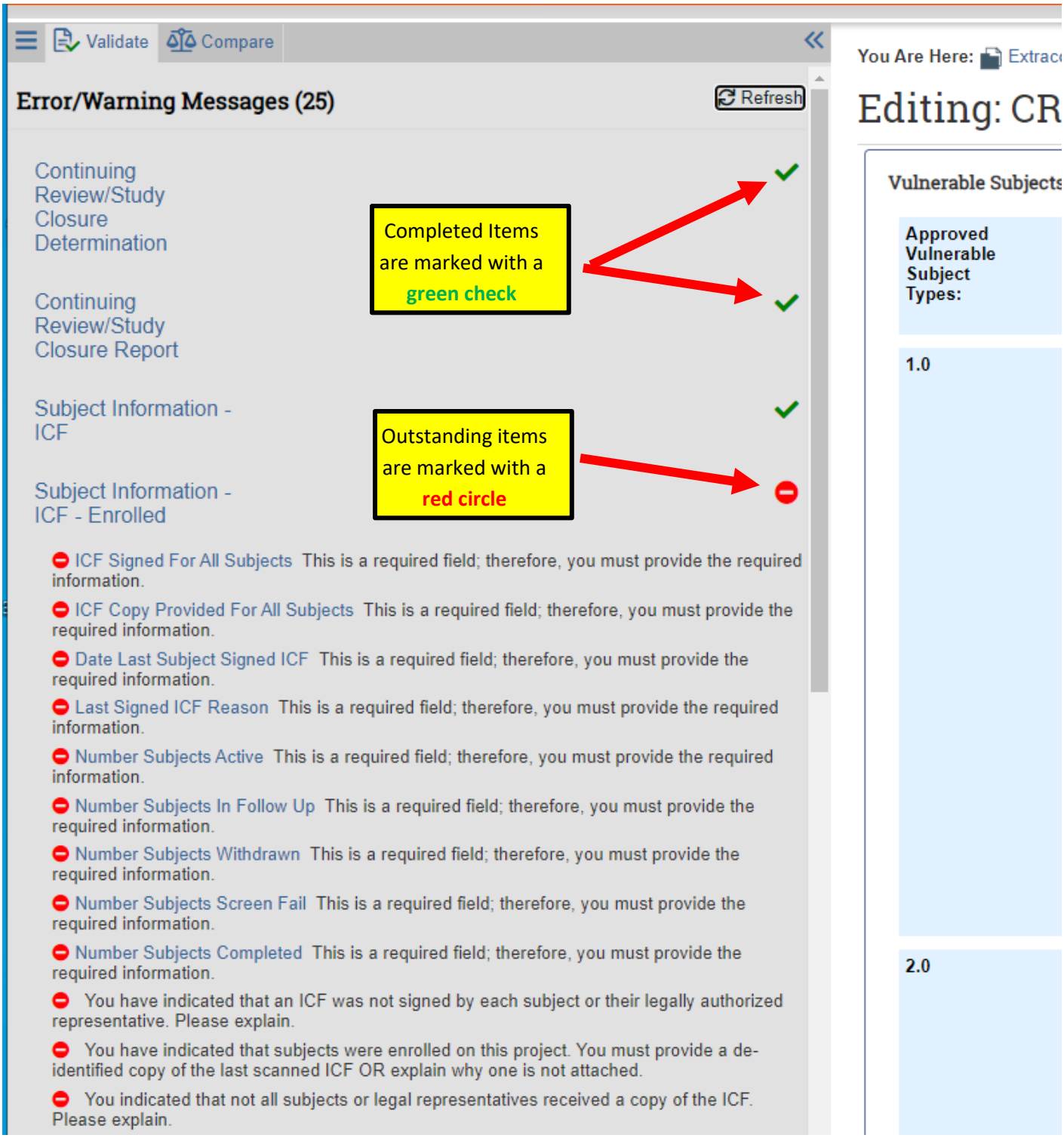


After completing all SmartForms, click **Validate** in the upper left-hand corner of the screen. This button holds the same function as during the initial study submission. In other words, clicking Validate will display any errors which must be resolved before submitting the CR to IRB.

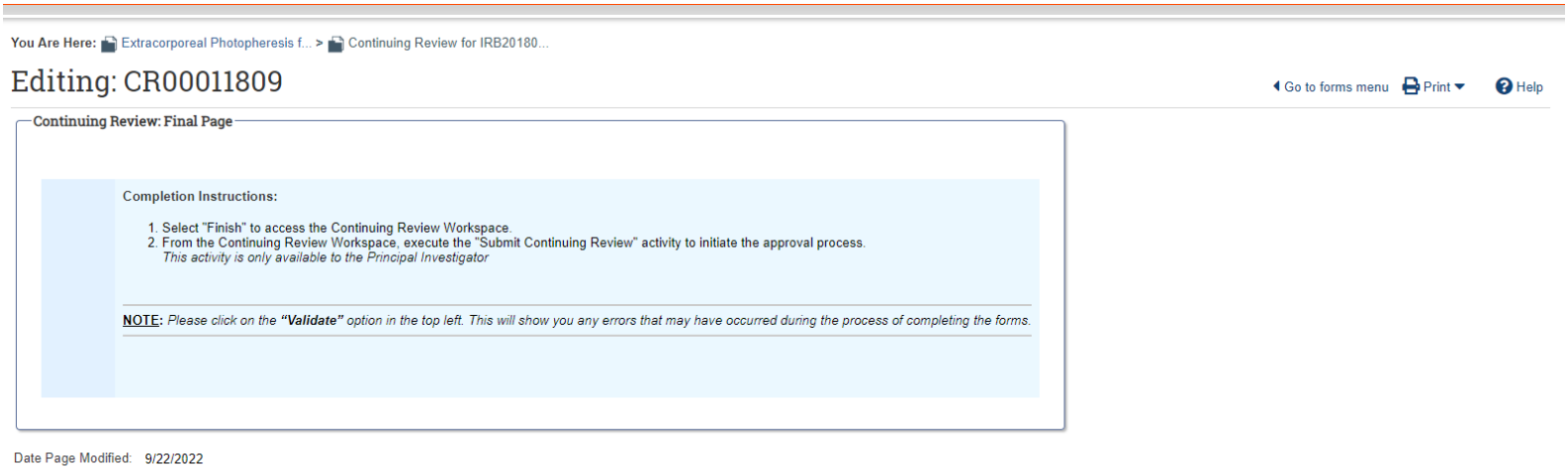


TIP: The system **will** allow you to click **Finish** on the final SmartForm even if errors remain in your submission. However, it is best practice to click Validate **before** clicking Finish so that the PI can resolve any outstanding errors before submitting to IRB.

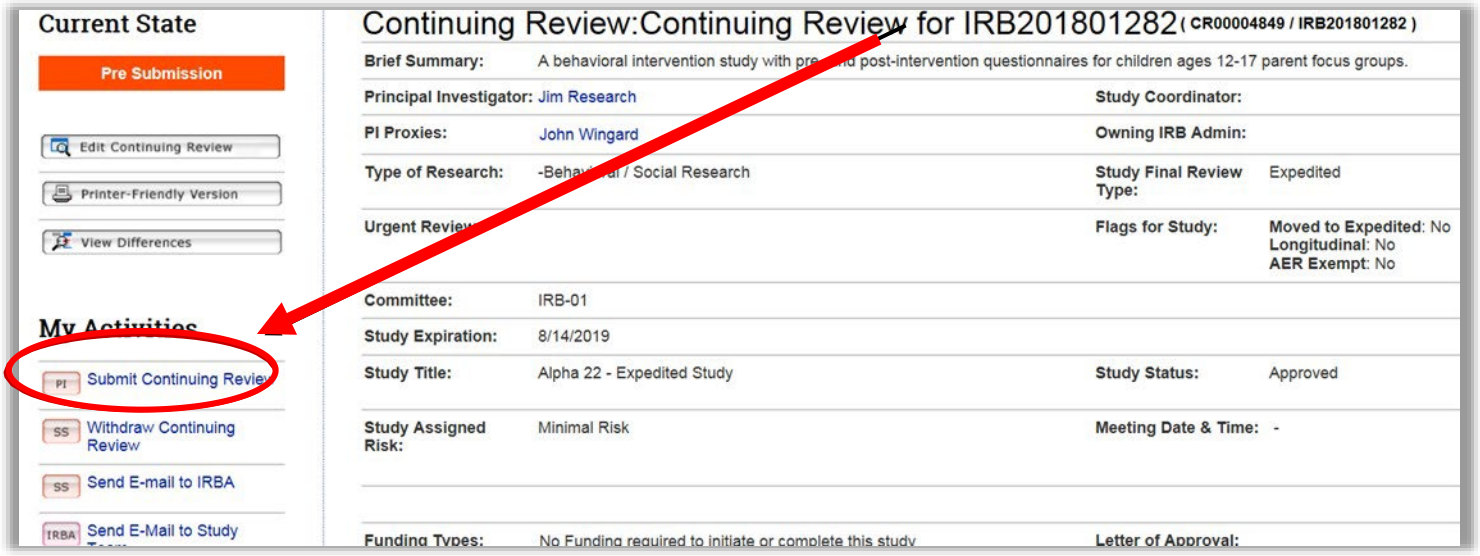
After clicking **Validate**, the Left Navigator will expand. There, both the completed and outstanding items will be displayed:



Scroll through the Left Navigator thoroughly to ensure all outstanding items are resolved. Then, after addressing all outstanding items, navigate to the **Continuing Review Final Page** (last SmartForm in the submission). Once there, click **Save,** and then click **Finish.**



Next, you will be redirected to the summary page for the Continuing Review. From here, look for the **My Activities** heading on the left-hand side of the page. There, the PI or PI Proxy should select **Submit Continuing Review** to send the CR to the IRB for review.



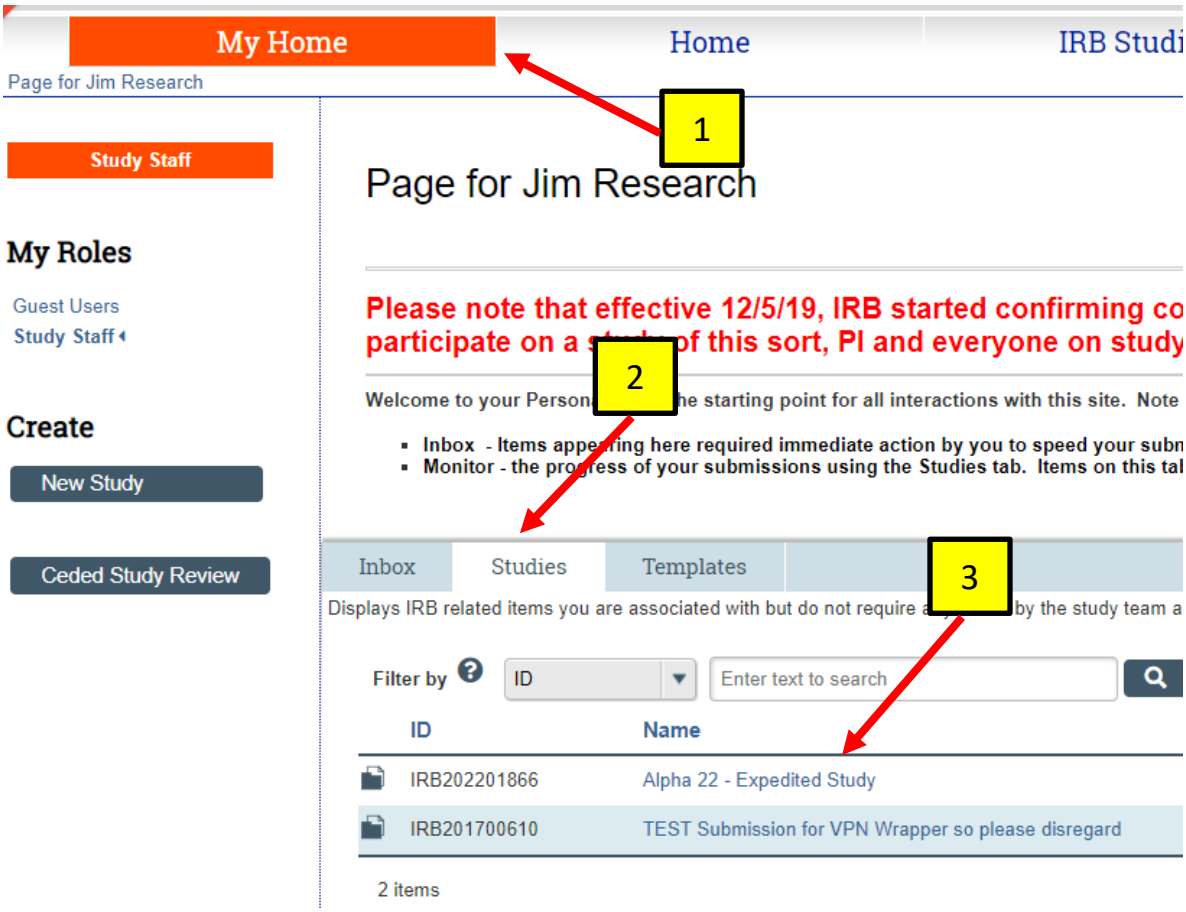
TIP: If a Continuing Review (CR) needs to be withdrawn, the study team may do so. However, withdrawing a Continuing Review is **final** (i.e., non-retrievable). If a study team forgets to include important information when submitting the initial CR, it is best to ask that it be returned from the IRB.

Submitting a Status Report

Expedited studies that meet Common Rule requirements are required to regularly submit a **Status Report**. When a study is close to expiration, the PI and study team will receive an email notification from IRB regarding the upcoming study closure deadline. From there, the PI will inform IRB if they wish to **continue** or **close** the study.

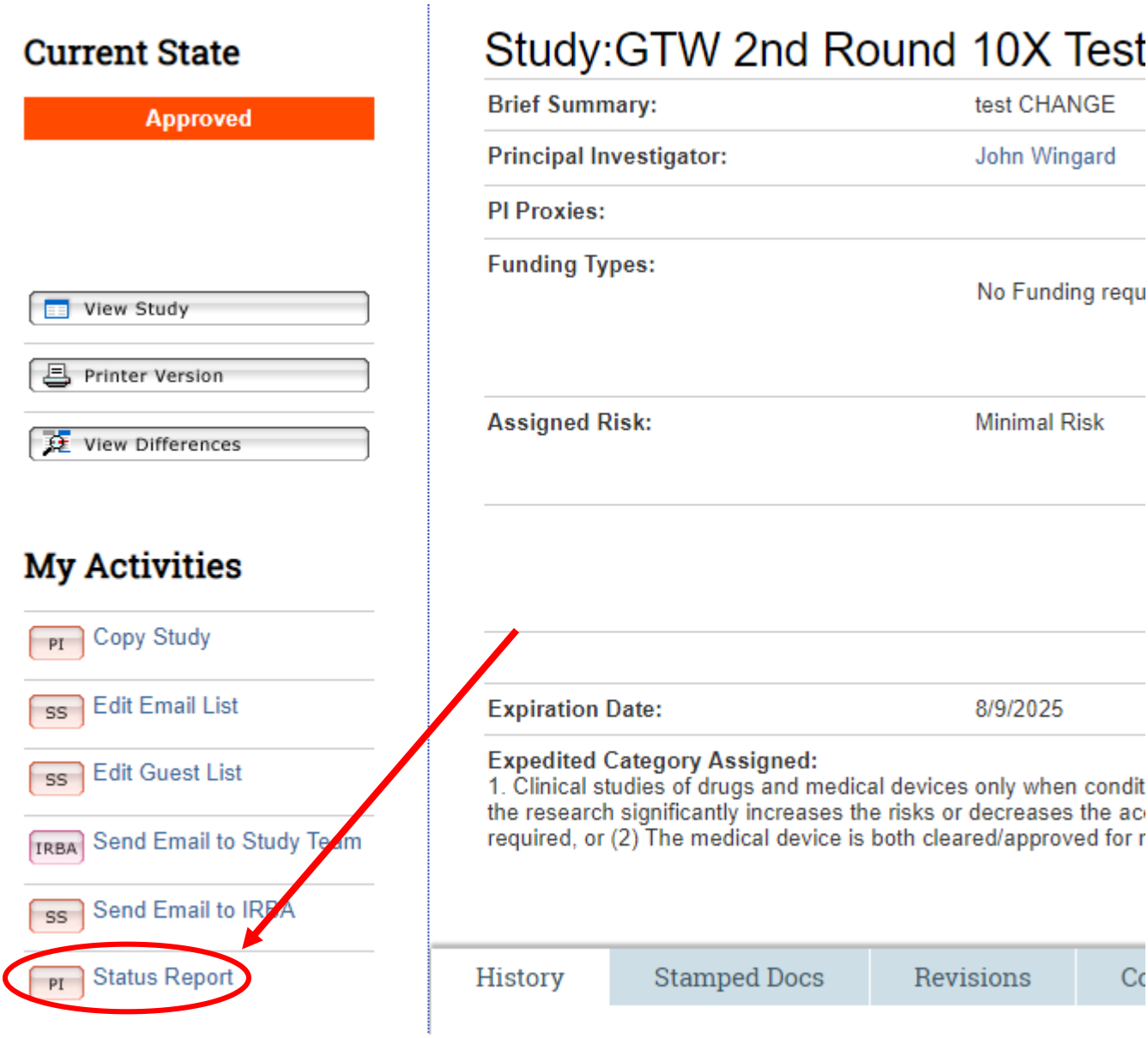
To submit a Status Report, follow these steps:

1. First, log-in to *myIRB.* Doing so will automatically redirect you to the **My Home** tab.
2. Next, click the **Studies** tab located in the middle of the page.
3. Then, look for and click on the desired study name to open the **Study Workspace.**

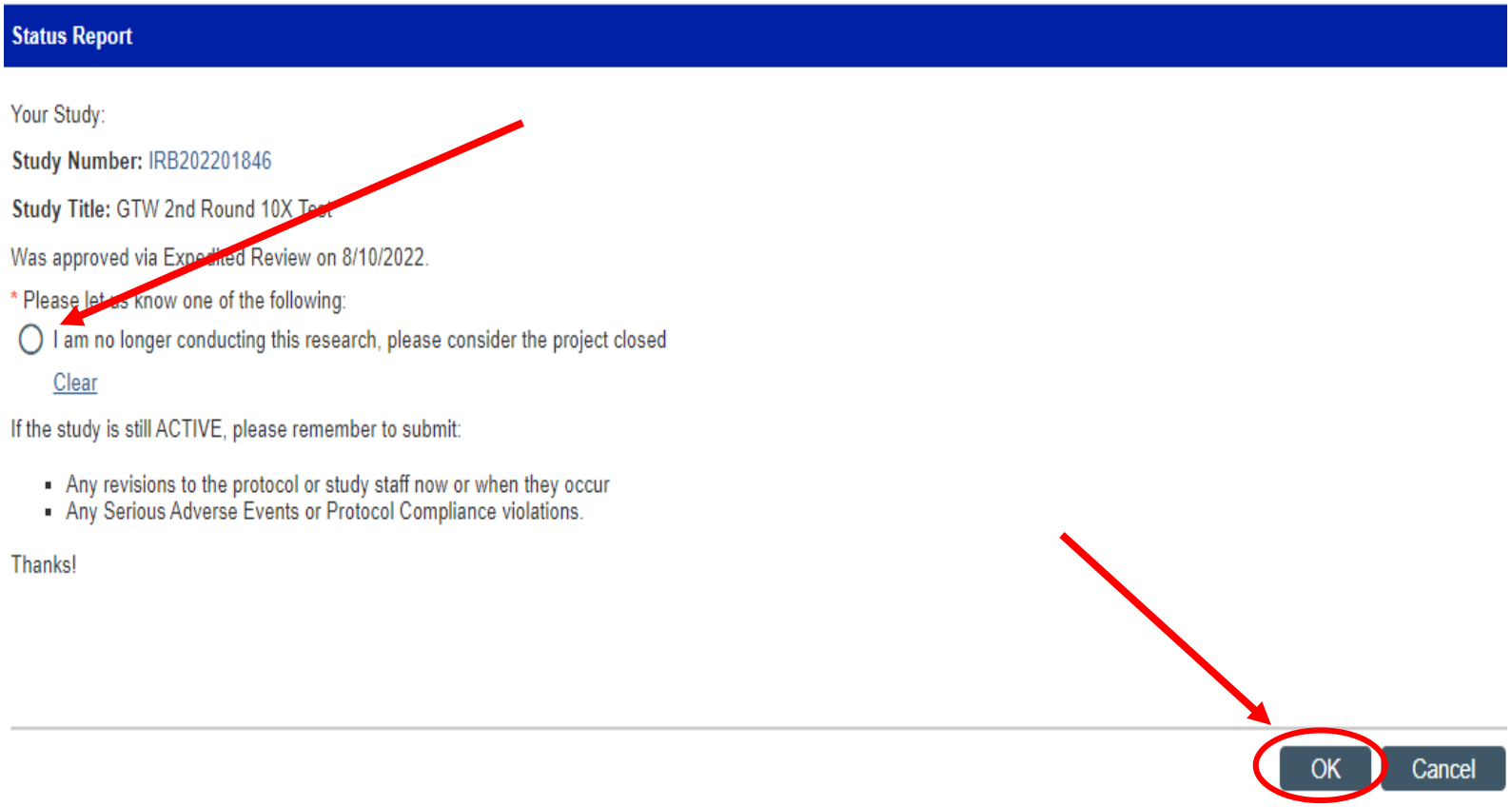


Once in the Study Workspace, look for the **My Activities** menu on the left side of the page.

From there, select **Status Report**.



TIP: If you select Status Report **before** receiving a 45 day notification to closure, you will only have the option to close the study. If you wish to close the study before its expiration, select **Status Report** and choose "*I am no longer conducting this research, please consider the project closed*."



If the study team wishes to **continue** the study, the PI should wait to submit a Status Report until **after they receive** the 45-day notification to closure from IRB. The PI will then be presented with the following options when selecting **Status Report**:

- I wish this to remain an ACTIVE research study.
- I am no longer conducting this research, please consider the project closed.

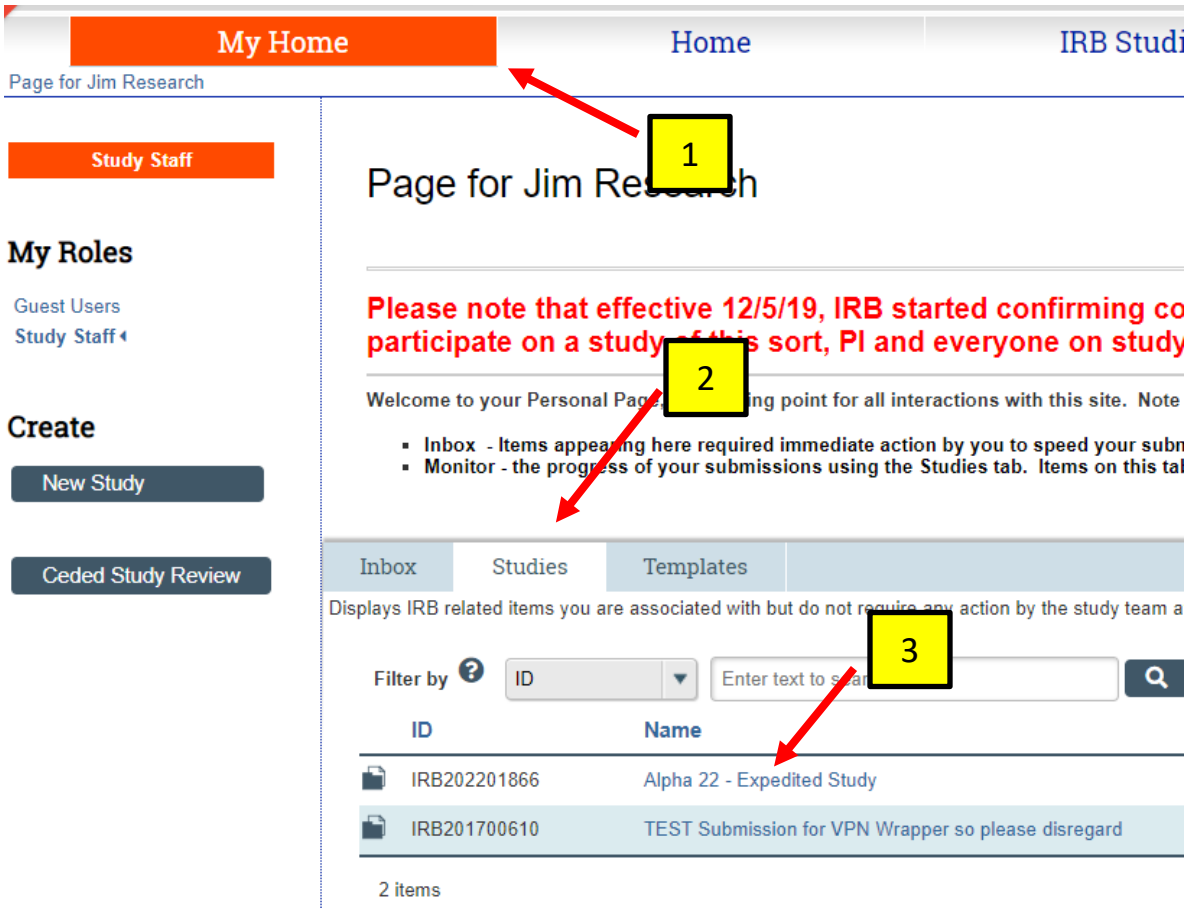
Submitting a New Revision

After a study has received initial IRB approval, study teams may need to submit revisions in order to update IRB on changes to their study. To submit a **New Revision**, study teams will need to follow these 3 steps in order:

1. Complete the New Revision SmartForm
2. Edit Modified Study
3. Revise necessary documents (e.g., ICF, Protocol, Flyer, etc.) and attach those documents to the Modified Study

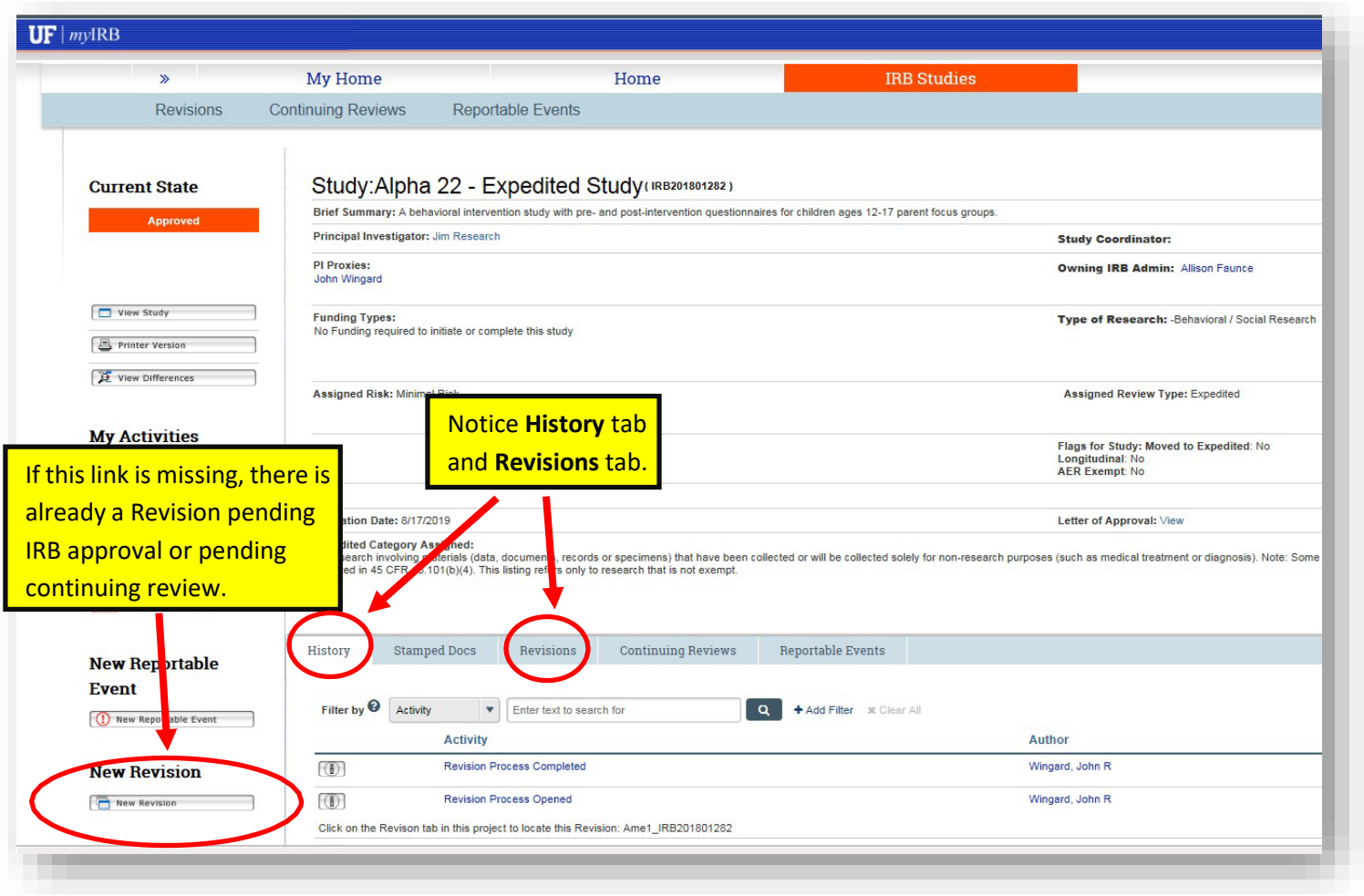
To begin the process, follow these directions:

a. First, log-in to *myIRB.* Doing so will automatically redirect you to the **My Home** tab.
b. Next, click the **Studies** tab located in the middle of the page.
c. Then, look for and click on the desired study name to open the **Study Workspace**.



- Once in the **Study Workspace,** the default tab is the **History** tab. Here, you can view all submission details in chronological order. You can also access prior revisions for this study by clicking on the **Revisions** tab.

- To start a New Revision, look in the left-hand column of the screen and click the **New Revision** tab.



TIP: Remember that **only one** Revision or Continuing Review can be in process at a time.

The only way to submit a new revision is if IRB has approved the previous revision/CR **or** if the PI has withdrawn the prior Revision/CR. If the **New Revision** link is not available on the screen above, a Revision/CR is already in the system pending approval.

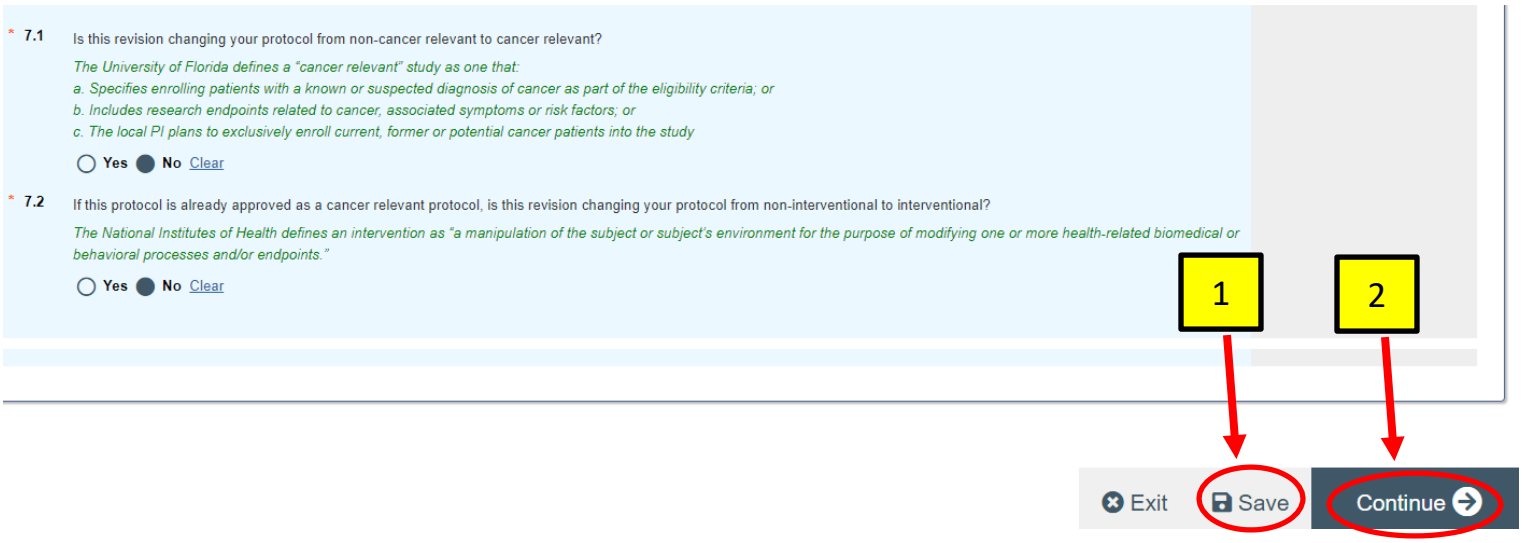
In this case, the PI must choose from one of the following options:

a) **Withdraw** the pending Revision and include it with the new Revision.
b) **Wait** for the pending Revision to be approved, and then submit a new Revision.
c) **Wait** for the Continuing Review to be approved and then submit a Revision
(See **Submitting a New Continuing Review** on pages 46-54 of this manual, if relevant).

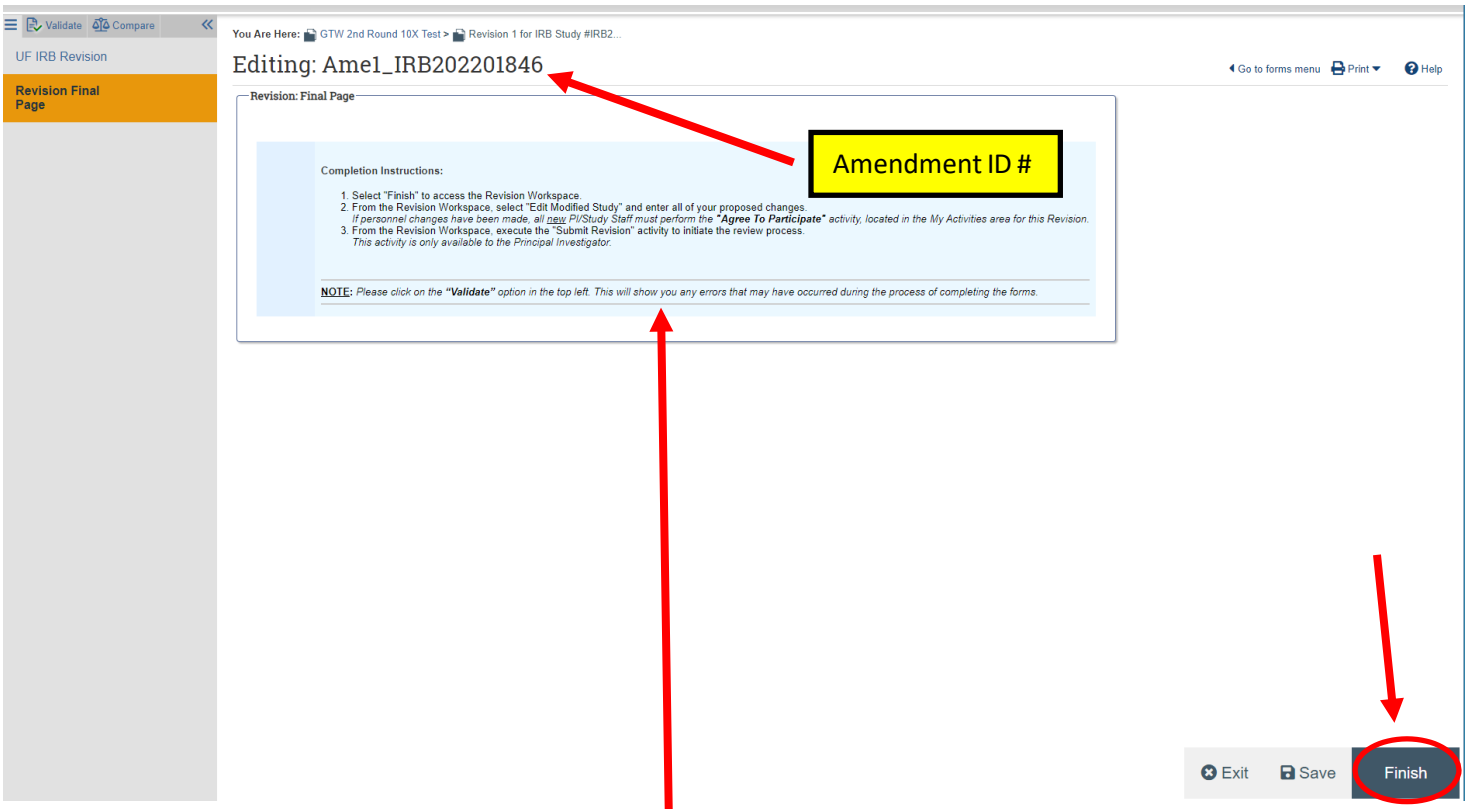
To continue submitting a New Revision, click the **New Revision** tab from the Study Workspace (see screenshot on previous page). From there, complete the SmartForm, paying special attention to Question 1.0. This question is where the PI/study team will list **all changes being made to the study under this revision**. Possible changes include, but are not limited to:

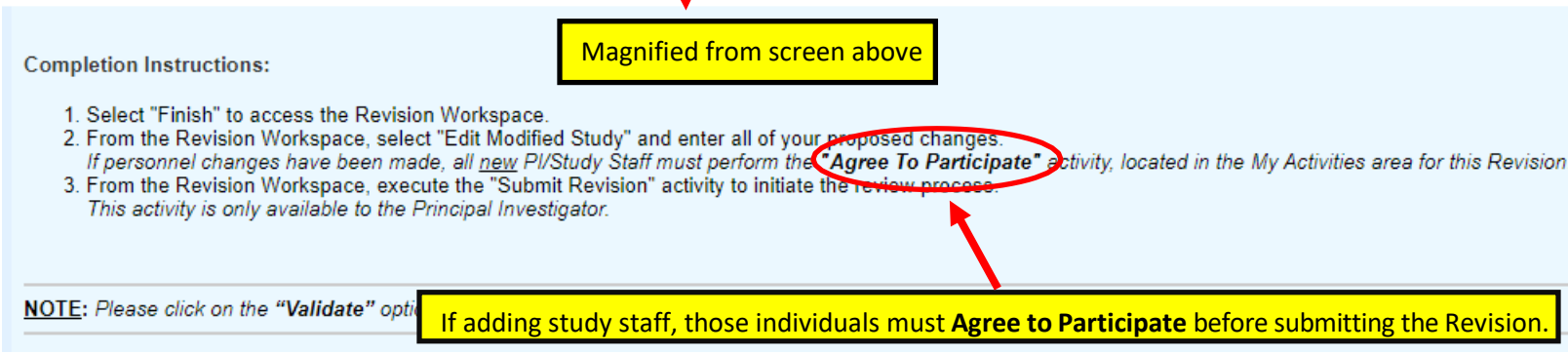
- Adding / removing study staff
- Adding research-only procedures, tests, questionnaires, etc.
- Updating protocol or ICF

Once all data have been entered, click **Save** and then **Continue** at the bottom of the page.

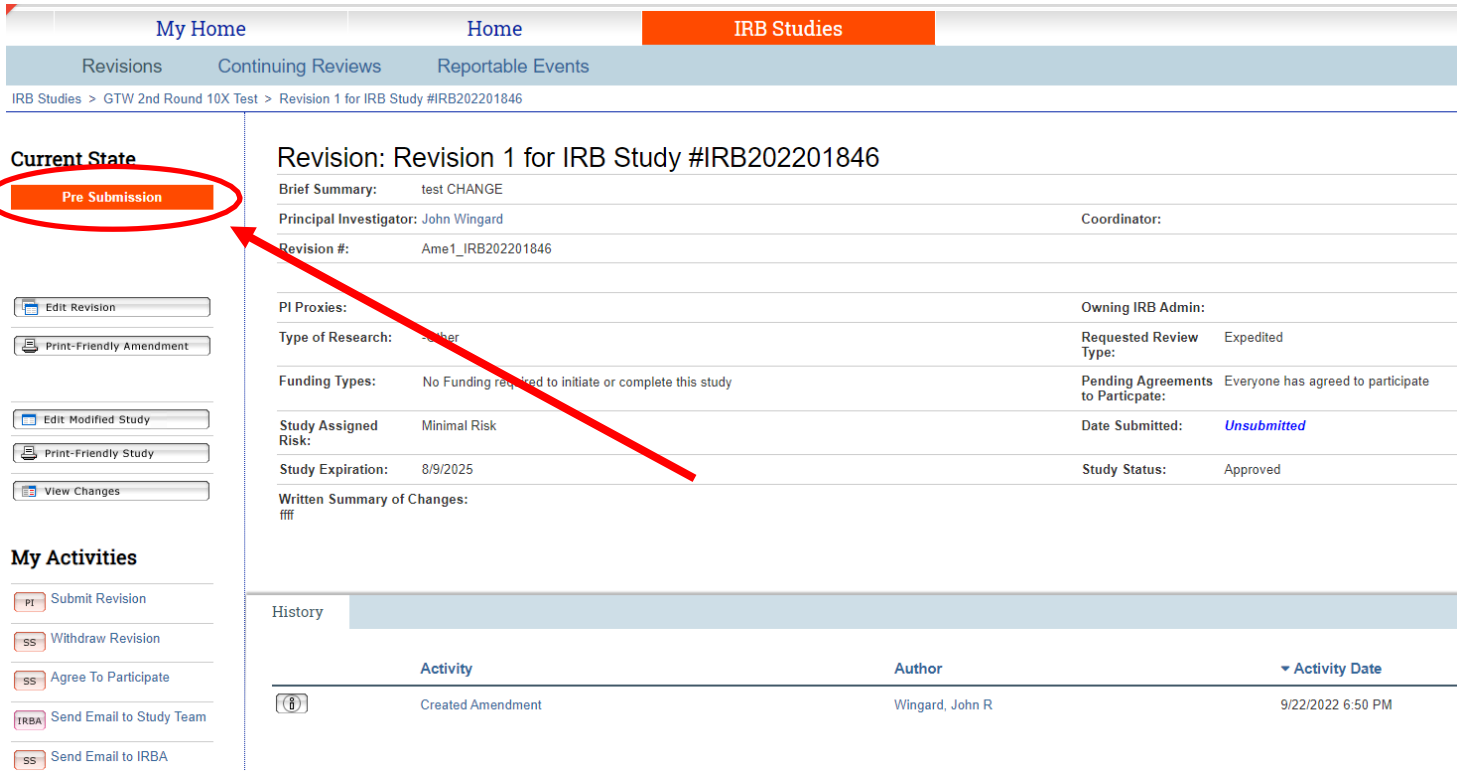


After completing the first SmartForm, you will be redirected to the **Revision Final Page**. Please review the information contained (see screenshots below). Once complete, click **Finish** in the lower right-hand corner of the screen to submit the SmartForm.





After clicking **Finish**, you will be redirected to the summary page for this revision. Note that the "Current State" of your Revision is **Pre-Submission.**



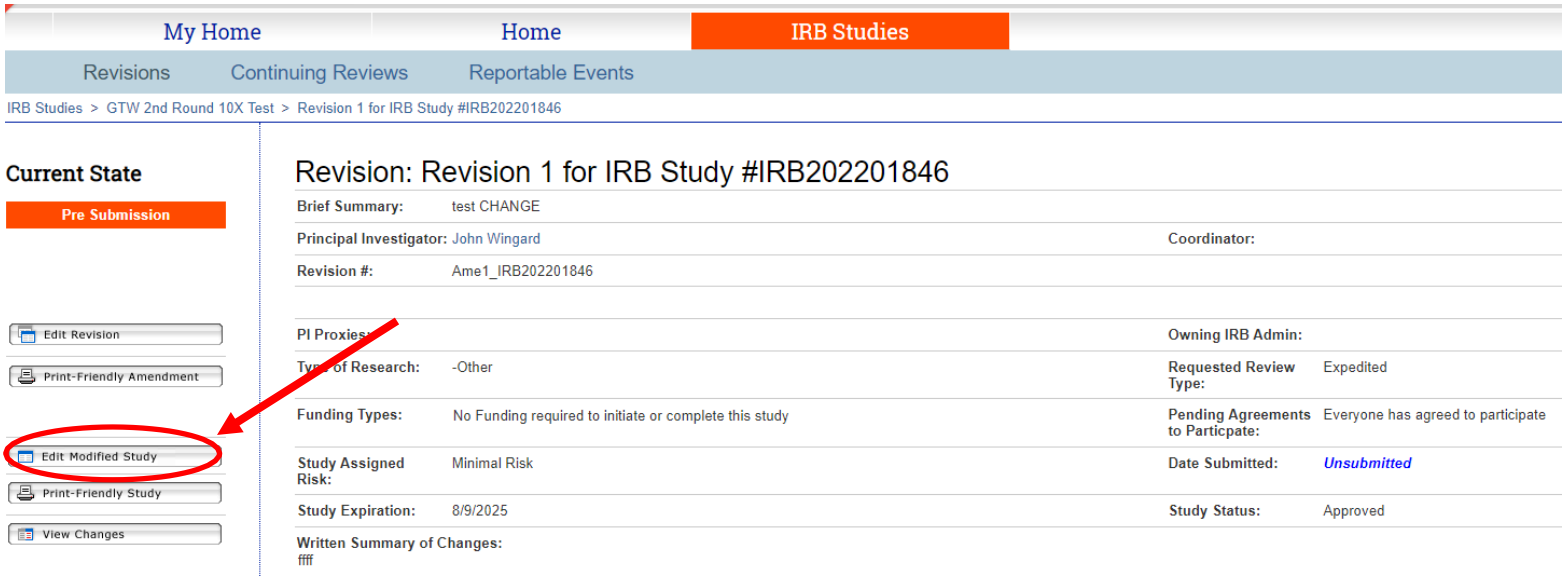
If needed, the study team can edit the Revision in the Pre-Submission state. If the Revision SmartForms need to be edited, follow these steps:

1. Open the study in *my*IRB.
2. Look for the **Revisions** tab.
3. Click on the Revision you wish to edit, and on the next screen, click **Edit Revision**.

After completing the Revision SmartForms, the next step is to access the study SmartForms and make the relevant revisions within the study itself.

Edit Modified Study

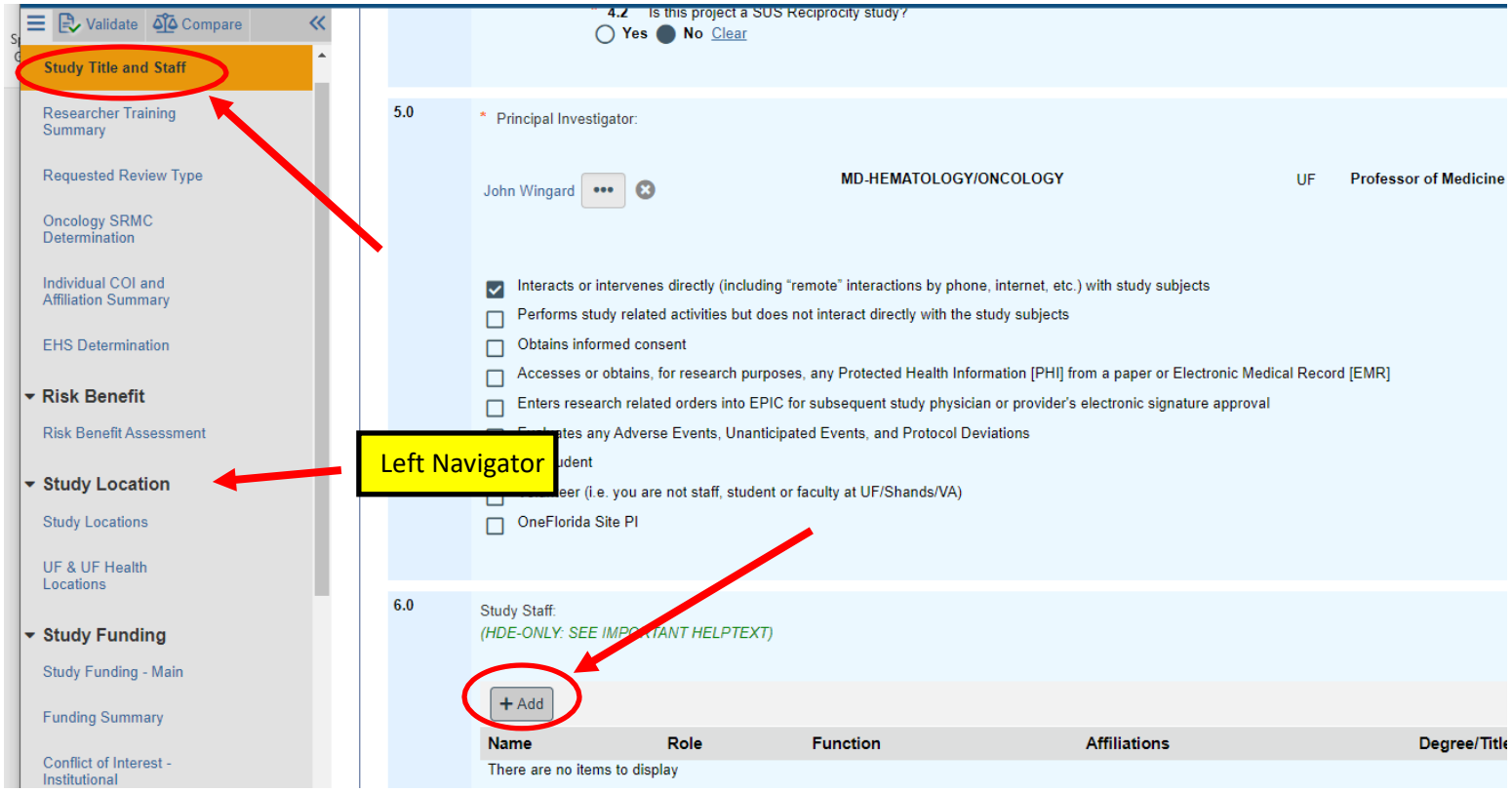
The Revision SmartForm contains information which informs IRB of the changes which will be made to the study. To edit the study SmartForms to reflect the changes outlined in the Revision, click **Edit Modified Study** on the left side of the **Revision Summary** page.

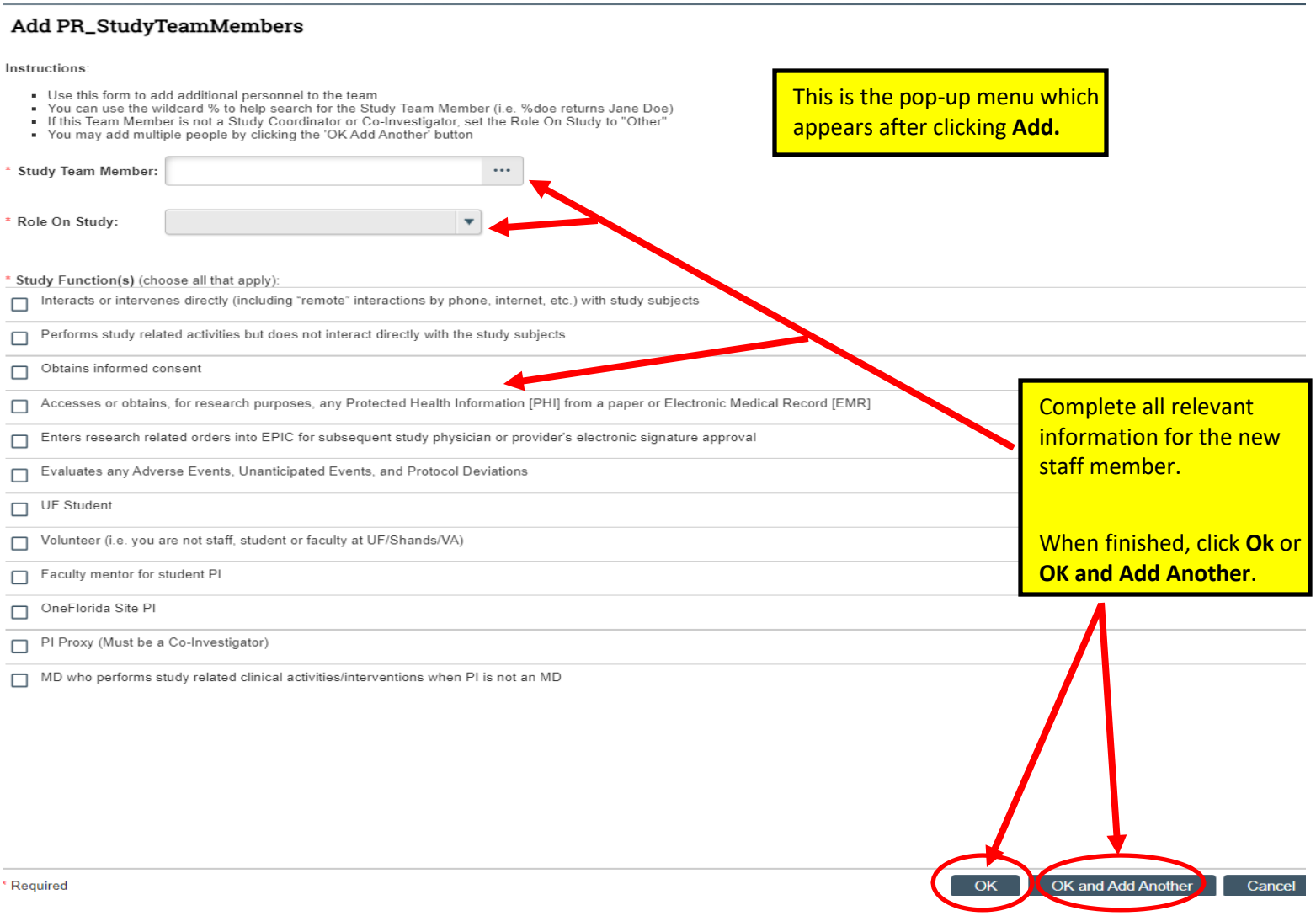


If your revision involves adding new study team member(s), follow these steps:

1. Click **Edit Modified Study** (screenshot above).
2. Then on the next screen, look for the **Left Navigator**. From there, click the **Study Title and Staff** SmartForm.
3. On that SmartForm, look for item 6.0: "Study Staff". From here, click **Add.** Doing so will open a pop-up window where you can complete the information relevant to this person (see screenshots below). When finished, click **OK** or **OK and Add Another**, depending on how many new staff you are adding to your study.
4. Lastly, utilize the Left Navigator to be redirected to a new SmartForm.

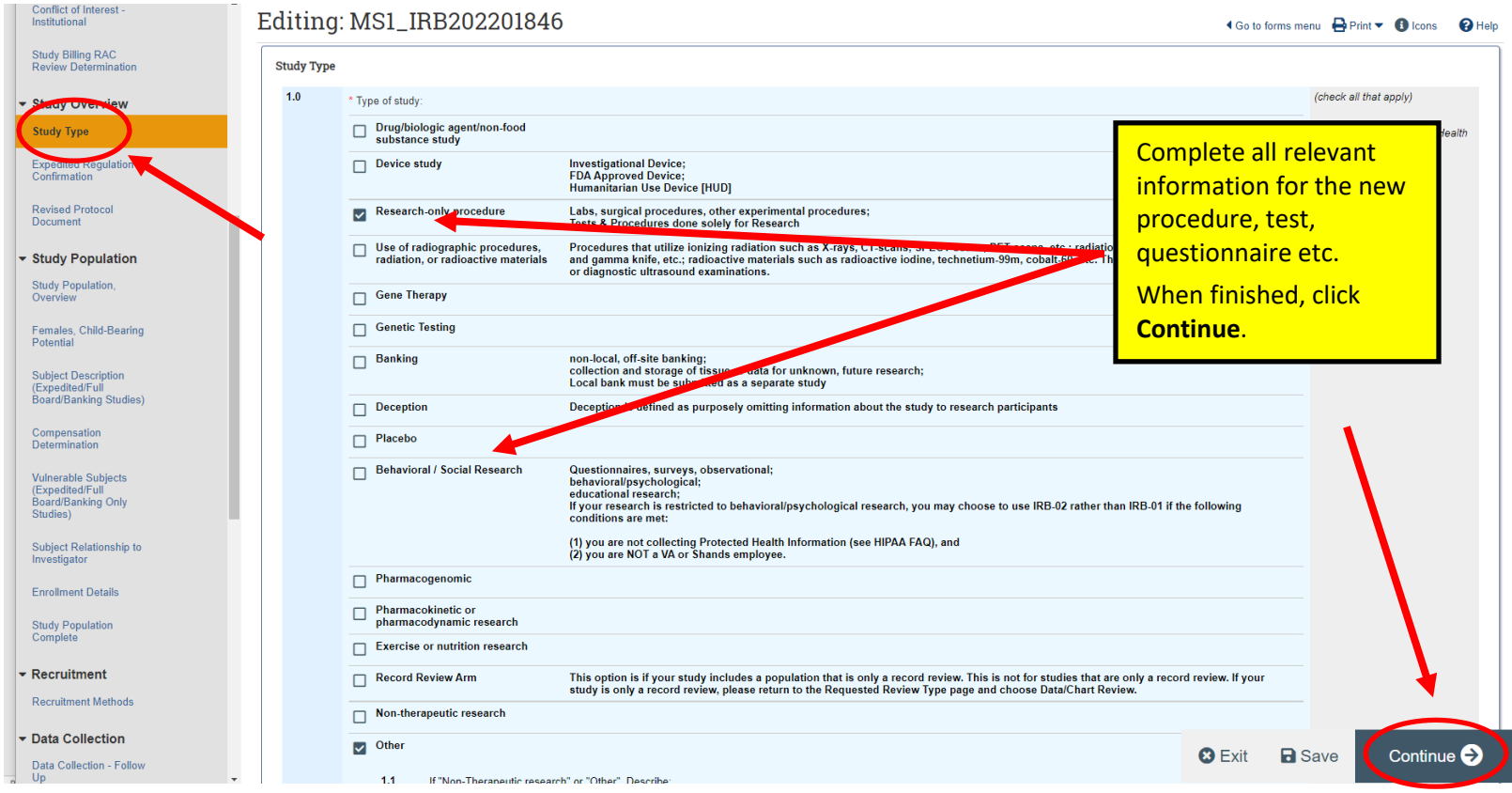
TIP: Before a person can be added to Study Staff, they **must** first register with *myIRB*. *See page 4 of this manual for details.*


Validate
Compare
Study Title and Staff
Researcher Training Summary
Requested Review Type
Oncology SRMC Determination
Individual COI and Affiliation Summary
EHS Determination
Risk Benefit
Risk Benefit Assessment
Study Location
Study Locations
UF & UF Health Locations
Study Funding
Study Funding - Main
Funding Summary
Conflict of Interest - Institutional
4.2 Is this project a SOS Reciprocity study?
Yes No Clear
5.0
* Principal Investigator:
John Wingard
MD-HEMATOLOGY/ONCOLOGY
UF
Professor of Medicine
Interacts or intervenes directly (including "remote" interactions by phone, internet, etc.) with study subjects
Performs study related activities but does not interact directly with the study subjects
Obtains informed consent
Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR]
Enters research related orders into EPIC for subsequent study physician or provider's electronic signature approval
OneFlorida Site PI
Left Navigator
6.0
Study Staff:
(HDE-ONLY: SEE IMPORTANT HELPTEXT)
+ Add
Name
Role
Function
Affiliations
There are no items to display


Add PR_StudyTeamMembers
Instructions:
Use this form to add additional personnel to the team
You can use the wildcard % to help search for the Study Team Member (i.e. %doe returns Jane Doe)
If this Team Member is not a Study Coordinator or Co-Investigator, set the Role On Study to "Other"
You may add multiple people by clicking the 'OK Add Another' button
This is the pop-up menu which appears after clicking Add.
* Study Team Member:
* Role On Study:
* Study Function(s) (choose all that apply):
Interacts or intervenes directly (including "remote" interactions by phone, internet, etc.) with study subjects
Performs study related activities but does not interact directly with the study subjects
Obtains informed consent
Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR]
Enters research related orders into EPIC for subsequent study physician or provider's electronic signature approval
Evaluates any Adverse Events, Unanticipated Events, and Protocol Deviations
UF Student
Volunteer (i.e. you are not staff, student or faculty at UF/Shands/VA)
Faculty mentor for student PI
OneFlorida Site PI
PI Proxy (Must be a Co-Investigator)
MD who performs study related clinical activities/interventions when PI is not an MD
Complete all relevant information for the new staff member.
When finished, click Ok or OK and Add Another.
* Required
OK
OK and Add Another
Cancel

To add a new, research only procedure (e.g., new chest X-Ray), the PI/Study Team must revise the **Study Type** smart form. Here, enter the information related to the new procedure. For example, this SmartForm was revised to include **Research-only procedure** given that the "new" chest X-Ray is for research purposes only.

If questionnaires are being added, click **Behavioral /Social Research**.



TIP: After adding a new Study Type, hit the **Continue** button to complete the associated SmartForm. Because changing the Study Type may alter branching for later SmartForms, it is best practice to **click through the remaining SmartForms** and view each page carefully to ensure no new SmartForms have appeared which need to be completed.

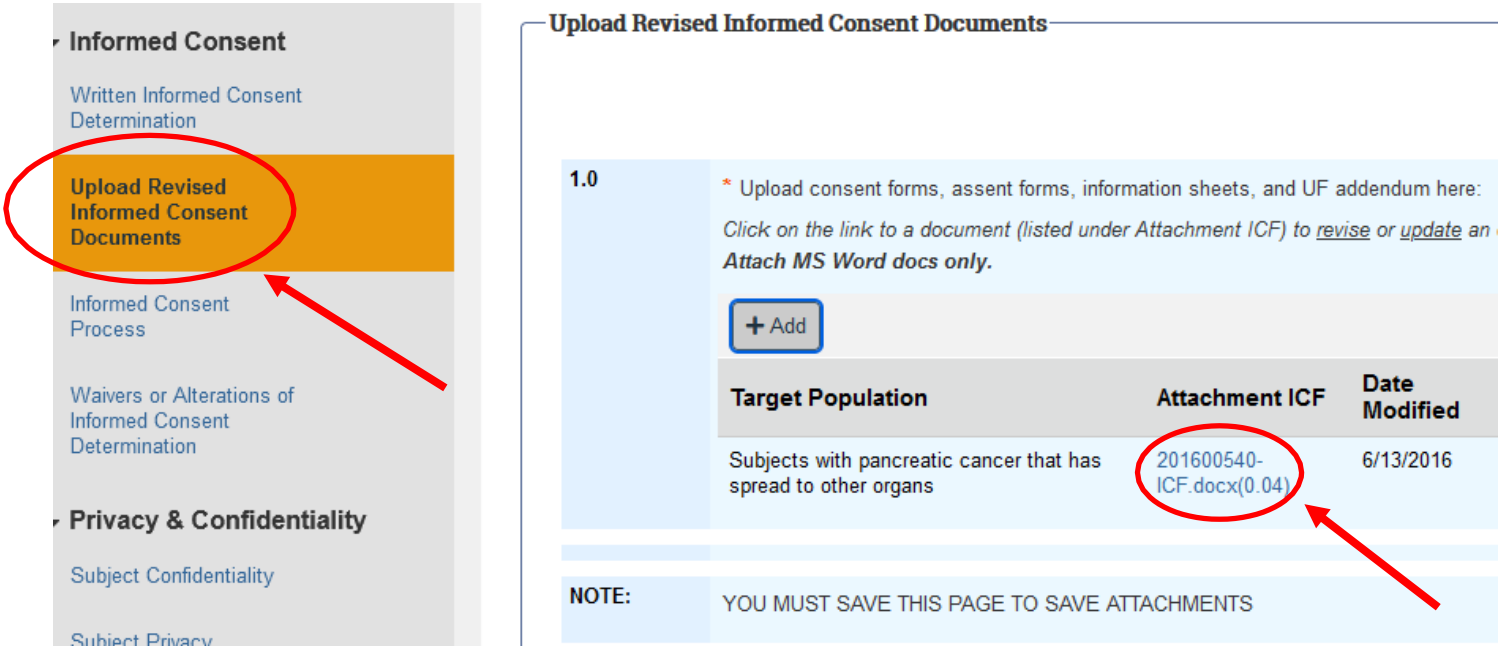
Revising Attached Documents (e.g., Protocol, ICF, Flyer)

To access documents that need to be revised, click on **Edit Modified Study**. From there, use the **Left Navigator** to access the appropriate SmartForm.

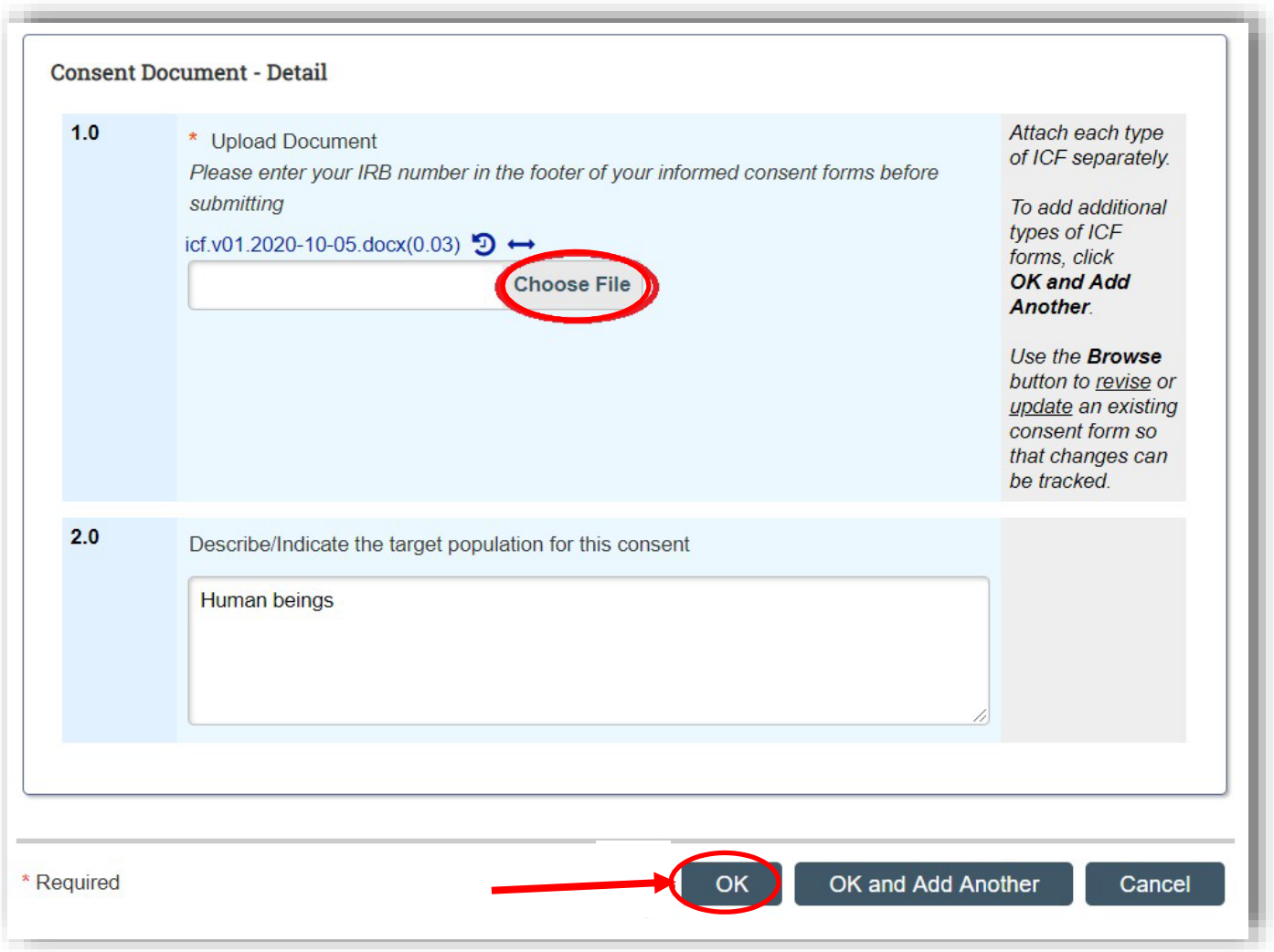
TIP: Best practices dictate that study teams should download these documents from their *myIRB* project submission. Doing so ensures the study team has the most current IRB approved version of the document. Do not upload document(s) from a personal computer.

To submit a Revised ICF, follow these steps (see screenshots below also):

1. Log in to the **Revision** and click **Edit Modified Study**.
2. With the **Left Navigator**, access the **Upload Revised Informed Consent** SmartForm.
3. Then, **download** the ICF from this page onto your computer.
4. Once downloaded, update the ICF as needed, using **Track Changes**.
5. Next, **save** the revised ICF to your computer or personal drive.
6. From there, return to the **Upload Revised Informed Consent Documents** SmartForm.
7. Next, click the **document name** to be replaced to upload your revised document.
    a. A reminder that all ICFs **must** be submitted in Microsoft Word format.



A new window will open with a **Choose File** command. Click on this button to upload the revised ICF. Once the SmartForm is complete, click **OK**.

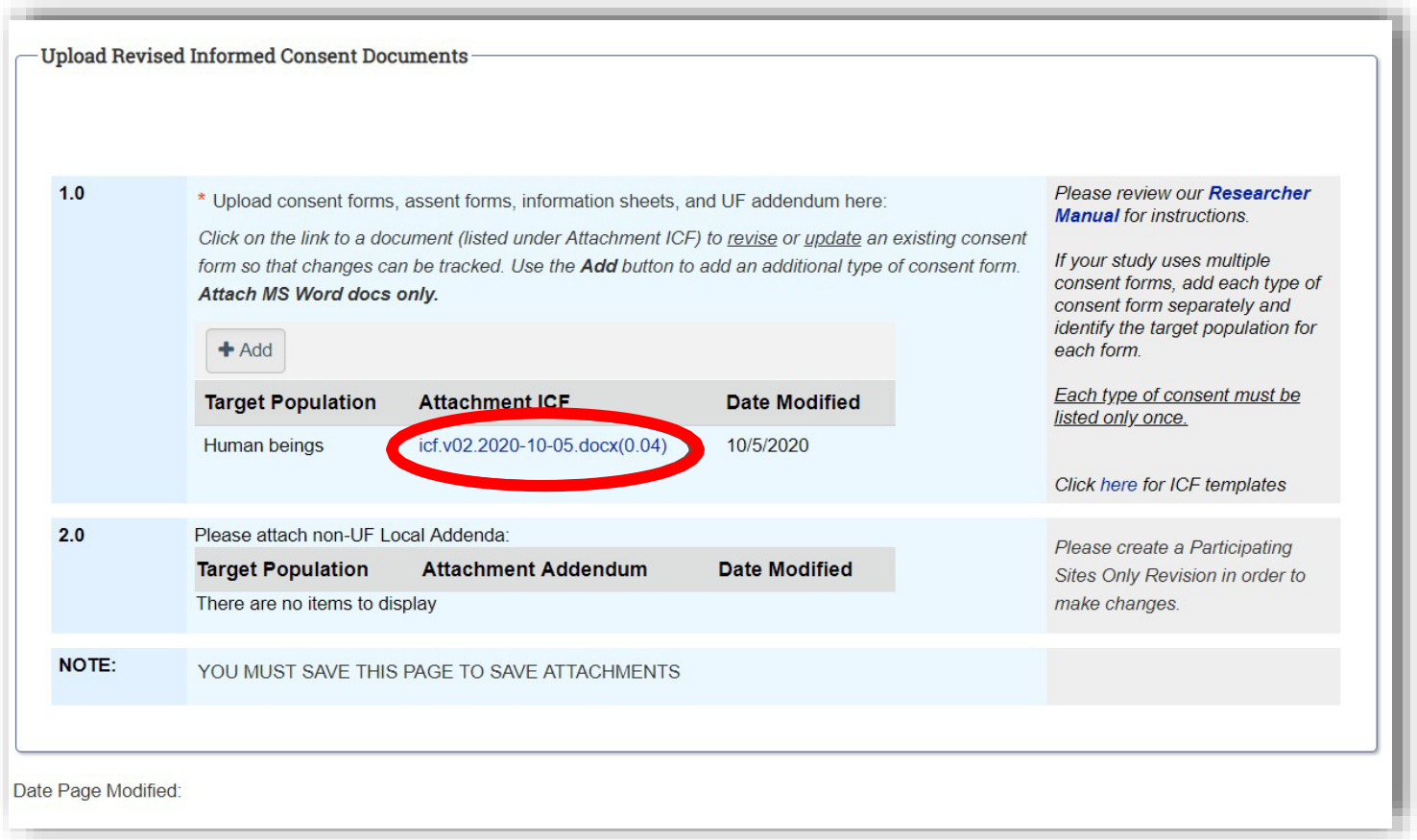


TIP: When uploading the ICF, only attach the revised version (i.e., the one with tracked changes included). **Do not** attach both a revised copy and a "clean" copy. If you do not attach a version with tracked changes, IRB will return the revision.

TIP: When updating your revised ICF, please include the document type as an extension at the end of your document title (e.g., ".doc" or ".docx").

On the **Consent Document – Detail** screen, provide a new title/identifier for this informed consent. If a study has multiple consents, each can be denoted by a specific title. The document title listed here will be recorded as the title in the **Stamped Documents** tab. This will occur once IRB approval is received and the document is finalized (i.e., IRB stamped).

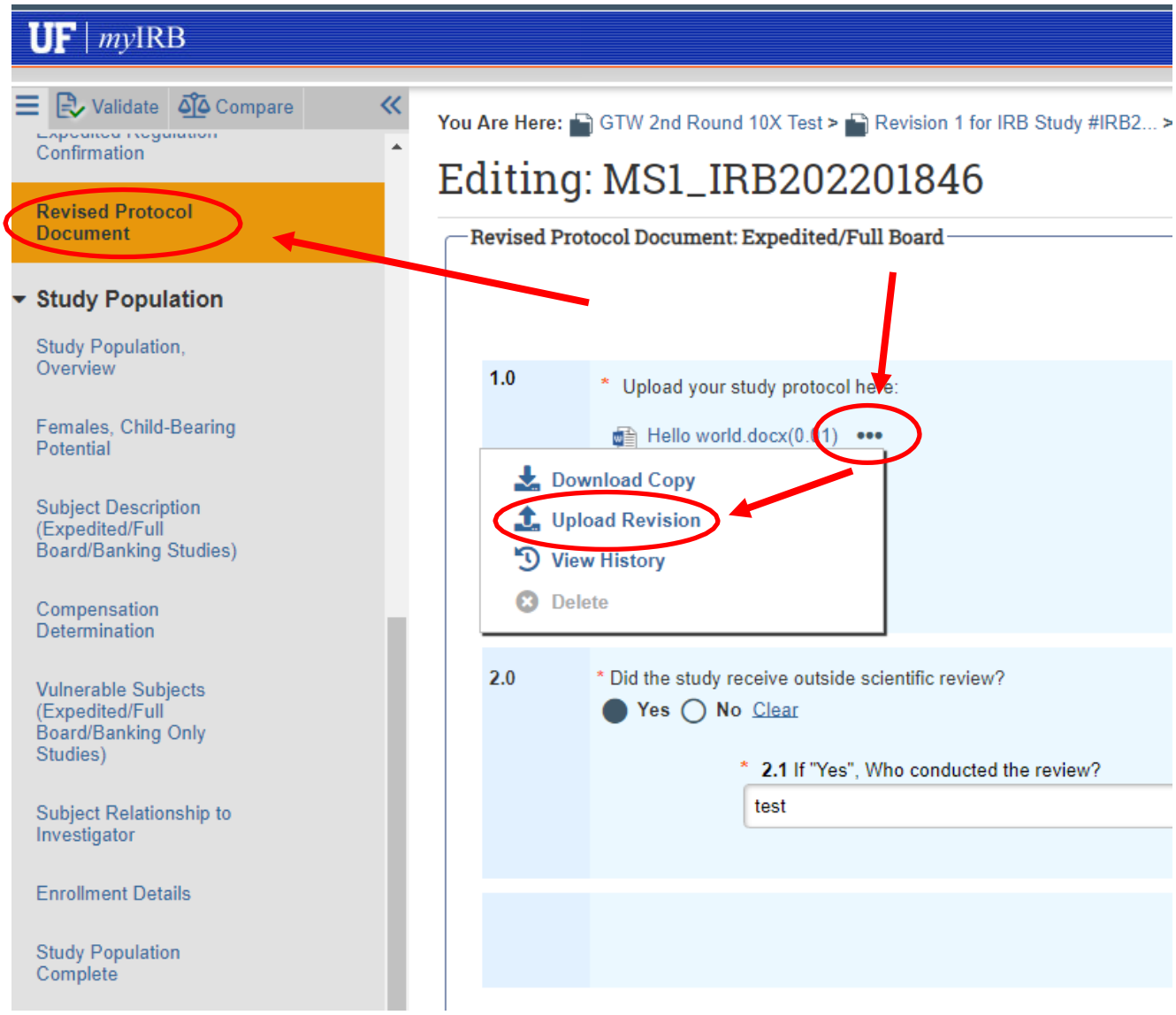
After uploading the revised ICF, click **OK** to exit. The newly uploaded ICF will replace the previous ICF version. Note the version number change below (from 0.03 to 0.04.)

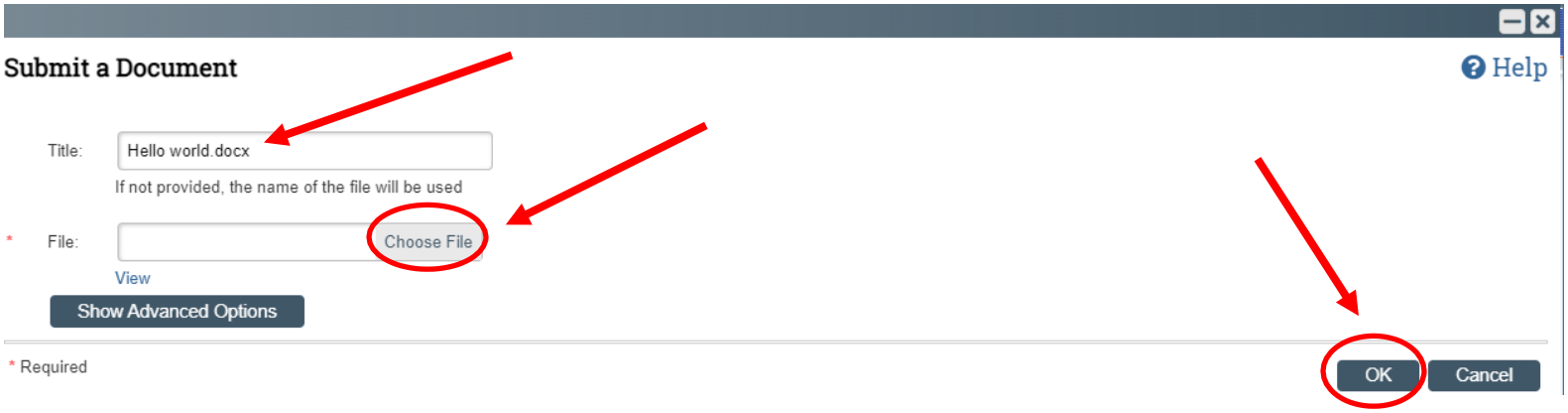


To revise the **Study Protocol**, follow these steps:

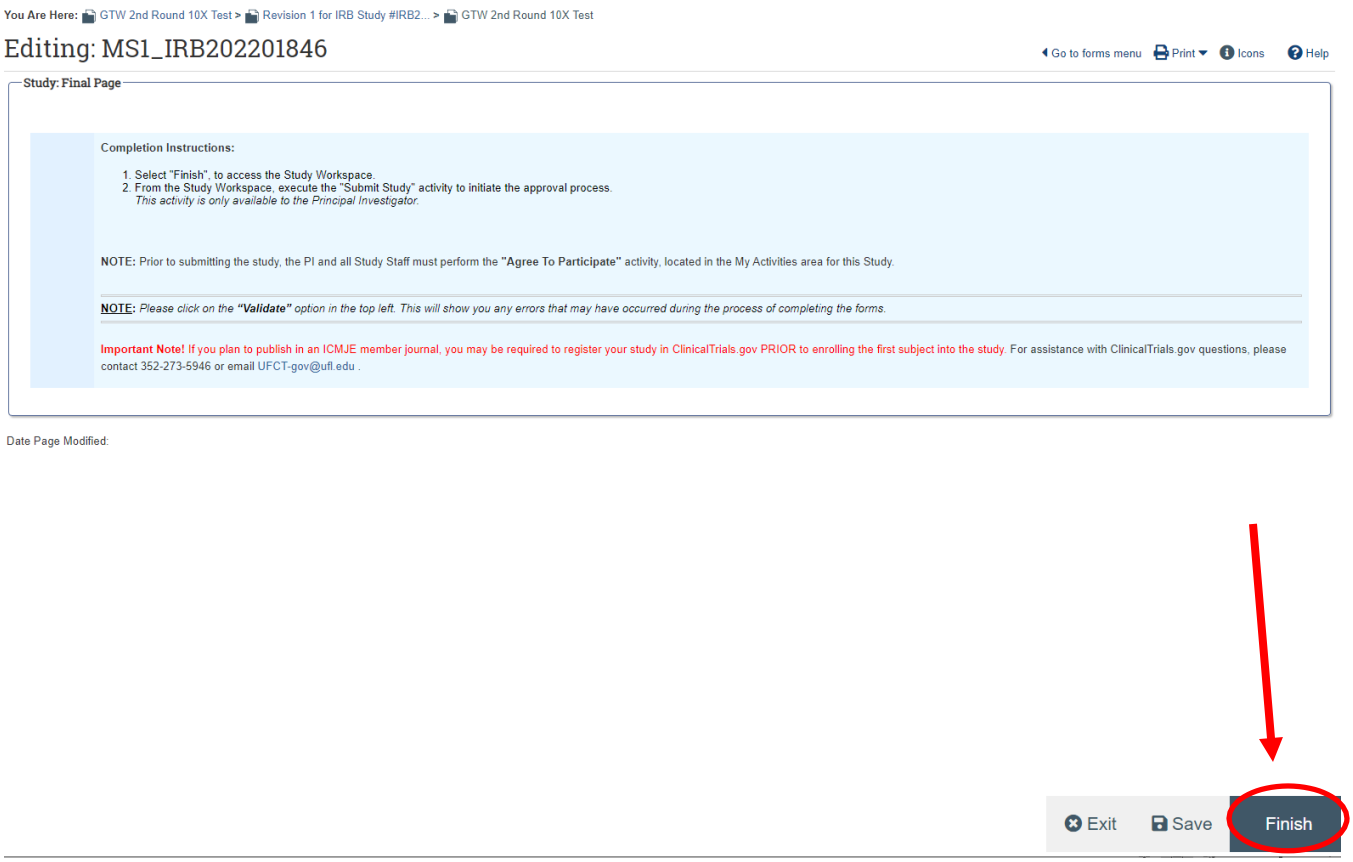
1. Log in to the **Revision** and click **Edit Modified Study**.
2. With the **Left Navigator**, access the **Revised Protocol Document** SmartForm.
3. Then, **download** the protocol from this page onto your computer.
4. Once downloaded, update the protocol as needed using **Track Changes**.
5. Next, **save** the revised protocol to your computer or personal drive.
6. From there, return to the **Revised Protocol Document** SmartForm.
7. After that, under Question 1.0, click the **3 horizontal dots** next to the protocol name. Then, select **Upload Revision**.
8. On the next screen, **title** the document, and then click **Choose File** to add the revised protocol to this SmartForm.
9. Lastly, click **OK** to exit.

A reminder that all Protocols must be submitted as Microsoft Word documents.





Once the revised protocol has been uploaded, proceed through the remaining SmartForms until reaching the **Final Page.** As with previous submission types, click **Finish** in the lower right-hand corner of the page to complete the revision and exit **Edit Modified Study**.



Revisions to flyers, brochures, questionnaires, and data tools will follow the same pattern as uploading a revised ICF or a revised Protocol. Be sure to review all SmartForms to identify the correct SmartForm where these new document(s) should be uploaded.

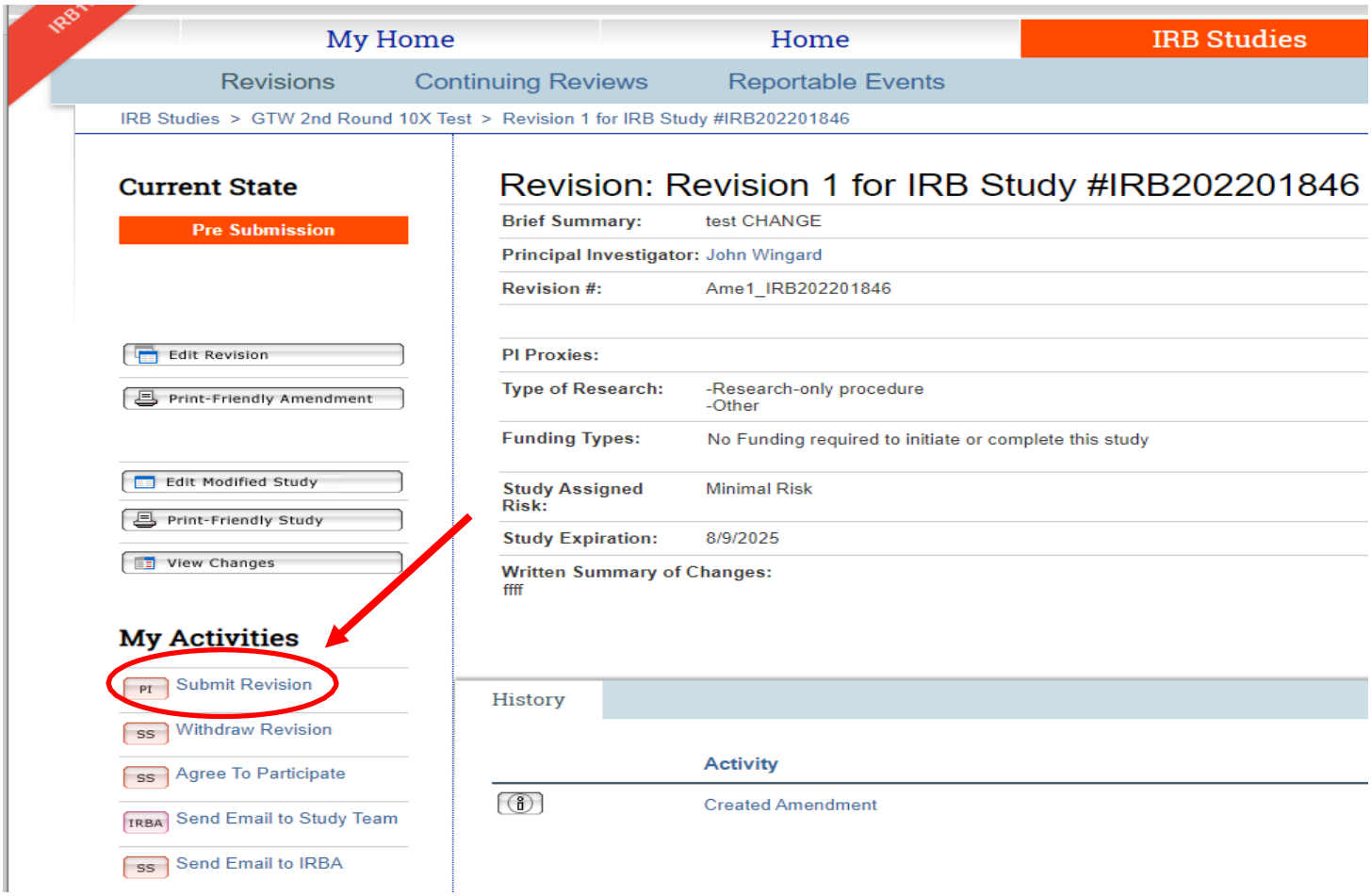
Since this revision involved the addition of study procedures for research purposes, it will require review by UF Office of Clinical Research (UF OCR). Please attach a revised OCR Grid and other documents alongside this revision. **Do not** submit these forms separately to OCR.

When all information for this Revision has been added to the **Edit Modified Study,** the PI / PI Proxy can submit the revision to IRB. Remember two key points:

1. If new study staff have been added under this Revision, all persons must **Agree to Participate** before submitting the Revision to IRB.
2. **Only** PIs or PI Proxies can submit revisions.

To submit a Revision, log-in to the Revision Workspace. There, in the left-hand column under

My Activities, click **Submit Revision**.



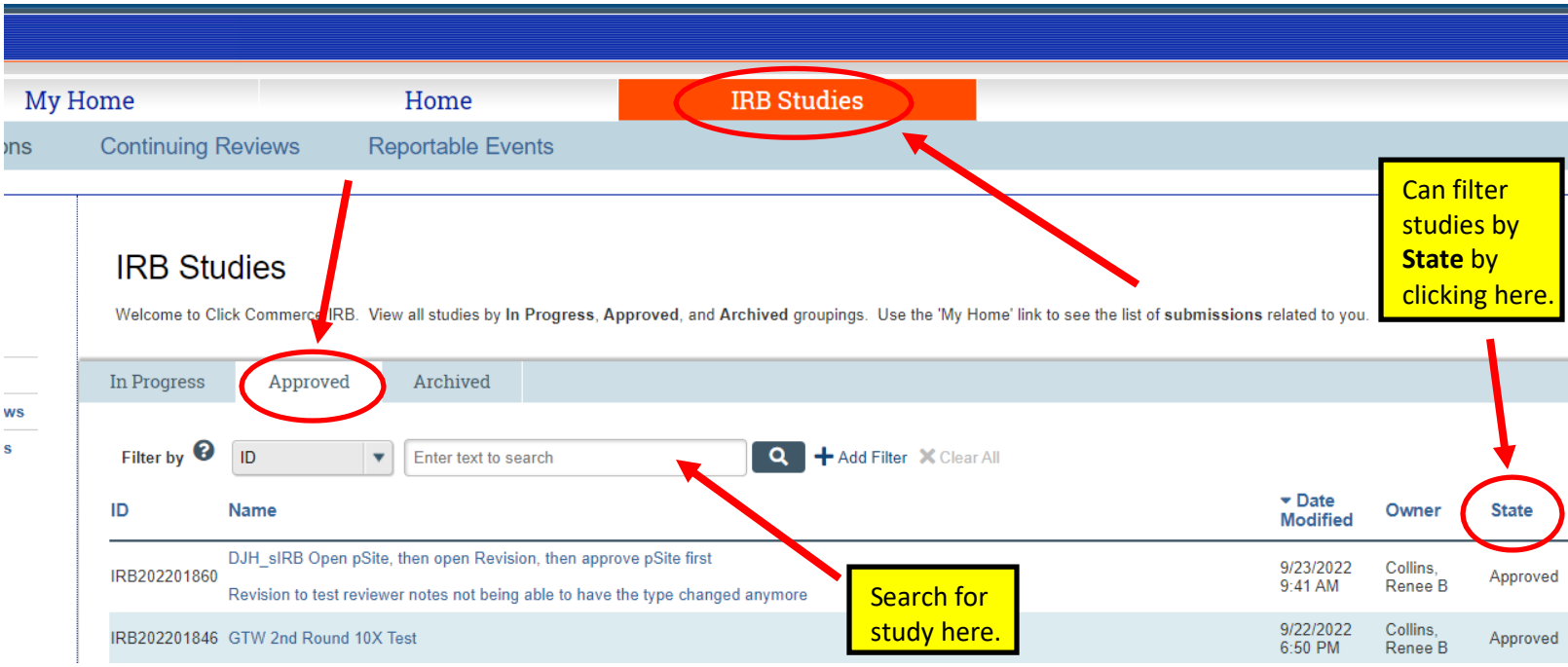
Once the PI/Proxy has submitted the Revision to IRB, the study team will receive an email notification if changes need to be implemented or if more information must be provided.

Copying Studies

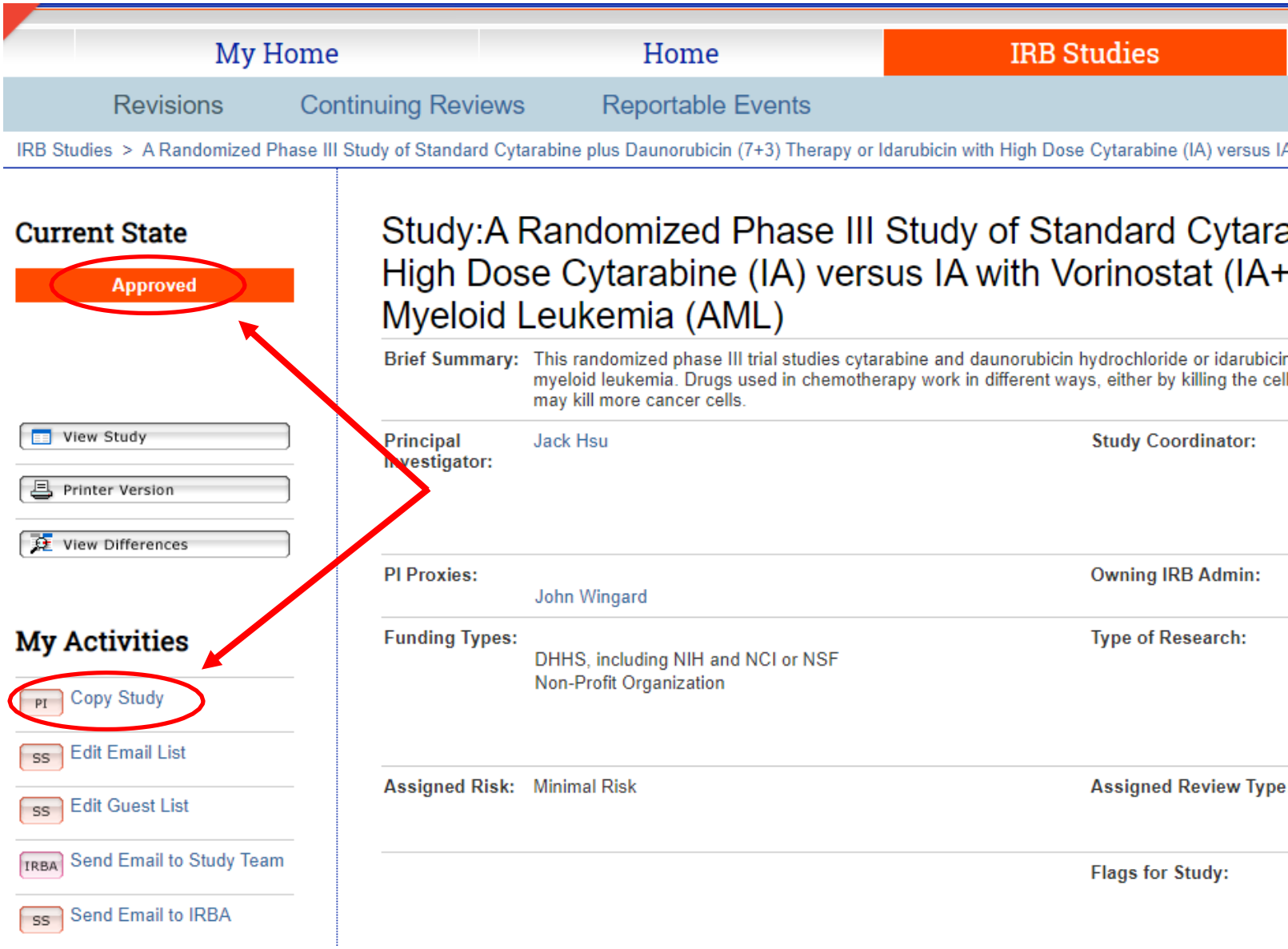
It is possible to copy the details of one study (i.e., all SmartForms) to use as a starting point for starting another study. To be eligible for copy, a study must be in the **Pre-Submission** or **Approved** state.

To copy a study, follow these steps:

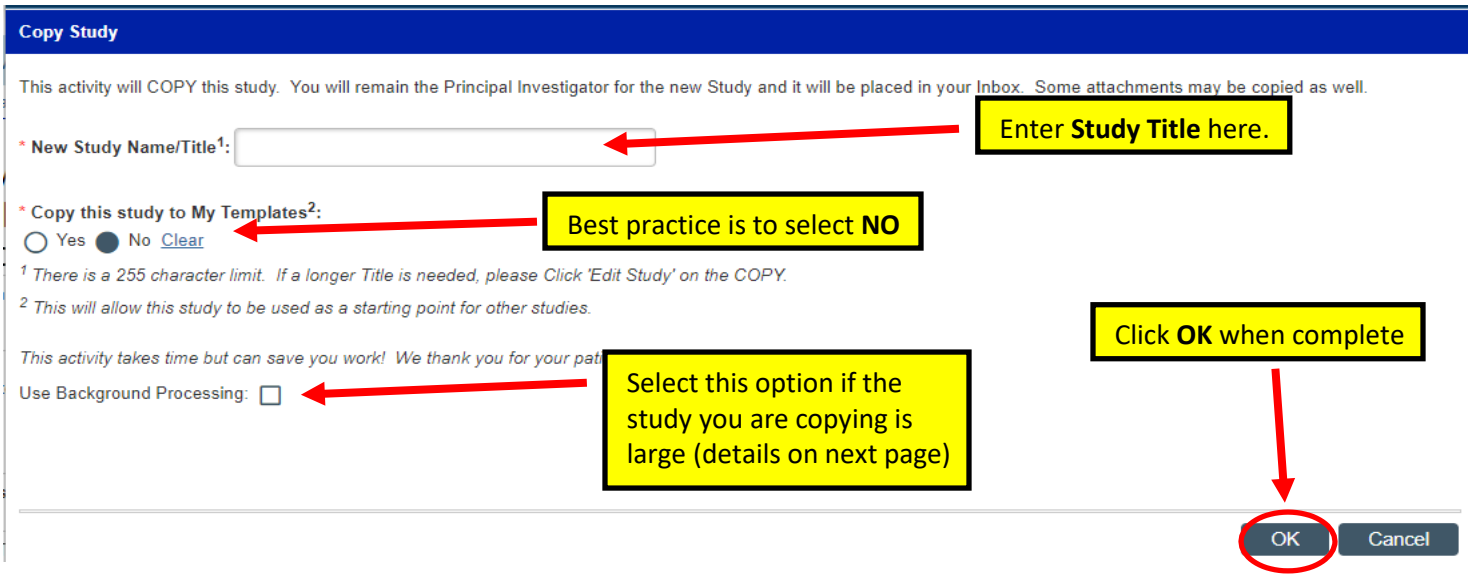
d. Log-in to *myIRB*. Doing so will automatically redirect you to the **My Home** tab.
e. From here, click the **IRB Studies** tab at the top of the page.
f. Next, click the **Approved** tab located in the middle of the page.
g. From here, search for the study you wish to copy and click the **Study Name**.



After clicking the study name, you will be redirected to the study workspace. From here, click **Copy Study** under **My Activities** on the left-hand side of the page.



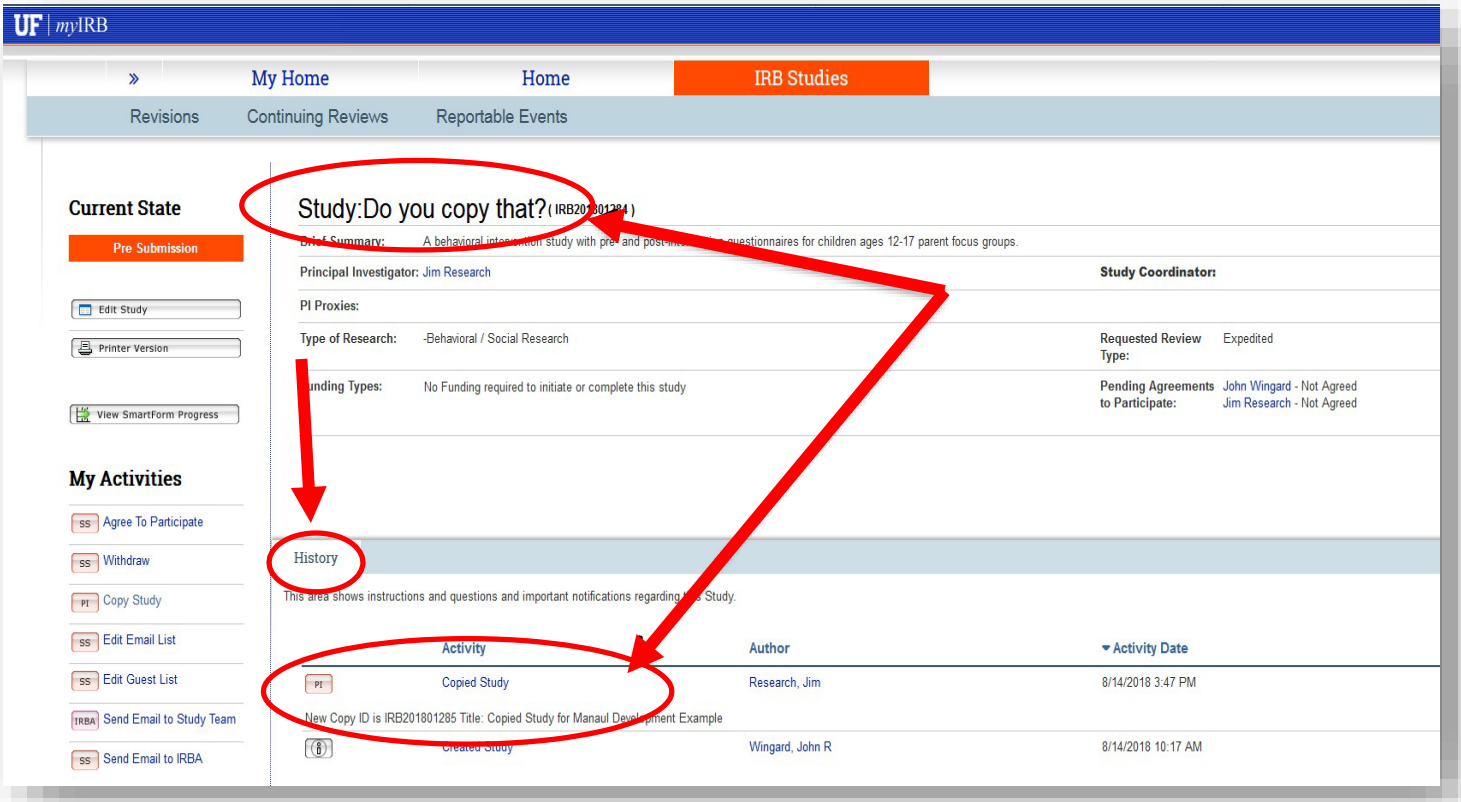
After clicking **Copy Study**, the following screen will appear. Follow directions in the screenshot:



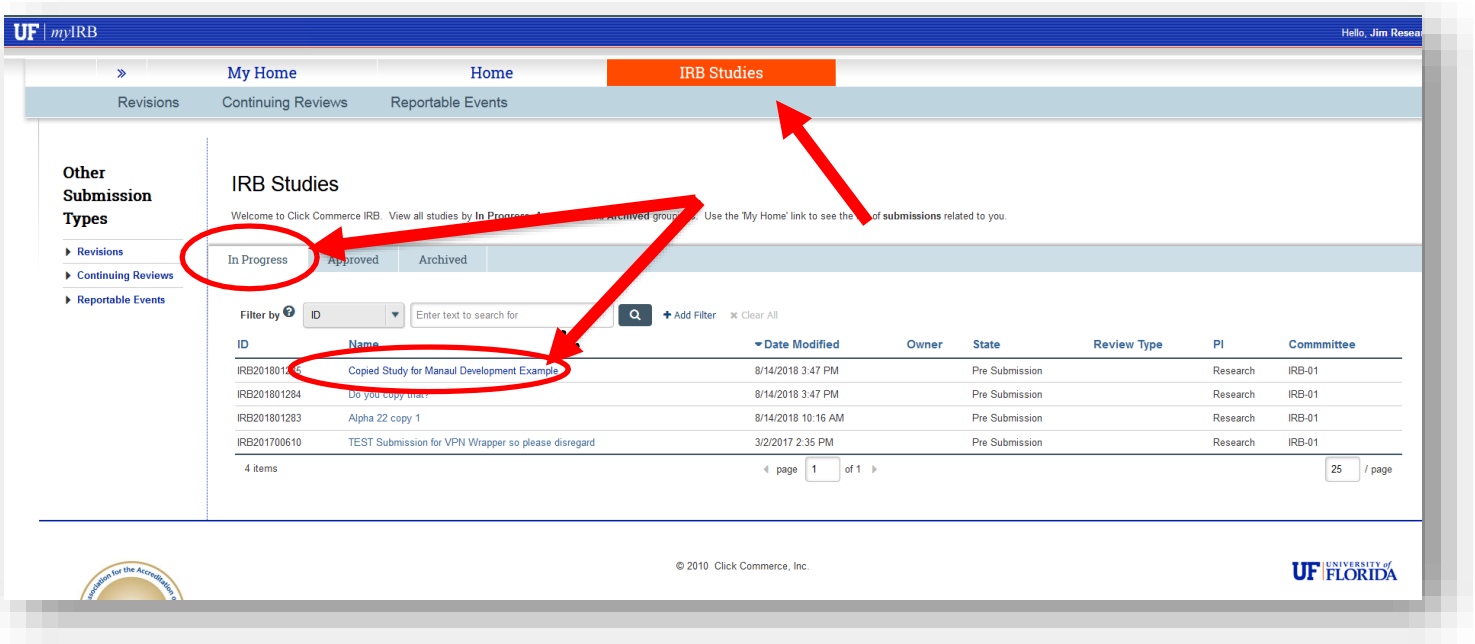
The copying process can take several minutes to complete. As referenced in the screenshot above, if the study being copied is large or has significant branching (e.g., involving drugs, questionnaires, devices, radiology, etc.), study teams are encouraged to select the **Use Background Processing** feature. If this item is checked, the **Copy Study** window disappears, and the user receives a message to refresh their screen to see when copying is finished.

If the Background Processing option **is not** chosen, users must wait until *my*IRB has copied the study entirely before attempting to complete any further work in myIRB.

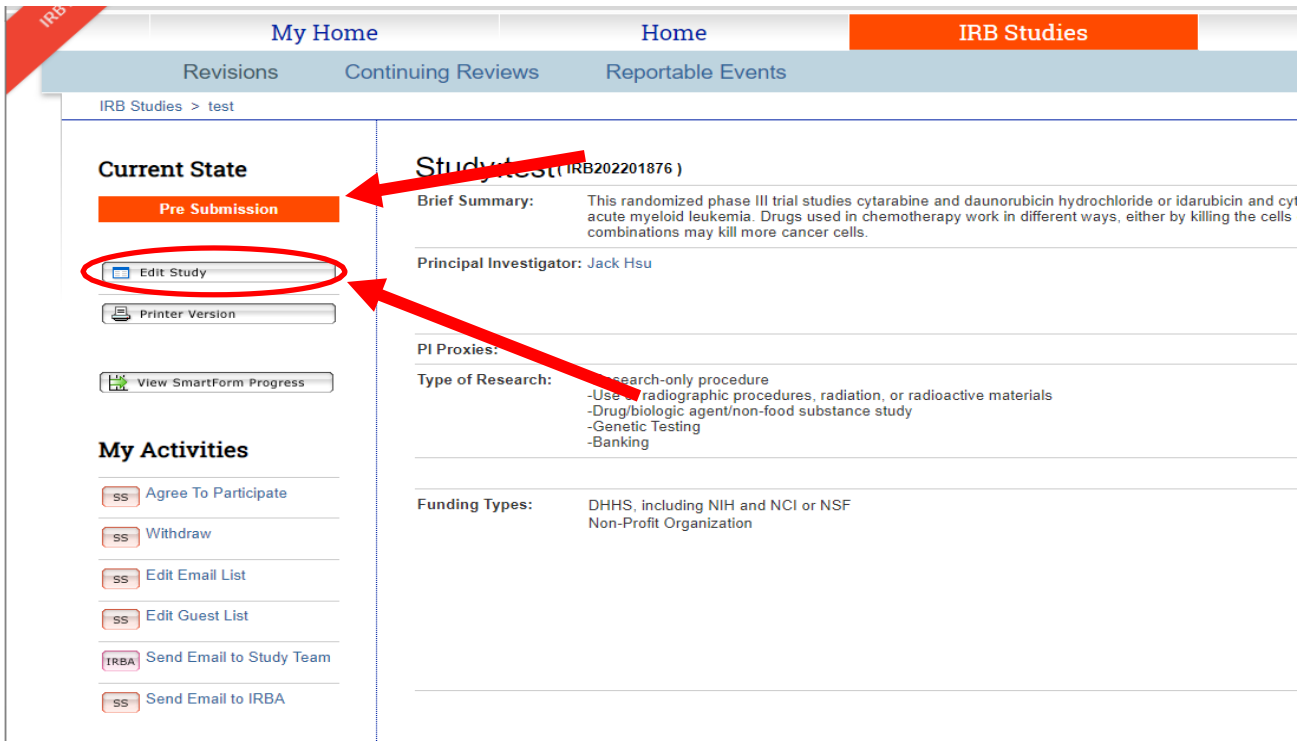
Once *my*IRB has copied the study, users will be redirected to the original approved study page. There under the **History** tab, the **Copied Study** will be listed as the first item.



To access the newly copied study, click the **IRB Studies** tab at the top of the screen. By default, the **In Progress** tab in the middle of the screen will be selected. Under that tab, the newly copied study (listed with a new title/IRB number) will appear. Click the **study name**.

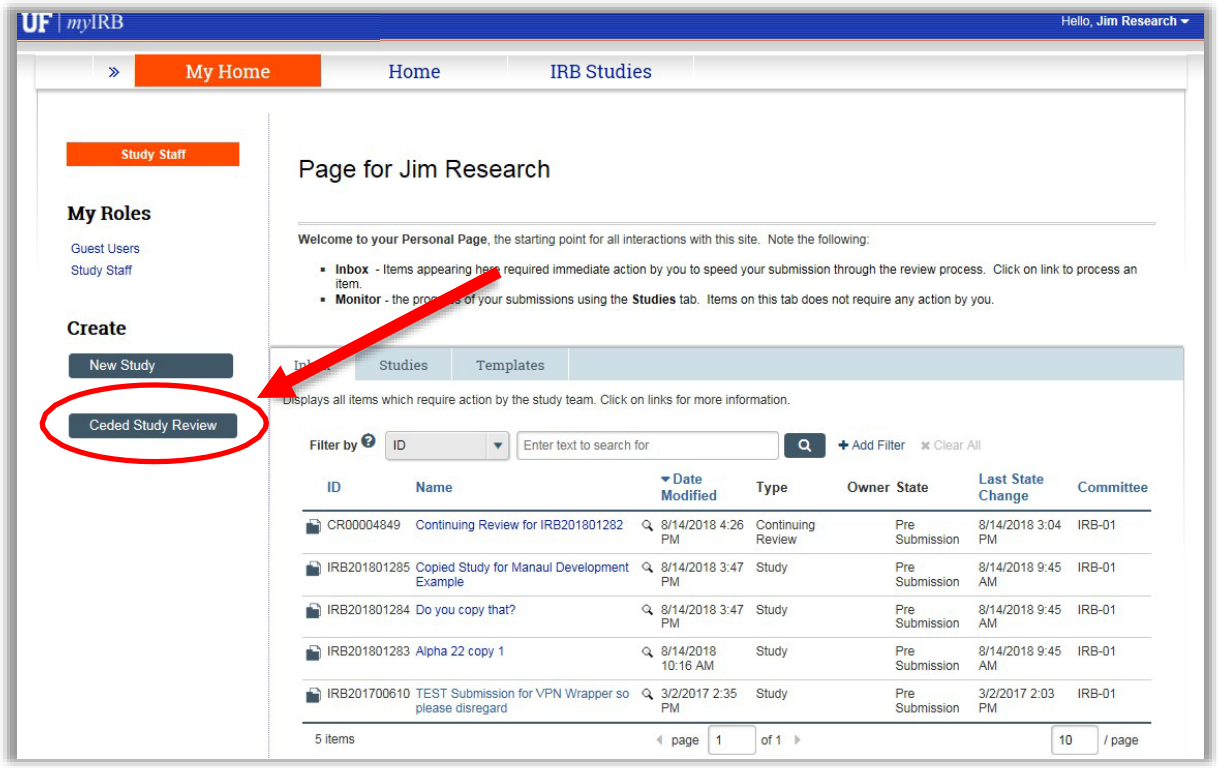


From there, users will be directed to the main study workspace. The study will be in **Pre-Submission** state. To edit SmartForms, click **Edit Study** on the left side of the page. As with other submissions, users will need to upload all documents specific to the new study.



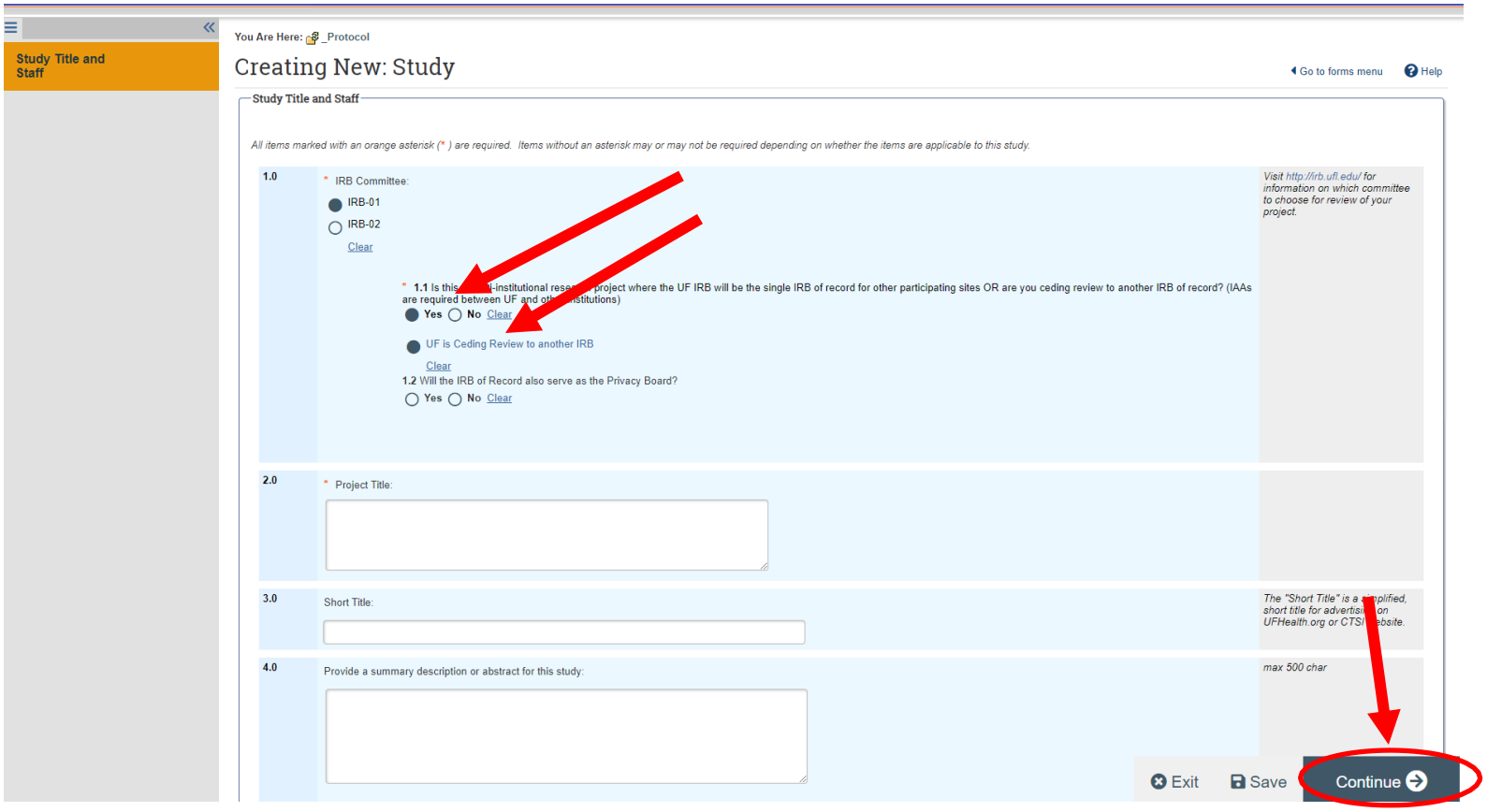
Creating a Ceded Study Review

To create a Ceded Study Review, first **log-in** to *myIRB.* Next, under **Create** on the left side of the page, select **Ceded Study Review.**

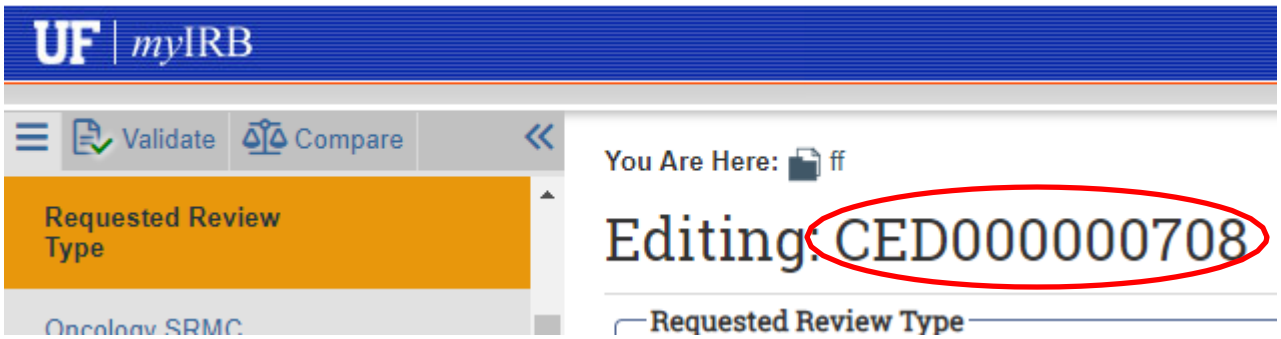


On the subsequent SmartForm, note the addition of Question 1.1 on the **Study Title and Staff** page. By default, both **Yes** and **UF is Ceding Review to another IRB** will be selected. If a user clears either option, they will receive an error message when clicking **Continue** at the bottom of the SmartForm. This pathway is for Ceded Submissions **only**.

If Ceded Study Review was selected in error, exit the SmartForm.



Ceded submissions have a unique ID#. The prefix will be **CED**, and the following number will not contain the year but rather, will be numbered chronologically. For example, this is the 708th Ceded submission in myIRB:



Next, complete the remaining SmartForms as per a normal study submission. Note that many of the branching SmartForms will be removed for a Ceded submission.

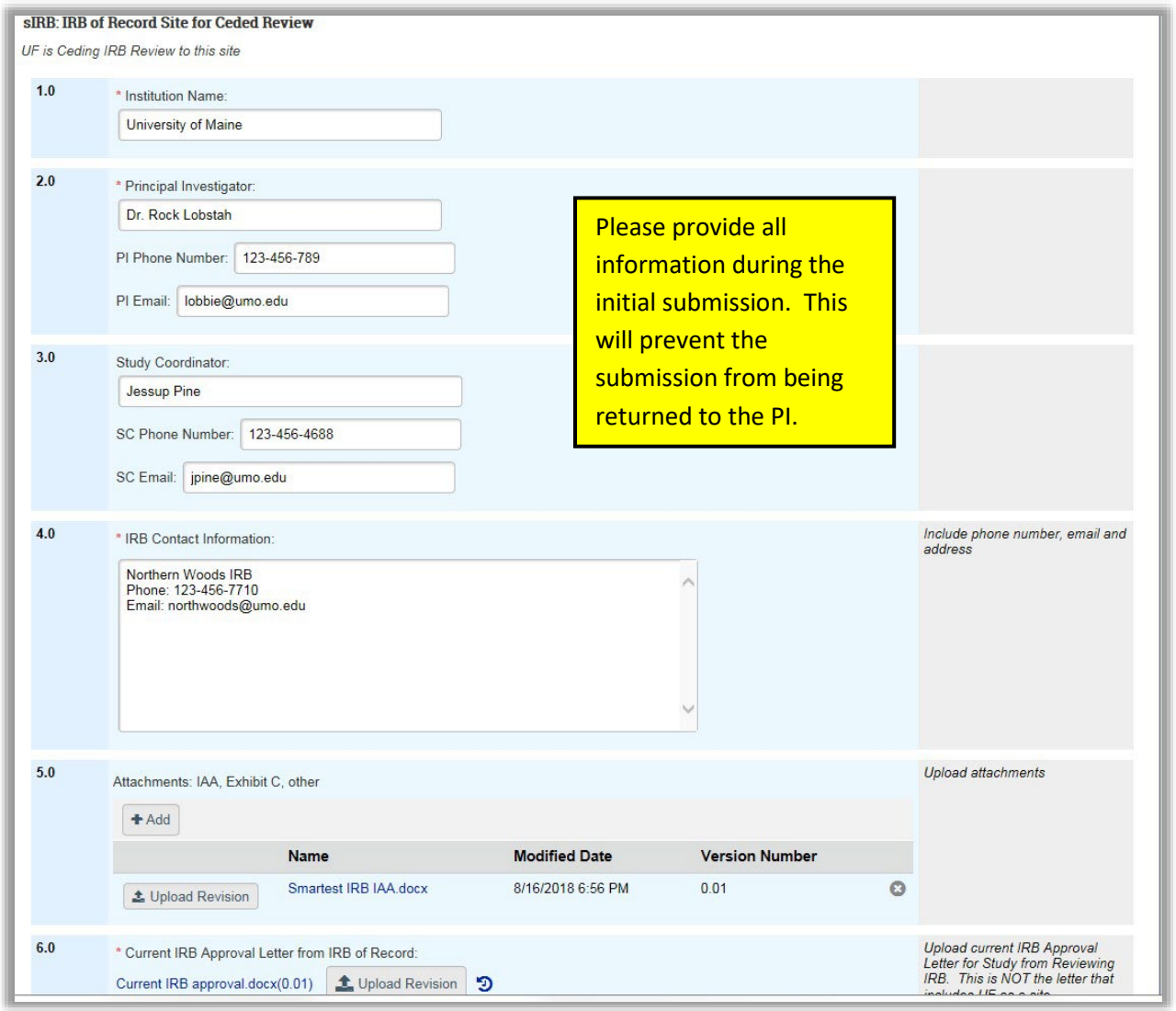
Ceded submissions contain several new SmartForms which are not present in a typical submission. Each is described below:

***s*IRB: IRB of Record Site for Ceded Review**

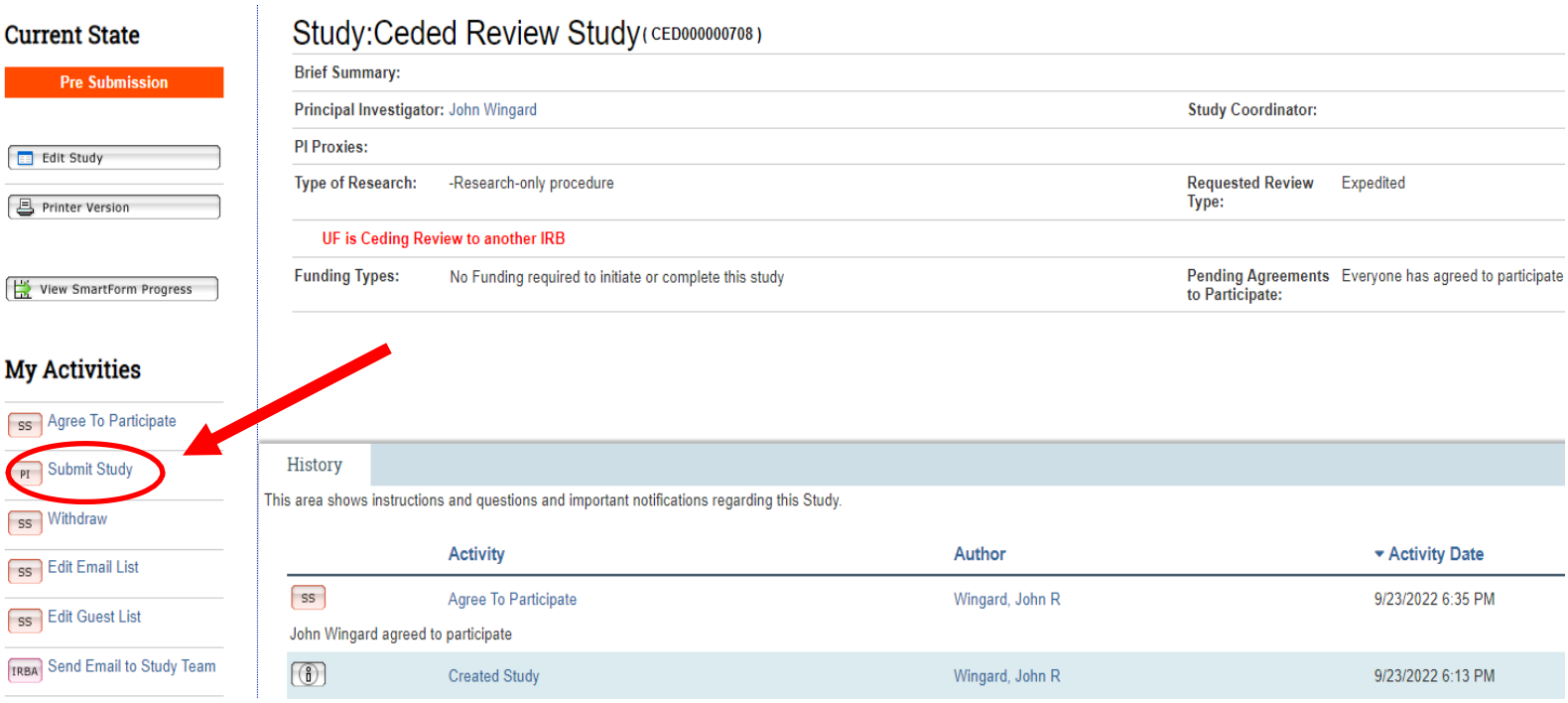
This page contains information for the IRB to whom UF is ceding oversight.

On this form, please provide:

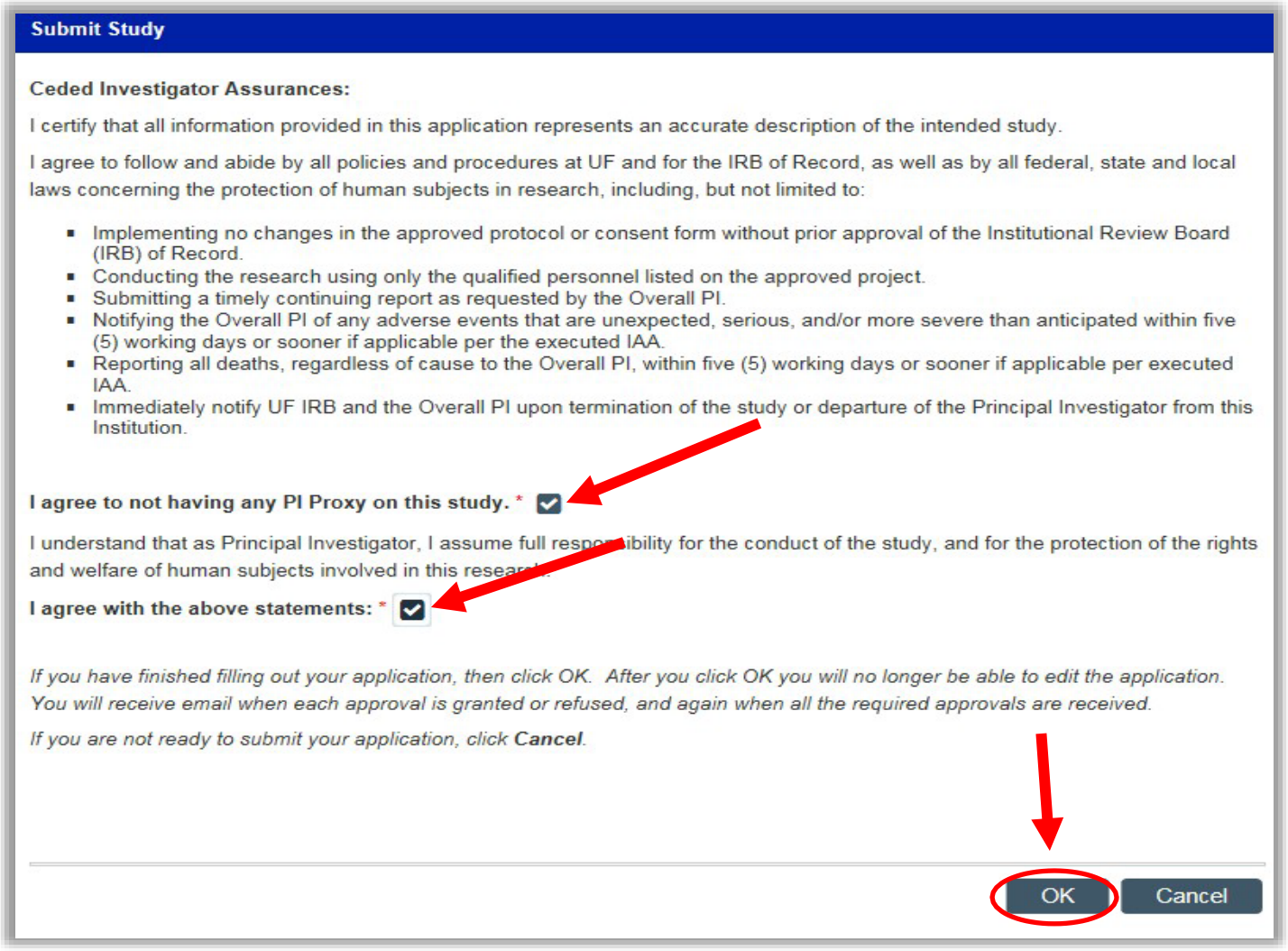
- The name of the Institution to whom UF is ceding review.
- Site PI name and Site Study Coordinator name.
- Site IRB Contact information.
- The fully executed IAA agreement (upload this document).
- Approval letter for the study from the institution overseeing regulatory oversight.



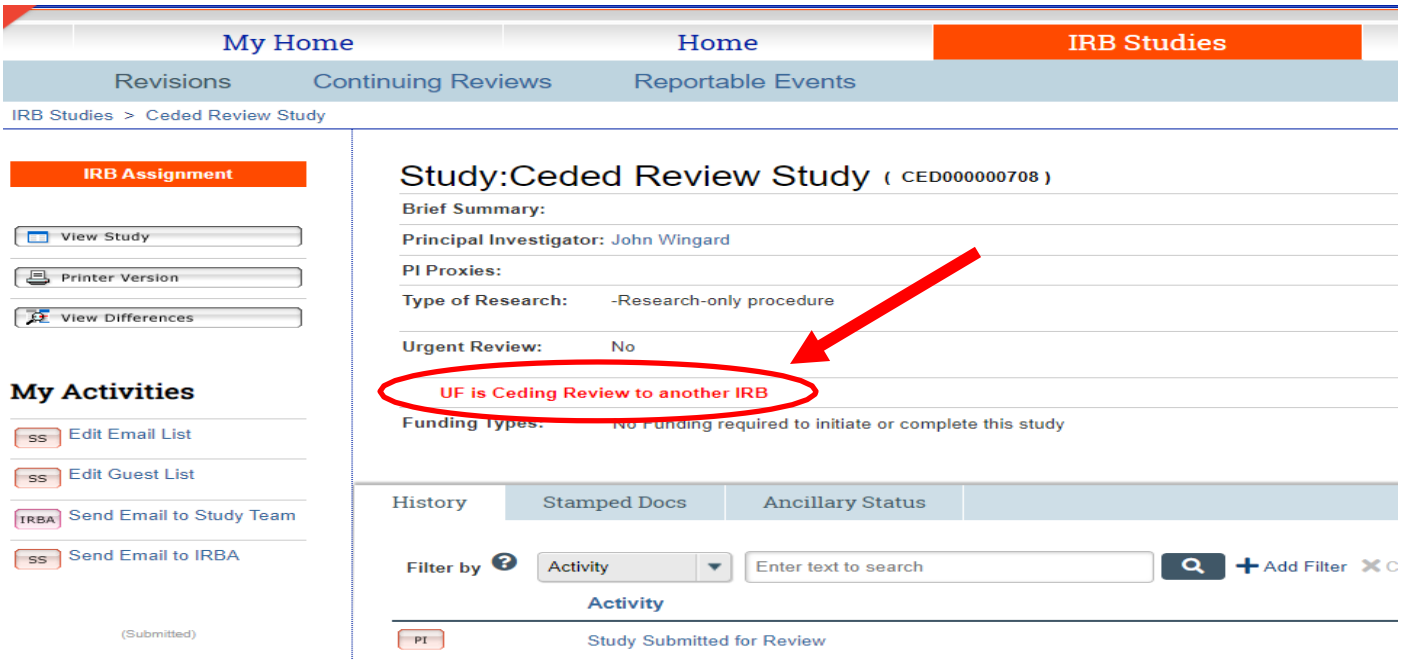
Remember that the PI or PI Proxy are the only individuals who can submit a Ceded Study Review. To submit the study, click **Submit Study** under **My Activities** on the left side of the main study workspace.



Before the system will execute the submission of a Ceded Study Review, the PI must agree to the **Ceded Investigator Assurances** language. The following screen will appear when the PI selects **Submit Study** (see prior screenshot). These assurances are repeated in the final **Approval to Cede Review** letter and **Ceded Continuing Review Renewal Letters.** The PI should select all relevant boxes and click **OK** to submit the study for review.



Below is a screenshot displaying how the study workspace will look once the Ceded Review has been submitted to IRB. Note the red font which indicates that this is a Ceded Review.



Once the study is submitted to IRB, here are the next steps:

In Ceded Review

- First, a designated IRB staff member takes ownership of the study and assigns it to an Executive Ceded Reviewer. The state of the study will be updated to **In Ceded Review**.

- The Executive Ceded Reviewer determines if there are any concerns with ceding study oversight to an external IRB. If nothing is preventing the ceding request, the Executive Ceded Reviewer will issue a **Needs Reply**, and the submission will return to the pre-review team.

- The pre-review staff member will note any required changes and return the submission to the study team while any ancillary reviews are completed. The study state would then be updated to **In Ceded Review – IRB Staff Changes Requested**.

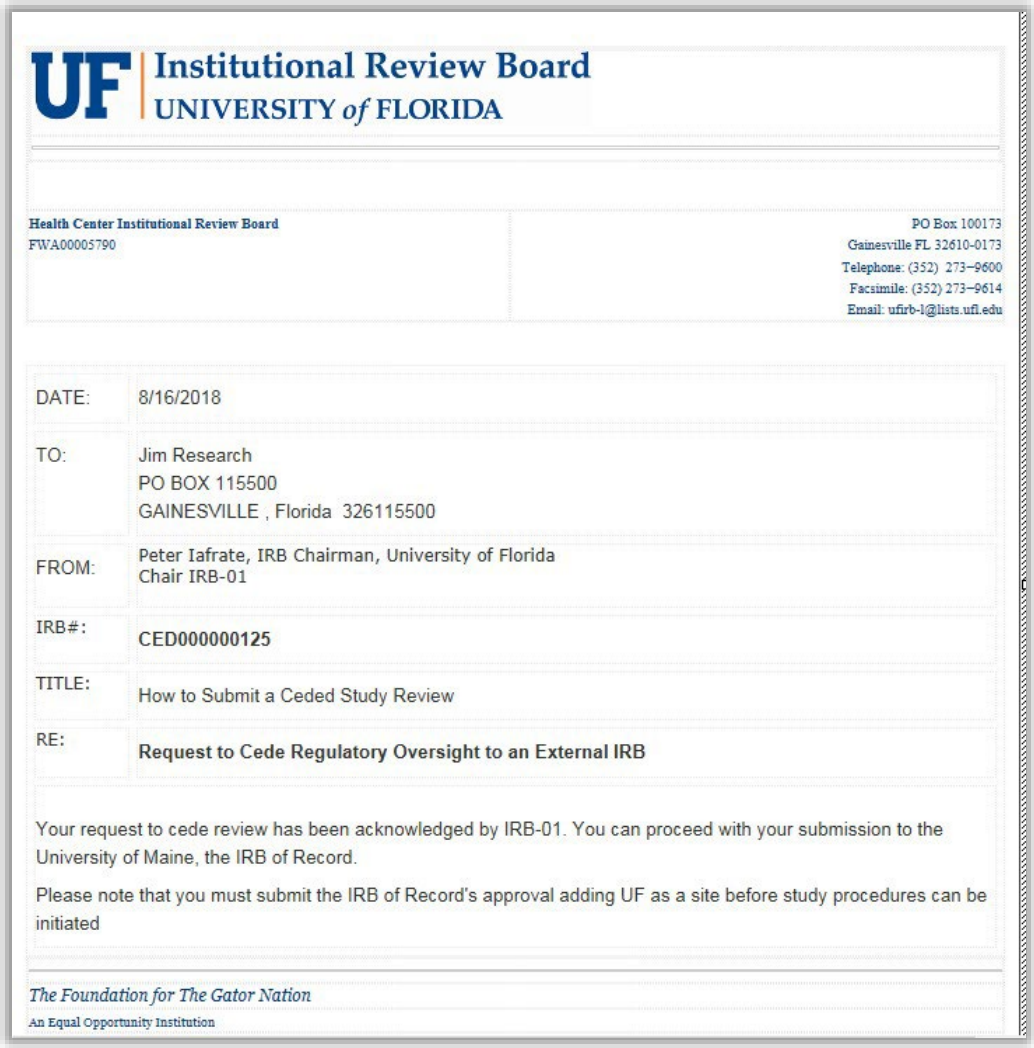
- Next, the study team will work with all relevant ancillaries and update all necessary language into all documents (e.g., ICF, protocol) and update all SmartForms as needed. The study team is required to upload the final track-changed ICF with all required ancillary language inserted using the **Update** button.
  - **NOTE:** UF IRB staff cannot add language into ICFs because UF IRB will not finalize the documents (due to IRB review being ceded to another institution).

- When pre-review is complete **and all relevant ancillaries have submitted approval,** UF IRB will **Acknowledge** the ceded submission via an Acknowledgement Letter sent to the PI / Coordinator. The state transition will change to **Awaiting Site Materials.**

  NOTE: The submission is "frozen" in this state. Study teams cannot make any changes to the submission in this state (other than uploading an IRB of Record of correspondence).

Awaiting Site Materials

Once the submission reaches the state of **Awaiting Correspondence**, the PI or Study Staff can submit documentation to the Overall PI demonstrating that UF has agreed to be added as a participating study site. To prove this agreement, the study team needs to send the reviewing IRB an **Acknowledgment Letter,** which states that UF IRB agrees to cede review:



UF | Institutional Review Board
UNIVERSITY of FLORIDA

Health Center Institutional Review Board
FWA00005790

PO Box 100173
Gainesville FL 32610-0173
Telephone: (352) 273-9600
Facsimile: (352) 273-9614
Email: ufirb-l@lists.ufl.edu

DATE:	8/16/2018
TO:	Jim Research PO BOX 115500 GAINESVILLE , Florida 326115500
FROM:	Peter Iafrate, IRB Chairman, University of Florida Chair IRB-01
IRB#:	**CED000000125**
TITLE:	How to Submit a Ceded Study Review
RE:	**Request to Cede Regulatory Oversight to an External IRB**

Your request to cede review has been acknowledged by IRB-01. You can proceed with your submission to the University of Maine, the IRB of Record.

Please note that you must submit the IRB of Record's approval adding UF as a site before study procedures can be initiated

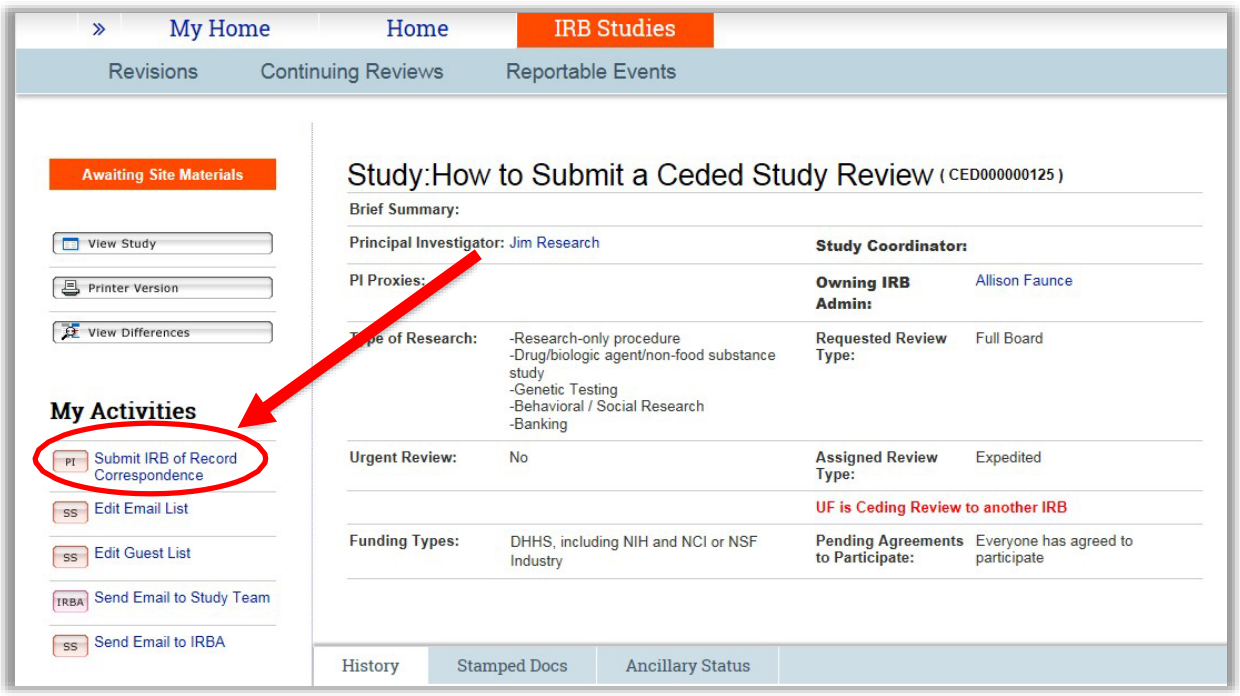
The Foundation for The Gator Nation
An Equal Opportunity Institution

Submit IRB of Record Correspondence

- When the PI and Study Staff have received correspondence back from the IRB of Record (whether in the form of a request to change UF template language **or** as an approval to add UF as a study site), the team must submit this documentation in *myIRB.*

- To do so, open the **Study Workspace** and click **Submit IRB of Record Correspondence** under the **My Activities** heading on the left-hand side of the page.

- Note that the **Submit IRB of Record Correspondence** activity can be completed by anyone on study staff, not only the PI (as is the case with other submission functions).



If the study team receives an approval letter adding UF as a study site, the study team must also upload the Informed Consent document (which must be approved by the IRB of Record).

Upon receiving correspondence from the IRB of record, the submission returns to the **In Ceded Review - IRB Staff Action Required** state**.**

- From here, UF IRB office staff will process the submission based on the letter of correspondence from the IRB of Record.
  - Contingencies: The Ceded Reviewer can move the submission to a **Needs Reply** state if changes are pending on the SmartForms, ICF, and/or protocol.
  - Approval for UF as a study site: In this case, the Ceded reviewer will **Approve** the request and move the submission to the **Awaiting Correspondence** state.
  - The approval period will be from the date UF was approved as a site to the expiration date of the study at the Reviewing Institution.
  - The PI / Coordinator will receive an **Approved as Ceded** letter from UF IRB, and the submission moves to **Approved** state. Study activities may now begin locally.

UF | Institutional Review Board
UNIVERSITY of FLORIDA

Health Center Institutional Review Board
FWA00005790

PO Box 100173
Gainesville FL 32610-0173
Telephone: (352) 273-9600
Facsimile: (352) 273-9614
Email: ufirb-l@lists.ufl.edu

DATE: 8/16/2018
TO: Jim Research
PO BOX 115500
GAINESVILLE , Florida 326115500
FROM: Peter Iafrate, IRB Chairman, University of Florida
Chair IRB-01

IRB#: **CED0000000125**
TITLE: How to Submit a Ceded Study Review

Approved as Ceded	**Expires on: 5/22/2019**

Approval of this project was granted by the IRB of Record. IRB-01 approves the ceding of this project.

Approval Includes, but is not limited to:

Documents as submitted and approved by the IRB of Record

Special notes to the Investigator (if applicable):

Principal Investigator Responsibilities for Ceded Study:

The Principal Investigator (PI) is responsible for the conduct of the study. Please review these responsibilities described at: http://irb.ufl.edu/irb01/researcher-information/researcherresponsibilities.html
Important responsibilities described include:

- I have read and will conduct the sIRB study in accordance with the federal regulations and the UF Human Research Protection Program (HRPP) Policies and Procedures
- I will accept responsibility for the conduct and supervision as a participating site in research at UF
- I will use the current approved informed consent(s) provided by the overall PI/IRB of Record to enroll subjects (if applicable)
- I will maintain informed consents and regulatory files locally as required by institutional policies
- I will submit annual study approvals from the Overall PI/IRB of Record to the UF via myIRB
- I will promptly report serious adverse events to the overall PI in accordance with the IRB of Record's policies and procedures
- I will promptly report serious non-compliance or unanticipated problems to the overall PI in accordance with the IRB of Record's policies and procedures
- I will obtain approval for revisions from the overall PI/IRB of record before implementation

UF Study Team: Bob Doane

Post Approved as Ceded Review Submission-Types

Once a ceded request has been approved by UF IRB, study teams can still submit **Reportable Events**, **Revisions**, and **Continuing Reviews/Closures**. Follow normal procedures as previously outlined in this manual for submitting these sorts of events.

New Reportable Event for a Ceded Study

Study teams should only submit a **New Reportable Event** for a Ceded Study if one or more of the following conditions are met:

a. Serious or continuing noncompliance that has occurred **locally**.

b. Local adverse events that are **serious**, **unexpected**, and ones for which the PI/PI Proxy has determined that the event was **more likely than not** related to study participation.

c. Non-local events **IF**:
   i. **Non-compliance** occurred. The IRB of record must determine that the event constitutes serious or continuing noncompliance. If this occurs, UF IRB would be responsible for reporting the event to federal oversight agencies.

   ii. **Adverse event(s)** occurred. The IRB of record must determine that an unanticipated problem occurred which increased risk to subjects. In this case, UF IRB would be responsible for reporting the event(s) to federal oversight agencies.

New Revision for a Ceded Study

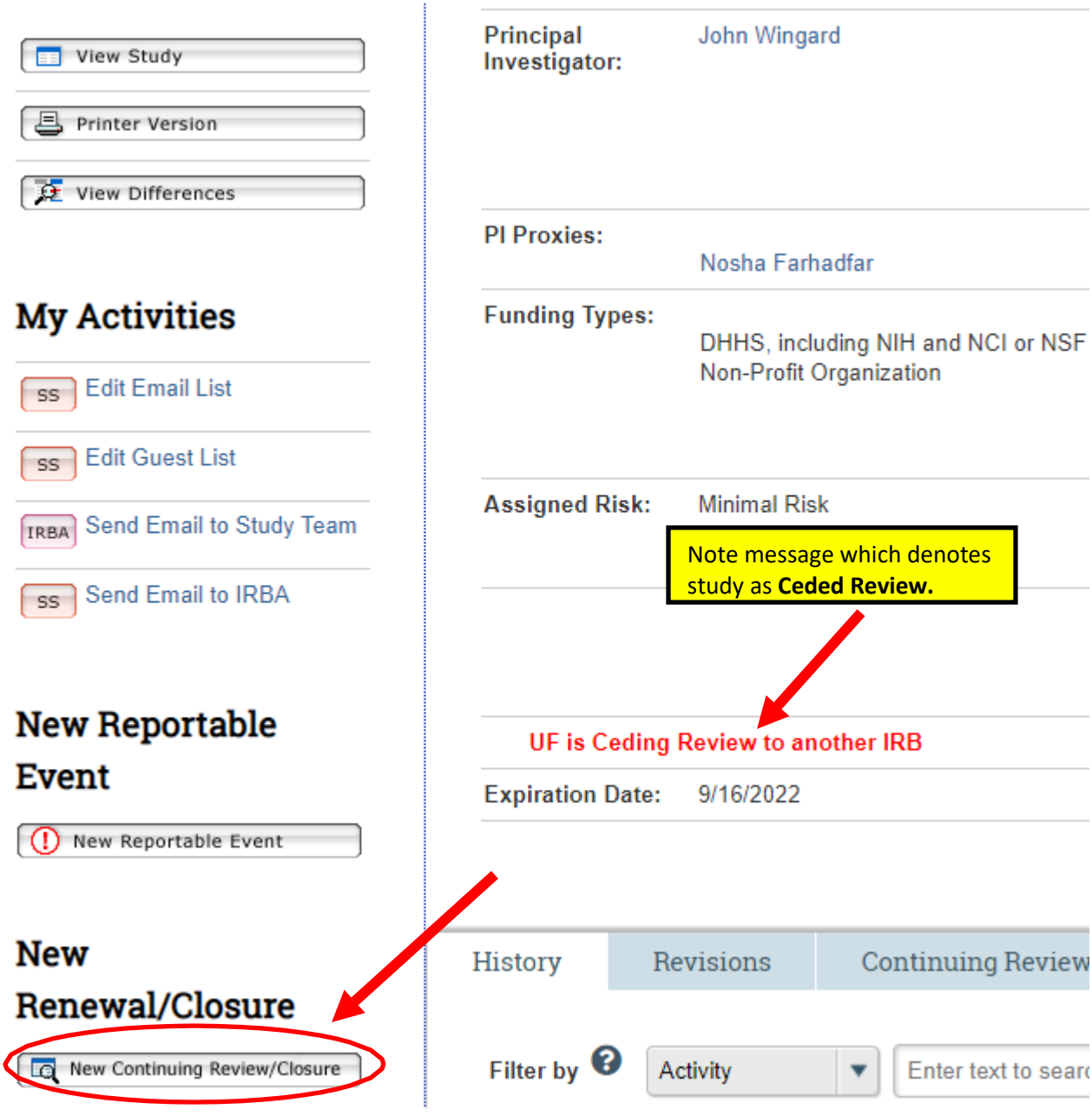
Study Staff must inform UF IRB of all PI and study staff changes promptly. Remember that new study staff **cannot** engage in research activities until the revision adding that person to the study has been approved by UF IRB.

Study staff should only submit other revision(s) if such revisions prompt re-review by UF ancillary committees (i.e., COI, OCR, IBC, CTSI, HURRC, SRMC, etc.).

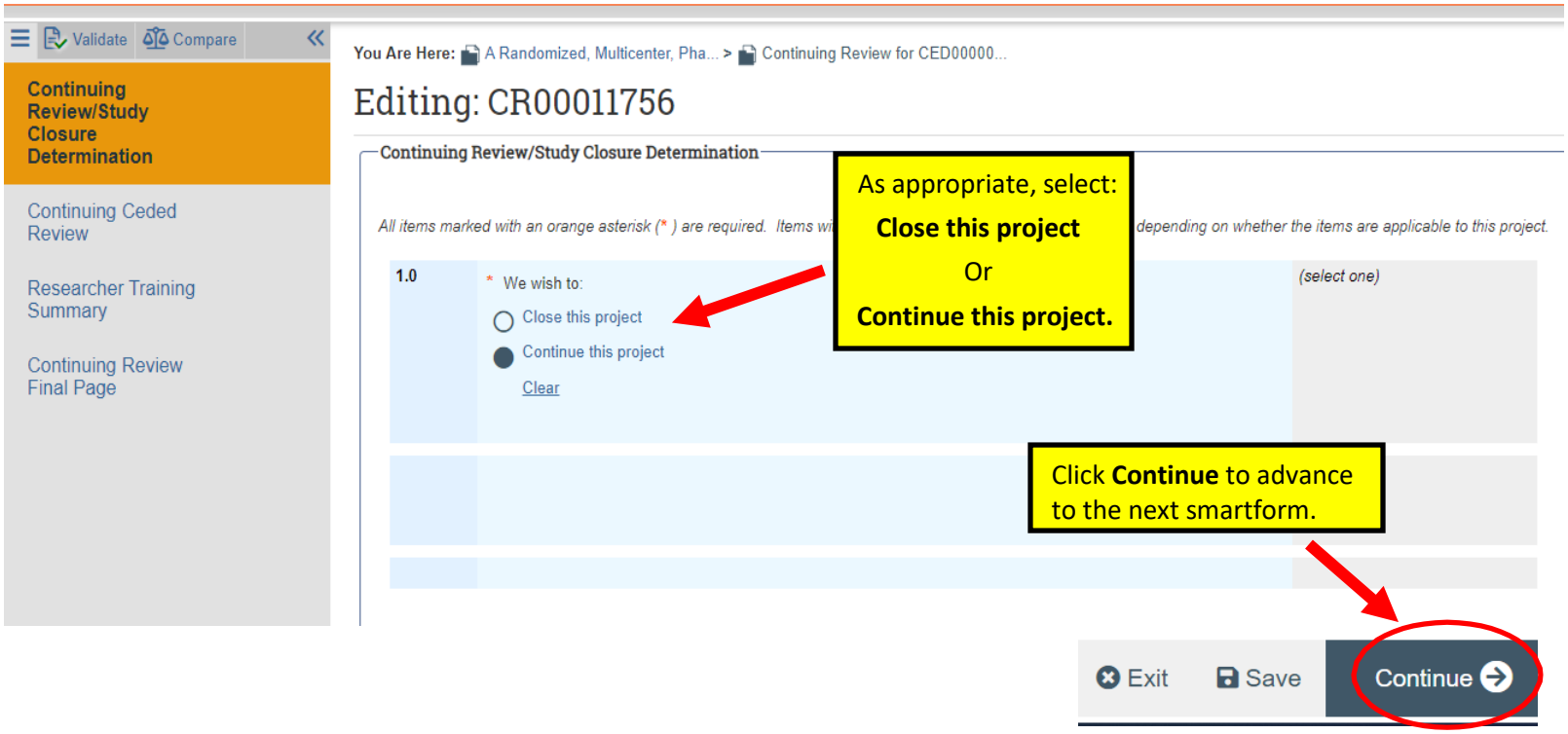
New Continuing Review/Study Closure for a Ceded Study

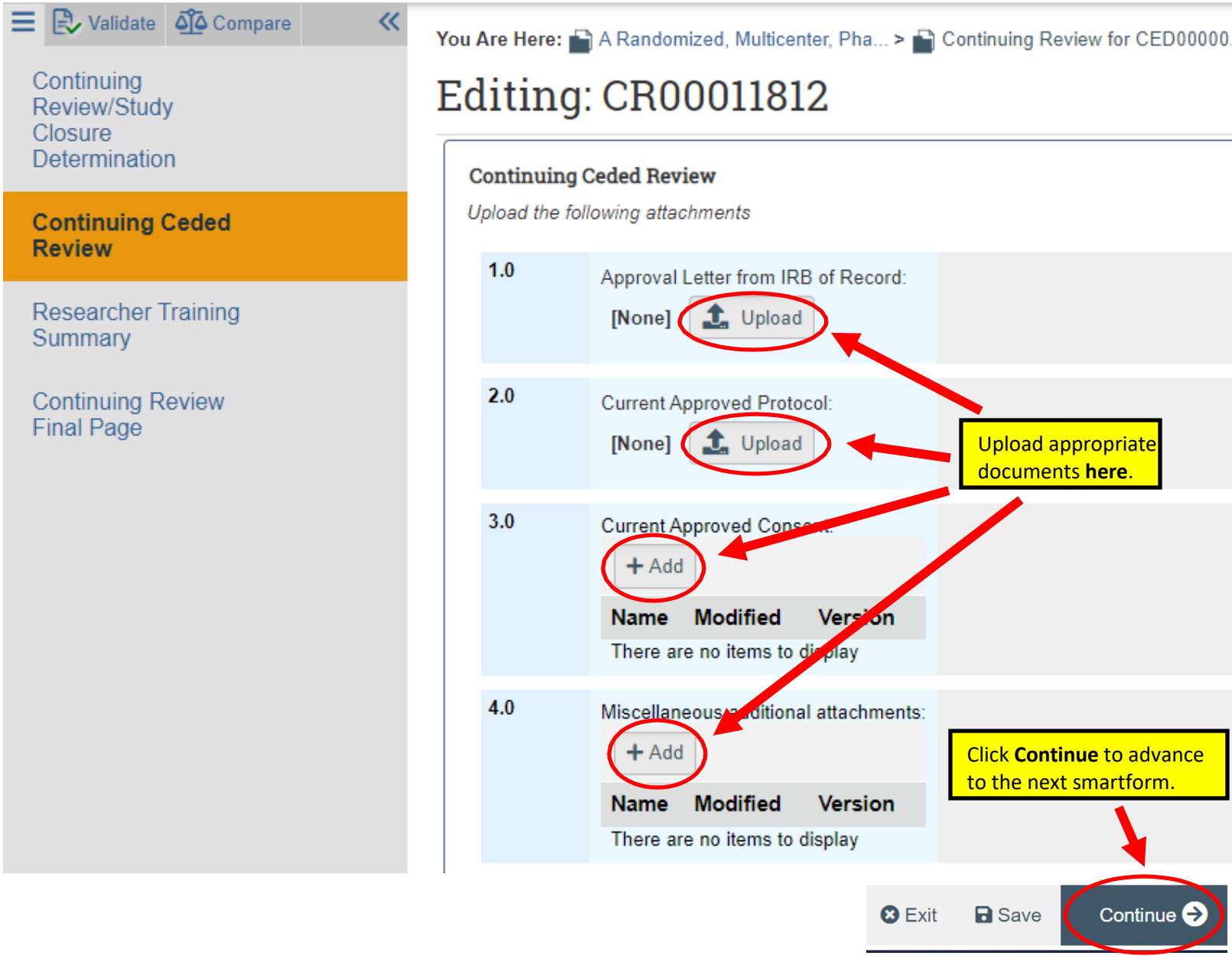
To submit a **Continuing Review for a Ceded Study** or a **Study Closure for a Ceded Study,** follow these steps. The process is identical except for the item chosen for question 1.0 on the **Continuing Review/Study Closure Determination** SmartForm (see screenshot on next page.

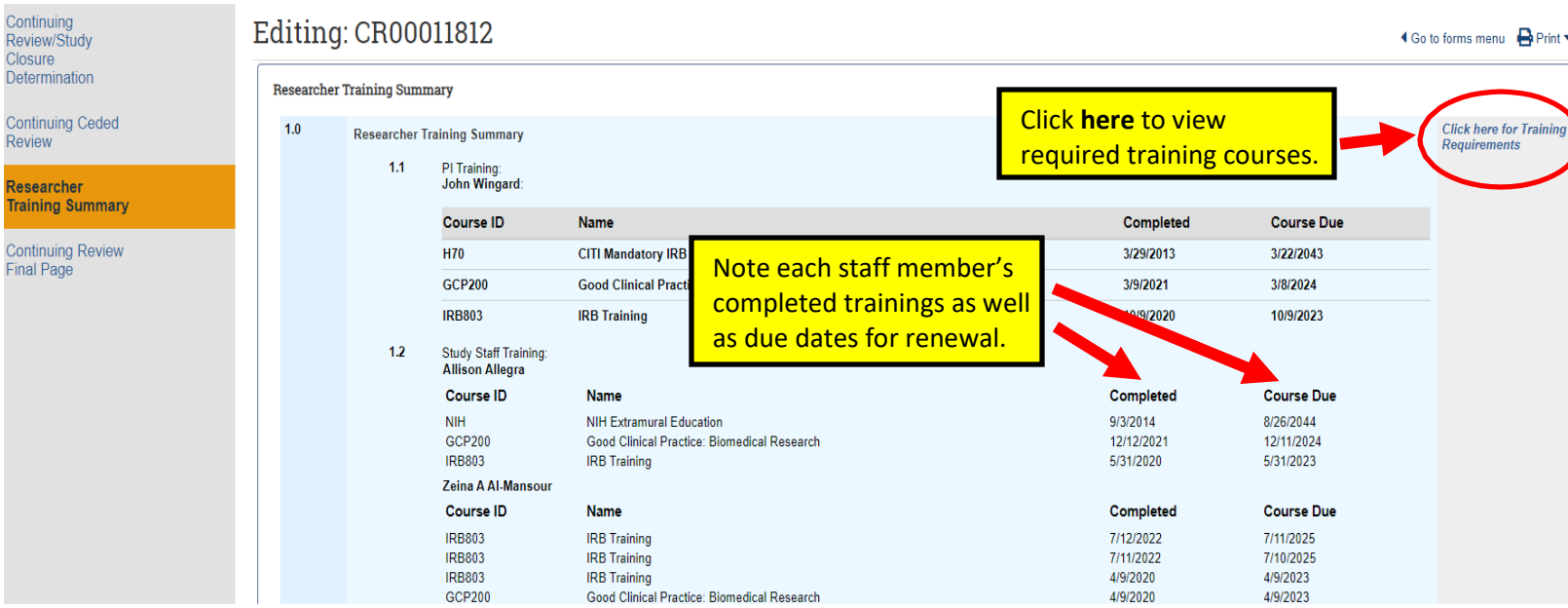
1. First, log-in to *myIRB* and access the main **study workspace** for the Ceded Study in Question.
2. Next, under the **New Renewal/Closure** heading in the left-hand column, click **New Continuing Review/Closure.**

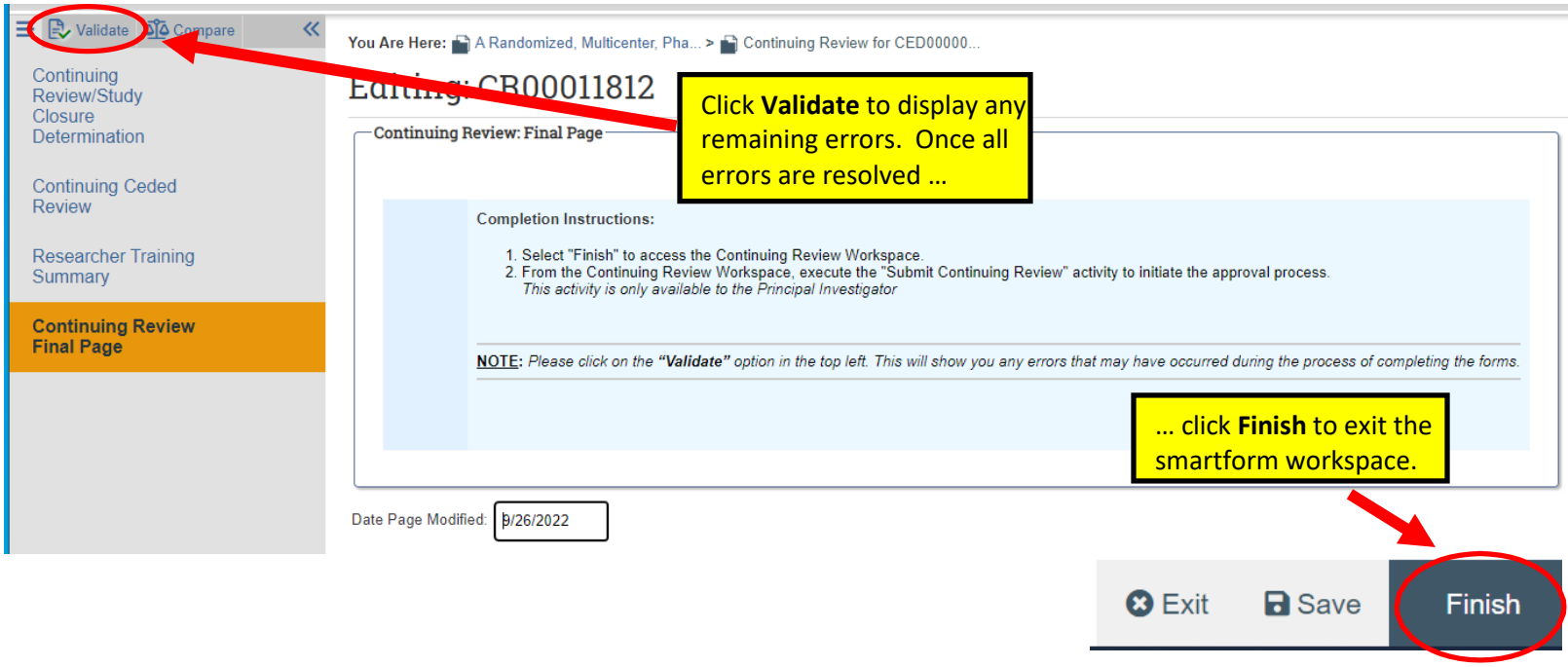


3. From there, study teams will be asked to complete a series of SmartForms. Please follow the directions in each screenshot to proceed.



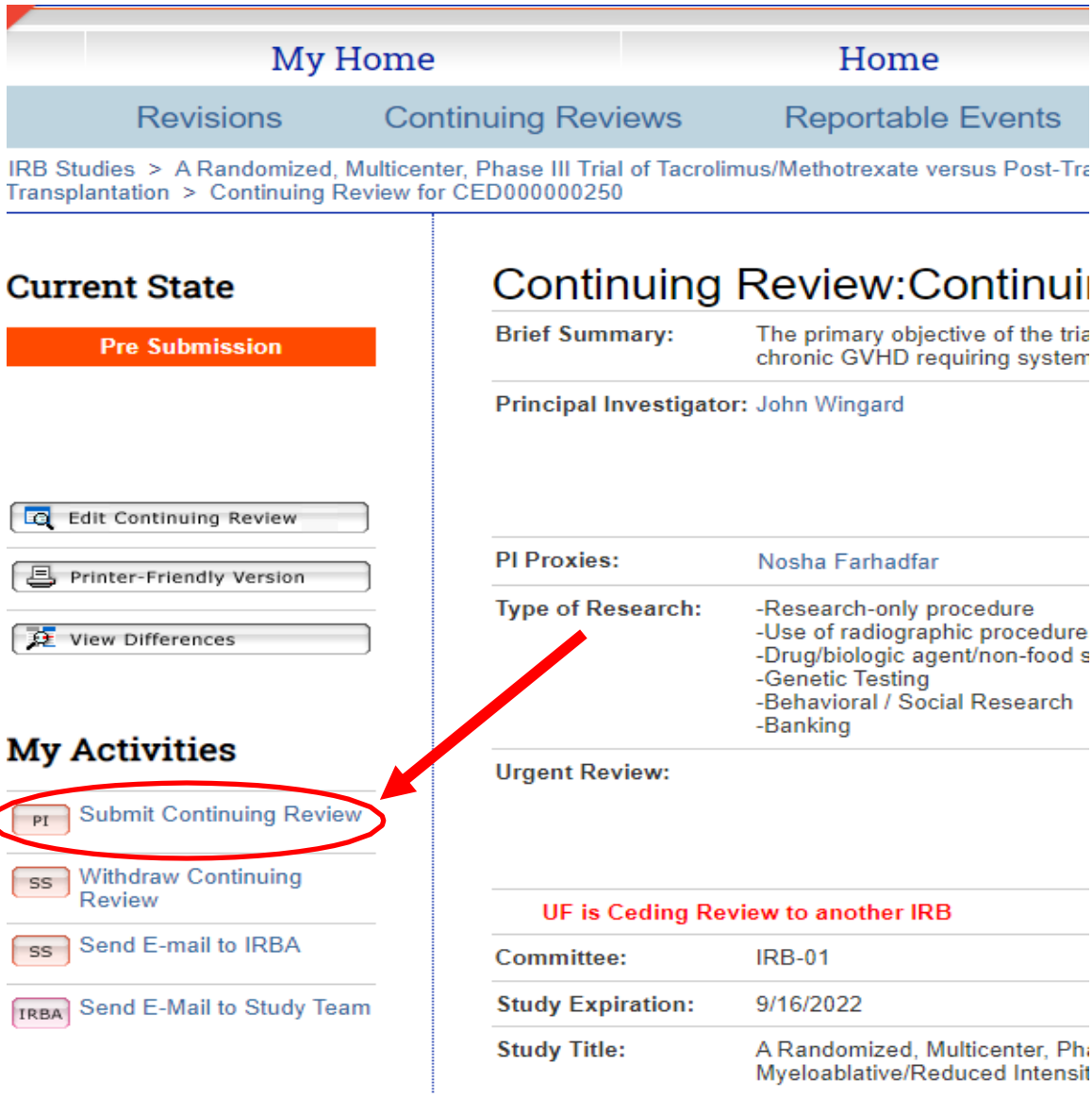

Validate
Compare
Continuing Review/Study Closure Determination
Continuing Ceded Review
Researcher Training Summary
Continuing Review Final Page
You Are Here: A Randomized, Multicenter, Pha... > Continuing Review for CED00000
Editing: CR00011812
Continuing Ceded Review
Upload the following attachments
1.0
Approval Letter from IRB of Record:
[None] Upload
2.0
Current Approved Protocol:
[None] Upload
3.0
Current Approved Consent:
+ Add
Name Modified Version
There are no items to display
4.0
Miscellaneous Additional attachments:
+ Add
Name Modified Version
There are no items to display
Upload appropriate documents here.
Click Continue to advance to the next smartform.
Exit
Save
Continue


Continuing Review/Study Closure Determination
Continuing Ceded Review
Researcher Training Summary
Continuing Review Final Page
Editing: CR00011812
Go to forms menu
Print
Researcher Training Summary
1.0 Researcher Training Summary
1.1 PI Training:
John Wingard:
Course ID | Name | Completed | Course Due
H70 | CITI Mandatory IRB | 3/29/2013 | 3/22/2043
GCP200 | Good Clinical Pract | 3/9/2021 | 3/8/2024
IRB803 | IRB Training | 10/9/2020 | 10/9/2023
1.2 Study Staff Training:
Allison Allegra
Course ID | Name | Completed | Course Due
NIH | NIH Extramural Education | 9/3/2014 | 8/26/2044
GCP200 | Good Clinical Practice: Biomedical Research | 12/12/2021 | 12/11/2024
IRB803 | IRB Training | 5/31/2020 | 5/31/2023
Zeina A Al-Mansour
Course ID | Name | Completed | Course Due
IRB803 | IRB Training | 7/12/2022 | 7/11/2025
IRB803 | IRB Training | 7/11/2022 | 7/10/2025
IRB803 | IRB Training | 4/9/2020 | 4/9/2023
GCP200 | Good Clinical Practice: Biomedical Research | 4/9/2020 | 4/9/2023
Click here for Training Requirements
Click **here** to view required training courses.
Note each staff member's completed trainings as well as due dates for renewal.


Validate
Compare
Continuing Review/Study Closure Determination
Continuing Ceded Review
Researcher Training Summary
Continuing Review Final Page
You Are Here: A Randomized, Multicenter, Pha... > Continuing Review for CED00000...
Editing: CR00011812
Continuing Review: Final Page
Completion Instructions:
1. Select "Finish" to access the Continuing Review Workspace.
2. From the Continuing Review Workspace, execute the "Submit Continuing Review" activity to initiate the approval process.
This activity is only available to the Principal Investigator
NOTE: Please click on the "Validate" option in the top left. This will show you any errors that may have occurred during the process of completing the forms.
Date Page Modified: 9/26/2022
Exit
Save
Finish
Click **Validate** to display any remaining errors. Once all errors are resolved …
… click **Finish** to exit the smartform workspace.

Clicking **Finish** will redirect the user to the main **Study Workspace** for the Continuing Review.

From here, the PI / PI Proxy will select **Submit Continuing Review** to send the SmartForms to UF IRB.



TIP: As with other Continuing Reviews, a reminder that **ONLY** the PI or PI Proxy can submit a Continuing Review for a Ceded Study.

Upon receipt of the Continuing Review, the UF IRB Ceded Reviewer will review the submission. If changes are needed, IRB will send the study team a **Needs Reply** notification.

If changes are not needed, IRB will approve the ceded Continuing Review and reset the approval period.

Upon receiving IRB approval, the study team will receive an approval letter similar to the one below:

UF | Institutional Review Board
UNIVERSITY of FLORIDA

Health Center Institutional Review Board
FWA00005790

PO Box 100173
Gainesville FL 32610-0173
Telephone: (352) 273-9600
Facsimile: (352) 273-9614
Email: ufirb-l@lists.ufl.edu

DATE: 8/20/2018

TO: Jim Research
PO Box 115500
Gainesville, Florida 326115500

FROM: Peter Iafrate, IRB Chairman, University of Florida
Chair IRB-01

IRB#: **Continuing Review for CED000000125**

TITLE: How to Submit a Ceded Study Review

Approved as Ceded: Continuing Review	**Expires on: 8/8/2019**

Thank you for submitting the continuing approval from the IRB of Record. UF IRB acknowledges receipt, you may continue with the study.

Approval Includes:

Documents as submitted and approved by the IRB of Record

Principal Investigator Responsibilities for Ceded Study:

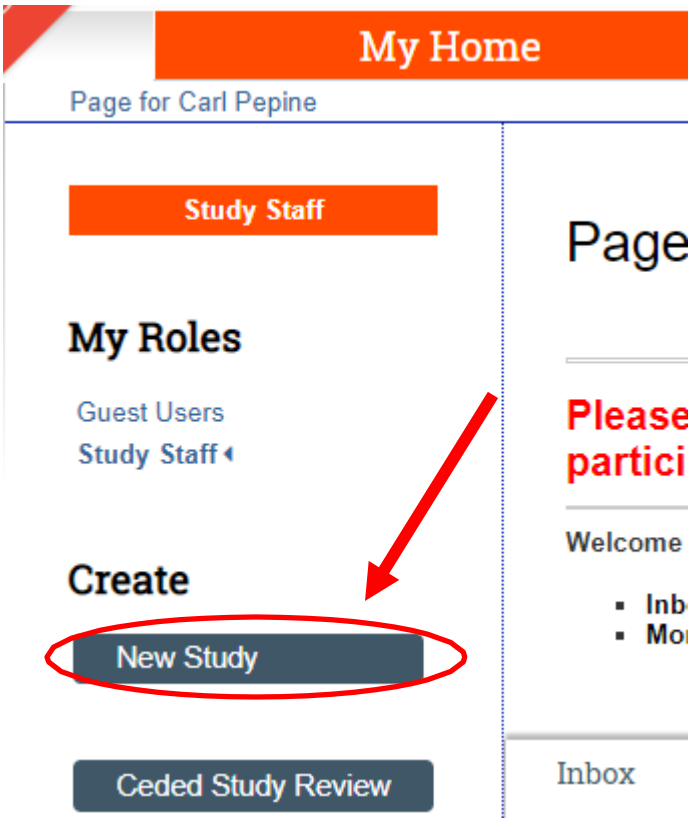
The Principal Investigator (PI) is responsible for the conduct of the study. Please review these responsibilities described at: http://irb.ufl.edu/irb01/researcher-information/researcherresponsibilities.html
Important responsibilities described include:

- I have read and will conduct the sIRB study in accordance with the federal regulations and the UF Human Research Protection Program (HRPP) Policies and Procedures
- I will accept responsibility for the conduct and supervision as a participating site in research at UF
- I will use the current approved informed consent(s) provided by the overall PI/IRB of Record to enroll subjects (if applicable)
- I will maintain informed consents and regulatory files locally as required by institutional policies
- I will submit annual study approvals from the Overall PI/IRB of Record to the UF via myIRB
- I will promptly report serious adverse events to the overall PI in accordance with the IRB of Record's policies and procedures
- I will promptly report serious non-compliance or unanticipated problems to the overall PI in accordance with the IRB of Record's policies and procedures
- I will obtain approval for revisions from the overall PI/IRB of record before implementation

UF Study Team:

Create a New Study/Revise a Study where UF is the IRB of Record (sIRB)

PI/PI Proxy or Study Staff can create a new *s*IRB study by logging-in to *myIRB* and clicking **New Study** under **Create** in the column on the left-hand side of the page. Note that study teams can also revise a currently approved study into an sIRB study.



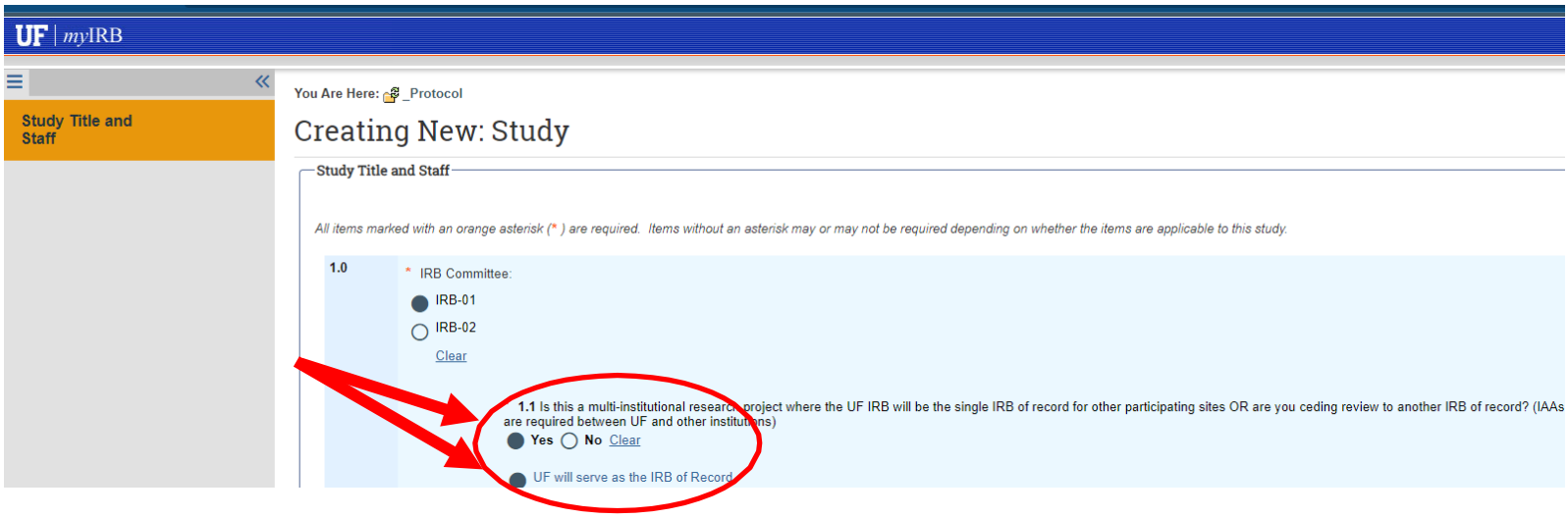
When submitting a revision to make IRB-01 the IRB of record, there are 3 steps to take, in order:

a) Complete the New Revision SmartForm
b) Edit Modified Study to revise key SmartForms
c) Revise attachments as needed

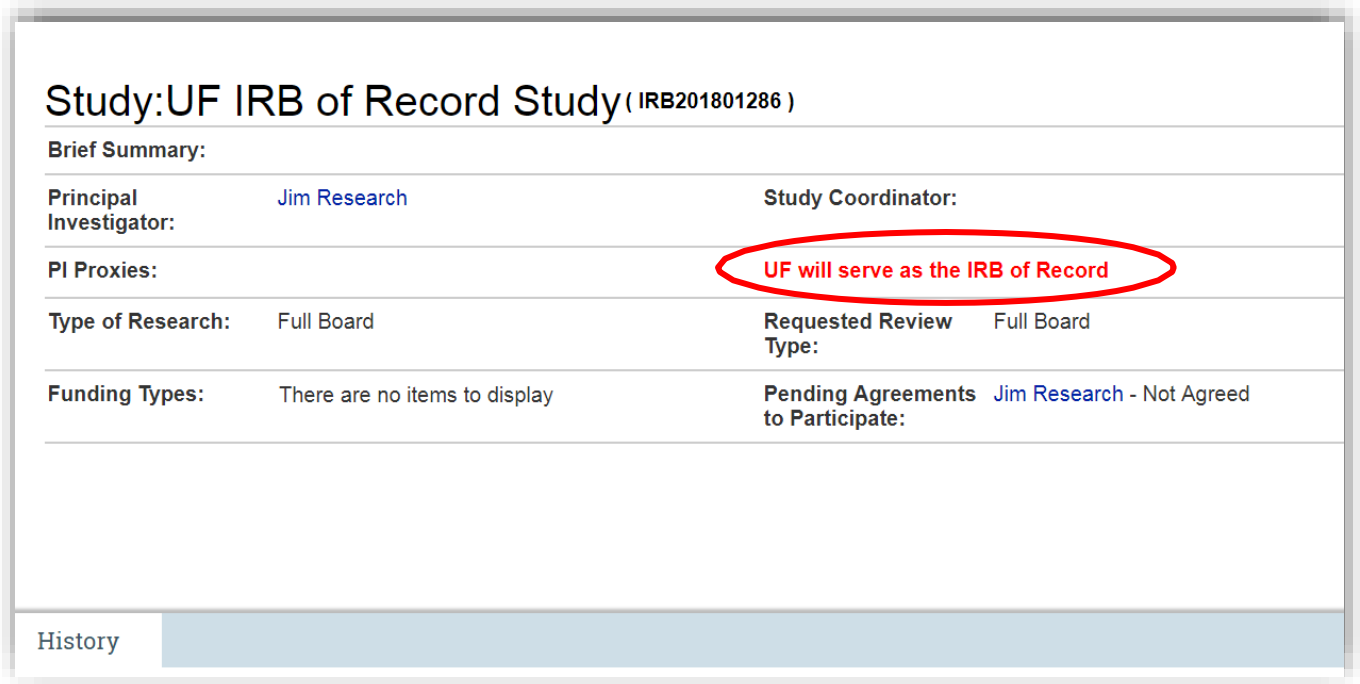
For simplicity, this demonstration will use the example of creating a new sIRB study.

After clicking **New Study,** users will be redirected to the SmartForms for a study submission. On the **Study Title and Staff** SmartForm, notice **question 1.0** and **question 1.1**. By selecting **Yes** for question 1.1, this automatically generates a subsequent item asking if **IRB will serve as the IRB of Record**. Ensure this radio button is selected.

TIP: **Do not** clear the radio button that states UF will serve as the IRB Record. If this was selected accidentally, simply select **No** for question 1.1 to clear the aforementioned item.



NOTE: Submissions where IRB-01 is the IRB of record have the same nomenclature as regular studies. However, ***s*IRB status** will be flagged on the main Study Workspace (see screenshot below).

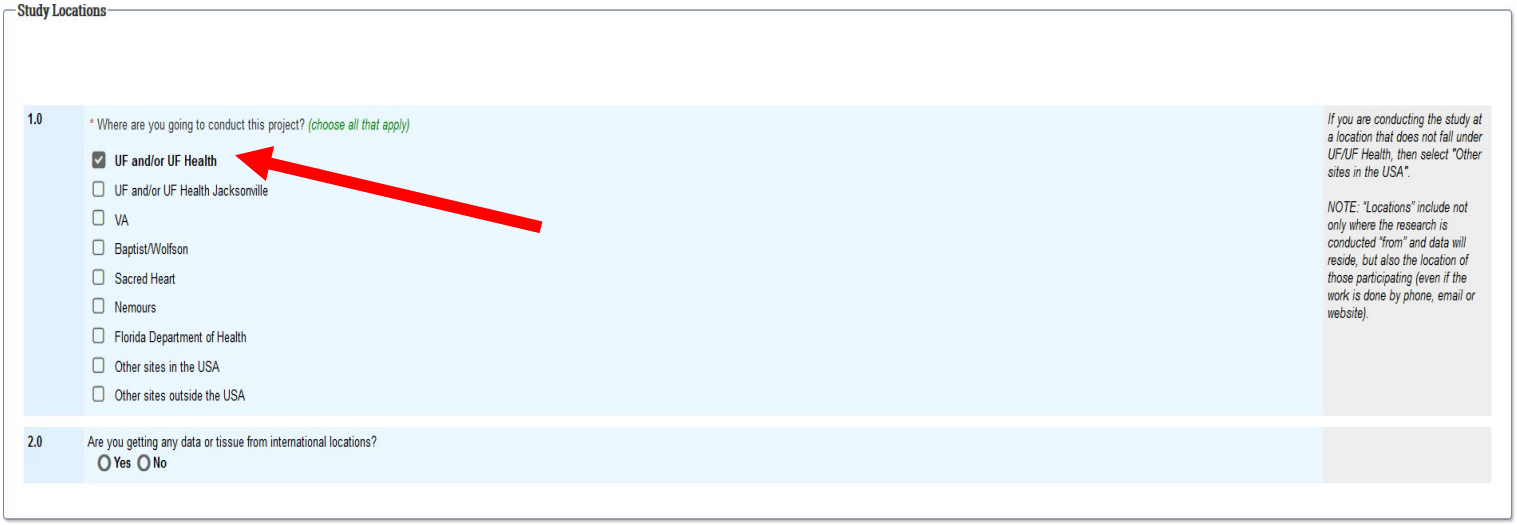


After making these changes on the Study Title and Staff SmartForm, complete the remaining SmartForms as usual. Most SmartForms will remain the same, including branching.

NOTE: If the overall study is **greater than minimal risk** (GMR), the review type for the study will be **Full Board** even if all procedures done at UF are considered minimal risk.

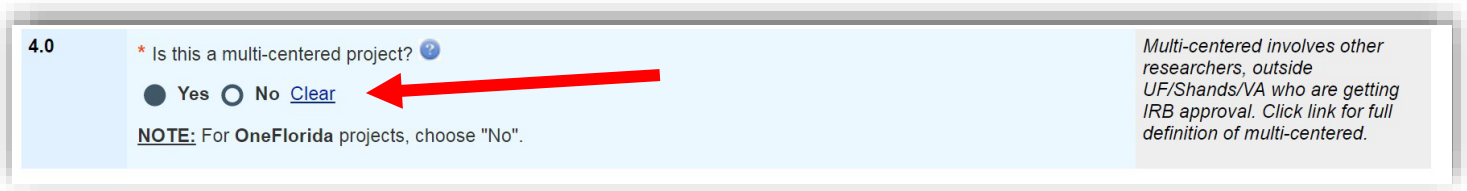
TIP: On the following SmartForm (**Study Locations**), select **UF and UF Health** but do not select **Other sites in the USA** given that this is a multi-center study.

Study Locations SmartForm

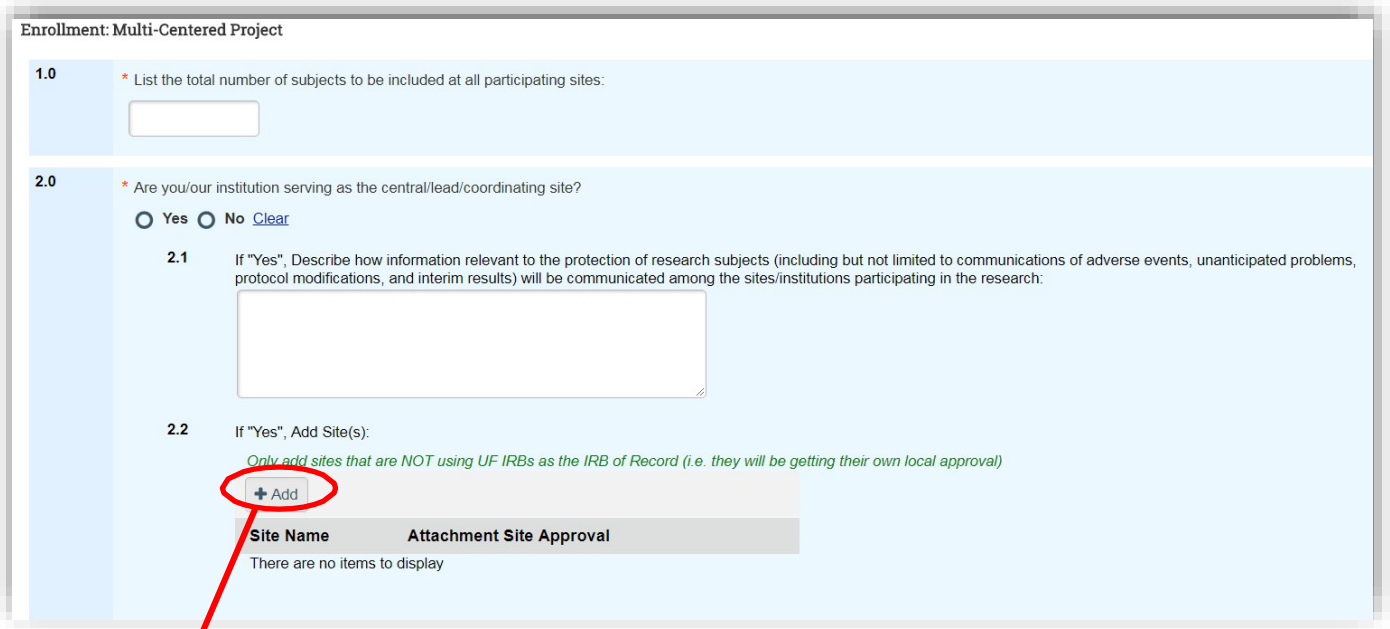


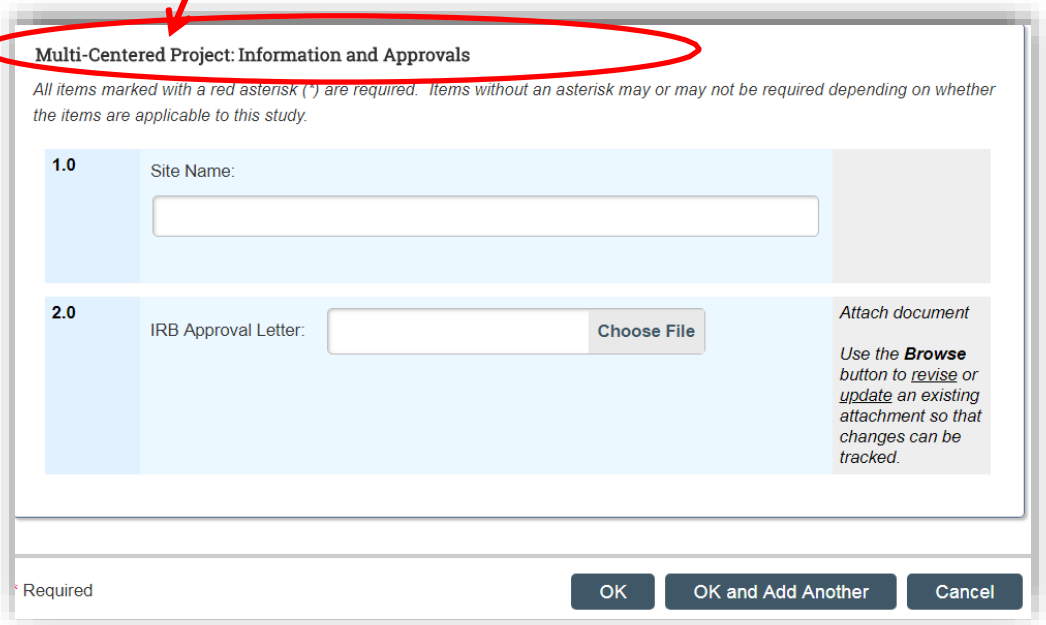
Enrollment Details SmartForm

On the **Enrollment Details** SmartForm, select **Yes** for question 4.0.



Enrollment: Multi-Centered Project





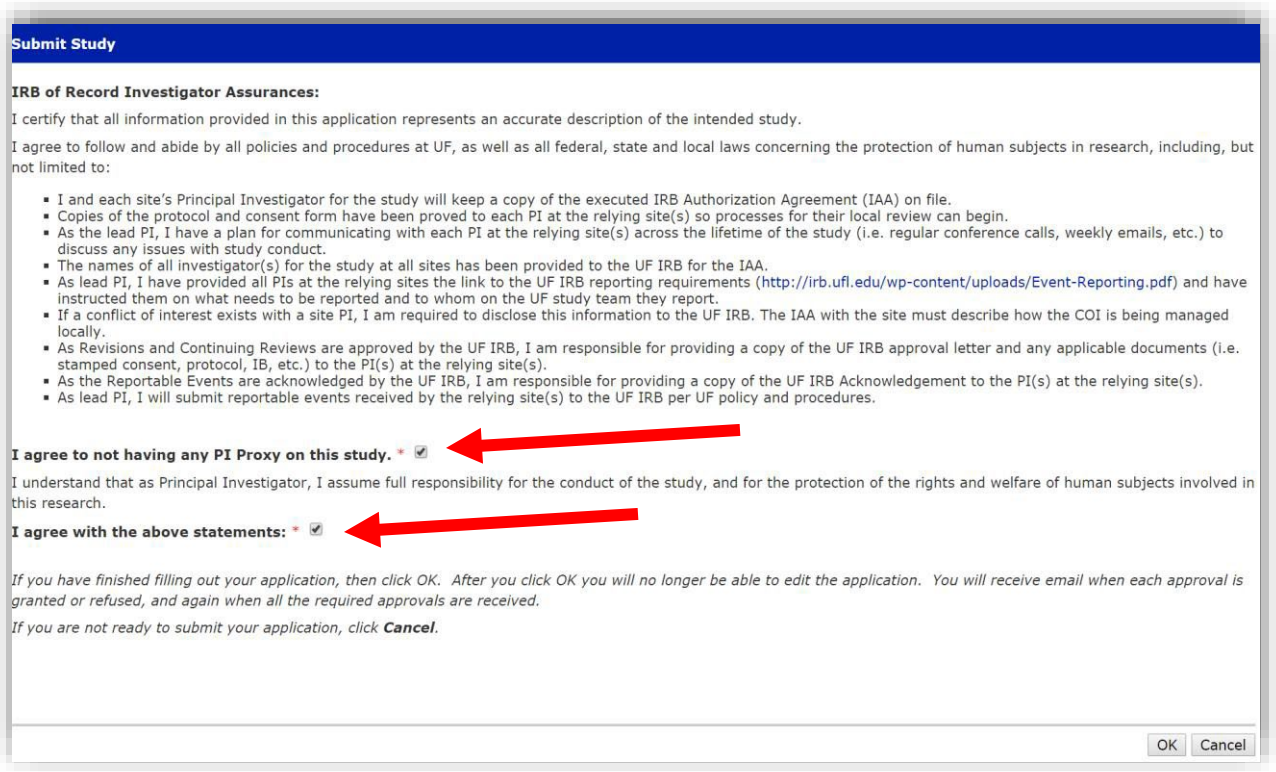
TIP: In the SmartForm above, see Question 1.0. There, state that, if non-sIRB sites **are not** ready to be added at the time of submitting this study to IRB, those sites will be added at a later date with a **revision**. If there are no non-sIRB sites to add, skip Q 2.2.

Upload Informed Consent

The consents which must be uploaded are the "UF Core" and "UF Addendum". Each participating site must also send their ICF addenda with the relevant local language to the UF PI who will add these documents as part of a p-site revision (see later sections of this manual).

Submit Study

Remember that the PI is the **only** individual who can submit the study. Upon submitting the study, the PI must agree to the **IRB of Record Investigator Assurances** language. These assurances are also on the final Approval letter and on Continuing Review letters.



Once a study is submitted, it will be in the **IRB Assignment** state. Then, once an IRB pre-reviewer is assigned to the study, the study state will advance to **IRB Staff Review**. From here, the review process is the same as for any other Full Board/Expedited study, including meeting deadlines, meeting discussion, addressing contingencies, needs replies, etc.

Approval Letter

UF | Institutional Review Board
UNIVERSITY of FLORIDA

Health Center Institutional Review Board
FWA00005790

PO Box 100173
Gainesville FL 32610-0173
Telephone: (352) 273-9600
Facsimile: (352) 273-9614
Email: ufirb-l@lists.ufl.edu

DATE: 5/15/2017
TO: Barry Byrne
2004 Mowry Road
GAINESVILLE , Florida 32610
FROM: Peter Iafrate, IRB Chairman, University of Florida
Chair IRB-01

IRB#: **IRB201701247**
TITLE: BEL TEST sIRB study 1

Approved as Expedited	Expires on: 5/15/2018

You have received IRB approval to conduct the above-listed research project. Approval of this project was granted on 5/15/2017 by IRB-01. This study is approved as expedited because it poses minimal risk and is approved under the following expedited category/categories:

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: hair and nail clippings, if collected in a non-disfiguring manner; deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; permanent teeth, if routine patient care indicates a need for extraction; excreta and external secretions (including sweat); uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; placenta removed at delivery; amniotic fluid obtained at the time of rupture of the membrane before or during labor; supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; sputum collected after saline mist nebulization.

Approval Includes, but is not limited to:

Dated and watermarked IRB-approved Informed Consent Form(s)

Consent Waiver Type(s):

Modification of Informed Consent
Written Informed Consent is obtained in a non-standard way, e.g. delaying written informed consent

HIPAA Waiver Type(s):

to identify, for the purpose of recruiting, potential subjects for the study

Special notes to Investigator (if applicable):

THIS IS A TEST
Reviewer Notes: 0 Reviewer Notes

IRB of Record PI responsibilities:

I agree to follow and abide by all policies and procedures at UF, as well as all federal, state and local laws concerning the protection of human subjects in research, including, but not limited to:

- I and each site's Principal Investigator for the study will keep a copy of the executed IRB Authorization Agreement (IAA) on file.
- Copies of the protocol and consent form have been proved to each PI at the relying site(s) so processes for their local review can begin.
- As the lead PI, I will have a plan for communicating with each PI at the relying site(s) across the lifetime of the study (i.e. regular conference calls, weekly emails, etc.) to discuss any issues with study conduct.
- The names of all investigator(s) for the study at all sites has been provided to the UF IRB for the IAA.
- As lead PI, I have provided all PIs at the relying sites the link to the UF IRB reporting requirements (http://irb.ufl.edu/wp-content/uploads/Event-Reporting.pdf) and have instructed them on what needs to be reported and to whom on the UF study team they report.
- If a conflict of interest exists with a site PI, I am required to disclose this information to the UF IRB. The IAA with the site must describe how the COI is being managed locally.
- As Revisions and Continuing Reviews are approved by the UF IRB, I am responsible for providing a copy of the UF IRB approval letter and any applicable documents (i.e. stamped consent, protocol, IB, etc.) to the PI(s) at the relying site(s).
- As the Reportable Events are acknowledged by the UF IRB, I am responsible for providing a copy of the UF IRB Acknowledgement to the PI(s) at the relying site(s).
- As lead PI, I will submit reportable events received by the relying site(s) to the UF IRB per UF policy and procedures.

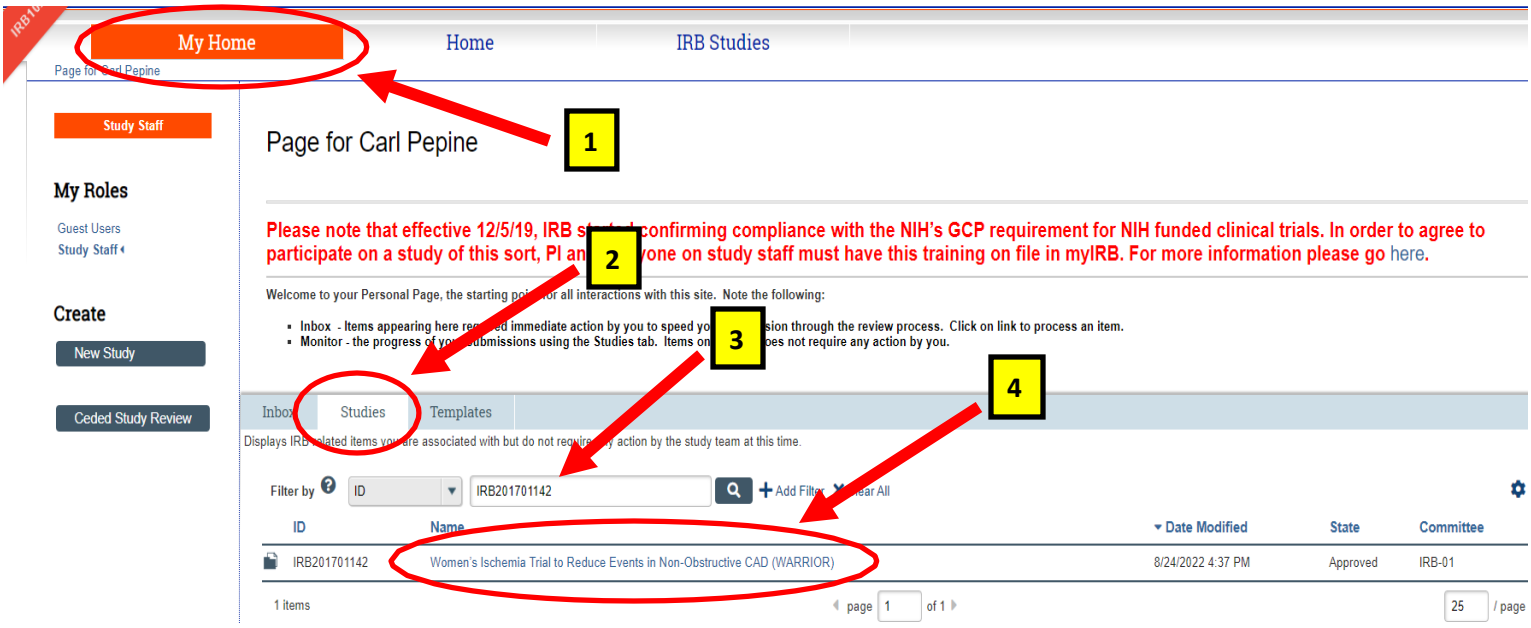
Study Team:

Adding a Participating Site (P-Site) where UF IRB is the IRB of Record

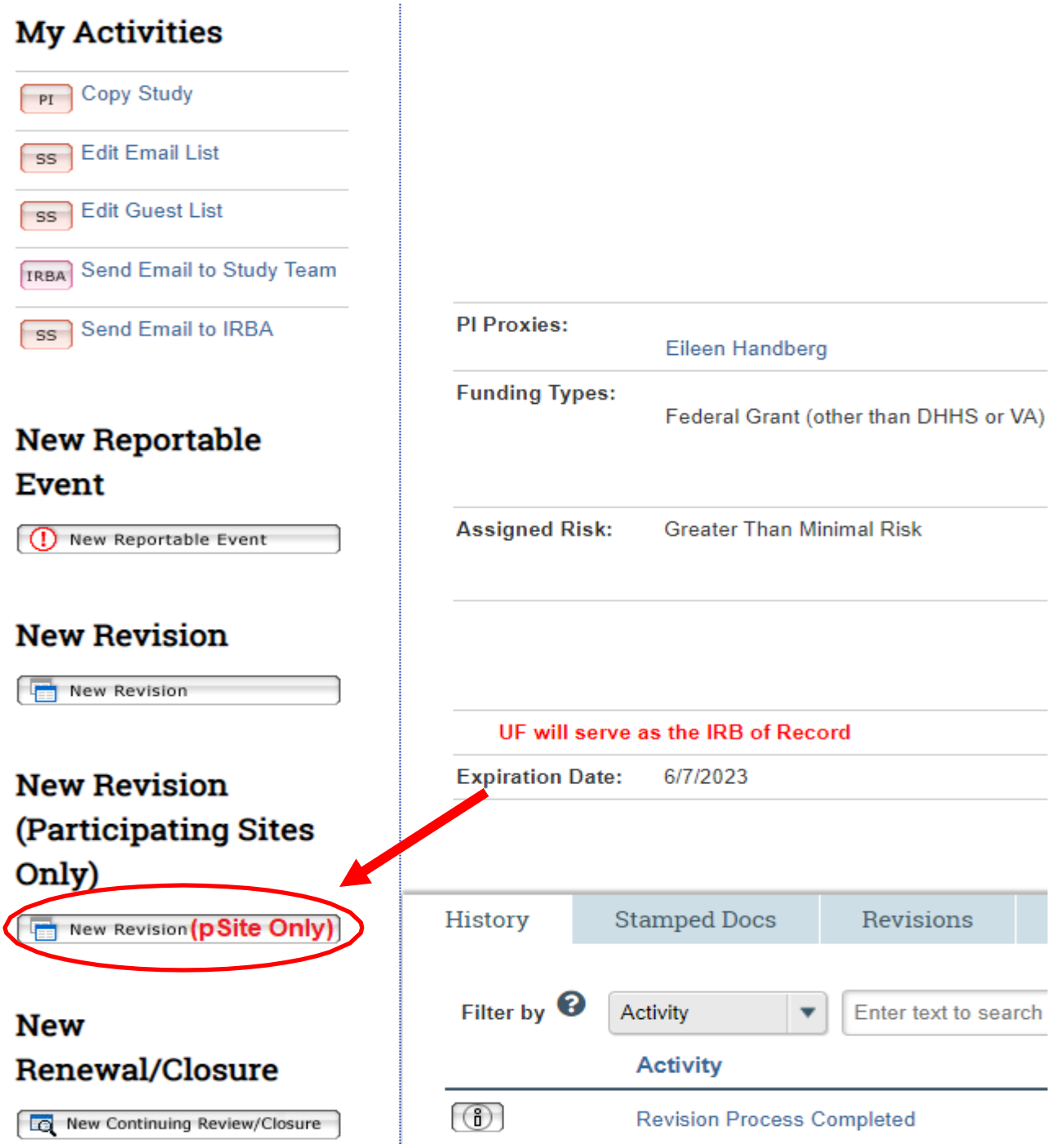
To add a new **Participating Site** (pSite) to a study where UF IRB is the IRB of Record, follow these steps:

1. Log in to *myIRB.* Once there, click the **My Home** tab in the top left corner of the screen.

2. Next, click the **Studies** tab in the middle of the screen, and search for the study in question using the study name, ID #, etc. Once the study name is located, click the **Study Name**.

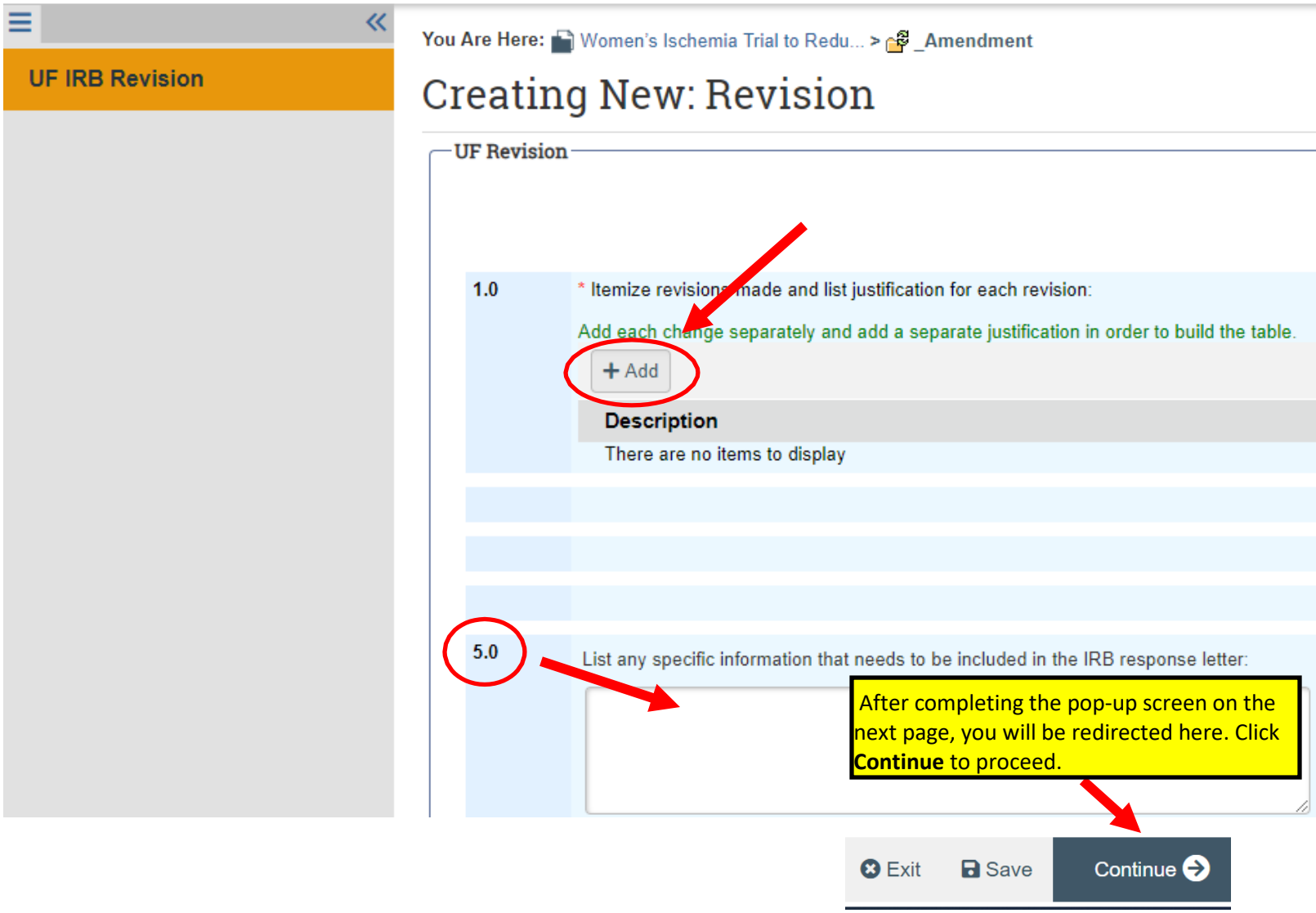


3. Clicking on the Study Name will redirect the user to the **Study Workspace.** From here, look for the click **New Revision (Participating Sites Only)** heading on the left side of the page and click **New Revision (pSite Only)**.

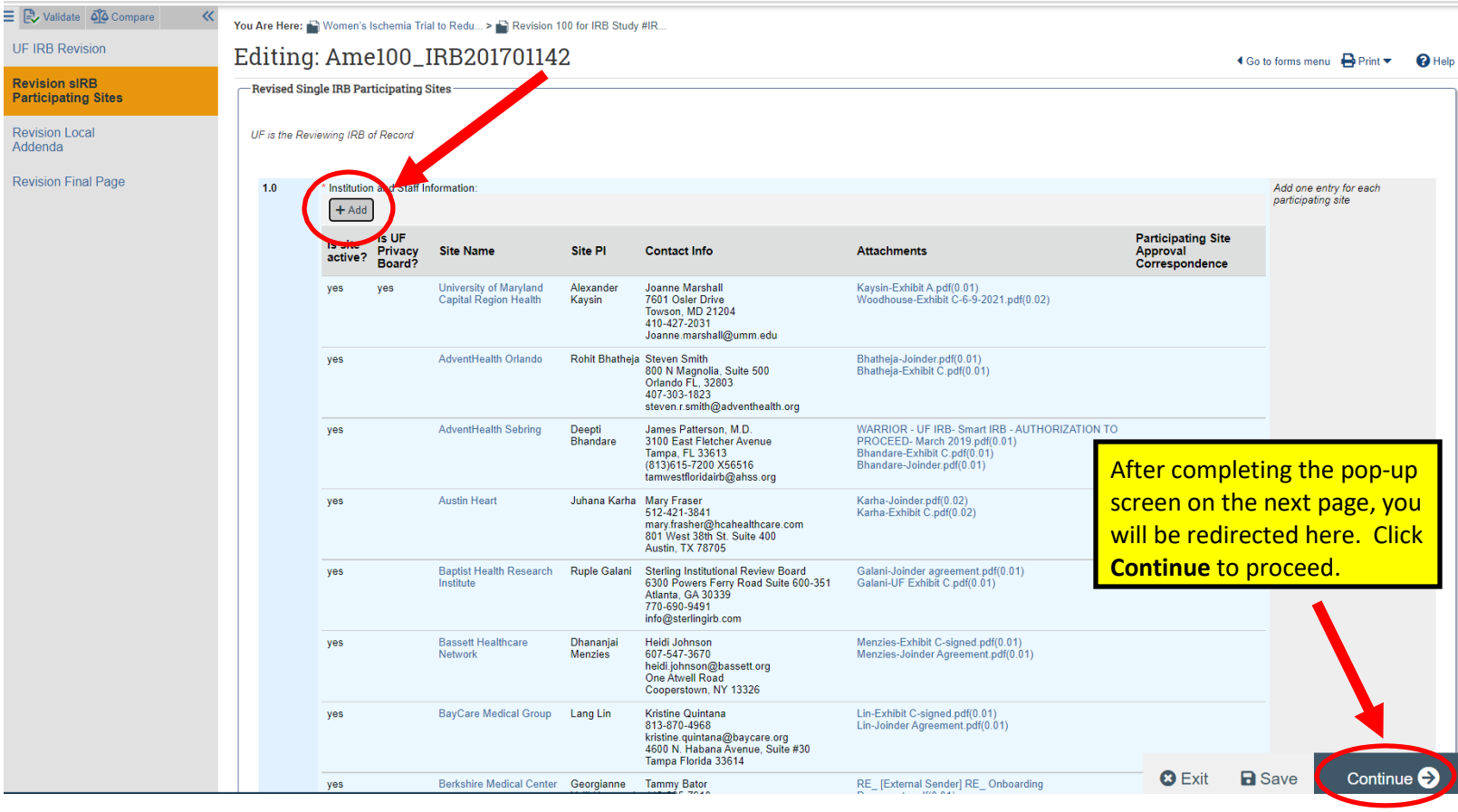


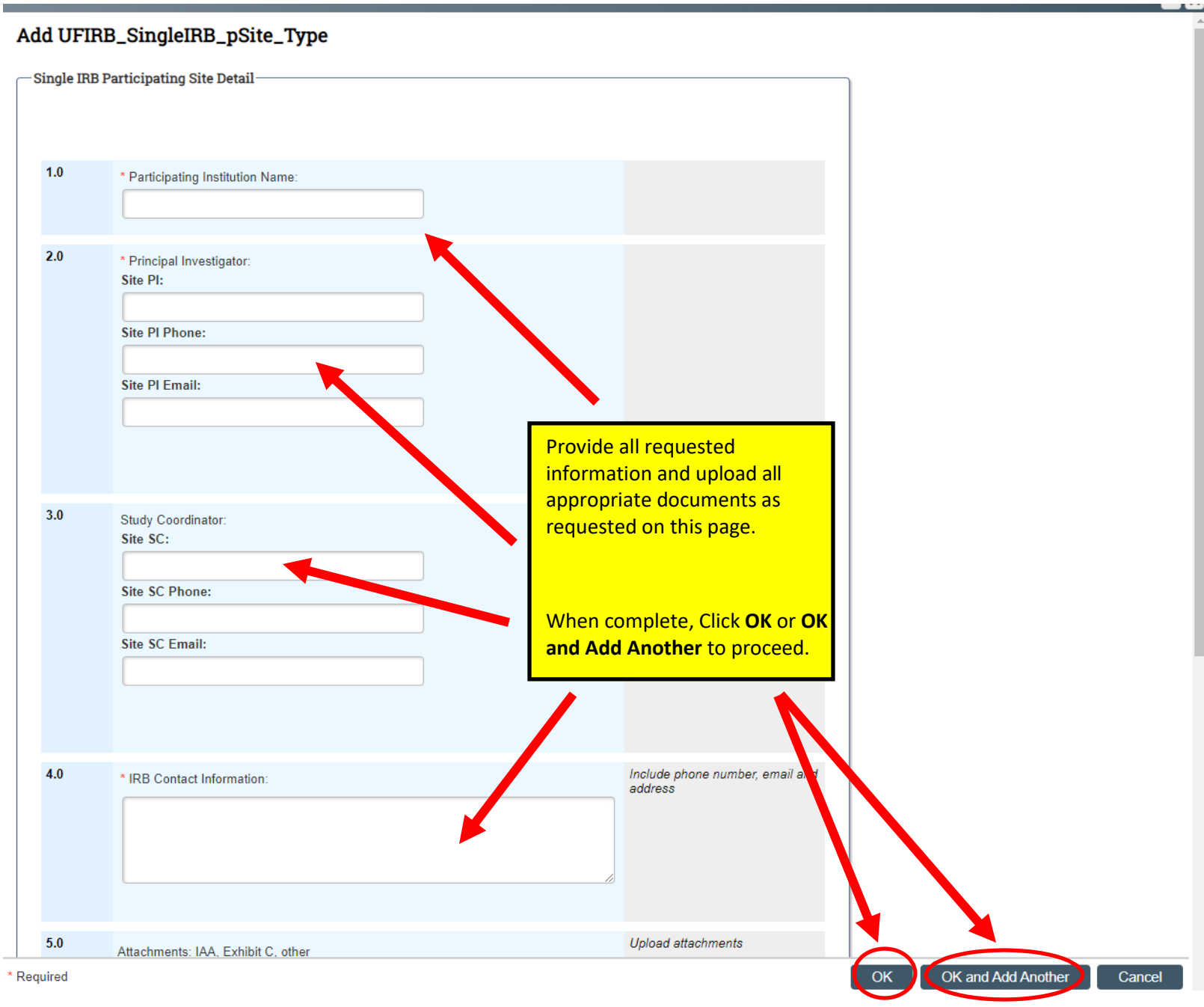
NOTE: pSite revisions **can** be open while there is another, regular revision pending in the IRB system. However, pSite revisions **cannot** be open while there is a continuing review in process. Please **do not** submit a regular revision to add a p-site.

4. Next, the user will be asked to enter information into SmartForms. On the first screenshot below, click **Add** to open the second screenshot where further information will be requested. Remember to answer **Question 5.0** on the first page as well (i.e., the specific information which needs to be included in the IRB response letter).

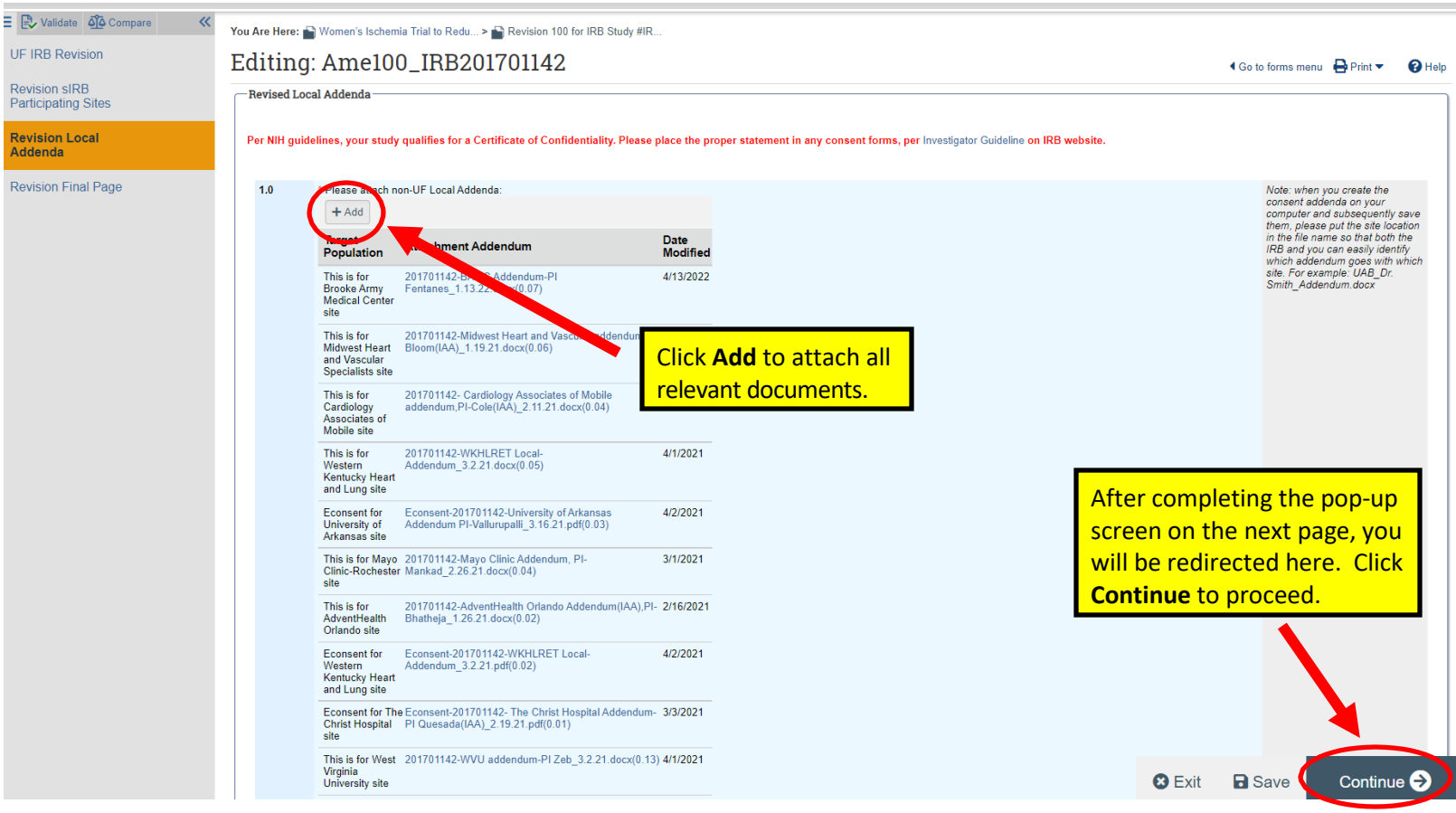


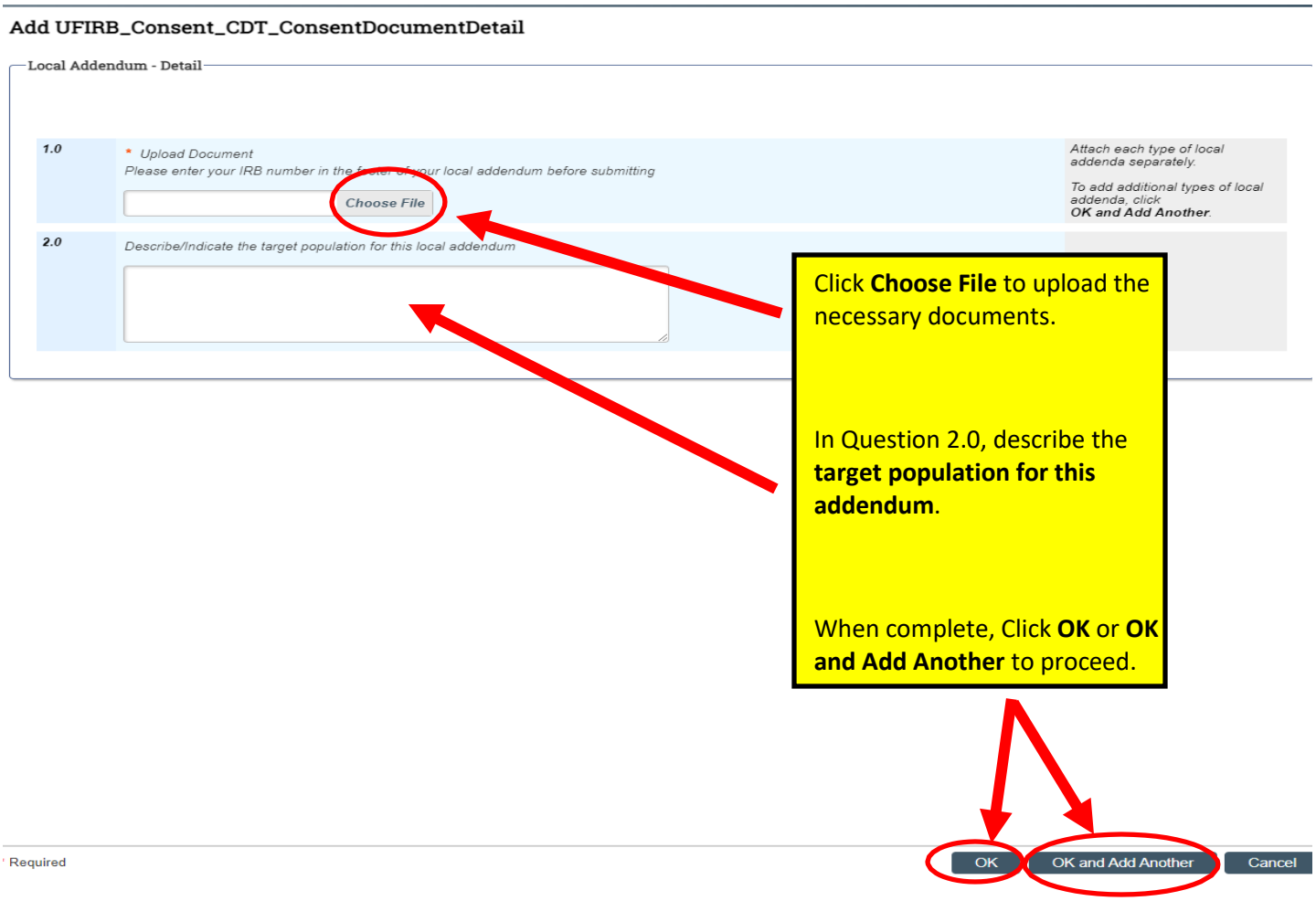
5. Next, on the **Revision sIRB Participating Sites** SmartForm (1st screenshot below), click **Add** to enter the information for the institution being added as a study site (2nd screenshot below). Remember to provide all required information and documents as indicated.


Validate
Compare
UF IRB Revision
Revision sIRB Participating Sites
Revision Local Addenda
Revision Final Page
You Are Here: Women's Ischemia Trial to Redu... > Revision 100 for IRB Study #IR...
Editing: Ame100_IRB201701142
Go to forms menu
Print
Help
Revised Single IRB Participating Sites
UF is the Reviewing IRB of Record
1.0
* Institution and Staff Information:
+ Add
Add one entry for each participating site
Is UF Privacy Board?
Site Name
Site PI
Contact Info
Attachments
Participating Site Approval Correspondence
yes yes University of Maryland Capital Region Health Alexander Kaysin Joanne Marshall 7601 Osler Drive Towson, MD 21204 410-427-2031 Joanne.marshall@umm.edu Kaysin-Exhibit A.pdf(0.01) Woodhouse-Exhibit C-6-9-2021.pdf(0.02)
yes AdventHealth Orlando Rohit Bhatheja Steven Smith 800 N Magnolia, Suite 500 Orlando FL, 32803 407-303-1823 steven.r.smith@adventhealth.org Bhatheja-Joinder.pdf(0.01) Bhatheja-Exhibit C.pdf(0.01)
yes AdventHealth Sebring Deepti Bhandare James Patterson, M.D. 3100 East Fletcher Avenue Tampa, FL 33613 (813)615-7200 X56516 tamwestfloridairb@ahss.org WARRIOR - UF IRB- Smart IRB - AUTHORIZATION TO PROCEED- March 2019.pdf(0.01) Bhandare-Exhibit C.pdf(0.01) Bhandare-Joinder.pdf(0.01)
yes Austin Heart Juhana Karha Mary Fraser 512-421-3841 mary.frasher@hcahealthcare.com 801 West 38th St. Suite 400 Austin, TX 78705 Karha-Joinder.pdf(0.02) Karha-Exhibit C.pdf(0.02)
yes Baptist Health Research Institute Ruple Galani Sterling Institutional Review Board 6300 Powers Ferry Road Suite 600-351 Atlanta, GA 30339 770-690-9491 info@sterlingirb.com Galani-Joinder agreement.pdf(0.01) Galani-UF Exhibit C.pdf(0.01)
yes Bassett Healthcare Network Dhananjai Menzies Heidi Johnson 607-547-3670 heidi.johnson@bassett.org One Atwell Road Cooperstown, NY 13326 Menzies-Exhibit C-signed.pdf(0.01) Menzies-Joinder Agreement.pdf(0.01)
yes BayCare Medical Group Lang Lin Kristine Quintana 813-870-4968 kristine.quintana@baycare.org 4600 N. Habana Avenue, Suite #30 Tampa Florida 33614 Lin-Exhibit C-signed.pdf(0.01) Lin-Joinder Agreement.pdf(0.01)
yes Berkshire Medical Center Georgianne Tammy Bator RE_ [External Sender] RE_ Onboarding
After completing the pop-up screen on the next page, you will be redirected here. Click **Continue** to proceed.
Exit
Save
Continue



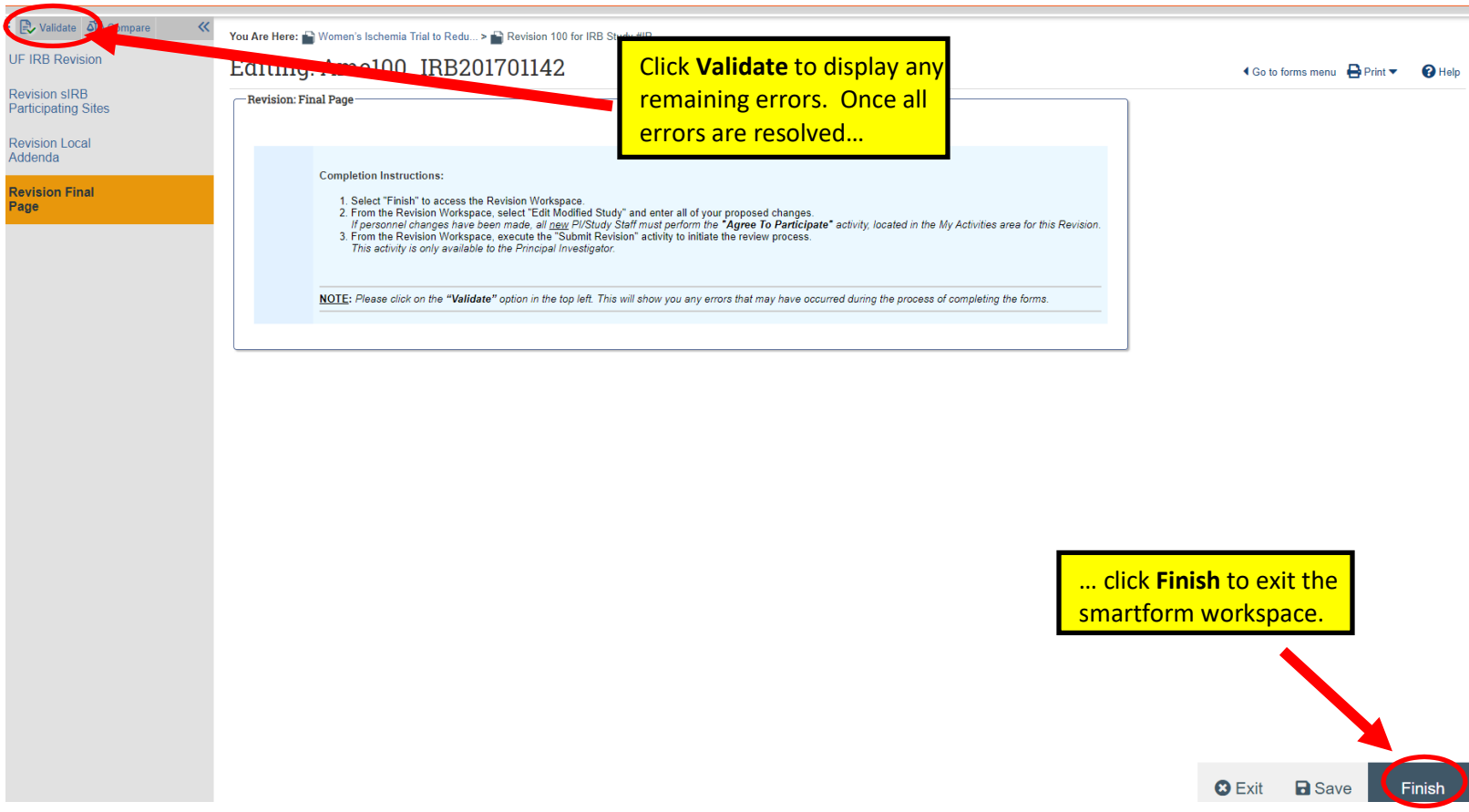
6. On the next screen, click **Add.** This will provide a pop-up detail page (2nd screenshot below) where users can attach any new documents which are relevant to the newly added site.


Validate
Compare
UF IRB Revision
Revision sIRB Participating Sites
Revision Local Addenda
Revision Final Page
You Are Here: Women's Ischemia Trial to Redu... > Revision 100 for IRB Study #IR...
Editing: Ame100_IRB201701142
Go to forms menu
Print
Help
Revised Local Addenda
Per NIH guidelines, your study qualifies for a Certificate of Confidentiality. Please place the proper statement in any consent forms, per Investigator Guideline on IRB website.
1.0
Please attach non-UF Local Addenda:
+ Add
Target Population
Attachment Addendum
Date Modified
This is for Brooke Army Medical Center site
201701142-BAMC Addendum-PI Fentanes_1.13.22.docx(0.07)
4/13/2022
This is for Midwest Heart and Vascular Specialists site
201701142-Midwest Heart and Vascular Addendum-PI Bloom(IAA)_1.19.21.docx(0.06)
This is for Cardiology Associates of Mobile site
201701142- Cardiology Associates of Mobile addendum,PI-Cole(IAA)_2.11.21.docx(0.04)
This is for Western Kentucky Heart and Lung site
201701142-WKHLRET Local-Addendum_3.2.21.docx(0.05)
4/1/2021
Econsent for University of Arkansas site
Econsent-201701142-University of Arkansas Addendum PI-Vallurupalli_3.16.21.pdf(0.03)
4/2/2021
This is for Mayo Clinic-Rochester site
201701142-Mayo Clinic Addendum, PI-Mankad_2.26.21.docx(0.04)
3/1/2021
This is for AdventHealth Orlando site
201701142-AdventHealth Orlando Addendum(IAA),PI-Bhatheja_1.26.21.docx(0.02)
2/16/2021
Econsent for Western Kentucky Heart and Lung site
Econsent-201701142-WKHLRET Local-Addendum_3.2.21.pdf(0.02)
4/2/2021
Econsent for The Christ Hospital site
Econsent-201701142- The Christ Hospital Addendum-PI Quesada(IAA)_2.19.21.pdf(0.01)
3/3/2021
This is for West Virginia University site
201701142-WVU addendum-PI Zeb_3.2.21.docx(0.13)
4/1/2021
Note: when you create the consent addenda on your computer and subsequently save them, please put the site location in the file name so that both the IRB and you can easily identify which addendum goes with which site. For example: UAB_Dr. Smith_Addendum.docx
Click Add to attach all relevant documents.
After completing the pop-up screen on the next page, you will be redirected here. Click Continue to proceed.
Exit
Save
Continue

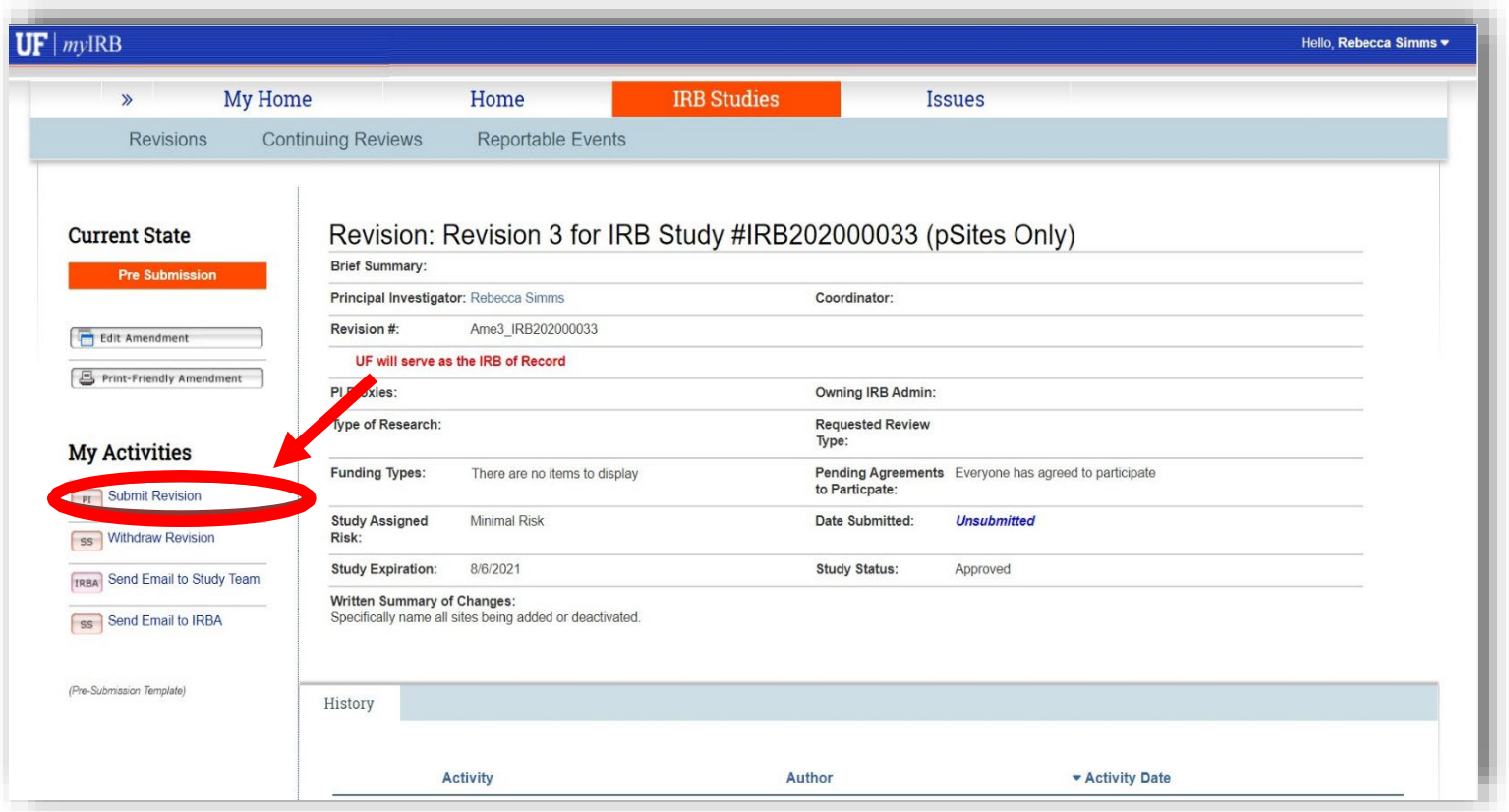

Add UFIRB_Consent_CDT_ConsentDocumentDetail
Local Addendum - Detail
1.0
* Upload Document
Please enter your IRB number in the footer of your local addendum before submitting
Choose File
Attach each type of local addenda separately.
To add additional types of local addenda, click OK and Add Another.
2.0
Describe/Indicate the target population for this local addendum
Click Choose File to upload the necessary documents.
In Question 2.0, describe the target population for this addendum.
When complete, Click OK or OK and Add Another to proceed.
Required
OK
OK and Add Another
Cancel

NOTE: For uploading documents on the screen above, please use the **recommended naming convention**: Site name_PI last name_Addendum (e.g., pSite_PI_Addendum.docx).

7. Next, follow the instructions on the screenshot below.



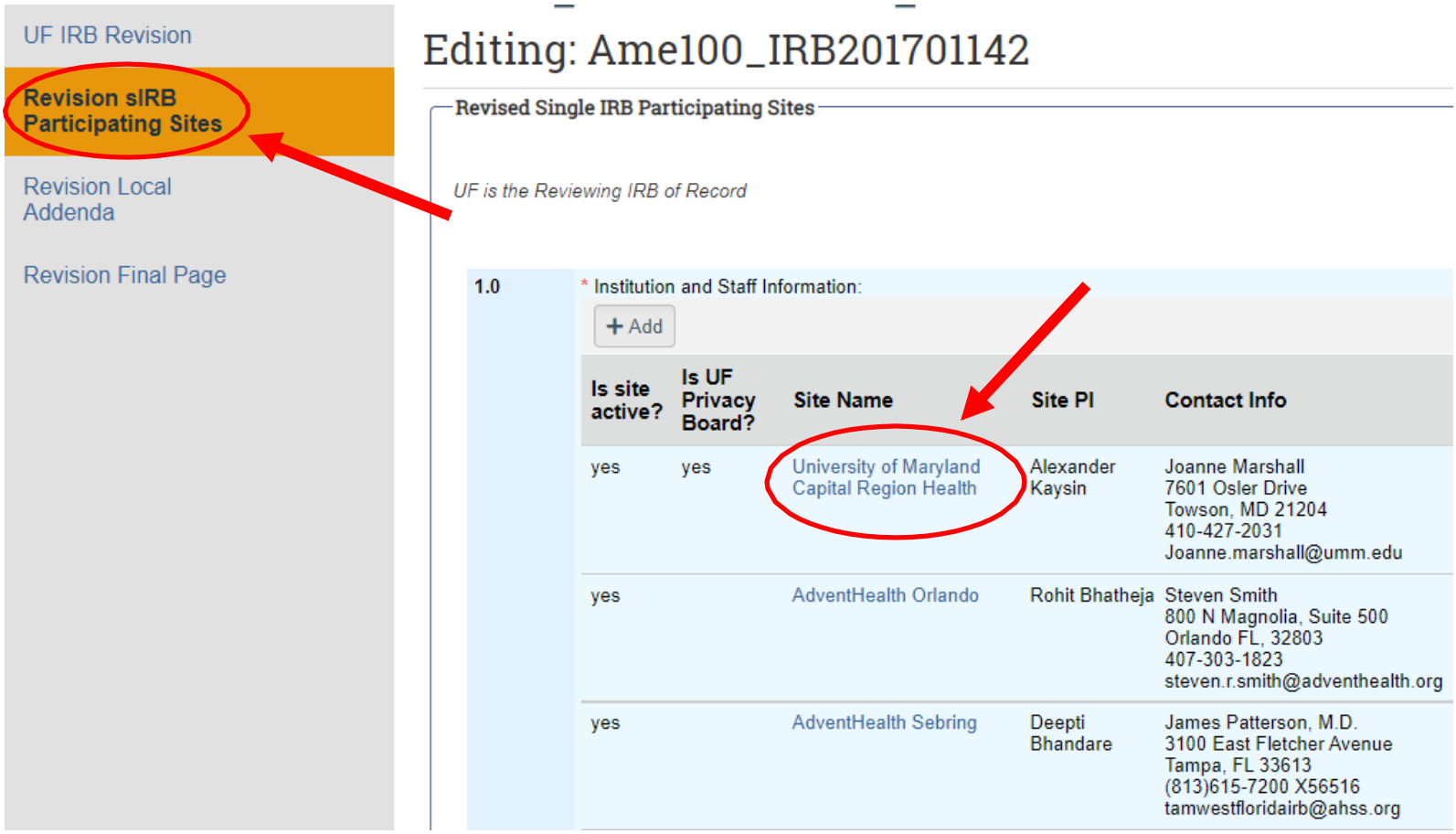
8. After completing the required SmartForms, users will be redirected to the **Revision workspace.** Here, the PI/PI Proxy can submit the Revision. To do so, look for the **My Activities** heading on the left side of the page and click **Submit Revision**.

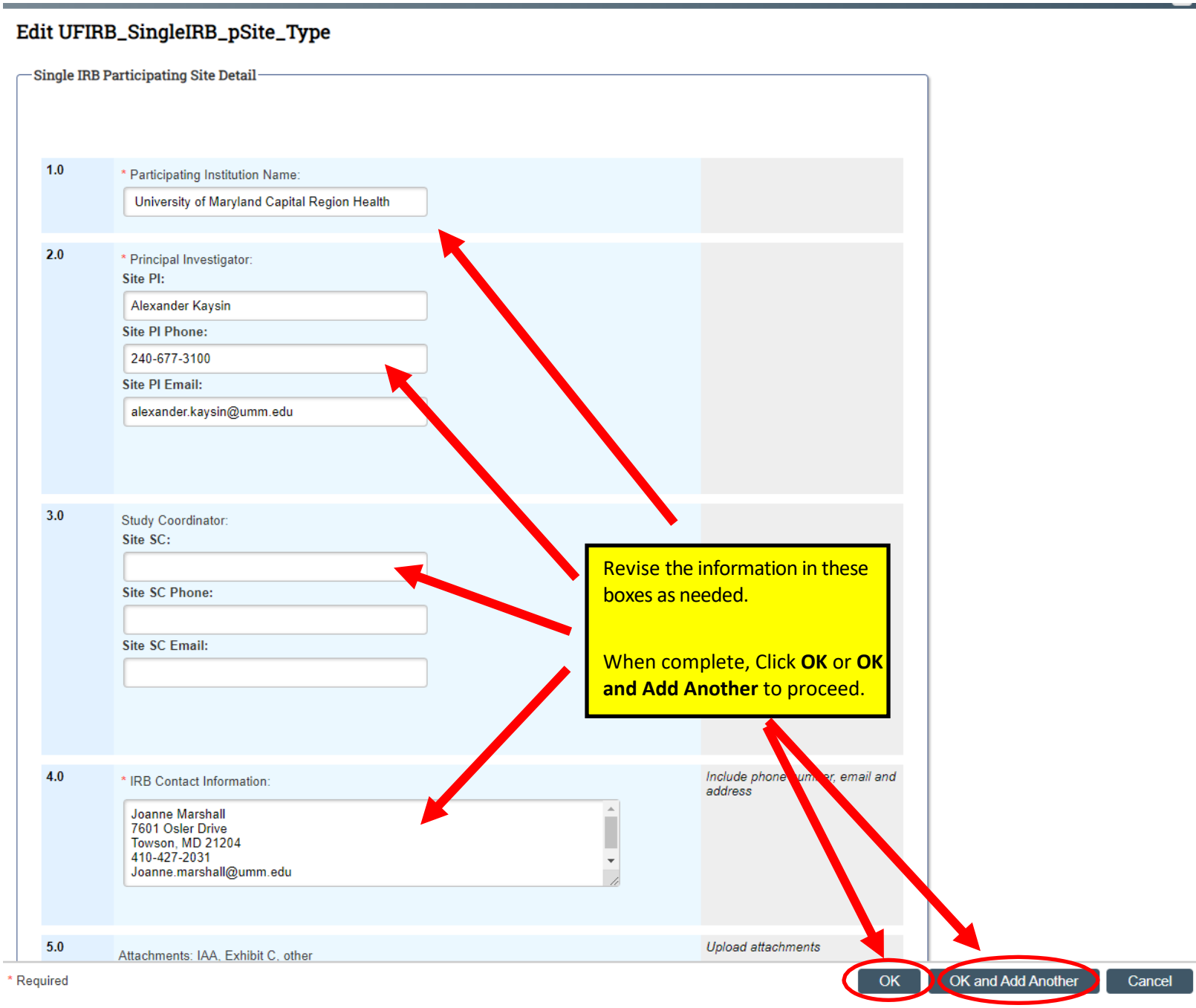


Revising a Participating Site (P-Site) where UF is the IRB of Record

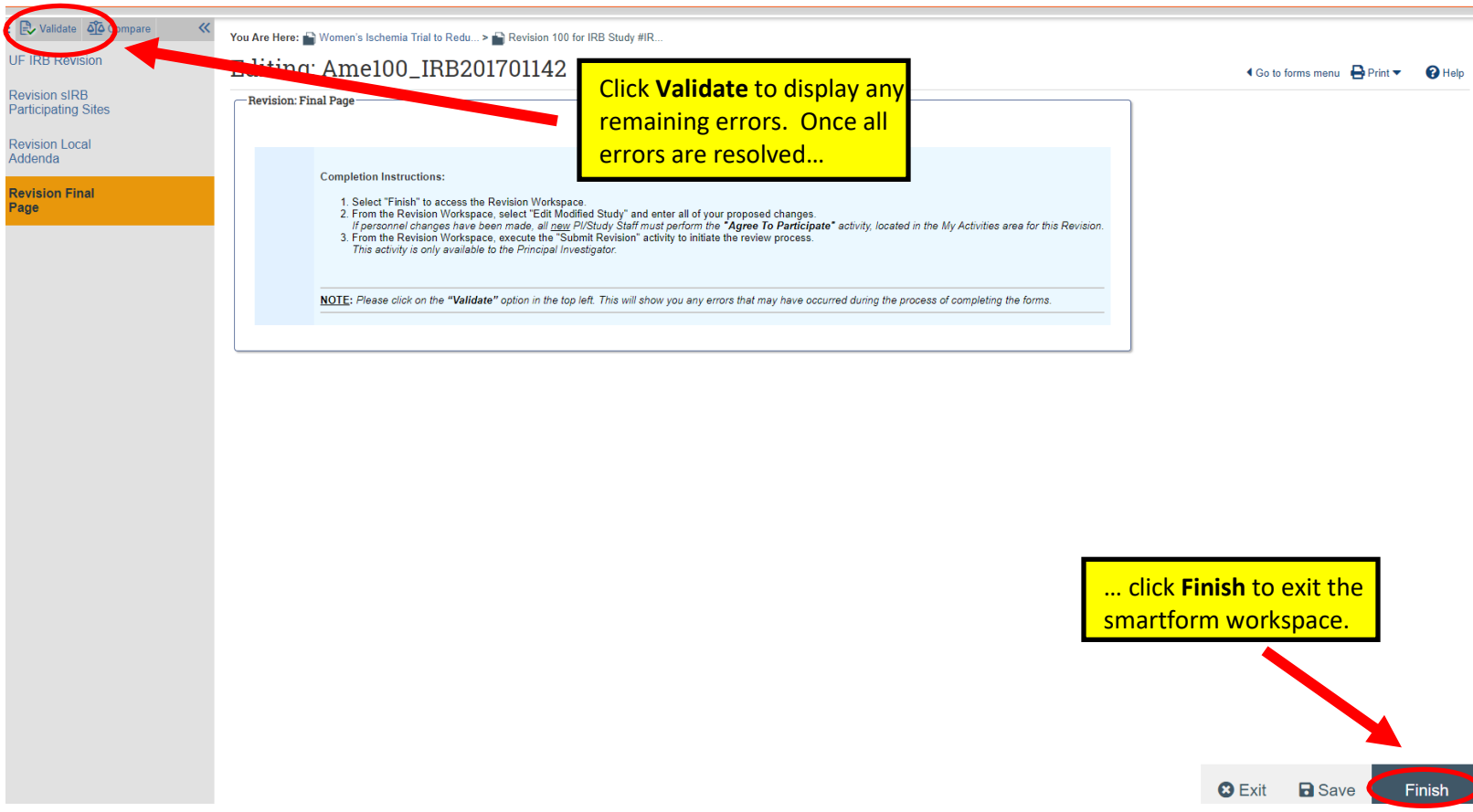
To revise a pSite which is already listed on study, follow the steps in the previous section of this manual to open a new **pSite only revision**. Then, follow these steps to complete the edit:

1. Log-in to the SmartForms, and click on the **Revision sIRB Participating Sites** SmartForm (1st screenshot below).
2. Next, click the name of the pSite you want to revise. Doing so will open the detail page for that pSite (2nd screenshot below). On this screen, make any necessary edits to the information for this pSite. When complete, click **OK** or **OK and Add Another.**

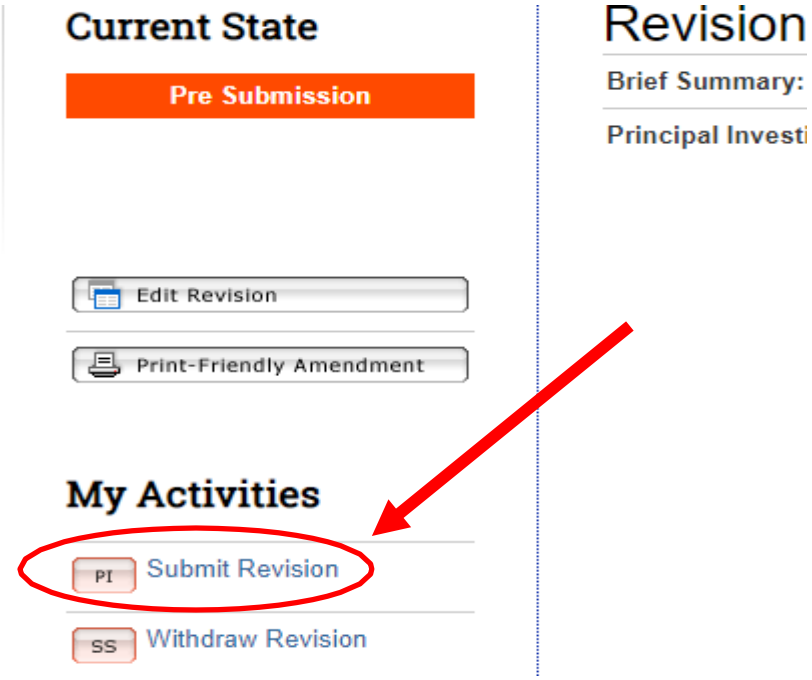




3. After updating the above screen, users will be redirected to the **Revision sIRB Participating Sites** smartform. From there, navigate through the remaining smartforms until you reach the **Revision Final Page**. Then, click **Finish** to be redirected to the Revision workspace.



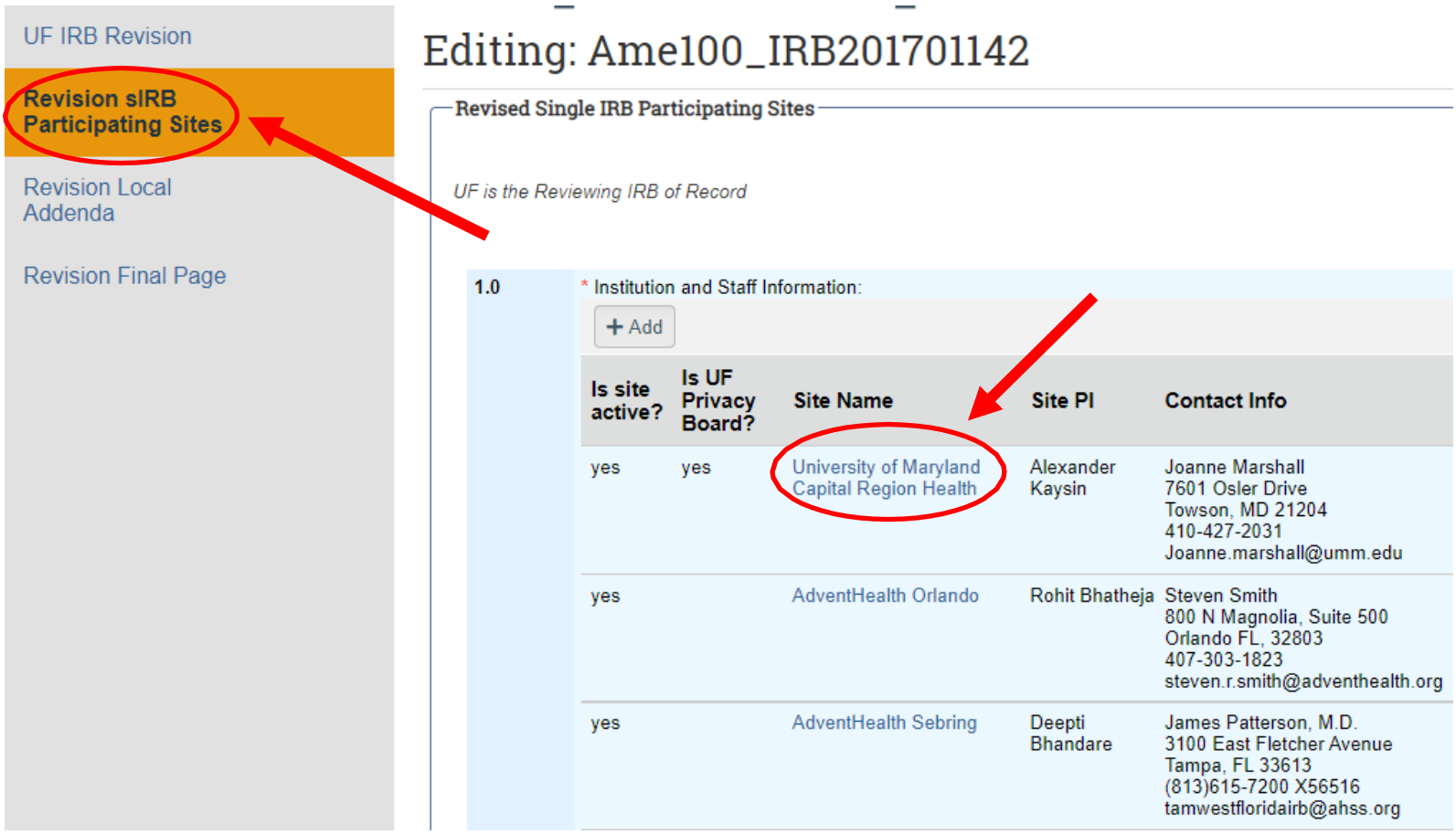
4. Lastly, after being redirected to the **Revision workspace,** the PI/PI Proxy should look for the **My Activities** heading on the left side of the page. Under that heading, click **Submit Revision**.



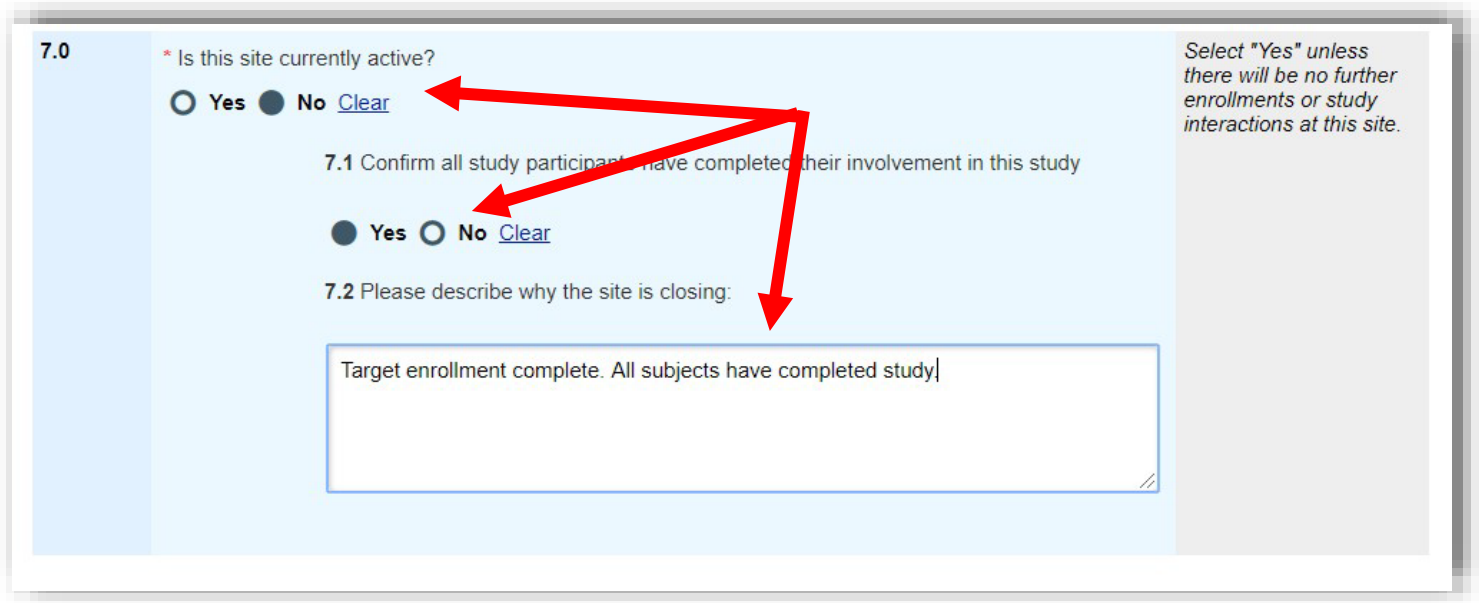
Deactivating a Participating Site (P-Site) where UF if the IRB of Record

To deactivate a pSite which is already listed on study, follow the steps outlined in the in the **Adding a Participating Site (P-Site) where UF IRB is the IRB of Record** section of this manual to open a new pSite only revision. Then, follow these steps to complete the edit.

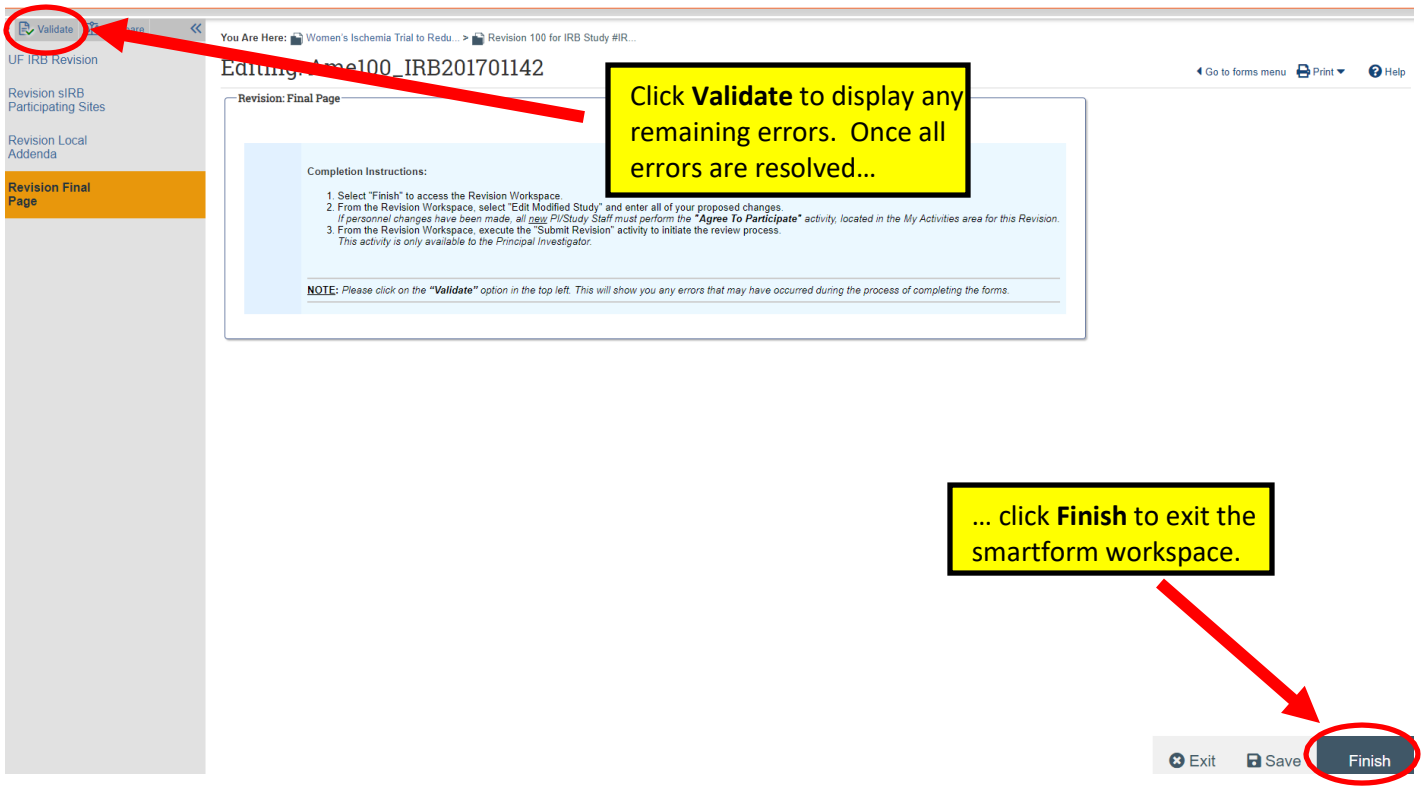
1. Log-in to the smartforms, and click on the **Revision sIRB Participating Sites** smartform (screenshot below).
2. Next, click the name of the pSite you want to deactivate. Doing so will open the detail page for that pSite.



3. Once on the detail page for the pSite that is being deactivated, look for **question 7.0.** There, change the answer for that item questions from "Yes" to "No". Remember to address questions 7.1 and 7.2 as well.



Once the detail page is updated, click **OK** at the bottom of the screen. After updating the above screen, users will be redirected to the **Revision sIRB Participating Sites** smartform. From there, navigate through the remaining smartforms until you reach the **Revision Final Page**. Then, click **Finish** to be redirected to the Revision workspace.



Lastly, after being redirected to the **Revision workspace,** the PI/PI Proxy should look for the **My Activities** heading on the left side of the page. Under that heading, click **Submit Revision**.