

*my*IRB

Electronic Submission

Researcher Manual

UF | UNIVERSITY *of*
FLORIDA

The Foundation for The Gator Nation

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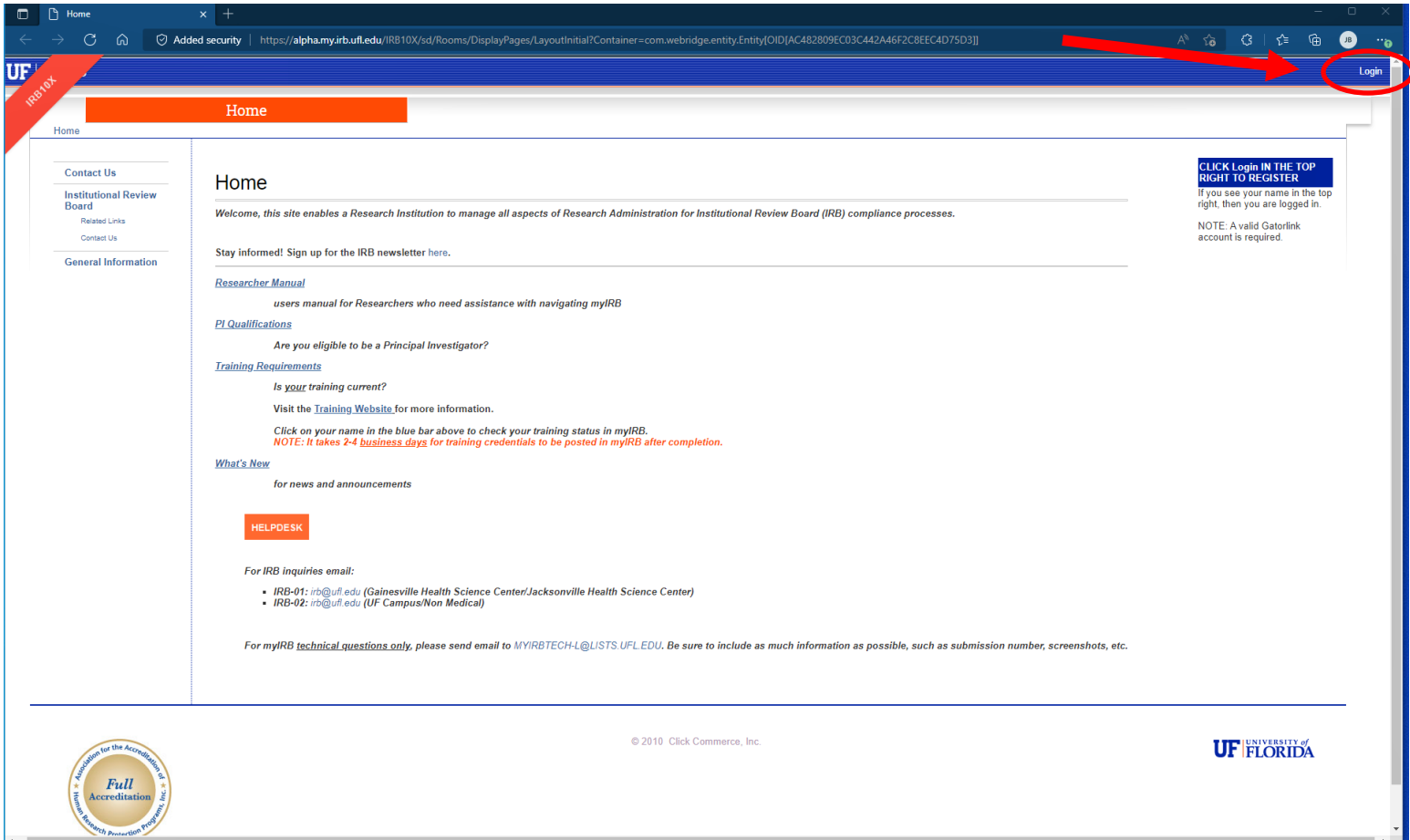
Each chapter is hyperlinked. Click on the name of the chapter to automatically navigate to that page in the manual.

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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**.

UF | myIRB

Login As

User Name:

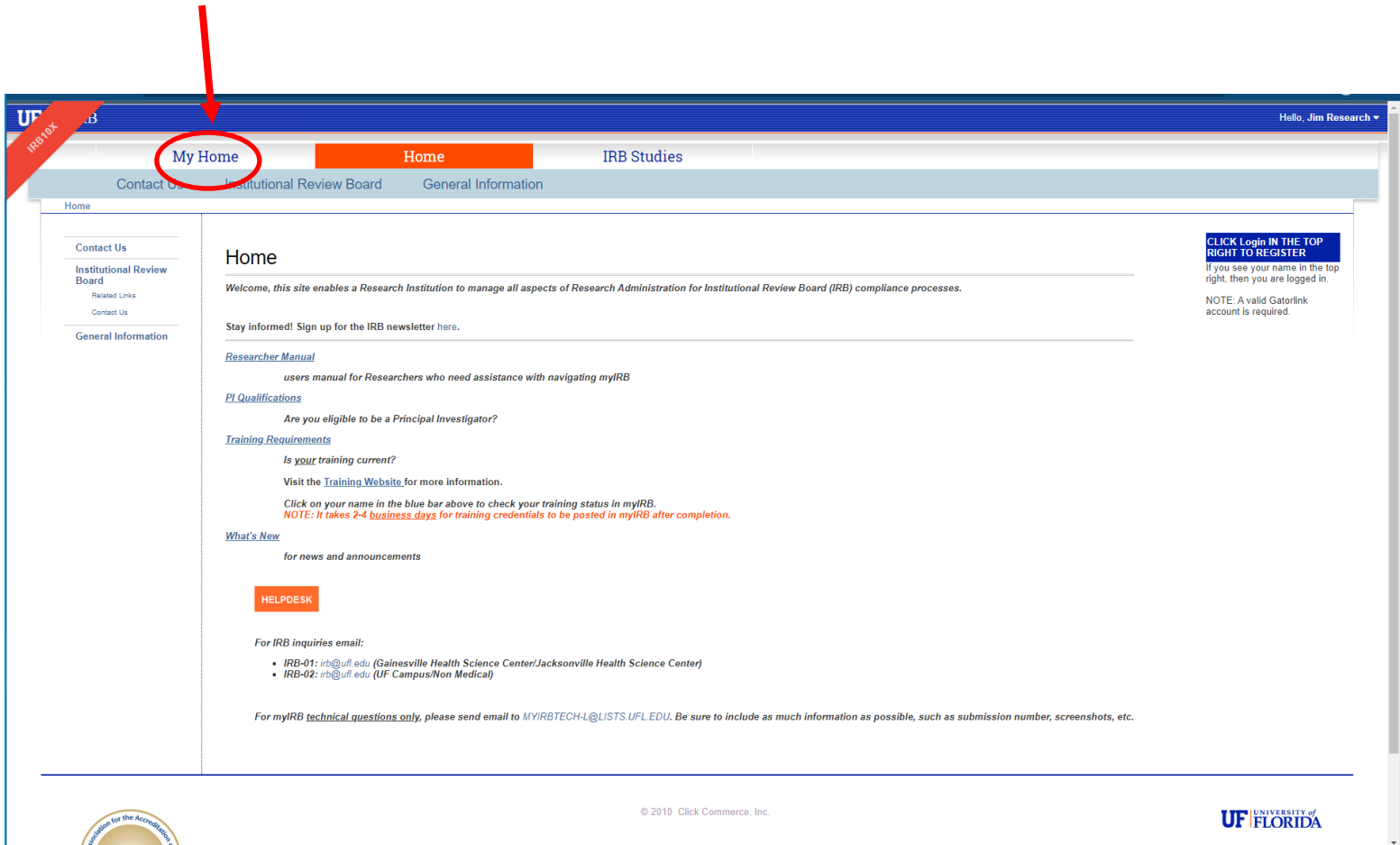
Password:

Remember me

After signing into this site, you are bound by the terms and conditions set forth when you received your account.

"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 screenshot shows the myIRB Home Page interface. At the top, there is a navigation bar with tabs for "My Home", "Home", and "IRB Studies". The "My Home" tab is circled in red, and a red arrow points to it from the text above. Below the navigation bar, there is a sidebar on the left with links for "Contact Us", "Institutional Review Board", "Related Links", and "General Information". The main content area is titled "Home" and contains a welcome message, a "Stay informed!" section, and links to "Researcher Manual", "PI Qualifications", and "Training Requirements". A "HELPDESK" button is visible, along with contact information for IRB inquiries. In the top right corner, there is a blue box with the text "CLICK Login IN THE TOP RIGHT TO REGISTER" and a note about Gatorlink accounts. The footer includes the University of Florida logo and copyright information.

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.

myIRB

Hello, Jim Research

My Home Home IRB Studies

Page for Jim Research

Study Staff

My Roles

Guest Users
Study Staff

Create

New Study

Ceded Study Review

Inbox Studies Templates

Please note that effective 12/5/19, IRB started confirming compliance with the NIH's GCP requirement for NIH funded clinical trials. In order to agree to participate on a study of this sort, PI and everyone on study staff must have this training on file in myIRB. For more information please go [here](#).

Welcome to your Personal Page, the starting point for all interactions with this site. Note the following:

- Inbox - Items appearing here required immediate action by you to speed your submission through the review process. Click on link to process an item.
- Monitor the progress of your submissions using the Studies tab. Items on this tab does not require any action by you.

Filter by ID Enter text to search + Add Filter X Clear All

ID	Name	Date Modified	Type	Owner	State	Last State Change	Committee
IRB202201866	Alpha 22 - Expedited Study	9/13/2022 12:06 PM	Study		Pre Submission	9/13/2022 12:06 PM	IRB-01

1 Items

page 1 of 1

10 / page



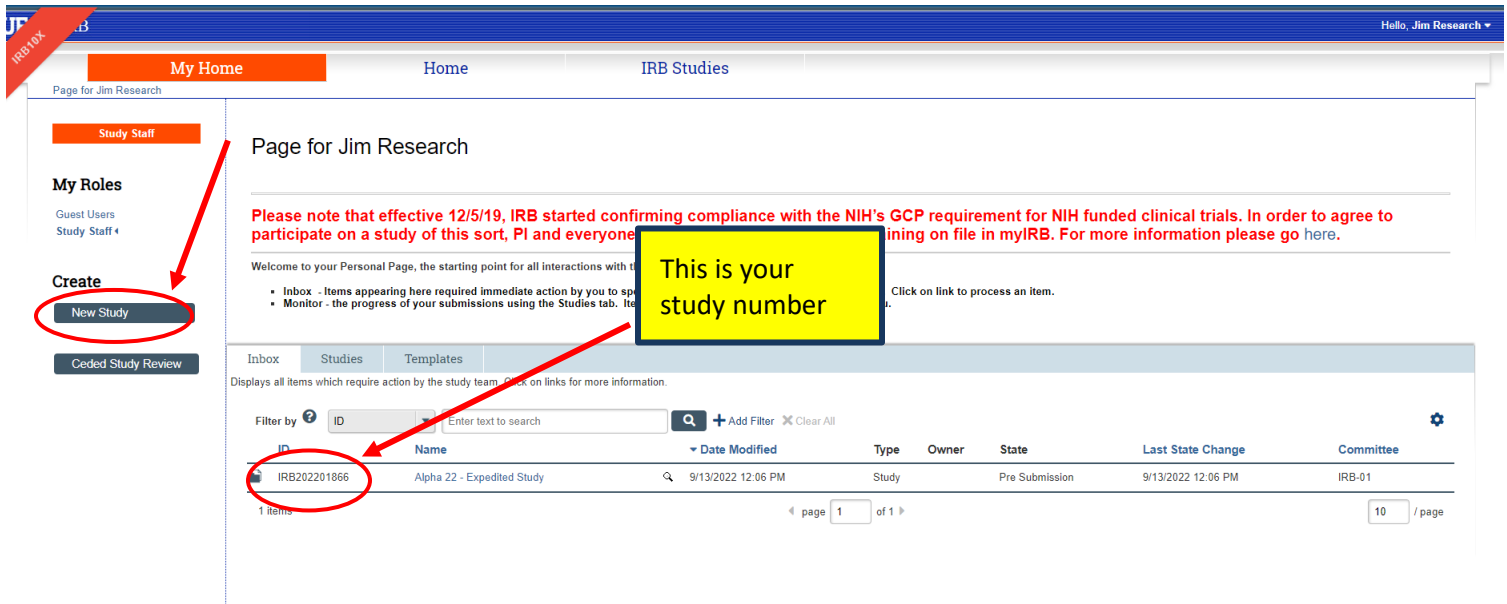
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Create New Study

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**.



The screenshot shows the myIRB website interface for a user named Jim Research. The page is titled "Page for Jim Research" and features a navigation menu with "My Home", "Home", and "IRB Studies". A sidebar on the left contains "Study Staff", "My Roles", and a "Create" section with a "New Study" button circled in red. A yellow box with the text "This is your study number" points to the ID "IRB202201866" in a table of studies. The table has columns for ID, Name, Date Modified, Type, Owner, State, Last State Change, and Committee. The table contains one row: IRB202201866, Alpha 22 - Expedited Study, 9/13/2022 12:06 PM, Study, Pre Submission, 9/13/2022 12:06 PM, IRB-01. A red arrow also points from the "New Study" button to the "IRB202201866" ID.

Page for Jim Research

Study Staff

My Roles

Guest Users

Study Staff

Create

New Study

Ceded Study Review

Page for Jim Research

Please note that effective 12/5/19, IRB started confirming compliance with the NIH's GCP requirement for NIH funded clinical trials. In order to agree to participate on a study of this sort, PI and everyone participating in file in myIRB. For more information please go [here](#).

Welcome to your Personal Page, the starting point for all interactions with the system.

- Inbox - Items appearing here required immediate action by you to speed up the process.
- Monitor - the progress of your submissions using the Studies tab. Items requiring action will appear in red.

Click on link to process an item.

Inbox Studies Templates

Displays all items which require action by the study team. Click on links for more information.

Filter by ID Enter text to search + Add Filter X Clear All

ID	Name	Date Modified	Type	Owner	State	Last State Change	Committee
IRB202201866	Alpha 22 - Expedited Study	9/13/2022 12:06 PM	Study	Pre Submission	9/13/2022 12:06 PM	IRB-01	

1 items

page 1 of 1

10 / page



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TIP: While accessing the *myIRB* 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.

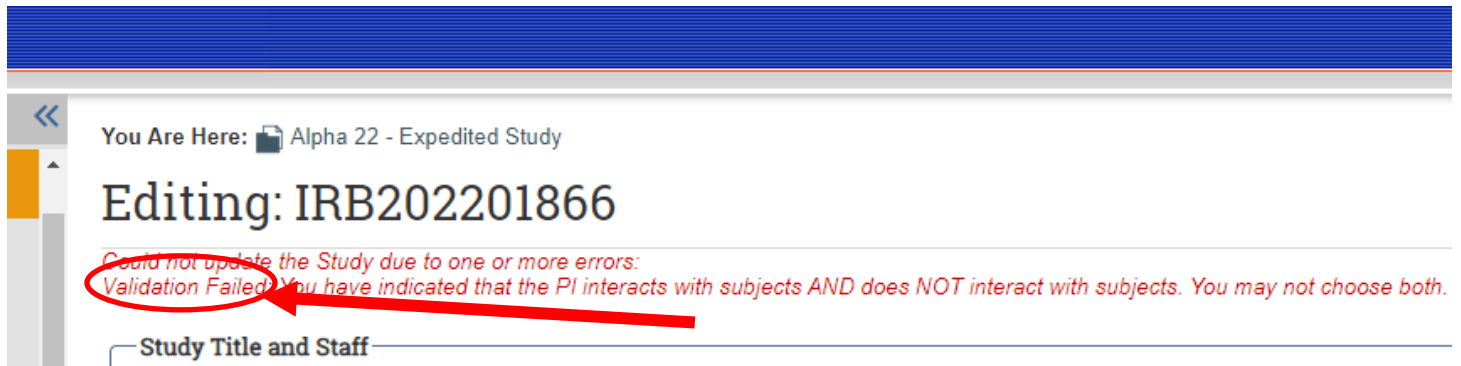
TIP: Throughout the SmartForms, required fields are marked with an orange asterisk *.

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:

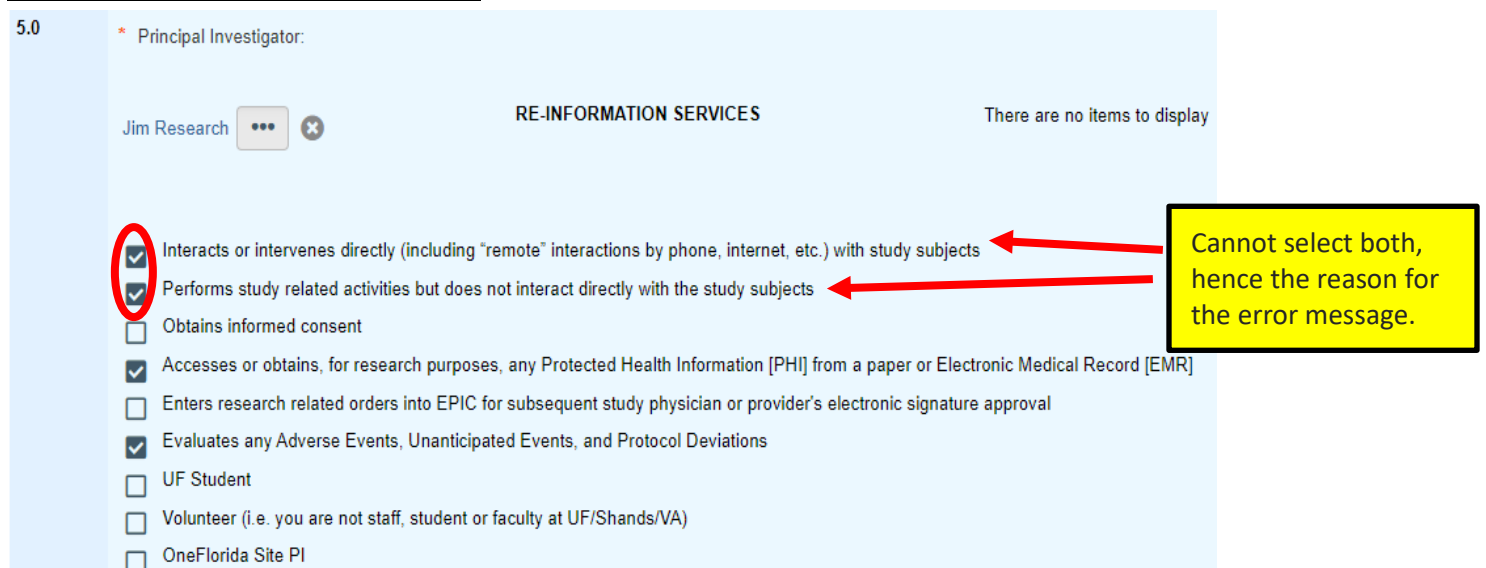
The screenshot displays the myIRB system interface. On the left, a vertical sidebar (Left Navigator) is highlighted with a red box and labeled 'Left Navigator'. It lists various SmartForm sections such as 'Study Title and Staff', 'Researcher Training Summary', 'Requested Review Type', 'Oncology SRMC Determination', 'Individual COI and Affiliation Summary', 'EHS Determination', 'Risk Benefit', 'Study Location', 'Study Funding', 'Study Overview', 'Study Population', and 'Subject Description'. The main content area shows the 'Study Title and Staff' form for IRB202201866. It includes a '1.0 IRB Committee' section with radio buttons for IRB-01 and IRB-02, and a '1.1' question about multi-institutional research. Below this are text boxes for '2.0 Project Title' (containing 'Alpha 22 - Expedited Study'), '3.0 Short Title', and '4.0 Provide a summary description or abstract for this study:'. In the bottom right corner, three buttons are circled in red and labeled 'Note placement of Exit, Save, and Continue buttons': 'Exit', 'Save', and 'Continue'.

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:

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Validate Compare

Review Determination

You Are Here: Alpha 22 - Expedited Study

Editing: IRB202201866

Miscellaneous

1.0	Certificate of Decedent Informa	[None] Upload
2.0	Approved Social Security Exce	[None] Upload
3.0	Upload miscellaneous study at	+ Add

Screenshot 2:

Submit a Document

Type file name

Title:

If not provided, the name of the file will be used

* File: Choose File

Show Advanced Options

* Required

OK OK and Add Another Cancel

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

1.0

* Select UF and/or UF Health sites where this study will be conducted:

There are no items to display

1.1 If "Other", specify:

Click here to open sub-page (second screenshot)

Select One or More UFIRB_List_Location Types

Filter by

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Type Value
<input type="checkbox"/> AG-Ag Education and Communication
<input type="checkbox"/> AG-Family, Youth and Community Sciences
<input type="checkbox"/> AG-Food and Resource Economics
<input type="checkbox"/> AG-Food Science and Human Nutrition
<input type="checkbox"/> AG-Forest Resources and Conservation
<input type="checkbox"/> AG-Wildlife Ecology and Conservation
<input type="checkbox"/> BA-Accounting
<input type="checkbox"/> BA-Economics
<input type="checkbox"/> BA-Management
<input type="checkbox"/> BA-Marketing
<input type="checkbox"/> Brooks Rehab Hospital
<input type="checkbox"/> Cardiology West at Doctors Park
<input type="checkbox"/> Cardiovascular Clinic at UF Health UF

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

Left Navigator: E.g., clicking on the “Study Locations” link in the menu will redirect you to that smartform.

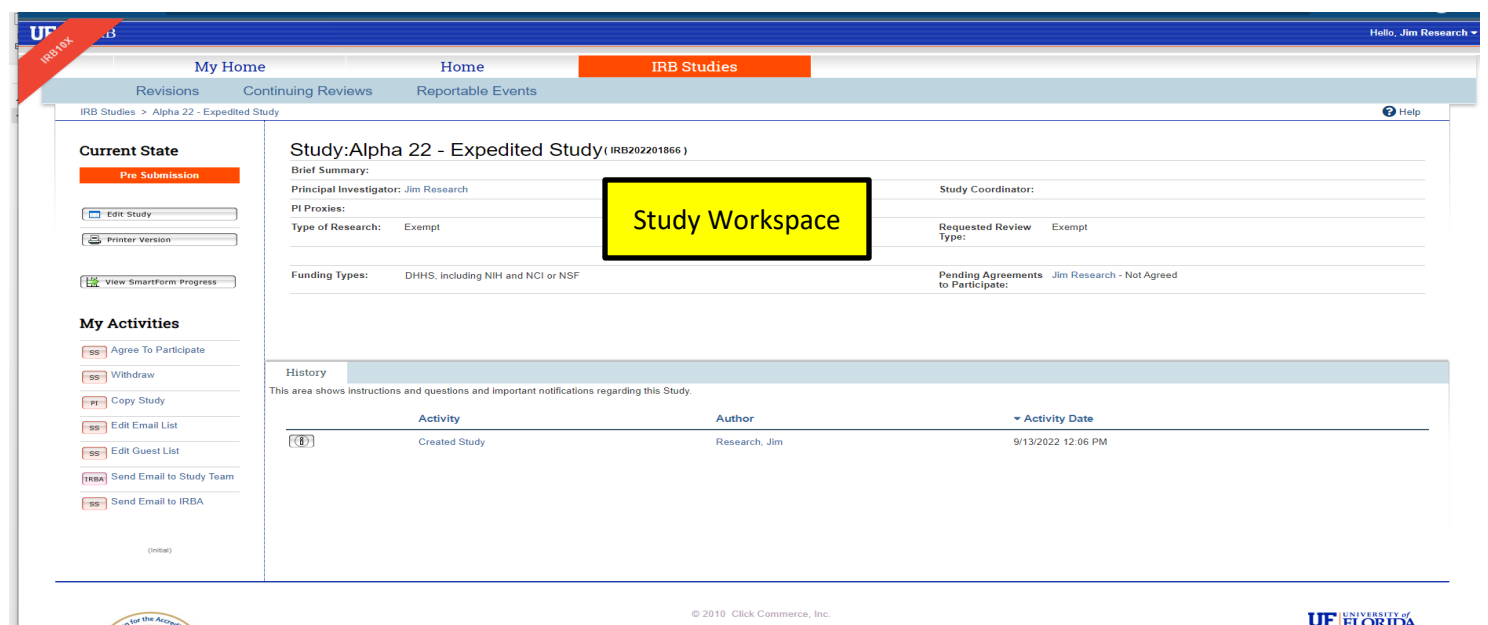
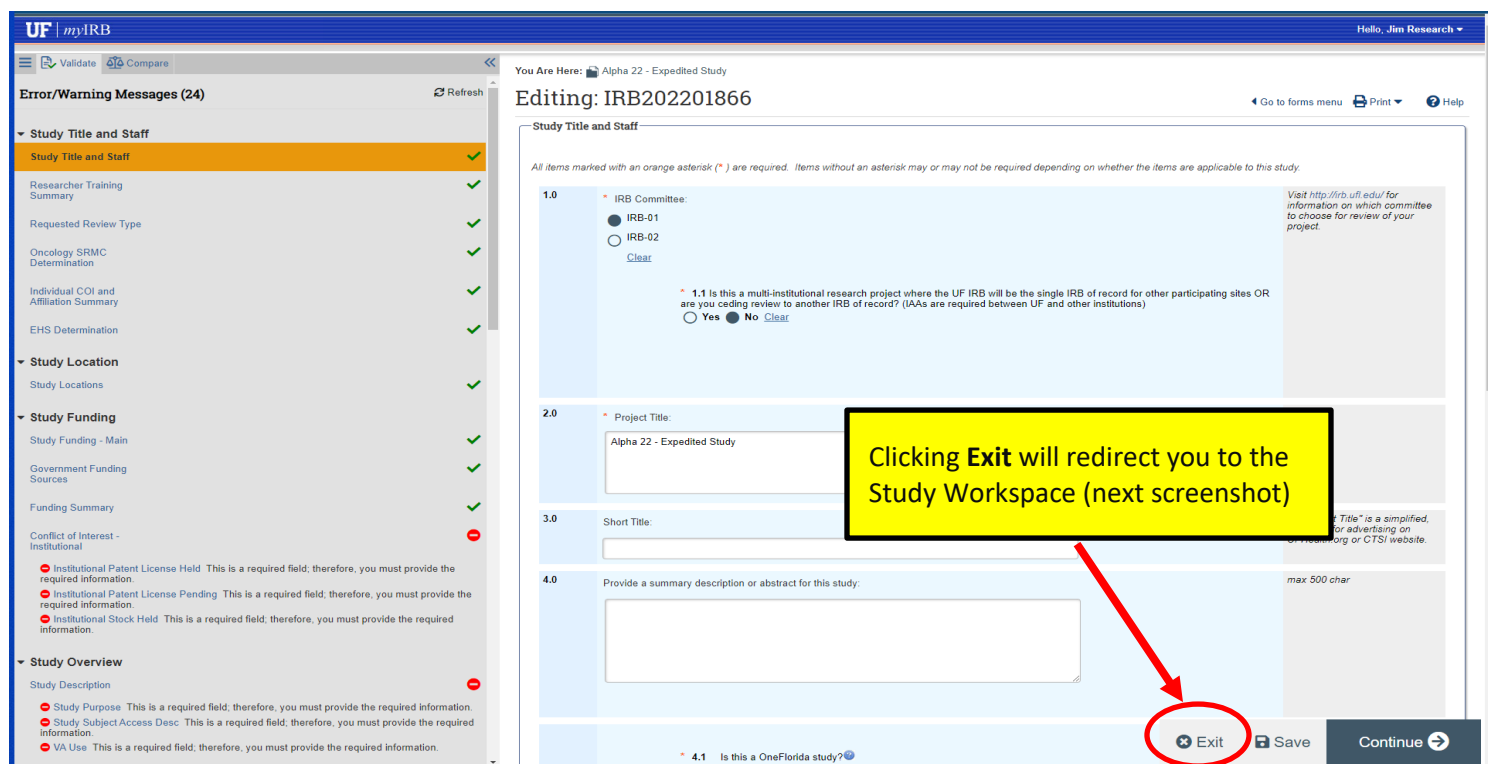
Click the **Continue** button to advance to the next relevant smartform.

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.

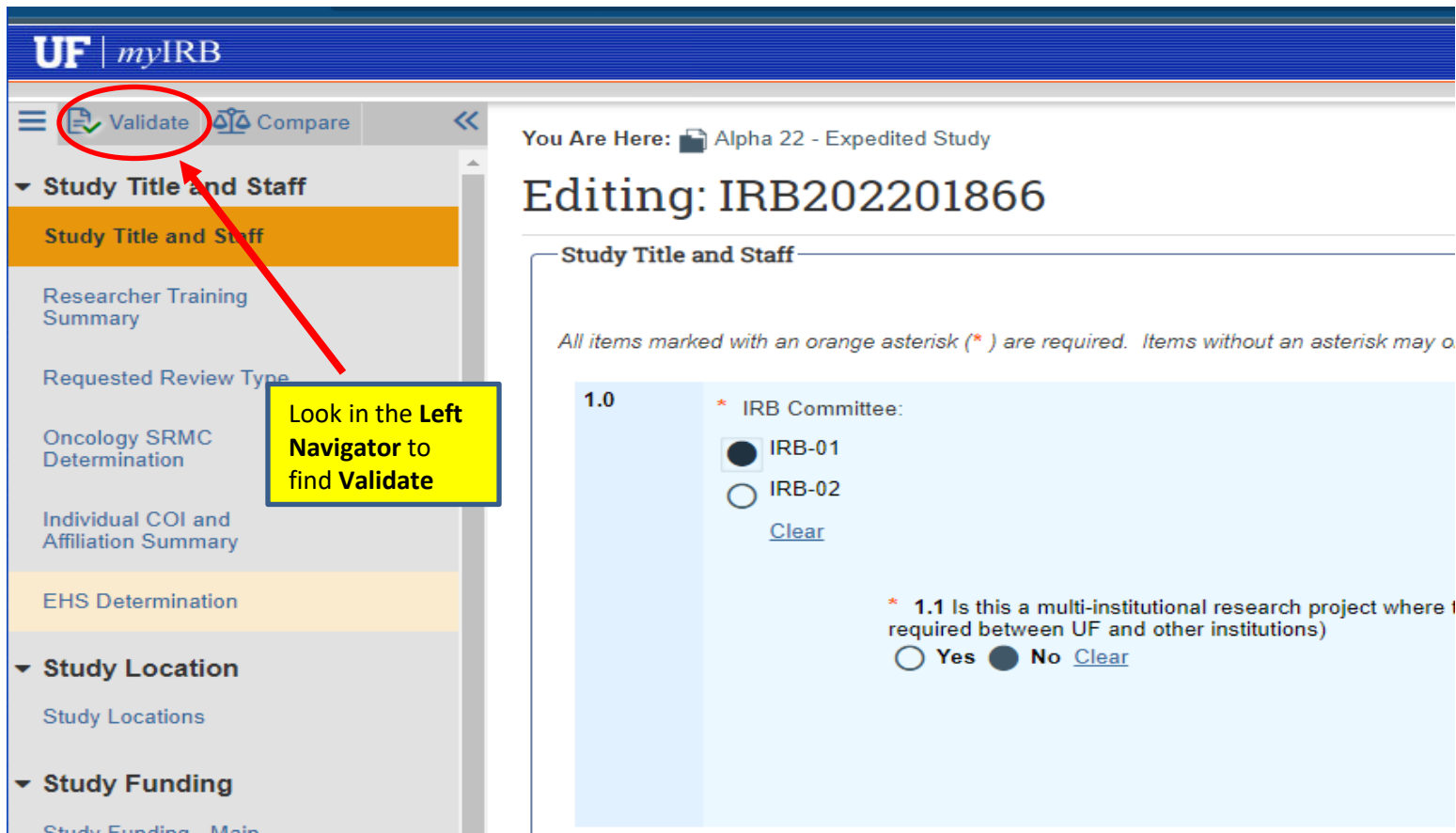
To check the progress of your submission, visit the **Study Workspace** (screenshot above). From there, click **View SmartForm Progress** on the left side of the page to open a window which will provide a status report on the SmartForms. Each will be listed as **Complete**, **Incomplete**, or **Not Required**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

The screenshot displays the 'Study Workspace' for 'Study: Alpha 22 - Expedited Study (IRB201801282)'. On the left sidebar, the 'View SmartForm Progress' button is highlighted with a red circle. A modal window is open, showing a progress report table. The table has three columns: 'Section', 'Description', and 'Progress'. The progress status for each section is as follows:

Section	Description	Progress
Study Title and Staff		Complete
Risk Benefit		Complete
Study Location		Complete
Study Funding		Complete
Study Overview		Incomplete
Drugs/Substances		Incomplete
Devices		Not Required
Research-only Procedures		Not Required
Radiation		Not Required

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).



The screenshot displays the myIRB interface. At the top left, the 'Validate' button is circled in red. A red arrow points from this button to a yellow callout box containing the text: 'Look in the Left Navigator to find Validate'. The left sidebar shows a 'Study Title and Staff' section with various sub-items. The main content area shows the 'Editing: IRB202201866' form, with a 'Study Title and Staff' section containing a form field for 'IRB Committee' with radio buttons for 'IRB-01' (selected) and 'IRB-02', and a 'Clear' link. Below this, there is a question '1.1 Is this a multi-institutional research project where required between UF and other institutions)' with radio buttons for 'Yes' and 'No' (selected), and a 'Clear' link.

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Validate Compare Refresh

Error/Warning Messages (24)

Study Title and Staff

Study Title and Staff ✓

Researcher Training Summary ✓

Requested Review Type ✓

Oncology SRMC Determination ✓

Individual COI and Affiliation Summary ✓

EHS Determination ✓

Study Location

Study Locations ✓

Study Funding

Study Funding - Main ✓

Government Funding Sources ✓

Funding Summary ✓

Conflict of Interest - Institutional ○

- Institutional Patent License Held This is a required field; therefore, you must provide the required information.
- Institutional Patent License Pending This is a required field; therefore, you must provide the required information.
- Institutional Stock Held This is a required field; therefore, you must provide the required information.

Study Overview

Study Description ○

- Study Purpose This is a required field; therefore, you must provide the required information.
- Study Subject Access Desc This is a required field; therefore, you must provide the required information.
- VA Use This is a required field; therefore, you must provide the required information.

Annotations:

- Sections with green checks are complete
- This expanded menu will appear after clicking **Validate**
- Pages with red circles are missing information

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:

The screenshot displays the myIRB web application interface. At the top, there is a navigation bar with 'UF myIRB' on the left and 'Hello, Jim Research' on the right. Below this is a secondary navigation bar with 'My Home', 'Home', and 'IRB Studies' (highlighted in orange). Underneath, there are tabs for 'Revisions', 'Continuing Reviews', and 'Reportable Events'. The main content area is divided into two columns. The left column contains a 'Current State' section with a 'Pre Submission' button and three links: 'Edit Study', 'Printer Version', and 'View SmartForm Progress'. Below this is a 'My Activities' section with a red circle around the 'Agree To Participate' link, which is also pointed to by a red arrow. Other links in this section include 'Withdraw', 'Copy Study', 'Edit Email List', and 'Edit Guest List'. The right column displays details for 'Study: Alpha 22 - Expedited Study (IRB201801282)'. It includes a 'Brief Summary', 'Principal Investigator: Jim Research', 'Study Coordinator', 'PI Proxies', 'Type of Research', 'Requested Review Type: Expedited', and 'Funding Types'. A 'History' table at the bottom shows a single entry: 'Created Study' by 'Research, Jim' on '8/12/2018 3:36 PM'.

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.

Individual Conflict of Interest and Affiliation

Certification: * Do you agree to participate in this study?
 Yes No [Clear](#)

Agree to participate?

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?

Yes No [Clear](#)

Conflict of Interest?

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]

1.2 If applicable, upload Office of Compliance Approval Letter here:

[None]

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.

- UF
- Shands
- VA
- Unaffiliated
- OneFlorida
- SUS

Researcher Affiliation?

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]

2.2 If applicable, upload CV here:

[None]

2.3 If applicable, upload Medical License here:

[None]

Upload supporting documents (if needed)

Please review and update your Registry Information 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.

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

The screenshot shows the myIRB interface for a study. The top navigation bar includes 'My Home', 'Home', and 'IRB Studies'. Below this are tabs for 'Revisions', 'Continuing Reviews', and 'Reportable Events'. The main content area is titled 'Study:Alpha 22 - Expedited Study (IRB201801282)'. It includes a 'Brief Summary', 'Principal Investigator: Jim Research', and 'Study Coordinator:'. The 'Requested Review Type' is 'Expedited'. The 'Pending Agreements' section shows 'Jim Research - Not Agreed to Participate', which is circled in red. A red arrow points to this section. The 'My Activities' section on the left lists 'Agree To Participate', 'Withdraw', 'Copy Study', and 'Edit Email List'. The 'History' table shows a single activity: 'Created Study' by 'Research, Jim' on '8/12/2018 3:36 PM'.

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

This screenshot is similar to the previous one, showing the same study details. In the 'My Activities' section on the left, the 'Send Email to Study Team' button is circled in red. A red arrow points to this button. The rest of the interface, including the 'Pending Agreements' section, remains the same as in the previous screenshot.

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:

1) Go to **Study Title and Staff** SmartForm

2) Add study staff by clicking [here](#)

Study Title and Staff

Researcher Training Summary

Requested Review Type

Oncology SRMC Determination

Individual COI and Affiliation Summary

EHS Determination

Study Location

Study Locations

Study Funding

Study Funding - Main

Funding Summary

Conflict of Interest - Institutional

Study Overview

Study Description

Human Subject Determination

5.0 Principal Investigator:

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)

OneFlorida Site PI

6.0 Study Staff:

(HDE-ONLY: SEE IMPORTANT HELPTXT)

+ Add

Name	Role	Function	Affiliations	Degree/Title
------	------	----------	--------------	--------------

3) A new screen will appear. From there, select that person's Name, their Role on Study, and all relevant Study Functions

4) Click to designate as PI Proxy (only one PI Proxy allowed per study)

5) Click OK or OK and Add Another

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.

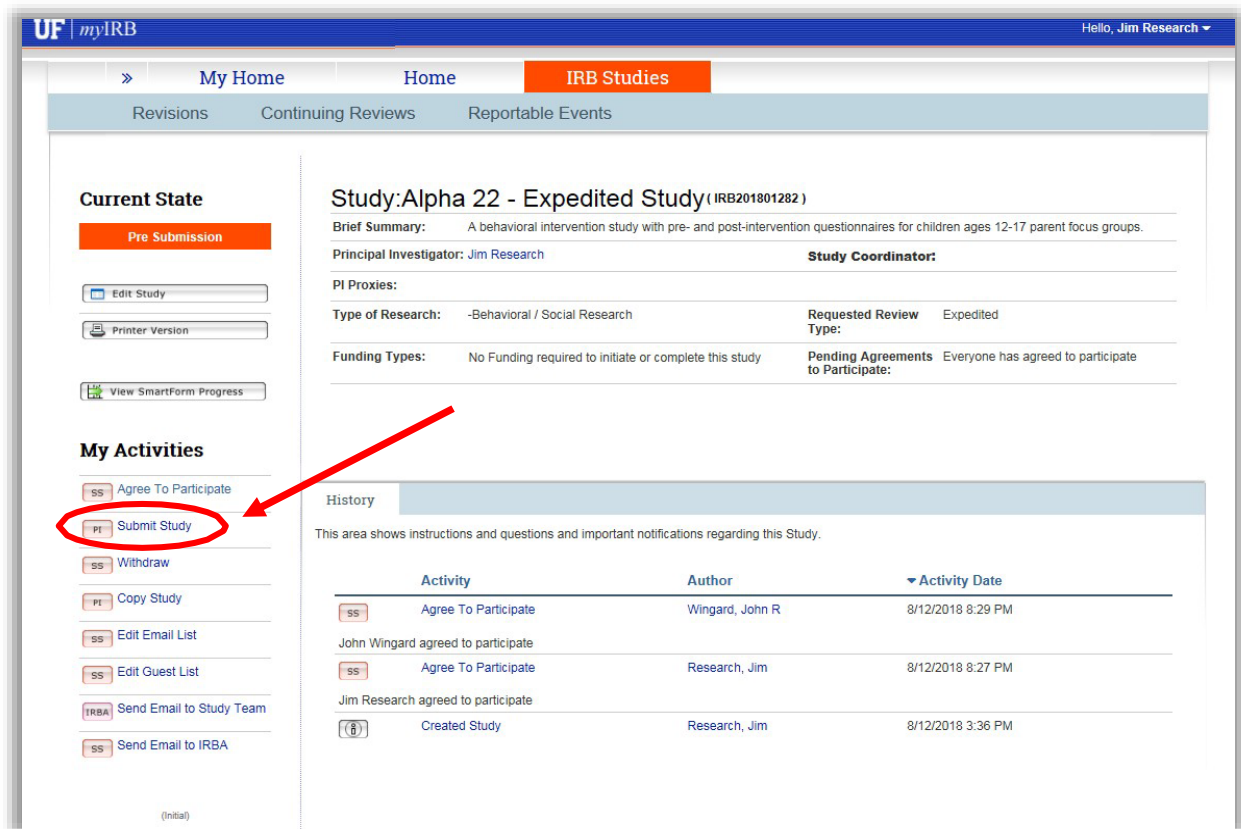
The **only** time the PI is notified of study changes is if the PI Proxy attempts to delete the PI from the study. Otherwise, the PI receives **no notifications** about study activities carried out by the PI Proxy.

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 screenshot displays the myIRB interface for a study titled "Study:Alpha 22 - Expedited Study (IRB201801282)". The left sidebar contains a "My Activities" section with several buttons: "Agree To Participate", "Submit Study" (circled in red with an arrow pointing to it), "Withdraw", "Copy Study", "Edit Email List", "Edit Guest List", "Send Email to Study Team", and "Send Email to IRBA". The main content area shows study details such as "Brief Summary", "Principal Investigator: Jim Research", "Study Coordinator", "PI Proxies", "Type of Research", "Requested Review Type", "Funding Types", and "Pending Agreements to Participate". A "History" table is also visible, listing activities like "Agree To Participate" and "Created Study" with their respective authors and dates.

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.

UF IRB

IRB10X

My Home Home IRB Studies

Revisions Continuing Reviews Reportable Events

IRB Studies > Alpha 22 - Expedited Study

Current State

Pre Submission

Edit Study

Printer Version

View SmartForm Progress

My Activities

Agree To Participate

Withdraw

Copy Study

Edit Email List

Edit Guest List

Send Email to Study Team

Send Email to IRBA

Study: Alpha 22 - Expedited Study (IRB202201866)

Brief Summary: A questionnaires for children ages 12-17

Principal Investigator: J

PI Proxies:

Type of Research: E

Funding Types: No Funding required to initiate or complete this study

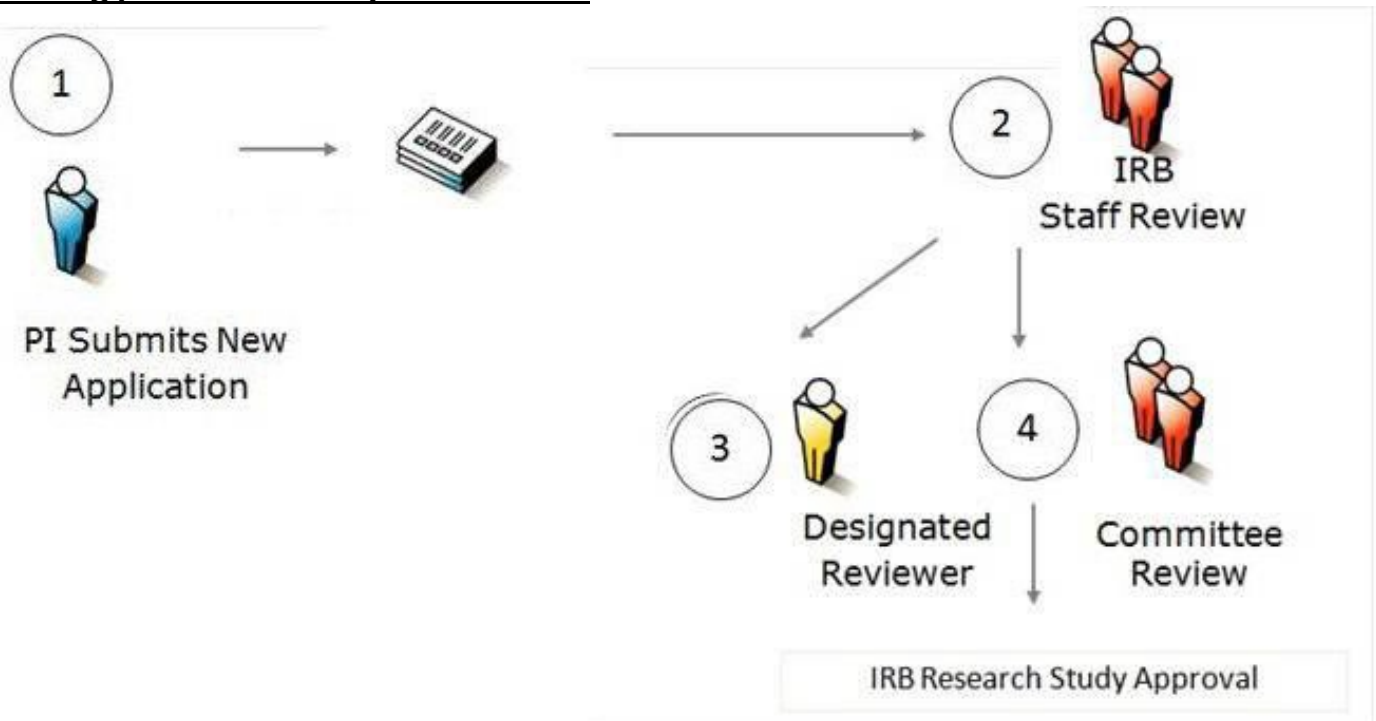
History

This area shows instructions and questions and important notifications regarding this Study.

Activity	Author
Created Study	Research, Jim

After study is submitted, the **Current State** will be updated from **Pre Submission** to **IRB staff review**

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**.

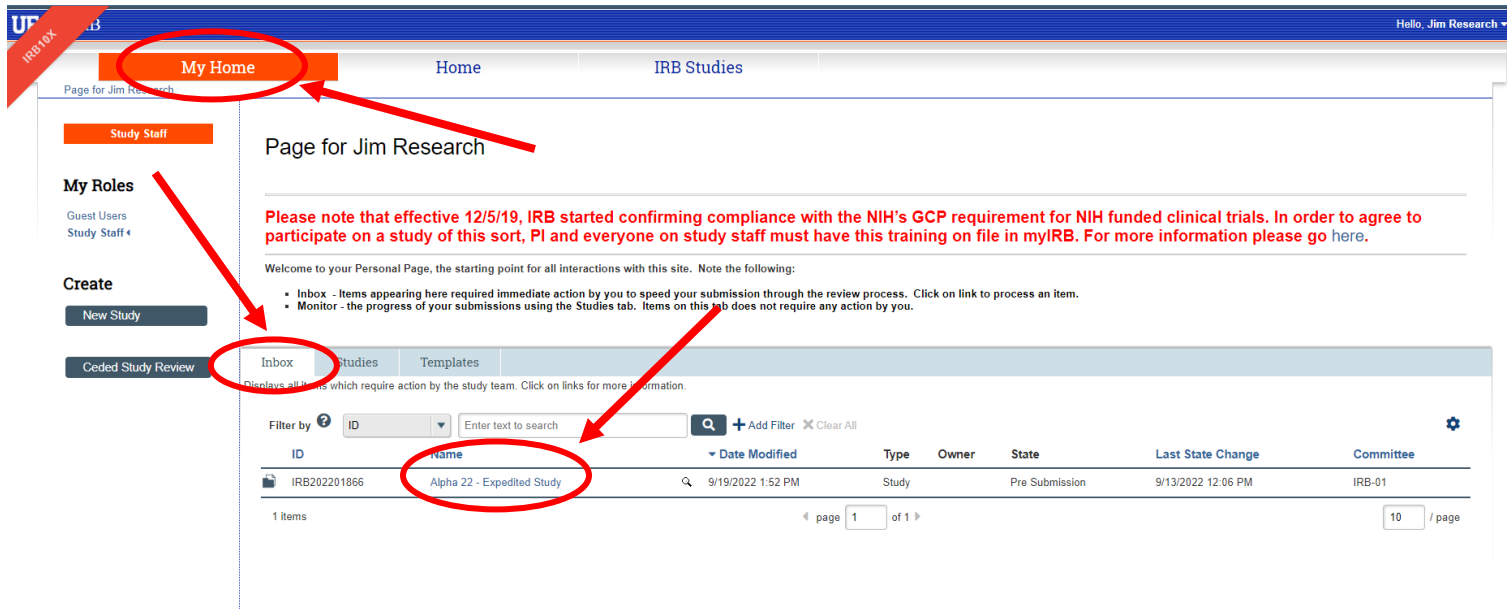
The screenshot shows the myIRB interface for Jim Research. The 'Inbox' tab is selected, displaying a table of items requiring action. The first study, 'Alpha 22 - Expedited Study', has its state updated to 'Changes Requested By IRB Staff'. A red circle highlights this state, and a red arrow points to the first study row.

ID	Name	Date Modified	Type	Owner	State	Last State Change	Committee
IRB201801282	Alpha 22 - Expedited Study	8/12/2018 8:59 PM	Study	Allison Faunce	Changes Requested By IRB Staff	8/12/2018 8:59 PM	IRB-01
IRB201700610	TEST Submission for VPN Wrapper so please disregard	3/2/2017 2:35 PM	Study		Pre Submission	3/2/2017 2:03 PM	IRB-01

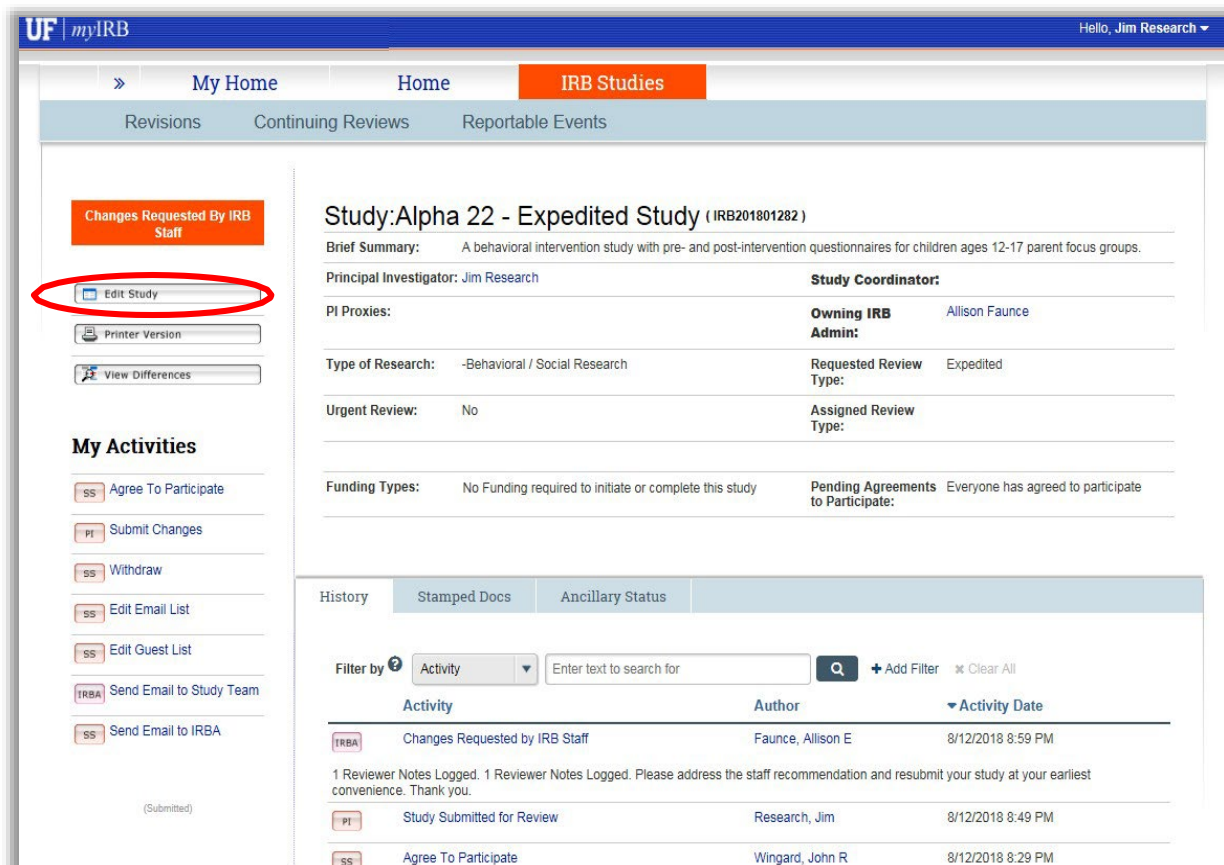
TIP: The study will show up in the *myIRB* inboxes of all study staff who have agreed to participate, so your team should establish a plan for who will respond to change requests.

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**.

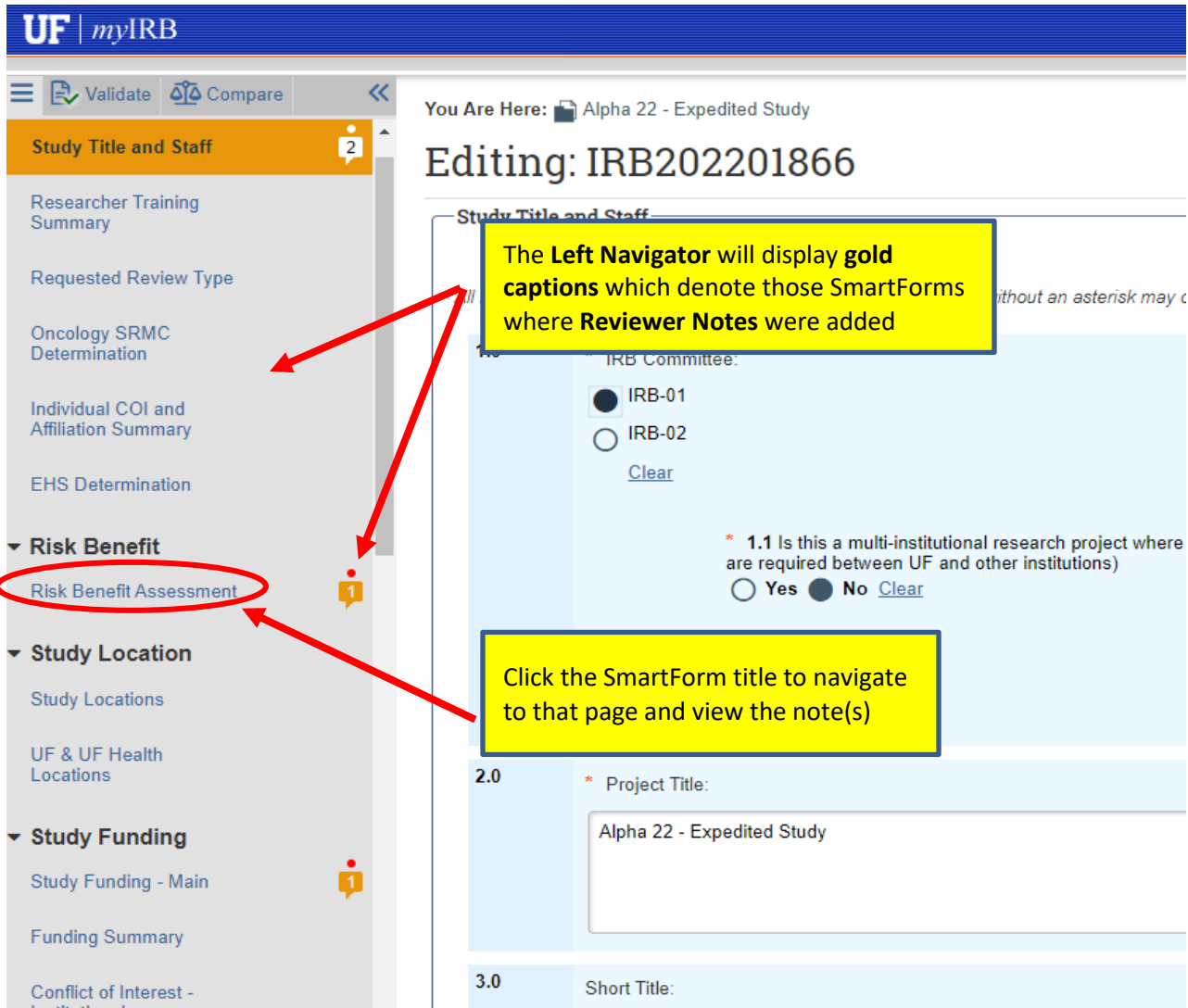


- 4). You will then be redirected to the Study Workspace. From here, click **Edit Study**.



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.

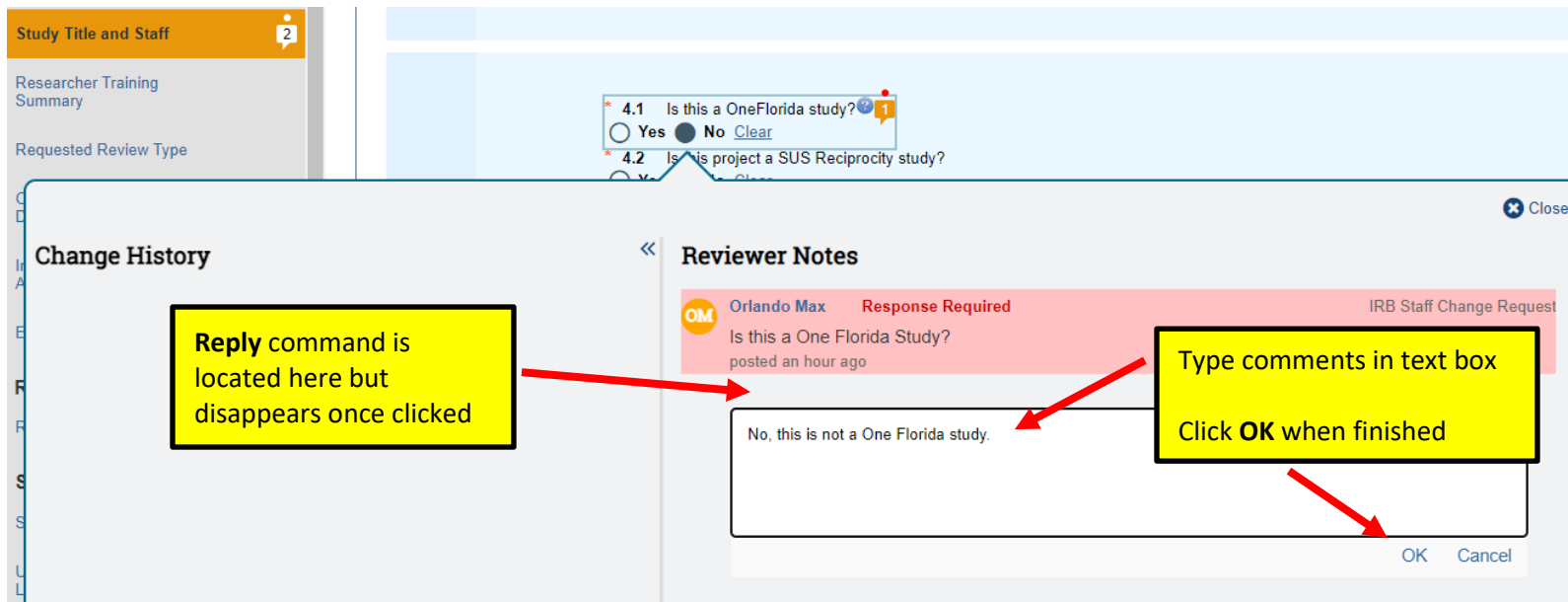
To view notes, first click on the relevant SmartForm in the Left Navigator:



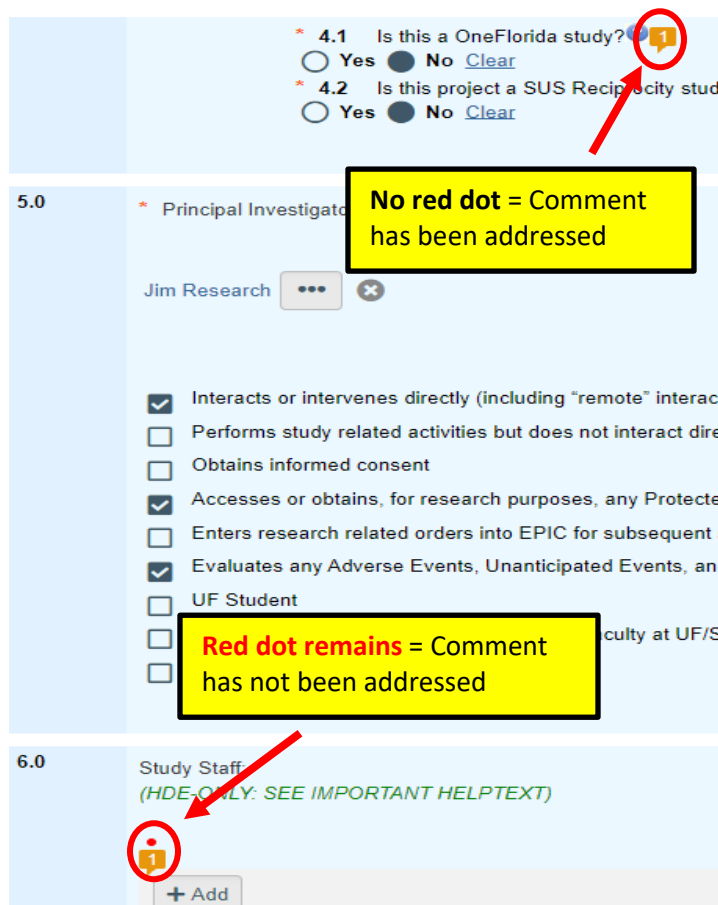
Once you have navigated to a SmartForm with a reviewer note added, click the icon(s) of the gold caption to open the comment(s).

The screenshot shows a SmartForm interface with a left-hand navigation menu and a main content area. The navigation menu includes sections for 'Study Title and Staff' (with a gold icon and the number '2'), 'Risk Benefit' (with a gold icon and the number '1'), 'Study Location', and 'Study Funding' (with a gold icon and the number '1'). The main content area contains several form sections: '4.1 Is this a OneFlorida study?' and '4.2 Is this project a SUS Reciprocity study?' with radio button options for 'Yes' and 'No' and a 'Clear' link; '5.0 Principal Investigator:' with a dropdown menu showing 'Jim Research' and a 'RE-INF' label; a list of checkboxes for various roles and responsibilities; and '6.0 Study Staff:' with a note '(HDE ONLY: SEE IMPORTANT HELPTXT)' and a '+ Add' button. Two red circles highlight gold speech bubble icons with numbers '1' and '2' next to them. Red arrows point from these icons to a yellow callout box that says 'Click icon(s) to see reviewer notes'.

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**.

Editing: IRB

Researcher Training

All reviewer notes have been addressed for this SmartForm

SmartForms with reviewer notes that still need to be addressed

Left Navigator:

- Study Title and Staff (2)
- Researcher Training Summary
- Requested Review Type
- Oncology SRMC Determination
- Individual COI and Affiliation Summary
- EHS Determination
- Risk Benefit**
 - Risk Benefit Assessment (1)
- Study Location**
 - Study Locations
 - UF & UF Health Locations
- Study Funding**
 - Study Funding - Main (1)

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:

* Are research subjects compensated? Yes No [Clear](#)

1.1 If "Yes", provide details on each type of compensation:

[+ Add](#)

Type	Amount	Undue Influence	Influence Description	Compensation Schedule
Update Monetary compensation or gift certificates	\$40.00 per study visit. For individuals with SCI, 21 study visits are involved during the study. A total of \$840.00 may be provided for compensation. For healthy individuals, there will be 1 study visit and total compensation will be \$40.	no		For healthy individuals, compensation will be provided immediately after the first visit. For individuals with SCI, compensation for study visits will be at regular intervals following each of the 3 study intervention blocks.

Note: you obtain the Security compensens insure th. Informed

Red dot remains = Comment has not been addressed

[Exit](#) [Save](#)

Edit UFIRB_SubjectCompensationDetail

Subject Compensation - Detail

1.0 * Indicate how research subjects are compensated? Choose one

Monetary compensation or gift certificates
 Reimbursement of expenses
 other compensation
[Clear](#)

"other compensation" includes non-clinical items such as cups, pens, etc.

2.0 * Amount /Description of compensation:

[Update](#) \$40.00 per study visit. For individuals with SCI, 21 study visits are involved during the

3.0 * Given the subjects being recruited, could the monetary compensation unduly influence a subject to participate in this study or remain in this study when other factors in the subject's health/environment would keep the subject from doing so?

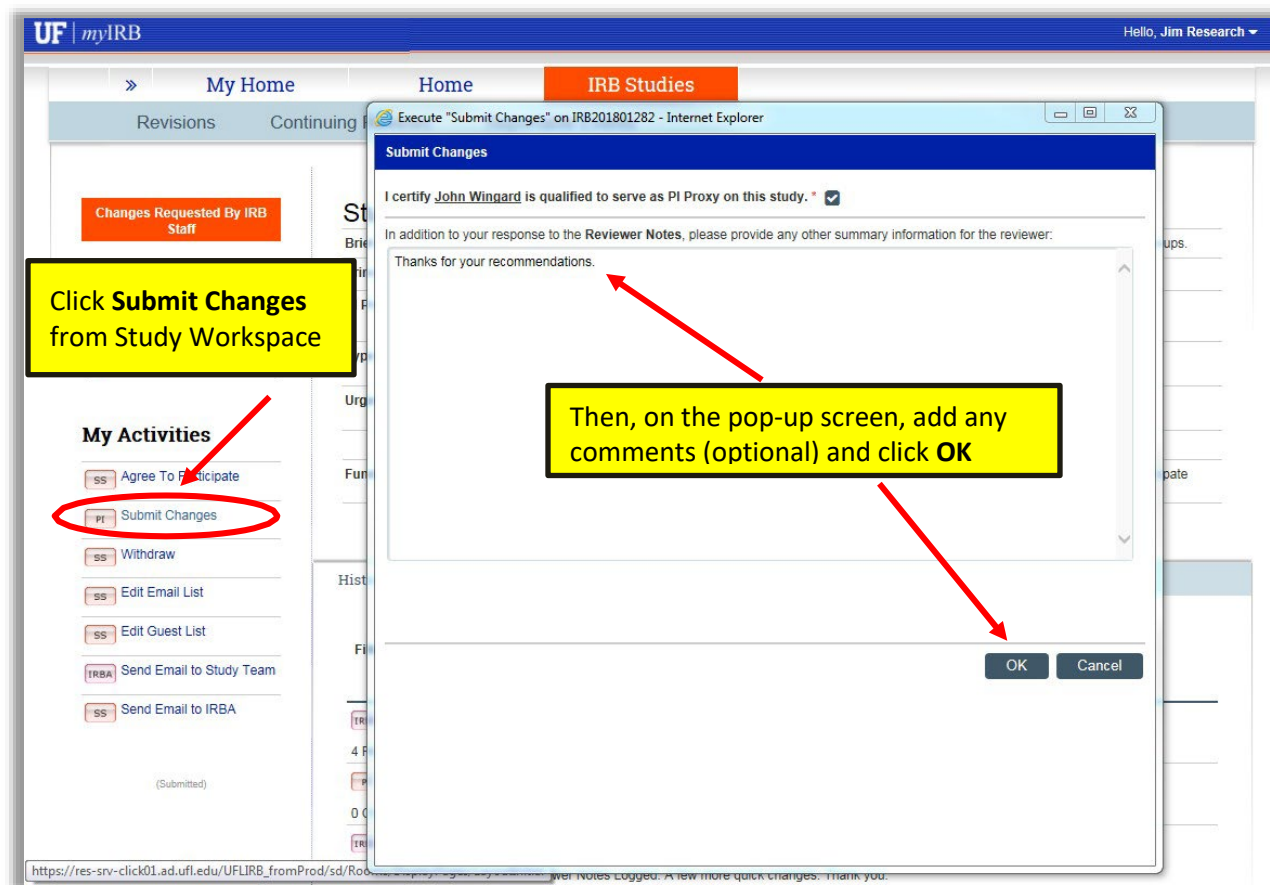
Yes No [Clear](#)

3.1 If "Yes", Explain

* Required [OK](#) [OK and Add Another](#)

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**.

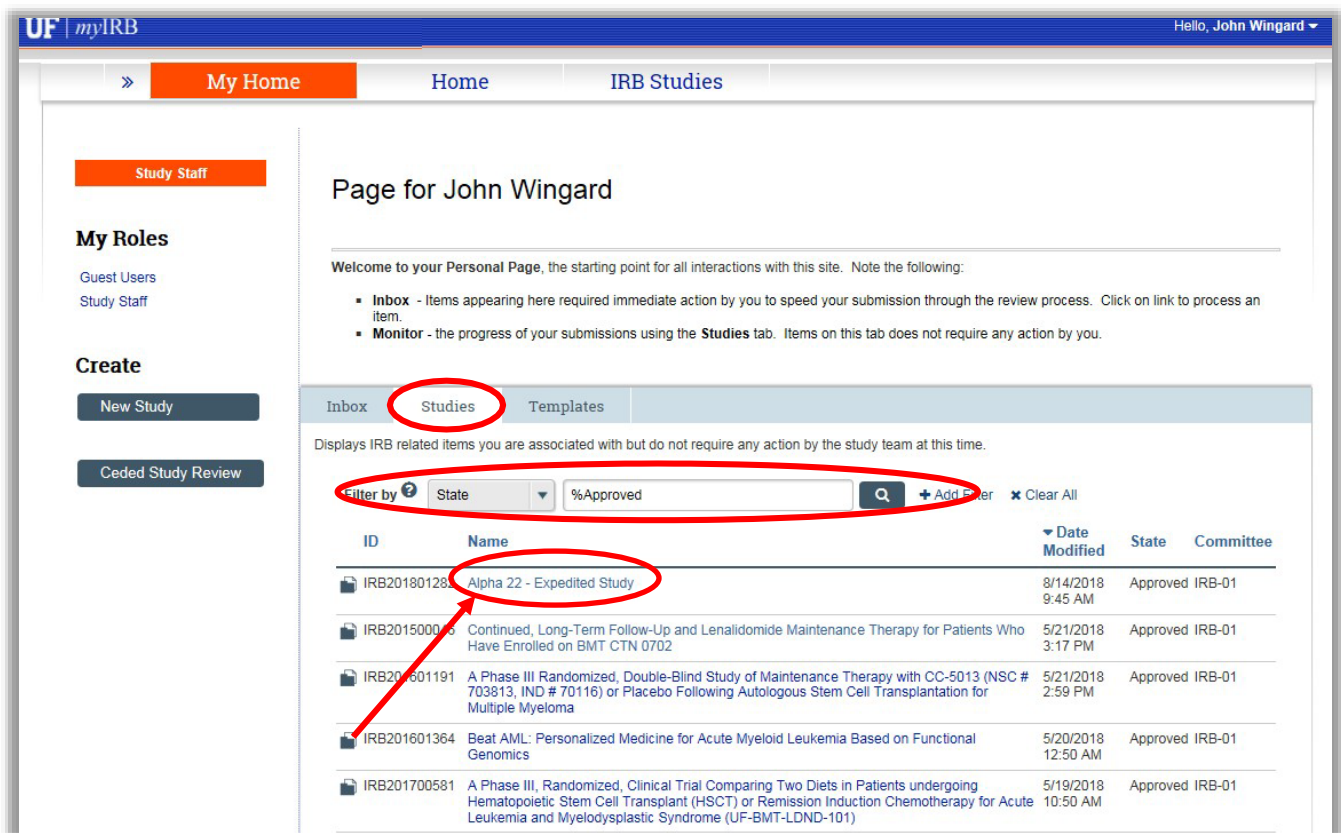


Full Board studies that are tabled will require response in the same way. The PI will receive a letter in their *myIRB* inbox that also has links to Reviewer Notes.

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.



The screenshot shows the myIRB web application interface. The top navigation bar includes 'My Home', 'Home', and 'IRB Studies'. The left sidebar contains 'Study Staff', 'My Roles' (Guest Users, Study Staff), and 'Create' (New Study, Ceded Study Review). The main content area is titled 'Page for John Wingard' and includes a welcome message and instructions. Below this, there are tabs for 'Inbox', 'Studies', and 'Templates'. The 'Studies' tab is active, displaying a list of IRB-related items. A search filter is applied, showing 'Filter by State' and '%Approved'. The search results table lists several studies, with the first entry, 'Alpha 22 - Expedited Study', highlighted by a red circle and a red arrow pointing to its name.

ID	Name	Date Modified	State	Committee
IRB20180128	Alpha 22 - Expedited Study	8/14/2018 9:45 AM	Approved	IRB-01
IRB2015000	Continued, Long-Term Follow-Up and Lenalidomide Maintenance Therapy for Patients Who Have Enrolled on BMT CTN 0702	5/21/2018 3:17 PM	Approved	IRB-01
IRB201601191	A Phase III Randomized, Double-Blind Study of Maintenance Therapy with CC-5013 (NSC # 703813, IND # 70116) or Placebo Following Autologous Stem Cell Transplantation for Multiple Myeloma	5/21/2018 2:59 PM	Approved	IRB-01
IRB201601364	Beat AML: Personalized Medicine for Acute Myeloid Leukemia Based on Functional Genomics	5/20/2018 12:50 AM	Approved	IRB-01
IRB201700581	A Phase III, Randomized, Clinical Trial Comparing Two Diets in Patients undergoing Hematopoietic Stem Cell Transplant (HSCT) or Remission Induction Chemotherapy for Acute Leukemia and Myelodysplastic Syndrome (UF-BMT-LDND-101)	5/19/2018 10:50 AM	Approved	IRB-01

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).

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 x 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.

The screenshot displays the IRB system interface. On the left, there are navigation options: '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 Revision', and 'New Renewal/Closure'. The main content area shows study details: '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', 'Expiration Date: 8/14/2019', and 'Letter of Approval View'. A yellow box highlights a 'Link to IRB Approval Letter' with a red arrow pointing to the 'View' link in the 'Letter of Approval' section. Below this, the 'History' tab is selected, showing a table of activities. A red circle highlights the 'Stamped Docs' tab. A red arrow points from the 'New Renewal/Closure' button to the 'Finalized Attachments' row in the history table, which contains links to 'Phone script.docx.pdf' and 'Brief ICF with HIPAA.doc.pdf'.

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
Correspondence from IRB Tue Aug 14 09:45:14 EDT 2018		
Correspondence from IRB (pdf) Tue Aug 14 09:45:35 EDT 2018		
Finalized Attachments	Faunce, Allison E	8/14/2018 9:39 AM
Phone script.docx.pdf		
Brief ICF with HIPAA.doc.pdf		
Set Approval Period	Faunce, Allison E	8/14/2018 9:39 AM
Submitted Changes	Research, Jim	8/13/2018 8:45 PM

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**.

The screenshot displays the IRB Studies workspace for a study titled "Study:UF BMT CTN 0101 Biorepository Study (IRB201601232)". The interface includes a navigation bar with "My Home", "Home", and "IRB Studies" tabs. Below the navigation bar are tabs for "Revisions", "Continuing Reviews", and "Reportable Events".

The main content area is divided into several sections:

- Current State:** Shows "Approved" with a button to "View Study", "Printer Version", and "View Differences".
- My Activities:** Includes options like "Copy Study", "Edit Email List", "Edit Guest List", "Send Email to Study Team", and "Send Email to IRBA".
- New Reportable Event:** A red circle highlights this section, which contains a "New Reportable Event" button. A red arrow points from this section to the "Assigned Risk" field in the study details.
- New Revision:** Contains a "New Revision" button.
- New Renewal/Closure:** Contains a "New Continuing Review/Closure" button.

The study details section includes:

- Brief Summary:** The purpose of this study is to act as a data and tissue bank for the following study: "CTN0101: A Randomized Double-Blind Trial of Fluconazole vs. Voriconazole for the Prevention of Invasive Fungal Infections in Allogeneic Blood and Marrow Transplant Patients".
- Principal Investigator:** John Wingard
- Study Coordinator:** Allison Trainor, Aaron Riggs
- PI Proxies:**
- Owning IRB Admin:** Jamie Mayfield
- Funding Types:** No Funding required to initiate or complete this study
- Type of Research:**
- Assigned Risk:** Minimal Risk
- Assigned Review Type:** Expedited
- Flags for Study:** Moved to Expedited: No, Longitudinal: No, AER Exempt: No
- Old IRB#:** 51601232
- Expiration Date:** 8/9/2019 Discretionary Policy In Effect
- Letter of Approval:** View

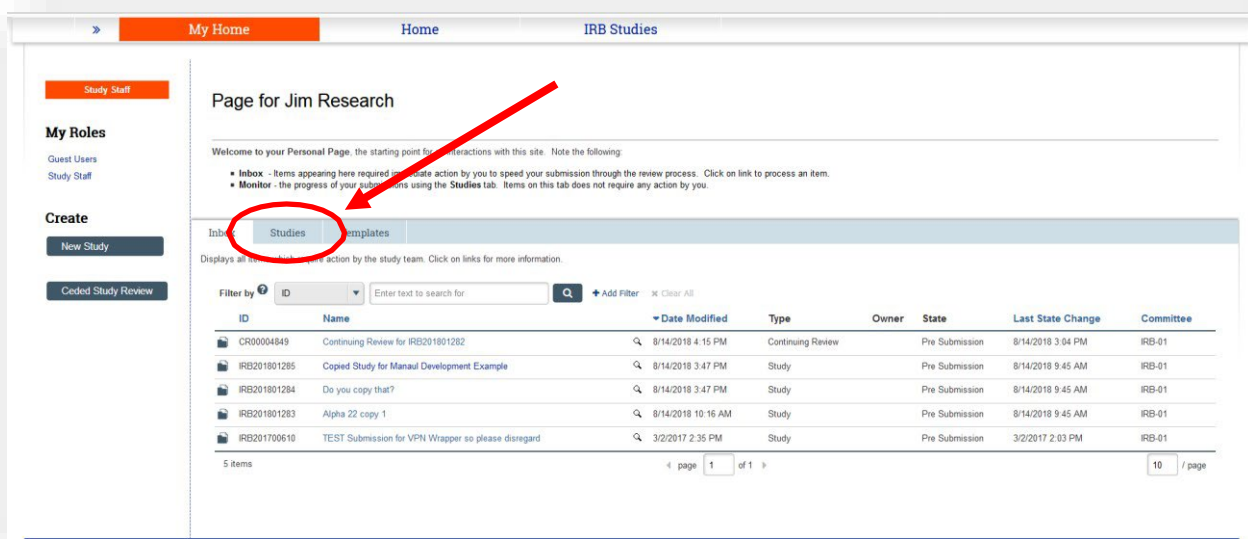
The "Expedited Category Assigned" section includes a note: "5. Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). Note: Some research in this category may be exempt 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."

At the bottom, there is a "History" table with tabs for "Stamped Docs", "Revisions", "Continuing Reviews", and "Activity". The "Activity" tab is selected, showing a list of activities with columns for "Activity", "Author", and "Activity Date".

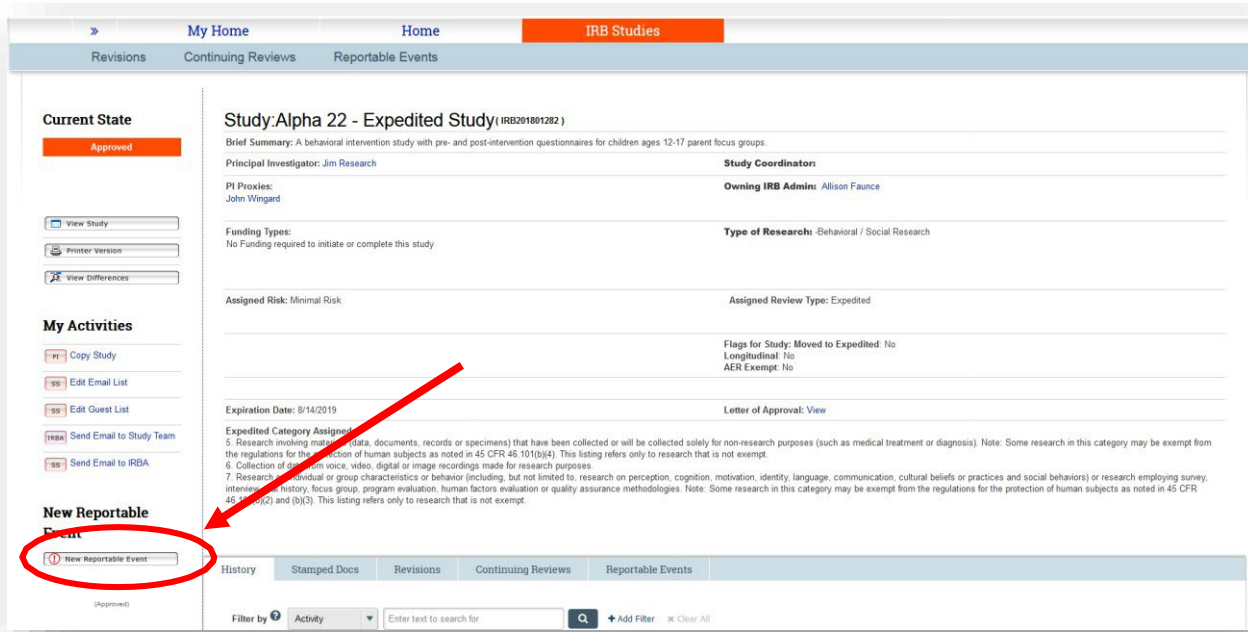
Activity	Author	Activity Date
Revision Process Completed	Mayfield, Jamie Lee	8/26/2016 10:58 AM
Revision Process Opened	Trainor, Allison Beth	8/23/2016 3:32 PM
Project Snapshot Generated	Mayfield, Jamie Lee	8/12/2016 12:33 PM
Project Snapshot Fri Aug 12 12:33:32 EDT 2016		
Study: Approved	Mayfield, Jamie Lee	8/12/2016 12:33 PM

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:

NOTE: This form is for submitting information about/related to a single issue/event.

1.0 * What are you submitting? (Check all that apply)

Regulatory Noncompliance [1]

Protocol Deviation: risk to subjects or research integrity [1]

Adverse Event that is Serious and Unexpected (5 day form) [1]

Miscellaneous [2]

DSMB Report [1]

NOTE: Protocol Deviation that presents NO RISK to subjects or research integrity should be reported at Continuing Review on the Minor Deviation Tracking Log.
Please refer to our Adverse Event Evaluation & Reporting Guide to determine how to report other Adverse Events.

2.0 Does the study PI consider this event to be an unanticipated problem?
 Yes No [Clear](#)

1. Unexpected (in terms of nature, severity, or frequency)
2. Related or the relationship is more likely than not to participation in the research
3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social needs) than was previously known or recorded

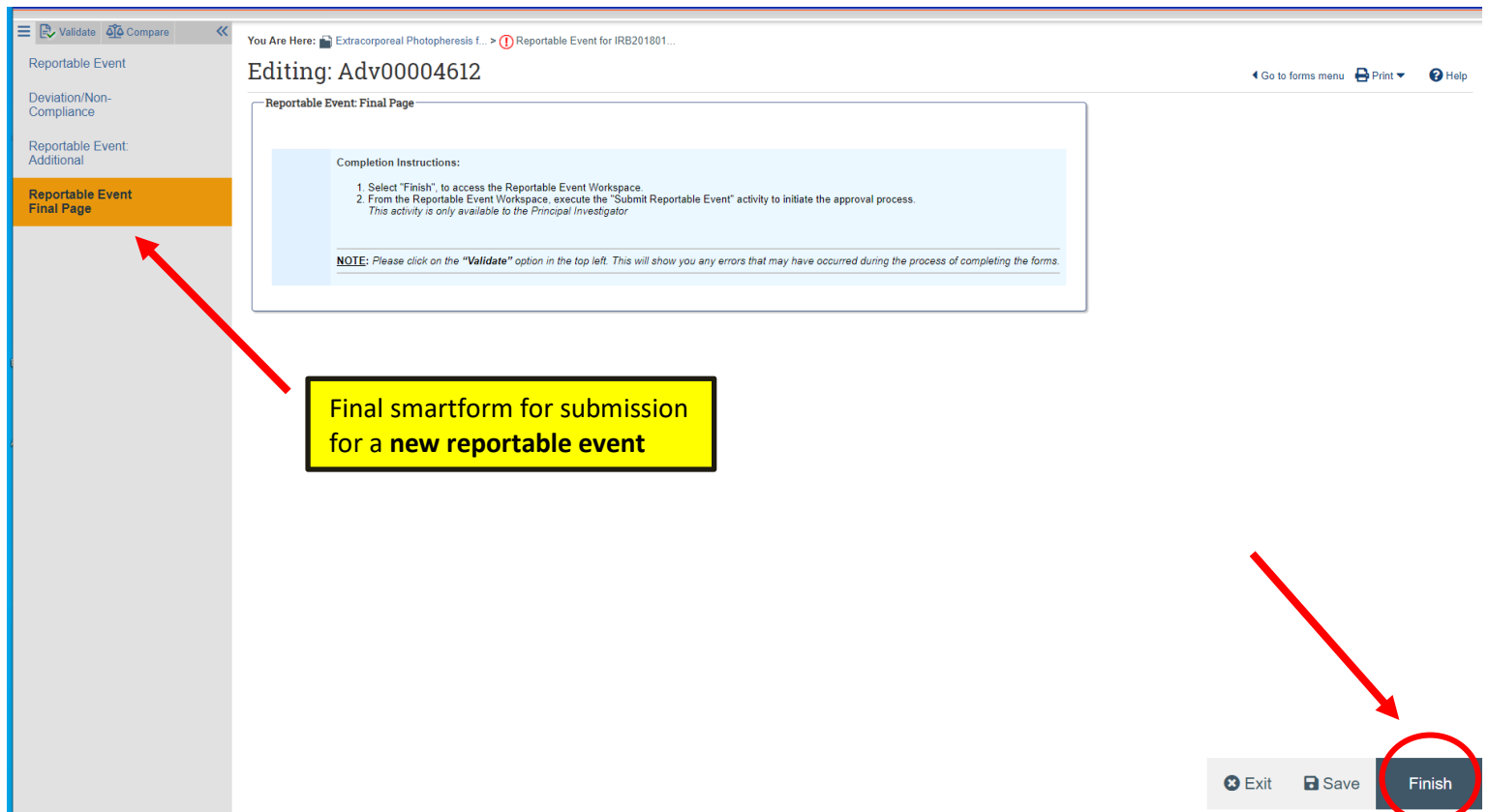
1: these items can be submitted together/simultaneously
2: submitted by itself

Items with a [1] next to them can be submitted simultaneously

Items with a [2] must be submitted individually

Refer to the description of what constitutes an Unanticipated Problem

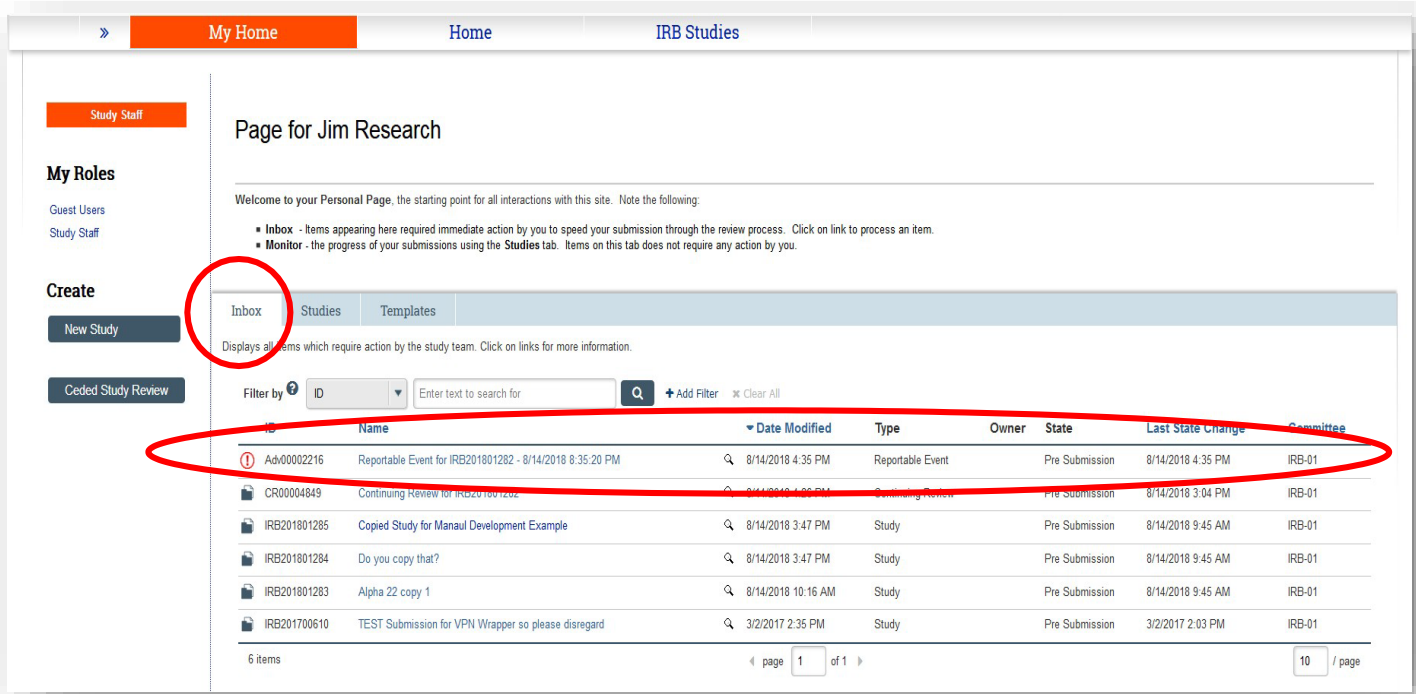
Depending on how the PI answers the page above, the system will present different SmartForms relevant to the details of the reportable event. Regardless of the nature of the event, the PI will be required to answer questions and provide additional background. And irrespective of the specifics of the 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.

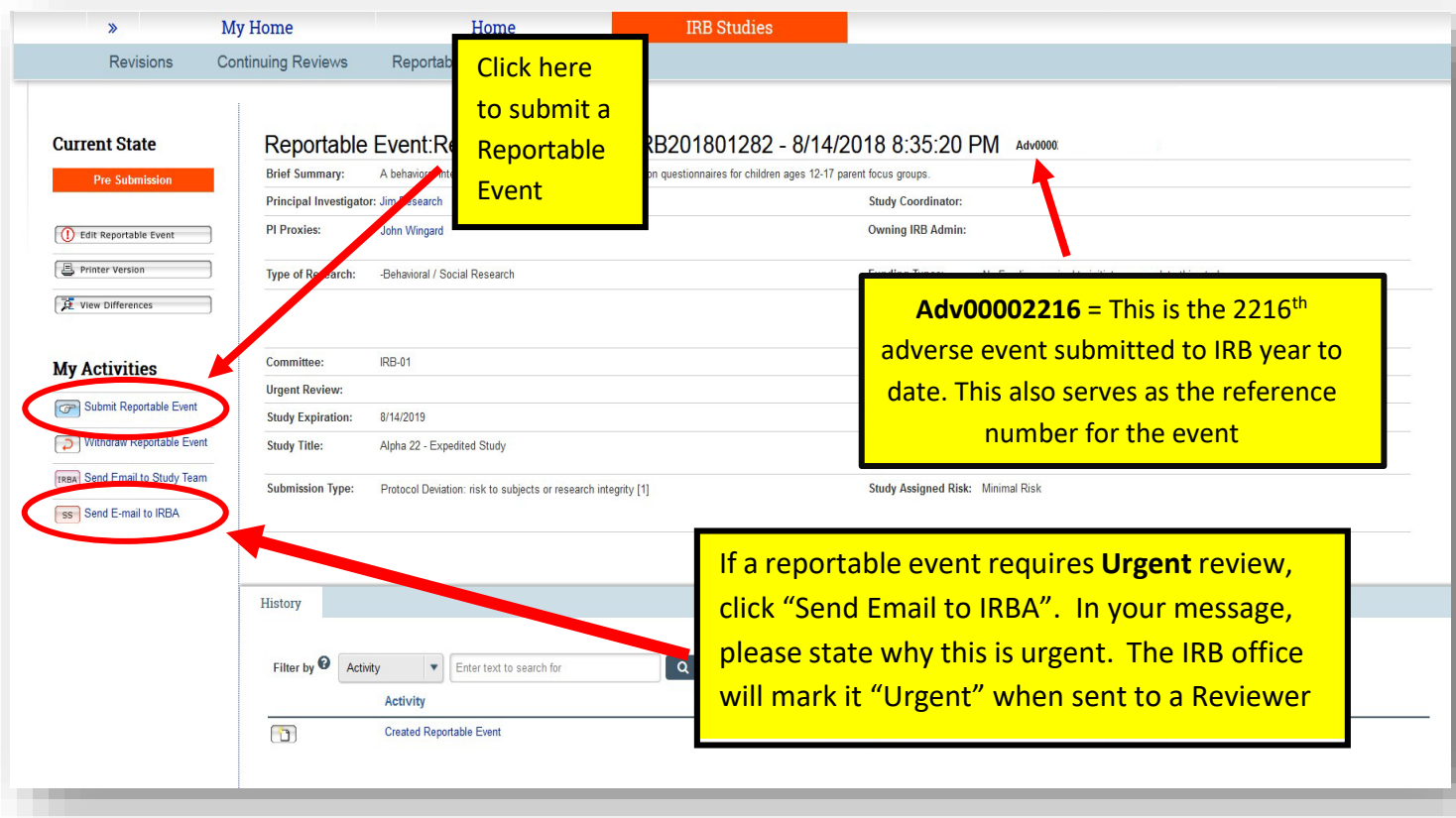
From here, return to the Study Summary Page and look in the **Inbox** for the Reportable Event you created. A red exclamation point denotes Reportable Events. Then, click the Reportable Event you need to submit to IRB.

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.

In the Studies Tab, click the study with the Reportable Event

Page for Jim Research

Welcome to your Personal Page, the starting point for all interactions with this site. Note the following:

- Inbox** - Items appearing here required immediate action by you to speed your submission through the review process. Click on link to process an item.
- Monitor** - the progress of your submissions using the **Studies** tab. Items on this tab do not require any action by you.

Displays IRB related items you are associated with but do not require any action by the study team at this time.

Filter by ID Name Date Modified State Committee

ID	Name	Date Modified	State	Committee
IRB201801282	Alpha 22 - Expedited Study	8/14/2018 4:35 PM	Approved	IRB-01
IRB201801285	Copied Study for Manual Development Example	8/14/2018 3:47 PM	Pre Submission	IRB-01
IRB201801284	Do you copy that?	8/14/2018 3:47 PM	Pre Submission	IRB-01
IRB201801283	Alpha 22 copy 1	8/14/2018 10:16 AM	Pre Submission	IRB-01
IRB201700610	TEST Submission for VPN Wrapper so please disregard	3/2/2017 2:35 PM	Pre Submission	IRB-01

5 items | page 1 of 1 | 25 / page

Click the Reportable Events Tab to check the status of your submission

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

PI Proxies: John Wingard

Funding Types: No Funding required to initiate or complete this study

Assigned Risk: Minimal Risk

Expiration Date: 8/14/2019

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, diagnosis, or quality assurance) and that are not intended to be used for generalizable research.
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, or interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies. Note: Some research in this category may be exempt from 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.

Study Coordinator:

Owning IRB Admin: Allison Faunce

Type of Research: Behavioral / Social Res

Assigned Review Type: Expedited

Flags for Study: Moved to Expedited: No
Longitudinal: No
AER Exempt: No

Letter of Approval: View

History | Stamped Docs | Revisions | Continuing Reviews | **Reportable Events**

Filter by Activity | Enter text to search for | Add Filter | Clear All

Activity | Author

Letter of Approval:

View

All Reportable Events will be listed under this tab. Notice the **State**, **Last State Change**, and **Date Submitted**

Continuing Reviews

Reportable Events

State

Last State Change

Date Submitted

1300 - 3/6/2020 5:27:09 PM

Withdrawn

5/12/2020 7:43 AM

1300 - 9/22/2022 2:34:08 PM

Pre Submission

9/22/2022 10:34 AM

This was taken from the **test** system, so the event was not submitted. However, the date submitted appears **here**

10 / page

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.

My Activities

SS Edit Email List

SS Edit Guest List

IRBA Send Email to Study Team

SS Send Email to IRBA

New Reportable Event

! New Reportable Event

Assigned Risk: Greater Than Minimal Risk

Expiration Date: 10/20/2022

History

Stamped Docs

Revisions

Filter by ?

Activity

Enter text to sea

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**.

The screenshot shows the myIRB interface for a user named Jim Research. The top navigation bar has three tabs: "My Home" (highlighted in orange), "Home", and "IRB Studi". A red arrow labeled "1" points to the "My Home" tab. Below the navigation bar, there is a "Study Staff" button and a "My Roles" section with "Guest Users" and "Study Staff". A "Create" section contains "New Study" and "Ceded Study Review" buttons. The main content area displays a message: "Please note that effective 12/5/19, IRB started confirming co participate on a study of report, PI and everyone on study". Below this is a "Welcome to your Personal Page" message and a list of items: "Inbox - Items appearing here required immediate action by you to speed your subn" and "Monitor - the progress of your submissions using the Studies tab. Items on this tal". A red arrow labeled "2" points to the "Studies" tab in the navigation bar. Below the tabs, there is a search bar and a table of studies. A red arrow labeled "3" points to the "Alpha 22 - Expedited Study" entry in the table, which is circled in red. The table has columns for "ID" and "Name".

ID	Name
IRB202201866	Alpha 22 - Expedited Study
IRB201700610	TEST Submission for VPN Wrapper so please disregard

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**

Current State
Approved

My Activities
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
New Continuing Review/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
PI Proxies: John Wingard
Study Coordinator:
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

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 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.

Activity	Author	Activity Date
Copied Study	Wingard, John R	8/14/2018 10:17 AM
New Copy ID is IRB201801284 Title: Do you copy that?	Wingard, John R	8/14/2018 10:16 AM
New Copy ID is IRB201801283 Title: Alpha 22 copy 1	Faunce, Allison E	8/14/2018 9:45 AM
Project Snapshot Generated	Faunce, Allison E	8/14/2018 9:45 AM
Project Snapshot Tue Aug 14 09:45:46 EDT 2018		
Study - Approved		

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.

Continuing Review/Study Closure Determination

Editing: CR00011809

ID Number for the Continuing Review

Left Navigator will display SmartForms

We wish to: (select one)
 Close this project
 Continue this project

Enrollment is defined as, but not limited to, the following:

- Anyone who is enrolled with a consent
- Anyone who is enrolled with a waiver of documentation. For example: the informational sheet that goes with a survey
- Anyone enrolled with a full waiver of consent. For example: medical records accessed for a chart review; secondary analysis of identifiable data; identifiable tissue etc.

List any specific information that needs to be included in the IRB response letter:

Date Page Modified:

Exit Save Continue

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, *myIRB* 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**.

Recruitment Methods:
Medical Records
Patient care meetings, rounds, tumor board meetings, etc.
Outpatient Population: Pre-review of outpatient records or lists or appointments prior to seeing the patient in clinic
Outpatient Population: Patients seen in clinics during normal appointments and approached about research

This is how you are Approved to recruit subjects.

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).

Prior CR:

Date first subject signed Informed Consent: 2/14/2019

Date last subject signed Informed Consent for prior Continuing Review period: 3/16/2021

These dates are displayed only if a prior CR was submitted.

1.0 * Provide the date on which the first subject signed the Informed Consent Form (ICF):

2/14/2019

Date of 1st and last signed ICF (per most recent CR)

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:

5.0 Provide scanned copy of last signed ICF:

For instructions on redacting informed consents, [click here](#)

Document **Description**

There are no items to display

5.1 Explain if not attached:

Prior CR Enrolled: Number of subjects enrolled using the Informed Consent as of the prior Continuing Review period:

Active Subjects	Subjects in Follow Up	Withdrawn (include Deaths)	Screen Failures	Completed Subjects	Total Subjects Enrolled
0	+ 0	+ 0	+ 0	+ 0	= 0

Redact/Do NOT include any "DIRECT IDENTIFIERS" (including, but not limited to names, DOB, SSN, MRN, address, etc.)

6.0 * How many subjects have been enrolled using the Informed Consent since the project started:

Active Subjects	Subjects in Follow Up	Withdrawn (include Deaths)	Screen Failures	Completed Subjects	Total Subjects Enrolled
1	* 0	* 0	* 0	* 0	= 1

Enter 0 (zero) if no subjects have been enrolled.

NOTE 1: all subjects who have signed an Informed Consent form are considered enrolled.

6.1 Total Males Enrolled: 0

6.2 Total Females Enrolled: 1

NOTE: total # of males and females added together must equal the total subjects enrolled above

Enrollment from the previous year will appear here

The enrollment reported here is cumulative; it will include the previous CR's enrollment

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**:

Subject Information: Enrollment Summary

Approved Enrollment:	Number of subjects approved to be enrolled:		View-only
	Total number of subjects that the PI is approved to enroll		
		# of Subjects	
	a. How many subjects do you need to complete the study?	40	
	b. How many additional subjects might be enrolled/included in this project but might discontinue participation in the study before completing all study interventions/interactions (either due to adverse event, withdrawal, etc.)?	5	
c. If 1.1 (above) is 'Yes', how many additional subjects do you believe will need undergo these screening procedures and will not count toward the numbers listed in question a and b above (these subjects would be screen failures)?	5		
TOTAL (a+b+c) =		50	

Current Enrollment:	Number of subjects enrolled as of this Continuing Review:		View-only
	Total number of subjects enrolled to date		
	Full Waiver of Informed Consent:		
	Waiver of Documentation of Informed Consent:		
ICF:			

If you have enrolled more subjects than you are approved for, submit **Reportable Event – Deviation**.

If you need to increase how many subjects you want to enroll, submit a **Revision** after your CR is approved.

1.0 Describe your enrollment:
(For example, if you have enrolled more subjects than the IRB approved, please explain why. Or explain/describe which subjects were enrolled under a waiver, rather than ICF if both are used.

2.0 If there are any discrepancies with or errors in previously reported information, explain the differences.

If discrepancies exist regarding any previously reported enrollments, describe them here

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

The screenshot shows two sections of the SmartForm. Section 2.0 asks, "Have any adverse events or unanticipated problems involving risks to subjects or others occurred during this review period?" and includes an "Upload Cumulative AE Table" section with a file named "AE Table.docx(0.01)" and an "Upload Revision" button. Section 3.0 asks, "Have any new minor deviations occurred during the past review period?" and includes an "Upload Cumulative Deviation Table" section with a file named "DevTable (1).doc(0.01)" and an "Upload Revision" button. A red circle highlights these two sections. A yellow box with the text "Links to the templates can be found here." has two red arrows pointing to the "Upload Revision" buttons. Another yellow box with the text "Upload current CAE and Deviation Tables here." has a red arrow pointing to the "Upload Revision" button in section 3.0. On the right side, there are two text boxes: "If applicable, include serious & unexpected events or unanticipated problems that have occurred to subjects enrolled on the same protocol at other sites." and "Adverse Event Table template can be found at: http://irb.ufl.edu/wp-content/uploads/AETable.doc". Below that, it says "Deviation Table template can be found at: http://irb.ufl.edu/wp-content/uploads/DevTable.doc".

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.

The screenshot shows the system interface for editing a continuing review (CR00011809). In the top left corner, there is a "Validate" button with a checkmark icon, which is circled in red. A red arrow points from this button to the "NOTE" section of the "Continuing Review: Final Page". The "NOTE" text reads: "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." The interface also shows a sidebar with navigation options like "Determination", "Continuing Review/Study Closure Report", "Subject Information - ICF", "Subject Information - ICF - Enrolled", "Subject Information - Enrollment Summary", "Multi-Centered", and "Vulnerable Subjects".

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:

The screenshot displays a software interface with a top navigation bar containing 'Validate' and 'Compare' buttons. The main content area is titled 'Error/Warning Messages (25)' and includes a 'Refresh' button. It lists several items with status indicators:

- Continuing Review/Study Closure Determination: Marked with a green checkmark.
- Continuing Review/Study Closure Report: Marked with a green checkmark.
- Subject Information - ICF: Marked with a green checkmark.
- Subject Information - ICF - Enrolled: Marked with a red circle.

Two yellow callout boxes with black borders provide additional context:

- A box labeled 'Completed Items are marked with a green check' has red arrows pointing to the green checkmarks of the first three items.
- A box labeled 'Outstanding items are marked with a red circle' has a red arrow pointing to the red circle of the fourth item.

Below the list, a series of error messages are displayed, each starting with a red circle icon and a minus sign, such as 'ICF Signed For All Subjects This is a required field; therefore, you must provide the required information.'

On the right side of the interface, there is a section titled 'You Are Here: Extract' and 'Editing: CR'. Below this is a 'Vulnerable Subjects' section with a list of 'Approved Vulnerable Subject Types' including '1.0' and '2.0'.

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**.

You Are Here: Extracorporeal Photopheresis f... > Continuing Review for IRB20180...

Editing: CR00011809 Go to forms menu Print Help

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: 9/22/2022



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.

Current State

Pre Submission

Edit Continuing Review

Printer-Friendly Version

View Differences

My Activities

- PI Submit Continuing Review
- SS Withdraw Continuing Review
- SS Send E-mail to IRBA
- IRBA Send E-Mail to Study

Continuing Review: Continuing Review for IRB201801282 (CR00004849 / 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:**

Type of Research: -Behavioral / Social Research **Study Final Review Type:** Expedited

Urgent Review: **Flags for Study:** Moved to Expedited: No
Longitudinal: No
AER Exempt: No

Committee: IRB-01

Study Expiration: 8/14/2019

Study Title: Alpha 22 - Expedited Study **Study Status:** Approved

Study Assigned Risk: Minimal Risk **Meeting Date & Time:** -

Funding Types: No Funding required to initiate or complete this study **Letter of Approval:**

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**.

The screenshot shows the myIRB interface. At the top, there are three tabs: 'My Home' (highlighted in orange), 'Home', and 'IRB Studi'. Below the tabs, there is a navigation bar with 'Study Staff' and 'My Roles' (Guest Users, Study Staff). Under 'My Roles', there are buttons for 'New Study' and 'Ceded Study Review'. The main content area shows a 'Page for Jim Research' with a red notice: 'Please note that effective 12/5/19, IRB started confirming co participate on a study of this sort, PI and everyone on study'. Below the notice, there is a 'Welcome to your Personal' message and a list of items: 'Inbox - Items appearing here required immediate action by you to speed your subn' and 'Monitor - the progress of your submissions using the Studies tab. Items on this tal'. At the bottom, there is a 'Filter by' dropdown set to 'ID' and a search box. Below the search box, there is a table with two columns: 'ID' and 'Name'. The table contains two rows: 'IRB202201866 Alpha 22 - Expedited Study' and 'IRB201700610 TEST Submission for VPN Wrapper so please disregard'. The number '2 items' is displayed below the table. Red arrows and yellow boxes highlight the steps: 1. Click 'My Home' tab, 2. Click 'Studies' tab, 3. Click on a study name.

ID	Name
IRB202201866	Alpha 22 - Expedited Study
IRB201700610	TEST Submission for VPN Wrapper so please disregard

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

From there, select **Status Report**.

Current State

Approved

View Study

Printer Version

View Differences

My Activities

PI Copy Study

SS Edit Email List

SS Edit Guest List

IRBA Send Email to Study Team

SS Send Email to IRBA

PI Status Report

Study:GTW 2nd Round 10X Test

Brief Summary: test CHANGE

Principal Investigator: John Wingard

PI Proxies:

Funding Types: No Funding requ

Assigned Risk: Minimal Risk

Expiration Date: 8/9/2025

Expedited Category Assigned:

1. Clinical studies of drugs and medical devices only when condit
the research significantly increases the risks or decreases the ac
required, or (2) The medical device is both cleared/approved for r

History

Stamped Docs

Revisions

Co

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.”*

Status Report

Your Study:

Study Number: IRB202201846

Study Title: GTW 2nd Round 10X Test

Was approved via Expedited Review on 8/10/2022.

* Please let us know one of the following:

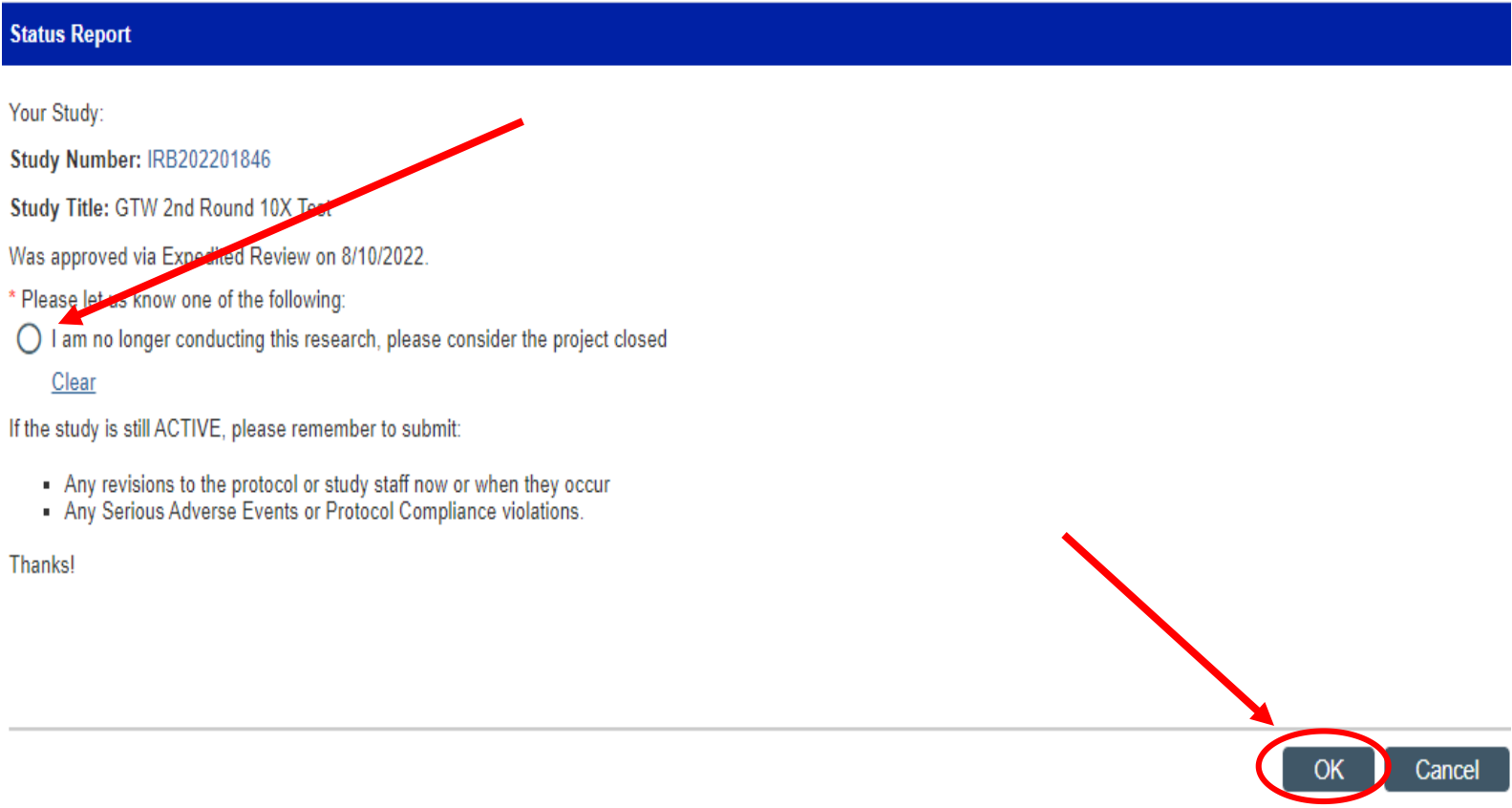
I am no longer conducting this research, please consider the project closed

[Clear](#)

If the study is still ACTIVE, please remember to submit:

- Any revisions to the protocol or study staff now or when they occur
- Any Serious Adverse Events or Protocol Compliance violations.

Thanks!



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**.

The screenshot shows the myIRB interface. At the top, there are three tabs: 'My Home' (highlighted in orange), 'Home', and 'IRB Studi'. Below the tabs, the page title is 'Page for Jim Research'. On the left sidebar, there are sections for 'Study Staff', 'My Roles' (with links for 'Guest Users' and 'Study Staff'), and 'Create' (with buttons for 'New Study' and 'Ceded Study Review'). The main content area has a red notice: 'Please note that effective 12/5/19, IRB started confirming co participate on a study of this sort, PI and everyone on study'. Below the notice, there is a 'Welcome to your Personal Page' message and a list of items: 'Inbox - Items appearing here required immediate action by you to speed your subn' and 'Monitor - the progress of your submissions using the Studies tab. Items on this tal'. At the bottom, there is a navigation bar with 'Inbox', 'Studies', and 'Templates' tabs. Below this, there is a search filter section with 'Filter by' (ID), a dropdown menu, and a search input field. A table of studies is displayed below the search section, with columns for 'ID' and 'Name'. The table contains two rows: 'IRB202201866 Alpha 22 - Expedited Study' and 'IRB201700610 TEST Submission for VPN Wrapper so please disregard'. The page footer indicates '2 items'.

1

2

3

ID	Name
IRB202201866	Alpha 22 - Expedited Study
IRB201700610	TEST Submission for VPN Wrapper so please disregard

2 items

- 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.

The screenshot shows the myIRB interface for a study titled "Study: Alpha 22 - Expedited Study (IRB201801282)". The current state is "Approved". The interface includes a navigation bar with "IRB Studies" selected, and a main content area with tabs for "History", "Stamped Docs", "Revisions", "Continuing Reviews", "Reportable Events", and "Reportable Events". The "History" and "Revisions" tabs are circled in red. A yellow box with a red arrow points to the "New Revision" link in the "New Reportable Event" section, with the text: "If this link is missing, there is already a Revision pending IRB approval or pending continuing review." Another yellow box with a red arrow points to the "History" and "Revisions" tabs, with the text: "Notice History tab and Revisions tab." The "New Reportable Event" section includes a "New Revision" link, which is also circled in red. The "Activities" table shows two entries: "Revision Process Completed" and "Revision Process Opened", both by "Wingard, John R".

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.

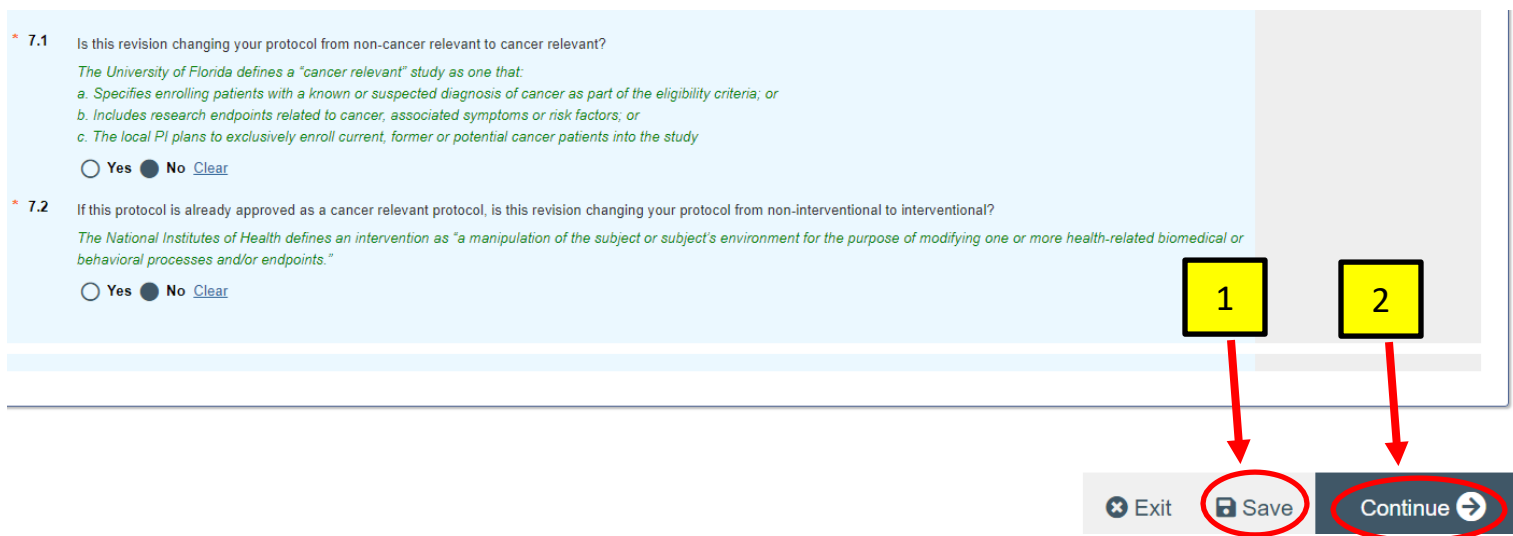
In this case, the PI must choose from one of the following options:

- 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).

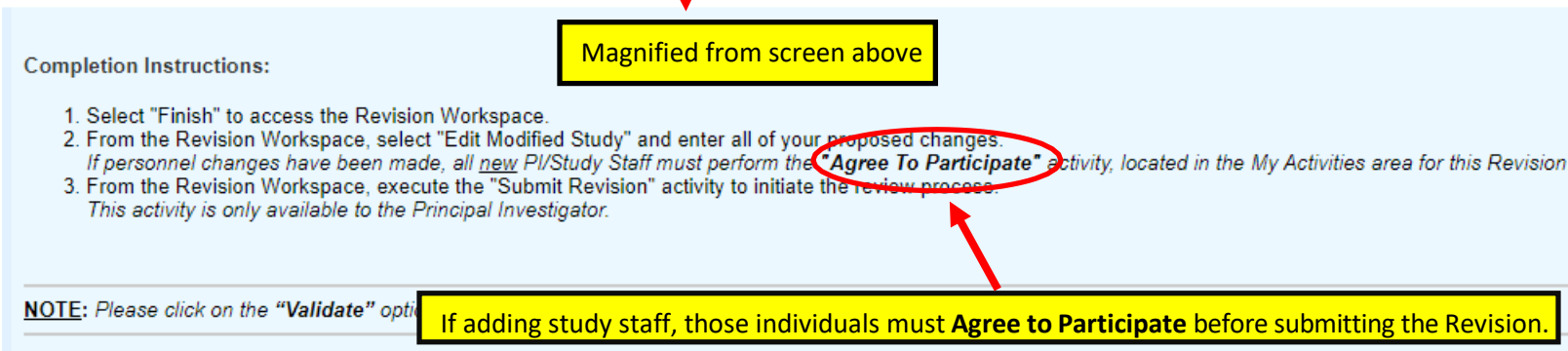
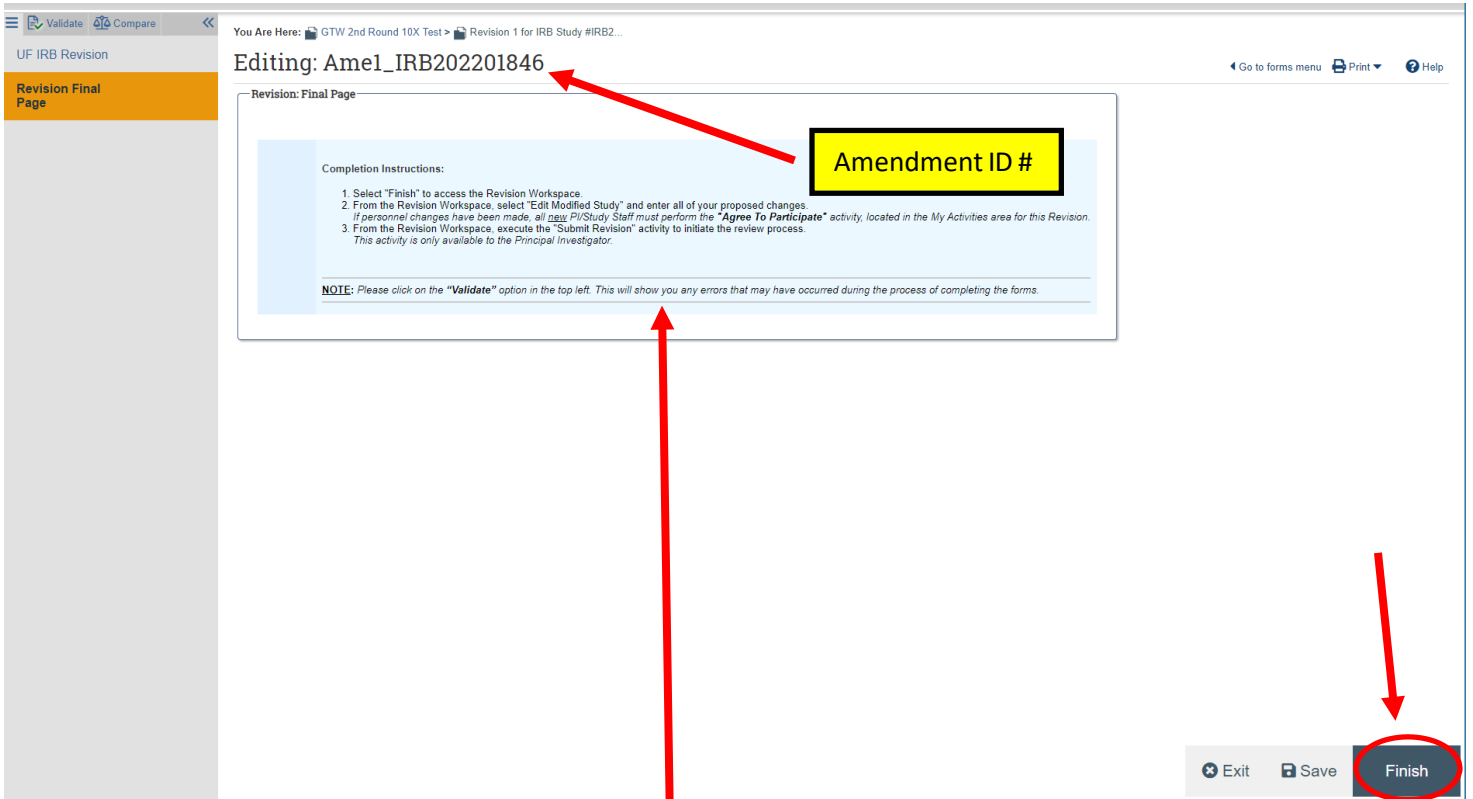
To continue submitting a New Revision, click the **New Revision** tab from the Study Workspace (see screenshot on previous page). From there, complete the SmartForm, paying special attention to Question 1.0. This question is where the PI/study team will list **all changes being made to the study under 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**.

The screenshot displays the myIRB interface for a specific revision. At the top, there are navigation tabs: 'My Home', 'Home', and 'IRB Studies' (which is highlighted in orange). Below these are sub-tabs: 'Revisions', 'Continuing Reviews', and 'Reportable Events'. The breadcrumb trail reads: 'IRB Studies > GTW 2nd Round 10X Test > Revision 1 for IRB Study #IRB202201846'.

On the left sidebar, under 'Current State', the 'Pre Submission' button is circled in red. Below it are several action buttons: 'Edit Revision', 'Print-Friendly Amendment', 'Edit Modified Study', 'Print-Friendly Study', and 'View Changes'. Under 'My Activities', there are buttons for 'Submit Revision', 'Withdraw Revision', 'Agree To Participate', 'Send Email to Study Team', and 'Send Email to IRBA'.

The main content area shows the details for 'Revision: Revision 1 for IRB Study #IRB202201846'. It includes fields for 'Brief Summary: test CHANGE', 'Principal Investigator: John Wingard', 'Revision #: Ame1_IRB202201846', 'PI Proxies:', 'Type of Research: Other', 'Funding Types: No Funding required to initiate or complete this study', 'Study Assigned Risk: Minimal Risk', and 'Study Expiration: 8/9/2025'. Other fields include 'Coordinator:', 'Owning IRB Admin:', 'Requested Review Type: Expedited', 'Pending Agreements to Participate: Everyone has agreed to participate', 'Date Submitted: Unsubmitted', and 'Study Status: Approved'. A 'Written Summary of Changes' section contains the text 'fff'.

At the bottom, there is a 'History' section with a table showing one activity:

Activity	Author	Activity Date
Created Amendment	Wingard, John R	9/22/2022 6:50 PM

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 *myIRB*.
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.

The screenshot shows the IRB Studies web application interface. At the top, there are navigation tabs: 'My Home', 'Home', and 'IRB Studies' (which is highlighted in orange). Below these are sub-tabs: 'Revisions', 'Continuing Reviews', and 'Reportable Events'. The breadcrumb trail reads: 'IRB Studies > GTW 2nd Round 10X Test > Revision 1 for IRB Study #IRB202201846'. On the left side, there is a 'Current State' section with a 'Pre Submission' button. Below this is a list of actions: 'Edit Revision', 'Print-Friendly Amendment', 'Edit Modified Study' (highlighted with a red circle and a red arrow), 'Print-Friendly Study', and 'View Changes'. The main content area displays the 'Revision: Revision 1 for IRB Study #IRB202201846' with various details:

Brief Summary:	test CHANGE			
Principal Investigator:	John Wingard	Coordinator:		
Revision #:	Ame1_IRB202201846			
PI Proxies:		Owning IRB Admin:		
Type of Research:	-Other	Requested Review Type:	Expedited	
Funding Types:	No Funding required to initiate or complete this study		Pending Agreements to Participate:	Everyone has agreed to participate
Study Assigned Risk:	Minimal Risk	Date Submitted:	Unsubmitted	
Study Expiration:	8/9/2025	Study Status:	Approved	
Written Summary of Changes:	fff			

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.

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

* 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

This is the pop-up menu which appears after clicking Add.

Complete all relevant information for the new staff member.

When finished, click Ok or OK and Add Another.

* Required

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**.

Conflict of Interest - Institutional

Study Billing RAC Review Determination

Study Overview

Study Type

Expedited Regulation Confirmation

Revised Protocol Document

Study Population

Study Population, Overview

Females, Child-Bearing Potential

Subject Description (Expedited/Full Board/Banking Studies)

Compensation Determination

Vulnerable Subjects (Expedited/Full Board/Banking Only Studies)

Subject Relationship to Investigator

Enrollment Details

Study Population Complete

Recruitment

Recruitment Methods

Data Collection

Data Collection - Follow Up

Editing: MS1_IRB202201846

Go to forms menu Print Icons Help

Study Type (check all that apply)

1.0 * Type of study:

Drug/biologic agent/non-food substance study

Device study Investigational Device: FDA Approved Device; Humanitarian Use Device [HUD]

Research-only procedure Labs, surgical procedures, other experimental procedures; Tests & Procedures done solely for Research

Use of radiographic procedures, radiation, or radioactive materials Procedures that utilize ionizing radiation such as X-rays, CT scans, PET scans, etc.; radiatio and gamma knife, etc.; radioactive materials such as radioactive iodine, technetium-99m, cobalt-60, etc. Th or diagnostic ultrasound examinations.

Gene Therapy

Genetic Testing

Banking non-local, off-site banking; collection and storage of tissue, data for unknown, future research; Local bank must be submitted as a separate study

Deception Deception defined as purposely omitting information about the study to research participants

Placebo

Behavioral / Social Research Questionnaires, surveys, observational; behavioral/psychological; educational research; If your research is restricted to behavioral/psychological research, you may choose to use IRB-02 rather than IRB-01 if the following conditions are met: (1) you are not collecting Protected Health Information (see HIPAA FAQ), and (2) you are NOT a VA or Shands employee.

Pharmacogenomic

Pharmacokinetic or pharmacodynamic research

Exercise or nutrition research

Record Review Arm This option is if your study includes a population that is only a record review. This is not for studies that are only a record review. If your study is only a record review, please return to the Requested Review Type page and choose Data/Chart Review.

Non-therapeutic research

Other

1.1 If "Non-Therapeutic research" or "Other" Describe

Exit Save Continue

Complete all relevant information for the new procedure, test, questionnaire etc. When finished, click Continue.

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.

Upload Revised Informed Consent Documents

1.0 * Upload consent forms, assent forms, information sheets, and UF addendum here:
Click on the link to a document (listed under Attachment ICF) to revise or update an
Attach MS Word docs only.

[+ Add](#)



Target Population	Attachment ICF	Date Modified
Subjects with pancreatic cancer that has spread to other organs	201600540-ICF.docx(0.04)	6/13/2016

NOTE: YOU MUST SAVE THIS PAGE TO SAVE ATTACHMENTS

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**.

Consent Document - Detail

1.0 * Upload Document
 Please enter your IRB number in the footer of your informed consent forms before submitting

icf.v01.2020-10-05.docx(0.03)  


Choose File

Attach each type of ICF separately.

*To add additional types of ICF forms, click **OK and Add Another**.*

*Use the **Browse** button to revise or update an existing consent form so that changes can be tracked.*

2.0 Describe/Indicate the target population for this consent

* Required  **OK** **OK and Add Another** **Cancel**

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.)

Upload Revised Informed Consent Documents

1.0

* Upload consent forms, assent forms, information sheets, and UF addendum here:

Click on the link to a document (listed under Attachment ICF) to *revise* or *update* an existing consent form so that changes can be tracked. Use the **Add** button to add an additional type of consent form.

Attach MS Word docs only.

+ Add

Target Population	Attachment ICF	Date Modified
Human beings	icf.v02.2020-10-05.docx(0.04)	10/5/2020

Please review our [Researcher Manual](#) for instructions.

If your study uses multiple consent forms, add each type of consent form separately and identify the target population for each form.

Each type of consent must be listed only once.

[Click here for ICF templates](#)

2.0

Please attach non-UF Local Addenda:

Target Population	Attachment Addendum	Date Modified
There are no items to display		

Please create a [Participating Sites Only Revision](#) in order to make changes.

NOTE:

YOU MUST SAVE THIS PAGE TO SAVE ATTACHMENTS

Date Page Modified:

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.

UF | myIRB

Validate Compare

You Are Here: GTW 2nd Round 10X Test > Revision 1 for IRB Study #IRB2... >

Editing: MS1_IRB202201846

Revised Protocol Document: Expedited/Full Board

Revised Protocol Document

Study Population

- Study Population, Overview
- Females, Child-Bearing Potential
- Subject Description (Expedited/Full Board/Banking Studies)
- Compensation Determination
- Vulnerable Subjects (Expedited/Full Board/Banking Only Studies)
- Subject Relationship to Investigator
- Enrollment Details
- Study Population Complete

1.0 * Upload your study protocol here:

Hello world.docx(0.1) ...

- Download Copy
- Upload Revision**
- View History
- Delete

2.0 * Did the study receive outside scientific review?

Yes No [Clear](#)

* 2.1 If "Yes", Who conducted the review?

test

Submit a Document

Title: Hello world.docx

If not provided, the name of the file will be used

* File: **Choose File**

[View](#)

[Show Advanced Options](#)

* Required

OK [Cancel](#)

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**.

Study: Final Page

Completion Instructions:

1. Select "Finish", to access the Study Workspace.
2. From the Study Workspace, execute the "Submit Study" activity to initiate the approval process.
This activity is only available to the Principal Investigator.

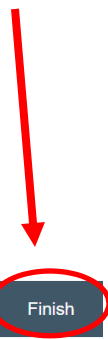
NOTE: Prior to submitting the study, the PI and all Study Staff must perform the "Agree To Participate" activity, located in the My Activities area for this Study.

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.

Important Note! If you plan to publish in an ICMJE member journal, you may be required to register your study in [ClinicalTrials.gov](https://clinicaltrials.gov) PRIOR to enrolling the first subject into the study. For assistance with ClinicalTrials.gov questions, please contact 352-273-5946 or email UFCT-gov@ufl.edu.

Date Page Modified:

Exit Save **Finish**



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.

The screenshot displays the IRB system interface. At the top, there are navigation tabs: 'My Home', 'Home', and 'IRB Studies' (highlighted in orange). Below these are sub-tabs: 'Revisions', 'Continuing Reviews', and 'Reportable Events'. The breadcrumb trail reads: 'IRB Studies > GTW 2nd Round 10X Test > Revision 1 for IRB Study #IRB202201846'.

Current State

Pre Submission

Buttons in the 'Current State' section include: 'Edit Revision', 'Print-Friendly Amendment', 'Edit Modified Study', 'Print-Friendly Study', and 'View Changes'.

My Activities

- PI** Submit Revision (highlighted with a red circle and arrow)
- SS** Withdraw Revision
- SS** Agree To Participate
- IRBA** Send Email to Study Team
- SS** Send Email to IRBA

Revision: Revision 1 for IRB Study #IRB202201846

Brief Summary: test CHANGE

Principal Investigator: John Wingard

Revision #: Ame1_IRB202201846

PI Proxies:

Type of Research: -Research-only procedure
-Other

Funding Types: No Funding required to initiate or complete this study

Study Assigned Risk: Minimal Risk

Study Expiration: 8/9/2025

Written Summary of Changes: fff

History

Activity

- (i)** Created Amendment

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**.

The screenshot shows the 'IRB Studies' page in the myIRB system. The 'IRB Studies' tab is highlighted in orange at the top. Below it, the 'Approved' tab is circled in red. A search bar is present with a dropdown menu set to 'ID' and a search button. A table of studies is displayed with columns for ID, Name, Date Modified, Owner, and State. The 'State' column is circled in red. A yellow box with the text 'Can filter studies by State by clicking here.' has an arrow pointing to the 'State' column. Another yellow box with the text 'Search for study here.' has an arrow pointing to the search bar. A third yellow box with the text 'Search for study here.' has an arrow pointing to the search bar. A fourth yellow box with the text 'Search for study here.' has an arrow pointing to the search bar.

ID	Name	Date Modified	Owner	State
IRB202201860	DJH_slIRB Open pSite, then open Revision, then approve pSite first Revision to test reviewer notes not being able to have the type changed anymore	9/23/2022 9:41 AM	Collins, Renee B	Approved
IRB202201846	GTW 2nd Round 10X Test	9/22/2022 6:50 PM	Collins, Renee B	Approved

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.

Current State

Approved

Study: A Randomized Phase III Study of Standard Cytarabine plus Daunorubicin (7+3) Therapy or Idarubicin with High Dose Cytarabine (IA) versus IA with Vorinostat (IA+V) in the Treatment of Newly Diagnosed Acute Myeloid Leukemia (AML)

Brief Summary: This randomized phase III trial studies cytarabine and daunorubicin hydrochloride or idarubicin hydrochloride in combination with high-dose cytarabine in the treatment of newly diagnosed acute myeloid leukemia. Drugs used in chemotherapy work in different ways, either by killing the cells that are growing rapidly, such as cancer cells, or by stopping the growth of those cells. The combination of these drugs may kill more cancer cells.

Principal Investigator: Jack Hsu

Study Coordinator:

PI Proxies: John Wingard

Owning IRB Admin:

Funding Types: DHHS, including NIH and NCI or NSF Non-Profit Organization

Type of Research:

Assigned Risk: Minimal Risk

Assigned Review Type:

Flags for Study:

My Activities

Copy Study

Edit Email List

Edit Guest List

Send Email to Study Team

Send Email to IRBA

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

Copy Study

This activity will COPY this study. You will remain the Principal Investigator for the new Study and it will be placed in your Inbox. Some attachments may be copied as well.

* New Study Name/Title¹: **Enter Study Title here.**

* Copy this study to My Templates²: Yes No [Clear](#) **Best practice is to select NO**

¹ There is a 255 character limit. If a longer Title is needed, please Click 'Edit Study' on the COPY.

² This will allow this study to be used as a starting point for other studies.

This activity takes time but can save you work! We thank you for your patience.

Use Background Processing: **Select this option if the study you are copying is large (details on next page)**

Click OK when complete

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.

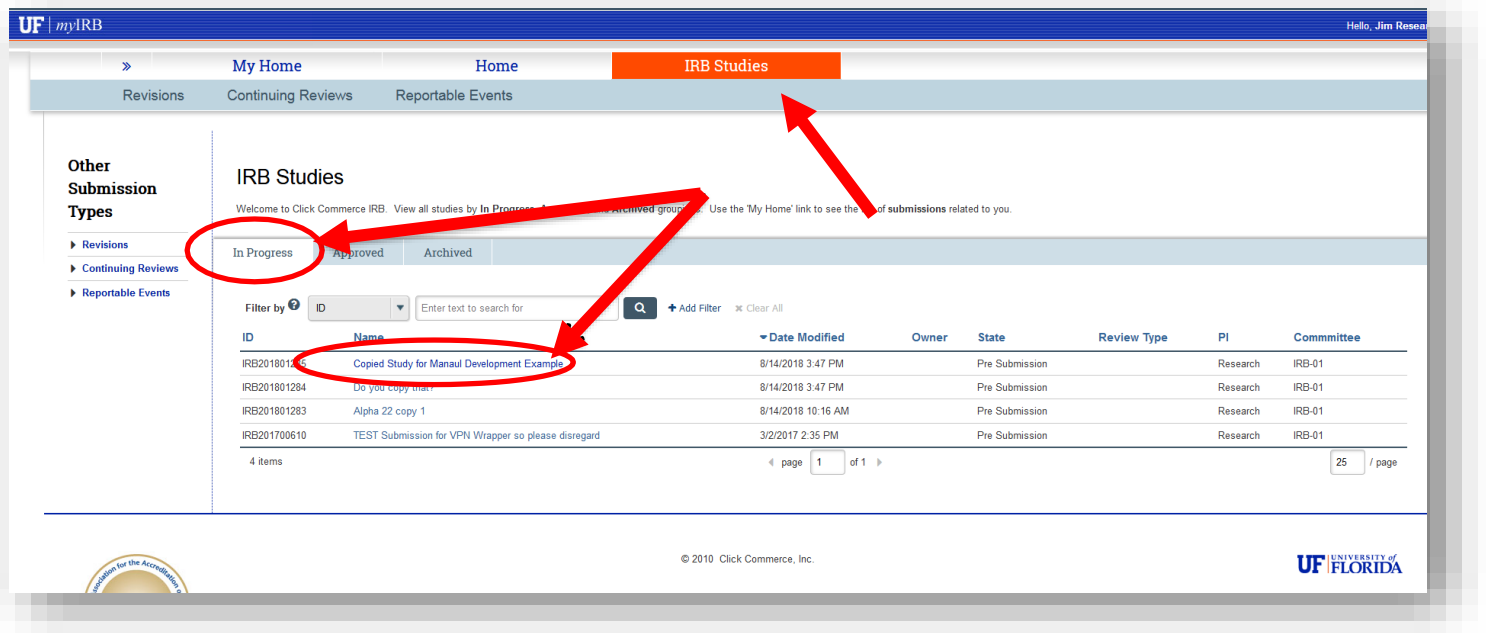
If the Background Processing option is **not** chosen, users must wait until *myIRB* has copied the study entirely before attempting to complete any further work in *myIRB*.

Once *myIRB* 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.

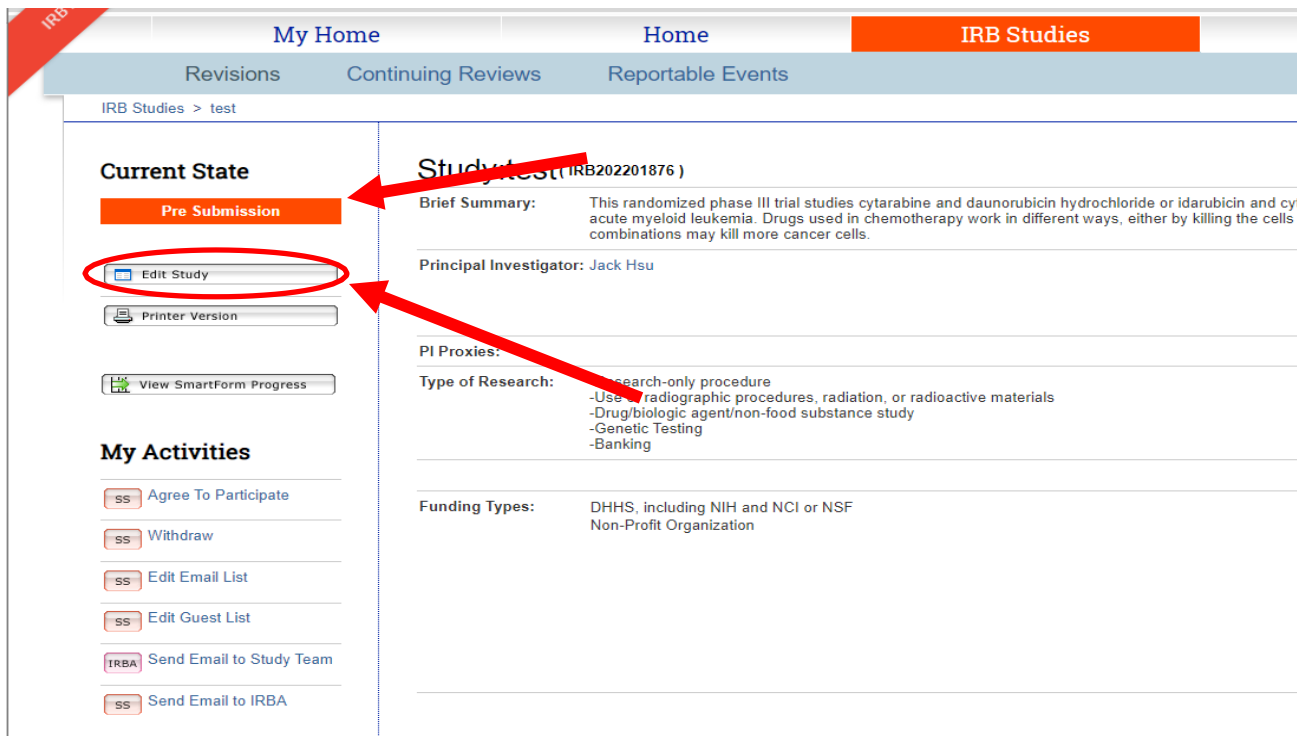
The screenshot shows the myIRB interface for a study titled "Study: Do you copy that? (IRB201801284)". The study is in the "Current State" of "Pre Submission". The "My Activities" list includes "Agree To Participate", "Withdraw", "Copy Study", "Edit Email List", "Edit Guest List", "Send Email to Study Team", and "Send Email to IRBA". The "History" tab is selected, showing a table of activities. The first activity is "Copied Study" by "Research, Jim" on "8/14/2018 3:47 PM". The second activity is "Created Study" by "Wingard, John R" on "8/14/2018 10:17 AM".

Activity	Author	Activity Date
Copied Study	Research, Jim	8/14/2018 3:47 PM
Created Study	Wingard, John R	8/14/2018 10:17 AM

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**.

The screenshot shows the myIRB interface for a user named Jim Research. On the left sidebar, under the 'Create' section, the 'Ceded Study Review' button is highlighted with a red circle. A red arrow points from this button to the 'Studies' tab in the main content area. The main content area displays a 'Page for Jim Research' with a welcome message and a list of items requiring action. Below this is a table of items with columns for ID, Name, Date Modified, Type, Owner State, Last State Change, and Committee.

ID	Name	Date Modified	Type	Owner State	Last State Change	Committee
CR00004849	Continuing Review for IRB201801282	8/14/2018 4:26 PM	Continuing Review	Pre Submission	8/14/2018 3:04 PM	IRB-01
IRB201801285	Copied Study for Manual Development Example	8/14/2018 3:47 PM	Study	Pre Submission	8/14/2018 9:45 AM	IRB-01
IRB201801284	Do you copy that?	8/14/2018 3:47 PM	Study	Pre Submission	8/14/2018 9:45 AM	IRB-01
IRB201801283	Alpha 22 copy 1	8/14/2018 10:16 AM	Study	Pre Submission	8/14/2018 9:45 AM	IRB-01
IRB201700610	TEST Submission for VPN Wrapper so please disregard	3/2/2017 2:35 PM	Study	Pre Submission	3/2/2017 2:03 PM	IRB-01

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:

sIRB: 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.

sIRB: IRB of Record Site for Ceded Review
UF is Ceding IRB Review to this site

1.0 * Institution Name:
University of Maine

2.0 * Principal Investigator:
Dr. Rock Lobstah
PI Phone Number: 123-456-789
PI Email: lobbie@umo.edu

3.0 Study Coordinator:
Jessup Pine
SC Phone Number: 123-456-4688
SC Email: jpine@umo.edu

4.0 * IRB Contact Information:
Northern Woods IRB
Phone: 123-456-7710
Email: northwoods@umo.edu
Include phone number, email and address

5.0 Attachments: IAA, Exhibit C, other
Upload attachments

Name	Modified Date	Version Number
Smartest IRB IAA.docx	8/16/2018 6:56 PM	0.01

6.0 * Current IRB Approval Letter from IRB of Record:
Current IRB approval.docx(0.01) *Upload Revision*
Upload current IRB Approval Letter for Study from Reviewing IRB. This is NOT the letter that includes IIRB site.

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.

The screenshot displays the 'Study: Ceded Review Study (CED000000708)' workspace. On the left, the 'My Activities' sidebar contains several buttons: 'Agree To Participate', 'Submit Study' (circled in red with a red arrow pointing to it), 'Withdraw', 'Edit Email List', 'Edit Guest List', and 'Send Email to Study Team'. The main workspace area shows the study details, including the Principal Investigator (John Wingard), PI Proxies, Type of Research (-Research-only procedure), and Funding Types (No Funding required to initiate or complete this study). A red warning message states 'UF is Ceding Review to another IRB'. Below the details is a 'History' section with a table of activities.

Activity	Author	Activity Date
Agree To Participate John Wingard agreed to participate	Wingard, John R	9/23/2022 6:35 PM
Created Study	Wingard, John R	9/23/2022 6:13 PM

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.

Submit Study

Ceded Investigator Assurances:

I certify that all information provided in this application represents an accurate description of the intended study.

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

- Implementing no changes in the approved protocol or consent form without prior approval of the Institutional Review Board (IRB) of Record.
- Conducting the research using only the qualified personnel listed on the approved project.
- Submitting a timely continuing report as requested by the Overall PI.
- Notifying the Overall PI of any adverse events that are unexpected, serious, and/or more severe than anticipated within five (5) working days or sooner if applicable per the executed IAA.
- Reporting all deaths, regardless of cause to the Overall PI, within five (5) working days or sooner if applicable per executed IAA.
- Immediately notify UF IRB and the Overall PI upon termination of the study or departure of the Principal Investigator from this Institution.

I agree to not having any PI Proxy on this study. *

I understand that as Principal Investigator, I assume full responsibility for the conduct of the study, and for the protection of the rights and welfare of human subjects involved in this research.

I agree with the above statements: *

If you have finished filling out your application, then click OK. After you click OK you will no longer be able to edit the application. You will receive email when each approval is granted or refused, and again when all the required approvals are received.

*If you are not ready to submit your application, click **Cancel**.*

OK **Cancel**

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.

My Home Home **IRB Studies**

Revisions Continuing Reviews Reportable Events

IRB Studies > Ceded Review Study

IRB Assignment

View Study
Printer Version
View Differences

My Activities

Edit Email List
Edit Guest List
Send Email to Study Team
Send Email to IRBA

(Submitted)

Study: Ceded Review Study (CED000000708)

Brief Summary:

Principal Investigator: John Wingard

PI Proxies:

Type of Research: -Research-only procedure

Urgent Review: No

UF is Ceding Review to another IRB

Funding Types: No funding required to initiate or complete this study

History Stamped Docs Ancillary Status

Filter by Activity Enter text to search + Add Filter X C

Activity

PI Study Submitted for 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

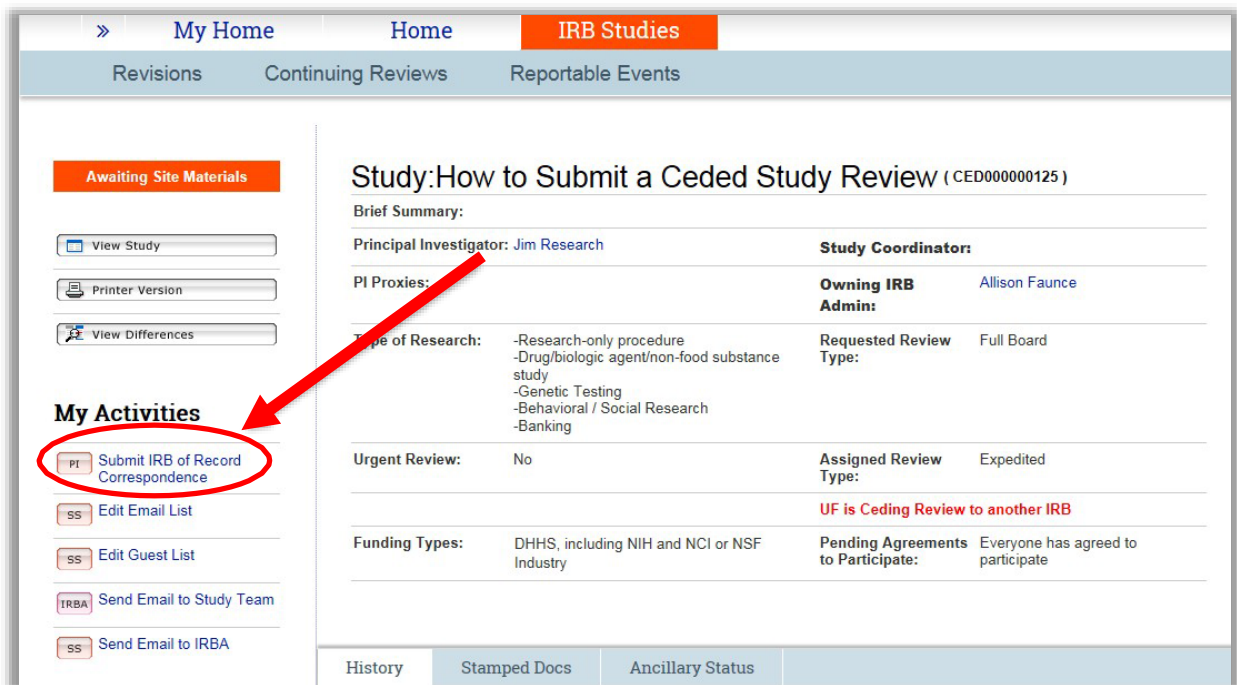
Awaiting Correspondence	Study: How to Submit a Ceded Study Review (CED000000125)	
View Study	Brief Summary:	
Printer Version	Principal Investigator: Jim Research	Study Coordinator:
View Differences	PI Proxies:	Owning IRB Admin: Allison Faunce
	Type of Research: -Research-only procedure -Drug/biologic agent/non-food substance study	Requested Review Type: Full Board

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-1@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	
<i>The Foundation for The Gator Nation</i> 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).



The screenshot displays the myIRB interface for a study titled "Study: How to Submit a Ceded Study Review (CED000000125)". The interface includes a navigation bar with "My Home", "Home", and "IRB Studies" tabs, and sub-tabs for "Revisions", "Continuing Reviews", and "Reportable Events".

On the left sidebar, under the "My Activities" heading, the "Submit IRB of Record Correspondence" activity is highlighted with a red circle and a red arrow pointing to it. Other activities listed include "Edit Email List", "Edit Guest List", "Send Email to Study Team", and "Send Email to IRBA".

The main content area shows study details:

- Brief Summary:**
- Principal Investigator:** Jim Research
- Study Coordinator:** Allison Faunce
- PI Proxies:**
- Owning IRB Admin:**
- Type of Research:** -Research-only procedure, -Drug/biologic agent/non-food substance study, -Genetic Testing, -Behavioral / Social Research, -Banking
- Requested Review Type:** Full Board
- Urgent Review:** No
- Assigned Review Type:** Expedited
- Funding Types:** DHHS, including NIH and NCI or NSF Industry
- Pending Agreements to Participate:** Everyone has agreed to participate

At the bottom, there are tabs for "History", "Stamped Docs", and "Ancillary Status". A red banner at the bottom of the main content area reads "UF is Ceding Review to another IRB".

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.

	
<small>Health Center Institutional Review Board FWA00005790</small>	<small>PO Box 100173 Gainesville FL 32610-0173 Telephone: (352) 273-5600 Facsimile: (352) 273-9614 Email: ufirb-1@lists.ufl.edu</small>
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#:	CE000000125
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: <ul style="list-style-type: none">• 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**.

The screenshot displays the myIRB interface. On the left, there are three buttons: 'View Study', 'Printer Version', and 'View Differences'. Below these is the 'My Activities' section with buttons for 'Edit Email List', 'Edit Guest List', 'Send Email to Study Team', and 'Send Email to IRBA'. The 'New Reportable Event' section has a 'New Reportable Event' button. The 'New Renewal/Closure' section has a 'New Continuing Review/Closure' button circled in red. On the right, the study details are shown: Principal Investigator: John Wingard; PI Proxies: Nosha Farhadfar; Funding Types: DHHS, including NIH and NCI or NSF Non-Profit Organization; Assigned Risk: Minimal Risk. A yellow box highlights a note: 'Note message which denotes study as Ceded Review.' A red arrow points from this note to a red text message: 'UF is Ceding Review to another IRB'. Another red arrow points from the 'New Continuing Review/Closure' button to the 'Continuing Review' tab in the bottom navigation bar. The bottom navigation bar includes 'History', 'Revisions', and 'Continuing Review' tabs, and a search filter set to 'Activity'.

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

The screenshot shows a web application interface for 'Continuing Review/Study Closure Determination'. The breadcrumb trail indicates the user is in 'A Randomized, Multicenter, Pha...' and 'Continuing Review for CED00000...'. The main heading is 'Editing: CR00011756'. The page title is 'Continuing Review/Study Closure Determination'. A sidebar on the left contains navigation links: 'Continuing Ceded Review', 'Researcher Training Summary', and 'Continuing Review Final Page'. The main content area displays a form with a question: '1.0 * We wish to:'. Below the question are two radio button options: 'Close this project' and 'Continue this project'. A red arrow points from a yellow callout box to the 'Close this project' radio button. The yellow callout box contains the text: 'As appropriate, select: Close this project Or Continue this project.' Another yellow callout box points to the 'Continue' button in the bottom right corner of the interface. This callout box contains the text: 'Click Continue to advance to the next smartform.' The bottom right corner of the interface features three buttons: 'Exit', 'Save', and 'Continue'. The 'Continue' button is circled in red.

Editing: CR00011812

- Continuing Review/Study Closure Determination
- Continuing Ceded Review**
- Researcher Training Summary
- Continuing Review Final Page

Continuing Ceded Review

Upload the following attachments

1.0 Approval Letter from IRB of Record:
 [None]

2.0 Current Approved Protocol:
 [None]

3.0 Current Approved Consent:

Name	Modified	Version
There are no items to display		

4.0 Miscellaneous additional attachments:

Name	Modified	Version
There are no items to display		

Upload appropriate documents here.

Click **Continue** to advance to the next smartform.

- Continuing Review/Study Closure Determination
- Continuing Ceded Review
- Researcher Training Summary**
- Continuing Review Final Page

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 to view required training courses.

Click here for Training Requirements

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**

Editing: CR00011812

Click **Validate** to display any remaining errors. Once all errors are resolved ...

Continuing Review: Final Page

Completion Instructions:

- Select "Finish" to access the Continuing Review Workspace.
- 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.

... click **Finish** to exit the smartform workspace.

Date Page Modified: 8/26/2022

Exit Save **Finish**

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.


The screenshot displays the IRB system interface for a continuing review. At the top, there are navigation tabs for 'My Home' and 'Home', and sub-tabs for 'Revisions', 'Continuing Reviews', and 'Reportable Events'. The breadcrumb trail indicates the current location: 'IRB Studies > A Randomized, Multicenter, Phase III Trial of Tacrolimus/Methotrexate versus Post-Transplantation > Continuing Review for CED000000250'. The 'Current State' section shows 'Pre Submission' as the active status. Below this are three buttons: 'Edit Continuing Review', 'Printer-Friendly Version', and 'View Differences'. The 'My Activities' section contains five buttons: 'Submit Continuing Review' (circled in red and pointed to by a red arrow), 'Withdraw Continuing Review', 'Send E-mail to IRBA', and 'Send E-Mail to Study Team'. The right-hand side of the page displays details for the 'Continuing Review:Continui'. This includes a 'Brief Summary' (The primary objective of the trial is chronic GVHD requiring system...), 'Principal Investigator: John Wingard', 'PI Proxies: Nosha Farhadfar', and 'Type of Research' (listing options like Research-only procedure, Use of radiographic procedure, etc.). A red banner states 'UF is Ceding Review to another IRB'. Other details include 'Committee: IRB-01', 'Study Expiration: 9/16/2022', and 'Study Title: A Randomized, Multicenter, Phase III Trial of Tacrolimus/Methotrexate versus Post-Transplantation'.

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

PO Box 100173
Gainesville FL 32610-0173
Telephone: (352) 273-9600
Facsimile: (352) 273-9614
Email: uifb-1@lists.ufl.edu

Health Center Institutional Review Board
FWA00005790

PO Box 100173
Gainesville FL 32610-0173
Telephone: (352) 273-9600
Facsimile: (352) 273-9614
Email: uifb-1@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

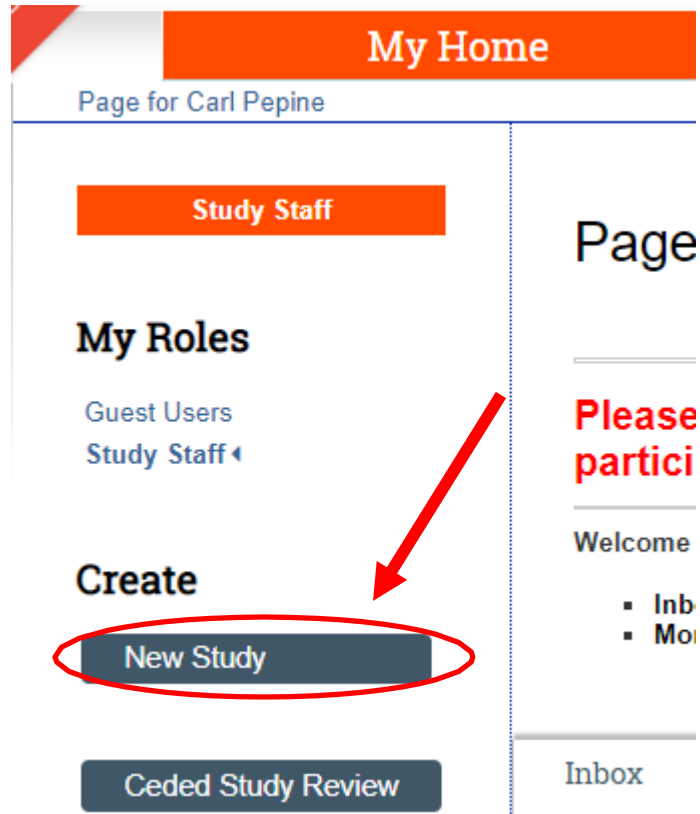
UF Study Team:

The Foundation for The Gator Nation
An Equal Opportunity Institution

Confidentiality Notice: This e-mail message, including any attachments, is for the sole use of the intended recipient(s), and may contain legally privileged or confidential information. Any other distribution, copying, or disclosure is strictly prohibited. If you are not the intended recipient, please notify the sender and destroy this message immediately. Unauthorized access to confidential information is subject to federal and state laws and could result in personal liability, fines, and imprisonment. Thank you.

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 sIRB 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.



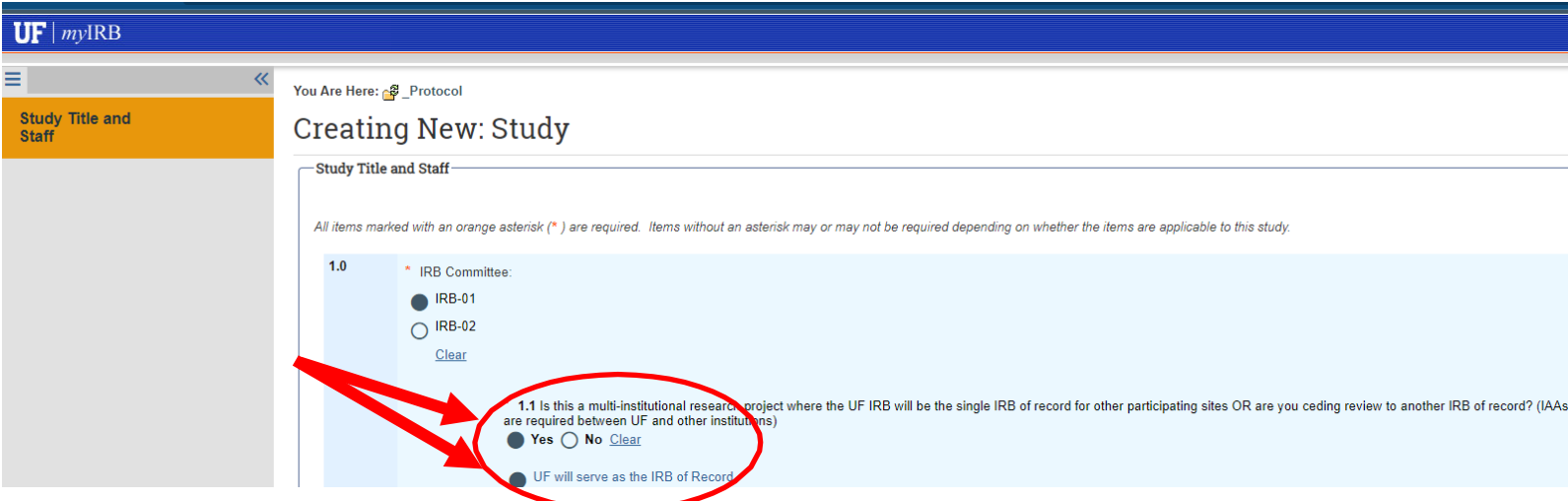
When submitting a revision to make IRB-01 the IRB of record, there are 3 steps to take, in order:

- 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, **sIRB status** will be flagged on the main Study Workspace (see screenshot below).

Study:UF IRB of Record Study (IRB201801286)	
Brief Summary:	
Principal Investigator:	Jim Research
PI Proxies:	UF will serve as the IRB of Record
Type of Research:	Full Board
Funding Types:	There are no items to display
Study Coordinator:	
Requested Review Type:	Full Board
Pending Agreements to Participate:	Jim Research - Not Agreed
History	

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

Study Locations

1.0 * Where are you going to conduct this project? (choose all that apply)

- UF and/or UF Health
- UF and/or UF Health Jacksonville
- VA
- Baptist/Wolfson
- Sacred Heart
- Nemours
- Florida Department of Health
- Other sites in the USA
- Other sites outside the USA


2.0 Are you getting any data or tissue from international locations?
 Yes No

If you are conducting the study at a location that does not fall under UF/UF Health, then select "Other sites in the USA".

NOTE: "Locations" include not only where the research is conducted "from" and data will reside, but also the location of those participating (even if the work is done by phone, email or website).

Enrollment Details SmartForm

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

4.0 * Is this a multi-centered project? 

Yes No [Clear](#) 

NOTE: For OneFlorida projects, choose "No".

Multi-centered involves other researchers, outside UF/Shands/VA who are getting IRB approval. Click link for full definition of multi-centered.

Enrollment: Multi-Centered Project

Enrollment: Multi-Centered Project

1.0 * List the total number of subjects to be included at all participating sites:

2.0 * Are you/our institution serving as the central/lead/coordinating site?

Yes No [Clear](#)

2.1 If "Yes", Describe how information relevant to the protection of research subjects (including but not limited to communications of adverse events, unanticipated problems, protocol modifications, and interim results) will be communicated among the sites/institutions participating in the research:

2.2 If "Yes", Add Site(s):

Only add sites that are NOT using UF IRBs as the IRB of Record (i.e. they will be getting their own local approval)

[+ Add](#)

Site Name	Attachment Site Approval
There are no items to display	

Multi-Centered Project: Information and Approvals

All items marked with a red asterisk () are required. Items without an asterisk may or may not be required depending on whether the items are applicable to this study.*

1.0 Site Name:

2.0 IRB Approval Letter: [Choose File](#) *Attach document*

*Use the **Browse** button to **revise** or **update** an existing attachment so that changes can be tracked.*

* Required

[OK](#) [OK and Add Another](#) [Cancel](#)

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.

Submit Study

IRB of Record Investigator Assurances:

I certify that all information provided in this application represents an accurate description of the intended study.

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 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.

I agree to not having any PI Proxy on this study. * ←

I understand that as Principal Investigator, I assume full responsibility for the conduct of the study, and for the protection of the rights and welfare of human subjects involved in this research.

I agree with the above statements: * ←

If you have finished filling out your application, then click OK. After you click OK you will no longer be able to edit the application. You will receive email when each approval is granted or refused, and again when all the required approvals are received.

*If you are not ready to submit your application, click **Cancel**.*

OK Cancel

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
FUA000005790

PO Box 100173
Gainesville FL 32610-0173
Telephone (352) 273-9600
Facsimile (352) 273-9614
Email: ufirb-1@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 provided 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**.

The screenshot shows the myIRB interface. The 'My Home' tab is selected in the top navigation bar. The 'Studies' tab is selected in the sub-navigation bar. A search bar contains the text 'IRB201701142'. Below the search bar, a table lists study results. The first row is highlighted with a red circle, and the study name 'Women's Ischemia Trial to Reduce Events in Non-Obstructive CAD (WARRIOR)' is circled in red. Yellow boxes with numbers 1, 2, 3, and 4 point to the 'My Home' tab, the 'Studies' tab, the search bar, and the study name, respectively.

ID	Name	Date Modified	State	Committee
IRB201701142	Women's Ischemia Trial to Reduce Events in Non-Obstructive CAD (WARRIOR)	8/24/2022 4:37 PM	Approved	IRB-01

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)**.

My Activities

- PI Copy Study
- SS Edit Email List
- SS Edit Guest List
- IRBA Send Email to Study Team
- SS Send Email to IRBA

New Reportable Event

- ! New Reportable Event

New Revision

- New Revision

New Revision (Participating Sites Only)

- New Revision (pSite Only)

New Renewal/Closure

- New Continuing Review/Closure

PI Proxies: Eileen Handberg

Funding Types: Federal Grant (other than DHHS or VA)

Assigned Risk: Greater Than Minimal Risk

UF will serve as the IRB of Record

Expiration Date: 6/7/2023

History | Stamped Docs | Revisions

Filter by ? Activity [v] Enter text to search

Activity

[i] Revision Process Completed

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).

UF IRB Revision

You Are Here: Women's Ischemia Trial to Redu... > _Amendment

Creating New: Revision

UF Revision

1.0 * Itemize revisions made and list justification for each revision:
Add each change separately and add a separate justification in order to build the table.
+ Add
Description
There are no items to display

5.0 List any specific information that needs to be included in the IRB response letter:

After completing the pop-up screen on the next page, you will be redirected here. Click **Continue** to proceed.

Exit Save **Continue**

Add UFIRB_Rev_DescEx

Revision Description and Justification Detail

1.0

* Describe the revision:

Enter detailed information here.

2.0

* What is the justification for and/or purpose of the revision:

Adding a new study site.

Click **OK** or **OK and Add Another** to proceed.

OK

OK and Add Another

Cancel

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.

Editing: Ame100_IRB201701142

- UF IRB Revision
- Revision sIRB Participating Sites**
- Revision Local Addenda
- Revision Final Page

Revised Single IRB Participating Sites

UF is the Reviewing IRB of Record

1.0 Institution and Staff Information: Add one entry for each participating site

Is site active?	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 Oster 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.fraser@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	Heldi Johnson 607-547-3870 heldi.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**

Add UFIRB_SingleIRB_pSite_Type

Single IRB Participating Site Detail

1.0 * Participating Institution Name:

2.0 * Principal Investigator:
Site PI:

Site PI Phone:

Site PI Email:

3.0 Study Coordinator:
Site SC:

Site SC Phone:

Site SC Email:

4.0 * IRB Contact Information:

Include phone number, email and address

5.0 Attachments: IAA, Exhibit C, other
Upload attachments

Provide all requested information and upload all appropriate documents as requested on this page.

When complete, Click **OK** or **OK and Add Another** to proceed.

* Required

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.

Editing: Ame100_IRB201701142

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

Population	Attachment Addendum	Date Modified
This is for Brooke Army Medical Center site	201701142-Brooke Army Medical Center 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 Specialists Addendum(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

2.0 Describe/Indicate the target population for this local addendum

Attach each type of local addenda separately.
To add additional types of local addenda, click **OK** and **Add Another**.

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.

The screenshot displays the IRB system interface. In the top left corner, the 'Validate' button is circled in red, with a red arrow pointing to a yellow callout box that reads: 'Click **Validate** to display any remaining errors. Once all errors are resolved...'. The main content area shows 'Revision: Final Page' with completion instructions. At the bottom right, the 'Finish' button is circled in red, with a red arrow pointing to a yellow callout box that reads: '... click **Finish** to exit the smartform workspace.' The interface also includes a breadcrumb trail, a sidebar with navigation options, and a top navigation bar with 'Go to forms menu', 'Print', and 'Help' options.

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**.

The screenshot displays the myIRB interface for a revision workspace. The top navigation bar includes 'UF | myIRB' and 'Hello, Rebecca Simms'. The main navigation menu has 'IRB Studies' highlighted. Below it, a sub-menu shows 'Revisions', 'Continuing Reviews', and 'Reportable Events'. The left sidebar contains 'Current State' with a 'Pre Submission' button and 'My Activities' with a red circle around the 'Submit Revision' button. The main content area shows details for 'Revision: Revision 3 for IRB Study #IRB202000033 (pSites Only)', including a brief summary, principal investigator (Rebecca Simms), coordinator, revision number (Ame3_IRB202000033), and a note that 'UF will serve as the IRB of Record'. Other details include PI Proxies, Owning IRB Admin, Requested Review Type, Pending Agreements to Participate (Everyone has agreed to participate), Date Submitted (Unsubmitted), Study Assigned Risk (Minimal Risk), Study Expiration (8/6/2021), and Study Status (Approved). A 'Written Summary of Changes' section is also present. At the bottom, a 'History' table is partially visible with columns for Activity, Author, and Activity Date.

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**.

UF IRB Revision

Revision sIRB Participating Sites

Revision Local Addenda

Revision Final Page

Editing: Ame100_IRB201701142

Revised Single IRB Participating Sites

UF is the Reviewing IRB of Record

1.0 * Institution and Staff Information:

+ Add

Is site active?	Is UF Privacy Board?	Site Name	Site PI	Contact Info
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
yes		AdventHealth Orlando	Rohit Bhatheja	Steven Smith 800 N Magnolia, Suite 500 Orlando FL, 32803 407-303-1823 steven.r.smith@adventhealth.org
yes		AdventHealth Sebring	Deepti Bhandare	James Patterson, M.D. 3100 East Fletcher Avenue Tampa, FL 33613 (813)615-7200 X56516 tamwestfloridaarb@ahss.org

Edit UFIRB_SingleIRB_pSite_Type

Single IRB Participating Site Detail

1.0 * Participating Institution Name:
University of Maryland Capital Region Health

2.0 * Principal Investigator:
Site PI:
Alexander Kaysin
Site PI Phone:
240-677-3100
Site PI Email:
alexander.kaysin@umm.edu

3.0 Study Coordinator:
Site SC:
Site SC Phone:
Site SC Email:

4.0 * IRB Contact Information:
Joanne Marshall
7601 Osler Drive
Towson, MD 21204
410-427-2031
Joanne.marshall@umm.edu
Include phone number, email and address

5.0 Attachments: IAA, Exhibit C, other *Upload attachments*

Revise the information in these boxes as needed.

When complete, Click **OK** or **OK and Add Another** to proceed.

OK

OK and Add Another

Cancel

* Required

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.

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

Revision: Final Page

Completion Instructions:

1. Select "Finish" to access the Revision Workspace.
2. From the Revision Workspace, select "Edit Modified Study" and enter all of your proposed changes. If personal changes have been made, all new PI/Study Staff must perform the "Agree To Participate" activity, located in the My Activities area for this Revision.
3. From the Revision Workspace, execute the "Submit Revision" activity to initiate the review 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.

Go to forms menu Print Help

... click **Finish** to exit the smartform workspace.

Exit Save Finish

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**.

Current State

Pre Submission

Edit Revision

Print-Friendly Amendment

My Activities

PI Submit Revision

SS Withdraw Revision

Revision

Brief Summary:

Principal Investi

Deactivating a Participating Site (P-Site) where UF is 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.

UF IRB Revision

Revision sIRB Participating Sites

Revision Local Addenda

Revision Final Page

Editing: Ame100_IRB201701142

Revised Single IRB Participating Sites

UF is the Reviewing IRB of Record

1.0 * Institution and Staff Information:

+ Add

Is site active?	Is UF Privacy Board?	Site Name	Site PI	Contact Info
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
yes		AdventHealth Orlando	Rohit Bhatheja	Steven Smith 800 N Magnolia, Suite 500 Orlando FL, 32803 407-303-1823 steven.r.smith@adventhealth.org
yes		AdventHealth Sebring	Deepti Bhandare	James Patterson, M.D. 3100 East Fletcher Avenue Tampa, FL 33613 (813)615-7200 X56516 tamwestfloridaairb@ahss.org

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.

7.0 * Is this site currently active?
 Yes No [Clear](#)

7.1 Confirm all study participants have completed their involvement in this study
 Yes No [Clear](#)

7.2 Please describe why the site is closing:

Target enrollment complete. All subjects have completed study

Select "Yes" unless there will be no further enrollments or study interactions at this site.

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.

Validation

You Are Here: Women's Ischemia Trial to Redu... > Revision 100 for IRB Study #IR...

Editing: **Am100_IRB201701142**

Revision: Final Page

Completion Instructions:

1. Select "Finish" to access the Revision Workspace.
2. From the Revision Workspace, select "Edit Modified Study" and enter all of your proposed changes. *If personnel changes have been made, all **new** PI/Study Staff must perform the "Agree To Participate" activity, located in the My Activities area for this Revision.*
3. From the Revision Workspace, execute the "Submit Revision" activity to initiate the review 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.

Go to forms menu Print Help

Exit Save **Finish**

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**.

The screenshot displays a web interface for a revision workspace. On the left, under the heading "Current State", there is an orange button labeled "Pre Submission". Below this are two buttons: "Edit Revision" and "Print-Friendly Amendment". Further down is the "My Activities" section, which contains two items: "PI Submit Revision" (circled in red) and "SS Withdraw Revision". On the right side, under the heading "Revision", there is a "Brief Summary:" section with the text "Principal Invest". A red arrow points from the right side towards the "Submit Revision" button in the "My Activities" section.