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**Introduction: Getting Started**

1. Go to IRB 01 website for the link:
   
   https://my.irb.ufl.edu

   **NOTE:** some campus users may have to VPN in to use myIRB. Instructions for accessing myIRB by using the CISCO AnyConnect VPN Client can be found on the following webpage:

   http://irb.ufl.edu/myirb/accessing-myirb.html

2. Go to the Login icon located on the right side of Home page:

   ![Login Icon](image)

   **TIP:** If you have not previously registered for a myIRB account, when you click on the Login link, the myIRB registration page will appear. The registration page will be pre-populated with the information obtained from your Gatorlink account. Please update/complete all mandatory and editable fields and submit. It will take approximately 24 – 48hrs for your registration to be finalized (per the NOTE on this screenshot).

   **TIP:** VA users registering in myIRB for the first time, please use the registration link to the left of the screen. After your myIRB account is finalized, the link on the right can be utilized.

   **DO NOT use this Registration link if you are NOT a VA user.**
3. 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 and you click on ‘Login’, you will be taken directly to your home page:
"My Home" Personal Folder

After logging into the site, you will be on the myIRB Home page. Please click on the “My Home” This is where you will be able to access and work with your studies.

The default tab will always be your “Inbox,” which includes all the submissions (new studies, reportable events, continuing reviews, or revisions) that require some action by you. The studies tab will list all the studies you have access to.
The link to "My Home" is available throughout the site. You can always click on that link to return to this page from other sections of myIRB.
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 once you complete the first page of the SmartForm and click Continue.

TIP: You will need to allow Pop-ups throughout myIRB website.
Working with SmartForms

All applications in myIRB use SmartForms which present only those questions that are relevant to your study based upon your previous responses.

Required fields are marked with an orange asterisk *. 

You can answer text questions by typing directly into the text box or by pasting in text from another document. Relevant documents can be uploaded where indicated.

Some screens will have an Add button. The Add button opens an additional window with more questions about the topic. You will have the choice of Ok or Ok and Add Another. For example if your study involves more than one medication, you will need to answer the additional questions for each one.
Other screens will have an option to make a selection from a drop down list (i.e., UF site locations); however, the word “Select” has been replaced with “---".
Navigation controls are located in the navigation bar at the top or bottom of each page. Use these SmartForm navigation controls instead of the controls in the browser bar (e.g. Internet Explorer, Safari, Firefox, Opera).

Use the **Continue** button to move to the next screen in the SmartForm.

**TIP:** It is recommended that you use the **Continue** button for your first pass through the SmartForms and responding to the questions, in order to ensure that all the questions your type of submission requires are presented to you. The branching logic is dependent on consecutive completion of the questions.

You can use the Back button to return to the previous page.

**TIP:** After you enter or edit data on a screen, click **Save** before clicking **Back**! The **Back** button does not save your data.

You can save your data in a study application by clicking **Save** or **Continue**.

Use **Exit** to close the application and return to the **Study Workspace**.

**TIP:** Always Save before exiting! Exit will prompt you to save before closing.

Once new or revised data on a page has been saved, you can navigate directly to other sections and questions by using the **Jump To:** drop-down menu. Your current page will show in red.
You do not have to complete your entire submission at one time. Your progress will be saved. You are able to check the progress of your submission using the View SmartForm Progress button.
While you are in a SmartForm, you can use this tool to gauge your progress with the application. In the menu bar, click **Hide/Show Errors** to list the required fields that still need to be completed. The link will take you to the SmartForm page that needs additional information.

Click **Hide/Show Errors** again to toggle off (hide) the Error/Warning Messages.

**TIP:** Study cannot be submitted until all errors are addressed and user training is up to date.
Agree to Participate

Before an application can be submitted, each study staff member assigned to the study must complete the **Agree to Participate Activity**.

Open the **Study Workspace** for the study and locate the **Agree To Participate** Activity link in the **My Activities** list in the left column. Click on the link to open the Activity Form.

Note: This includes the PI.
You can see who has not completed the Agree to Participate on the Study Workspace.
You can use the **Email the Study Team** activity to notify the study team that they need to Agree to Participate.

**TIP:** If a team member does not Agree to Participate in a timely manner. You can remove them from the study and add them back on with a revision at a later date.

---

**PI Proxy**

PIs can designate a Co-Investigator on the study team as a Proxy. This person will be able to submit revisions, reportable events, and continuing reviews if the PI is unavailable. The PI Proxy is a “function” that can be assigned to a single co-investigator on the study.

**TIP:** It is recommended that the PI designate this person when submitting the study otherwise it will have to be done as a revision.
Steps to add/delete PI Proxy on myIRB studies

The option to add a PI Proxy can be done at the beginning of the study prior to submitting or with a revision and does require IRB approval.

PI Proxy, once approved is enabled to have all the same functions as the PI.

If a PI Proxy is not designated prior to initial approval, a revision would need to be submitted to add/delete a PI Proxy.

Adding a PI Proxy

When a PI Proxy is added to a study, the Proxy will have to agree to participate in order to accept the function.

PIs will also need to acknowledge the PI Proxy role when the study is submitted.
Deleting a PI Proxy

A revision will need to be submitted deleting the function of PI proxy from a co-investigator.

A PI Proxy will have all the same activities as the PI:

- They can submit revisions, adverse events, continuing reviews, etc.
- They can withdraw the study, revisions, adverse events, continuing reviews, etc.
- The only time the PI is notified is if the Proxy tries to delete the PI from the study; otherwise the PI receives no notifications about study activities carried out by the PI Proxy

It is the PI’s responsibility to confirm that the designated co-investigator is:

- Qualified to fulfill the role of proxy (i.e. coordinator performing duties that are best assessed by an M.D.)
- Has the appropriate roles assigned to them to intervene as necessary (i.e. lab manager should not be engaged in the consenting process if their role states that they will not have any interaction with the subject)
Application Submission

Only the Principal Investigator for the study can **Submit** the application.

To submit the study, the PI should open the **Study Workspace** and click **Submit Study** on the **My Activities** listing. The system will run a final validation check on the entire application before submission. If there are any errors, they will be displayed and your application will not be submitted.

**TIP:** The person who creates the study can use the Hide/Show Errors feature prior to asking the PI to submit.

**TIP:** Hitting Finish at the end of the SmartForm application does not send it to the IRB.

Once the study team members have agreed to participate, and the application has been submitted, it is automatically routed to the required entities in the review process.

When the PI submits the study, the State of the study will be IRB Staff Review.
**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 notification at the following times:

- Requests for information and changes to the application
- Official actions from the IRB (i.e. when the application is scheduled for a board meeting, once an application is approved/disapproved, etc.)

You can also check the progress of your 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.

Your study could be in the State:

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

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

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

- **Assigned to IRB meeting** – Study has been assigned to a meeting and reviewers. You may receive questions from the reviewers. In order to make changes you will need to contact the IRB office to request **Removal From Agenda**, and the IRB office will push the study back to you in a state you can edit.

**TIP**: Remove from Agenda with caution. Your study may not be reassigned to the same meeting depending on your response time and the meeting lock time. It may be more efficient to respond to all reviewers after the meeting.
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 “Changes Requested by... IRB Staff or by Reviewer”.

**TIP:** The study will show up in all the inboxes of all the staff who have agreed to participate, so you should have a system of deciding who responds.
You will click on the study title to open the study workspace. Then you should click on **Edit Study**.

At the top of the page you will see **Reviewer Notes**. Click on the small triangle next to the words to expand the Change requests.
When responding to **Reviewer Notes**, you must change the SmartForm item if applicable as well as respond in the pop-up window. So you choose “Click here to respond”, and complete the response and click ok.
You can choose different types of responses in order to help communicate your response clearly:

- Change Request Completed
- Change Request Not Completed
- Information Only

If the response asks you to change a SmartForm question, you also need to go to the specific question and change your response or provide additional information directly on that item.
Studies may have multiple Reviewer Notes on different SmartForm pages. You can use the **Next** button to progress through. The next button takes you to each SmartForm with Reviewer Notes whether or not you have already responded.

If your study has multiple completed Reviewer Notes, you can also use Hide/Show Errors to see the Reviewer Notes that still require action on your part. You can use the Jump to Links to get to the page quickly.
When you have finished responding to all the Reviewer Notes, the PI should **Submit Changes**. A pop-up window will appear. You can make additional comments, but it is not required, then click OK. This will send the study back to the IRB staff for further action.

![Submit Changes window](image)

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

If the changes requested are to an uploaded attachment (protocol, ICF, advertisements), you need to download the document from the SmartForm page, track changes, and re-upload on the appropriate SmartForm. For a visual explanation of this process, please see page 51.
Accessing Letters and Attachments

Once your study is approved, you will receive a notification of a status change.

You can access all your approved studies under the study tab. You should filter by state, using %Approved.

You access the study workspace by clicking on the Name of the study.

You are able to see the entire History of your submission and access your stamped documents.
### Study: Alpha 22 - Expedited Study (IRB201801202)

**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

**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

**Expeditors Category:**

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 behaviors (including, but not limited to, research on perception, cognition, evaluation, identity, language, communication, cultural beliefs or practices and social behavior) 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)(4). This listing refers only to research that is not exempt.

**Expiry Date:** 8/14/2019

**Letter of Approval:**

**New Reportable Event**

**New Revision**

**New Renewal/Closure**
To access correspondence, click on the links next to the paperclips. You can also view the approval letter at the top of the screen.

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

**TIP:** Do not print the consent form for enrollment or any other stamped documents from the individual SmartForm page. It is not a finalized, stamped version.
OTHER SUBMISSION TYPES

New Reportable Event

a) Serious Adverse Events (local and non-local)
b) Non-Reportable Event
c) Deviations (regulatory or subject related)
d) Unanticipated Problem
e) Miscellaneous

New Continuing Review/Study Closures

Status Report

New Revision

The link for each of these submission types is in the lower left hand corner of the study summary page.
I. Submitting a New Reportable Event:

- Remember, when you log in, the default tab is your Inbox, you will need to click on the “Studies” tab to find the study you need to submit the reportable event for.

- Click on the designated study.
- In the left hand column of your screen, you will see your available submission types.
- Click on the New Reportable Event Activity.
The first page of the SmartForm will guide you along for your submission type.

**TIP:** Be sure to pay attention to the numeric subscripts next to each type of Reportable Event. Some reportable events can be submitted simultaneously and the SmartForms will branch you along, but others will require you to re-open the study again and submit a separate reportable event.

Complete all smart forms and when you get to the **Reportable Event Complete** SmartForm, click on ‘Finish’ to finalize the application.

**TIP:** Even though you hit “Finish” at the end of completing the SmartForm, it has not been submitted to the IRB.

Return to the Study Summary Page and look in the Inbox for the Reportable Event you just created. Look for the red exclamation point, these represent Reportable Events. Click on the one you need to submit to the IRB.

**TIP:** Anything in the ‘State’ column that says “Pre Submission” has not been submitted to the IRB.
Once you open the Reportable Event to be submitted, under My Activities, click on “Submit Reportable Event”.

Note: this is the 2216th adverse event submitted to the IRB to date. It is also the ID# for your Reportable Event.

If a reportable event requires Urgent review, you will need to execute “Send Email to IRBA” found on the Study Summary Page under My Activities. You must state why this is an urgent review. The IRB office will mark it Urgent when they forward it to the Reviewer.
To check on the status of your reportable event, go to the Studies tab, click on the study that the reportable event was submitted on, and click on the Reportable Events tab. Look in the state column to see where it is within the IRB review process.
TIP: Once your reportable event is in the IRB Staff Review state, the only way to withdraw the submission is to contact the IRB office who will send the submission back to the PI. You must use “Send Email to IRBA” so that it can be tracked in the history log for this study.

TIP: Once a submission has been withdrawn by the PI or study staff, it is non-recoverable. The only way to resubmit is to re-create the entire submission.
II. Submitting a New Continuing Review or Study Closure:

NOTE: If your study is Expedited then you may not have this option. Expedited studies will have a Status Report option unless the IRB has determined that a Continuing Review is required.

- Click on the designated study under the Study Tab
- In the left hand column of your screen, there are 3 bolded categories,
- Click “New Renewal/Closure”

The CR# displayed on the summary page of the Continuing Review is the ID# for your CR
myIRB will guide you through all the relevant SmartForms.

**TIP:** Continuing Reviews and Revisions cannot be “in process” at the same time. If a CR or Revision is pending approval, and a CR or Revision needs to be submitted, the PI will have to decide on the following:

a) Withdraw the pending submission and submit the more urgent CR or Revision
b) Wait for the pending submission to be approved and then submit another revision with the additional changes or the CR at that time. In the interim, when a CR is approved, myIRB will automatically renew the most current IRB approved ICF for the new CR year.

Responses from the initial study submission (aka: IQ) will be pulled to show on certain smart forms to help the PI and study team remember what they originally submitted and if they are still following those procedures.

Responses from previous CRs will also appear, including the dates of the first and last signed ICF as previously reported:
Total enrollments from last CR:

Total number of subjects the PI has been approved to enroll:
Total number of subjects the PI has been approved to enroll:

You will need to upload your current cumulative adverse event and deviation tracking log tables within the SmartForm.

**TIP:** It is no longer required to update your consent form into the current template. Your currently approved consent will be re-stamped. If a change is required to the consent form, a request for a revision will be made.

Remember after you have completed the CR SmartForm application:
a) Click on “Hide Show Errors” before clicking “Finish” to display any errors that will prevent you from submitting the CR to the IRB.

**TIP:** the system will allow you to click “Finish” even though there are errors within the form, it is not until you try to submit the form to the IRB that you will get error messages.

b) If you have an error(s) within the SmartForm, it will display the error and provide the link taking you directly to the form that needs to be changed.
c) In order to save the changes you have made you can either click on “Save” at the top of the screen or click on “Continue”

**TIP:** When you open the SmartForm containing the error, the error message will appear at the bottom of the SmartForm to help you identify where the error occurred on this page. If you click ‘Continue’, the error message will continue to display on the next form. To close the **Error/Warning Messages**, click on **Refresh**. The Error Message you just fixed should disappear. Click on **Hide/Show Errors** at the top of the screen to hide the Error/Warning Messages box.

When all errors have been addressed, you will click “Finish”,

![SmartForm screenshot with error message and made change highlighted]
and be taken to the summary page for this submission type. From here, under “My Activities” the PI/Proxy will execute the “Submit Continuing Review” to send it to the IRB.

**TIP:** If for some reason the Continuing Review needs to be withdrawn, there is the option to do so, but once it is withdrawn, it is final (i.e. non-retrievable). If you realize you forgot to include some information, it is best to request it be returned from the IRB.
III. Status Report

Expedited studies that meet the Common Rule requirements will be moved to Status Report. When the study is close to expiration an email notification will be sent out and the PI will then notify the IRB if they wish to continue or close the study.

Go to the study workspace and select ‘Status Report’ under My Activities.

Note: If you select status report prior to the 45 day notification you will only be given the option to close the study. If you wish to close the study prior to the expiration then you will submit a status report and select “I am no longer conduction this research, please consider the project closed.”
If you wish to continue the study then wait until you receive the notification from the IRB that your study is close to expiration.

You should then have an additional option when you select ‘Status Report’ to continue the study.
III. Submitting a New Revision

Click on the ‘Studies’ to locate the study that has to be revised.

When submitting a revision, there are 3 steps to take (in this order):

a) Complete the New Revision smart form
b) Edit Modified Study (aka, the IQ)
c) Revise necessary documents (ICF, protocol, flyer, etc) to attachment with the Modified Study

Click on the study you need to revise, when the screen opens, you will see that the default tab is the ‘History’ tab which will detail all submission types in chronological order. Or, if you would like to see what Revisions have been submitted or are pending, you can click on the ‘Revisions’ tab.

Only ONE Revision/CR can be in process at a time and the only way to submit another revision is if the previous revision/CR has been approved or withdrawn. If “New Revision” link is not available it means a Revision/CR is already in the system pending approval, the PI will have to decide on the following:
a) Withdraw the pending revision and include it with the new revisions; or
b) Wait for the pending Revision to be approved and subsequently submit another revision; or
c) Wait for the CR to be approved and submit the revision (please see CR instructions if waiting is not an option).

**TIP:** Remember a Revision and a CR cannot be “in process” at the same time. If a button is not available, please check for other outstanding revisions or CRs, and decide if you can wait or if you need to withdraw the other submissions.

Complete the Revision SmartForm, and click ‘Continue’ up in the far right corner of the screen. A Revision Complete screen will come up letting you know you are at the end of the form, and to click ‘Finish’ to finalize and exit the Revision SmartForm.
For the purposes of this training manual, this revision included adding a new study team member, adding a Chest X-Ray for research only, and a new protocol from the sponsor.

Once you click ‘Finish’, you are taken back to the summary page for this revision. Note that the state of your Revision is “Pre-submission”

**NOTE:** you will still be able to make edits to the Revision in the Pre-Submission state. If the Revision smart form needs to be edited, open the study in myIRB, go under the ‘Revisions’ tab and click on the Revision. This will take you to the summary page for the revision, click on “Edit Revision” link

Now that you have completed the Revision SmartForm, you need to go in to the study and make the relevant revisions.
IV. Edit Modified Study

To edit the study application (i.e. IQ) you will have to go into **Edit Modified Study** link on the Revision Summary page.

To add the new study team member(s), go to 5.0 Study Staff in the Edit Modified Study, click on the ‘add’ button. To find the person you want to add, begin typing in their name and myIRB will generate a list to choose from. **NOTE**: the person you are adding HAS to be registered with myIRB in order to be able to add them to your study.
TIP: Until you get comfortable with the information on each SmartForm, you may need to keep hitting Continue to make sure all pages are updated as needed. Once you are more comfortable with the content on each SmartForm, you can use the Jump To menu to pull up the specific SmartForm.

To add the Chest X-Ray, the Study Type smart form needs to be revised to include Research-only procedure since the Chest X-Ray is for research purposes only.
**TIP:** once you add a Study Type, you will need to hit the ‘Continue’ button to make sure you get the associated SmartForm to complete. Keep in mind that the associated SmartForm may not show up right away, in this case the SmartForm associated with Experimental Procedure was about 4 SmartForms away.

This is the page to add a new or updated RAC grid. If you already have a RAC grid, you may include it here; OR, complete the Research-only Procedures - Detail page. If RAC makes changes to your grid, you will need to submit a revision to include the updated grid.

For the purposes of this section of the manual, the Research-only Procedure - Detail page was completed. You can add on as many procedures as you need to by selecting the ‘Ok, add another’ option at the bottom of the detail page. When you have added all of your procedures, select ‘Ok’ and the detail page will display in table format.
Here is what the final Research-only Procedures page will look like:
V. Revising Attached Documents (ex. Protocol, ICF, Flyer)

To access documents that need to be revised:

Click on “Edit Modified Study” and go to the appropriate smart form page.

**TIP:** it is best to pull these documents from myIRB to be assured you have uploaded the most current IRB approved version instead of uploading the document from your computer word documents.

Revise ICF: Update the ICF, save it to your computer, make the strike-through/underline changes, and save the document. Go back in to ‘Edit Modified Study’ to the ‘Jump To Menu’, click on ‘Upload Informed Consent Documents’ smart form, and click on the blue document hyperlink to open a new window “Consent Document – Detail” smartform page.
The new window will open that will allow you to “Choose File” so that you may upload your revised consent document. Once you've done with your updates, click the “OK” button. Please see below.

**TIP:** When updating your revised, you only need to attach a tracked change version of the consent. Please do not attach a tracked change version and a clean copy. If you do not attach a version with the changes tracked the office will return the submission to you for corrections.

**TIP:** When updating your revised ICF, be sure to include the document type 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 your informed consent, so if you have a study with multiple consents, you will be able name them here.

**NOTE:** whatever title you provide for your document will be the title associated with it in
the ‘Stamped Documents’ tab once IRB approval is received and the documents are finalized (i.e. IRB stamped).

After you have uploaded your revised ICF, click ‘Ok’ to exit, and you will see your newly uploaded ICF has replaced the previous ICF. Note the version number change. As shown in the example, the version number changed from (0.03) to (0.04).
To revise the Protocol, select “Upload Revision” to open the new smartform window “Submit at Document.” Choose the new protocol file and click “OK”:

Revisions to flyers, brochures, questionnaires, data tools will follow the same pattern. You may have to open the current IRB approved study to locate the smart form where the attachment was uploaded. **NOTE:** if you use the ‘View Study’ feature, it will NOT display attachments.

Since this revision involved the addition of a study procedure for research purposes, it will require review by the OCR-RAC office, and you can attach your revised RAC Grid and other documents with this revision, DO NOT SUBMIT separately to OCR-RAC.
The OCR-RAC office will be sent a notification from myIRB that there is a revision requiring their review.

As with previous submission types, remember to click ‘Finish’ on the Final Page SmartForm to complete your revisions and exit the ‘Edit Modified Study’ SmartForm. Again, the only person who can submit the revision is the PI or Proxy.
Once the PI/Proxy has submitted the Revision to the IRB, you will receive an email notification if there are changes that need to be fixed.
Copying Studies

It is possible to copy a study (i.e. all the SmartForms) for a study to be used as a starting point for doing another similar study. You must copy the study in the Pre-Submission or Approved state.

Go in to myIRB, ‘Studies’ Tab, and click on the Approved or Pre-Submission Study to copy; then select ‘Copy Study’ located under ‘My Activities’

You will see the following screen, and you can re-name it here.

**TIP:** Do NOT copy this study to your templates
The copying process can take myIRB some time to complete. If you have a very large study that included a lot of branching (eg. a study involving drugs, questionnaires, devices, radiology, radiation,) you may want to check the ‘Use Background Processing:’ feature. If you use this feature, the ‘Copy Study’ window will disappear and you will be given a message to refresh your screen to see when the copying has been completed, and you can continue to work within myIRB on other items.

If you choose not to use the Background Processing option, you will need to wait until myIRB has copied the study before you can do any other work within the site.

Once myIRB has copied the study, you will be brought back to the original approved study page, to the ‘History’ tab and ‘Copied Study’ will be listed as the first item.
To access your copied study, click on the ‘IRB Studies’ link in the center on the top of the screen, and the default screen that shows are the studies ‘In Progress’. The copied study with the new title will be listed, with the new IRB number. The state is ‘Pre Submission’.

From here, click on the study to start editing the SmartForms to contain the information pertinent to this study. You will also need to upload the informed consent, protocol and other documents specific to this study.

Note: Copying an approved study follows the same process as the above pre-submission.
Creating a Ceded Study Review

Log in to myIRB, select ‘Ceded Study Review’

Please note the addition of Q1.1 on the Study Title and Staff SmartForm page. Both options are correctly defaulted to “Yes”.

If you clear either option, you will get an error notification when you click ‘Continue’. This pathway is for Ceded Submissions only.

If you selected “Ceded Study Review” in error, exit the SmartForms and withdraw the submission:
NOTE: Ceded submissions have a different ID#. The pre-fix will begin with “CED” and will not contain the year but will numbered chronologically. For this example, this is the 125<sup>th</sup> Ceded submission in myIRB:

**Q1.1:** Both options must be ‘Yes’ for a Ceded Submission; otherwise you will be prevented from moving forward with the submission.

**SmartForms**

Complete the remainder of the select SmartForms, most of the branching logic has been removed for Ceded submissions.
There are some new SmartForms which will be shown/described below.

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

This is the IRB that UF is ceding oversight to, on this form we need:

- The name of the Institution, Overall PI and Coordinator, and IRB Contact information.
- If you have the fully executed IAA agreement, upload it.
- The approval letter for the study at the institution overseeing regulatory oversight

**NOTE:** The PI is still the only person who can submit the study, upon submitting the study the PI agrees to the **Ceded Investigator Assurances** language. These assurances are repeated in the final Approval to Cede Review letter and Ceded CR Renewal Letters:
NOTE: Here is how the study summary page will look once submitted to the IRB, please note the red font to always indicate that this is a Ceded submission:

Once the study is submitted to the IRB, here is how it is processed:
In Ceded Review

- Designated IRB staff member takes ownership and assigns it to an Exec Ceded Reviewer. The state of the study will be ‘In Ceded Review’

- The Exec Ceded Reviewer determines if there are any concerns or issues with ceding oversight of the study to an external IRB. If nothing is preventing the ceding request, they will issue a ‘Needs Reply’ and the submission transitions back to the office for Pre-Review

- The office pre-review staff member will note any required changes, and return the study to the study team while the ancillary reviews are completed. The state would say ‘In Ceded Review IRB Staff Changes Requested’

- The study team will work with all the ancillaries, and insert all necessary language in the consent form and the submission. Please upload the final track-changed consent with all of the required ancillary language inserted using the “Update” button.

  **NOTE:** the UF IRB staff cannot add this language for you because the UF IRB will not be finalizing the documents.

- When Office Pre-Review is done **and all ancillaries have submitted their approval** the office will “Acknowledge” the ceded submission and an Acknowledgement Letter will be sent to the PI / Coordinator. The state transition will change to “Awaiting Site Materials”.

  **NOTE:** The submission is “frozen” in this state, you will not be able to make any changes other than to upload the IRB of Record correspondence.
Awaiting Site Materials

Once the submission is in this state, the PI/SS can now proceed with submitting to the Overall PI to add UF as a participating site. The Acknowledgment letter is what you will need to submit to the reviewing IRB stating that UF IRB has agreed to cede review:
Submit IRB of Record Correspondence

- When the PI/SS have received correspondence back from the IRB of Record (whether it is in the form of request to change UF template language or the approval adding UF as a site), this will be submitted in myIRB via the ‘Submit IRB of Record Correspondence’ activity.

- The ‘Submit IRB of Record Correspondence’ activity can be completed by anyone on the study staff not just the PI as with other submit functions.
If it is an approval letter adding UF as the site, you will also upload the approved consent:

![Add the IRB of Record correspondence letter adding UF as a participating site: if it is a Contingency letter, UF IRB staff will move it to a state to allow you to make changes. If it is an approval letter, upload the final approved consent as well.]

The submission is back in the IRB in the state of “In Ceded Review IRB Staff Action Required”

- Office staff will process the submission based on the letter of correspondence from the IRB of Record.
  - Contingencies: The Ceded Reviewer will move the submission in to a state of “Needs Reply” so that changes can be made to the SmartForms, consent, and/or protocol.
  - Approval for UF to be a participating site: The Ceded reviewer will “Approve” the ceded request and the submission will move in to the state of “Awaiting Correspondence”
  - 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 the UF IRB, and the submission moves in to the state of “Approved”
- Study activities may now begin locally
DATE: 8/16/2018
TO: Jim Research
PO BOX 115500
GAINESVILLE, Florida 326115500
FROM: Peter Tafraze, IRB Chairman, University of Florida
Chair IRB-01
IRB#: CED0000000125
TITLE: How to Submit a Ceded Study Review

<table>
<thead>
<tr>
<th>Approved as Ceded</th>
<th>Expires on: 5/22/2019</th>
</tr>
</thead>
</table>

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

Approval Includes, but is not limited to:
Documents as submitted and approved by the IRB of Record

Special notes to the Investigator (if applicable):

Principal Investigator Responsibilities for Ceded Study:

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

Important responsibilities described include:

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

UF Study Team: Bob Doane
Post “Approved as Ceded Review” Submission-Types:

Once a ceded request has been approved by the UF IRB, you will still have the ability to submit Reportable Events, Revision, and Continuing Review/Closures.

**Current State**

**Approved**

**My Activities**

- View Study
- Printer Version
- View Differences

**New Reportable Event**

**New Revision**

**New Renewal/Closure**

You will still have the ability to submit REs, Revisions and CRs/Closures.

The SmartForms for REs and Revisions have not been modified.

The SmartForms for CR/Closure have been abbreviated.
New Reportable Event

Only submit:

a. Serious or continuing noncompliance that has occurred locally

b. Local adverse events that are serious, unexpected, and related or the relationship was more likely than not related to study participation.

c. Non-local events ONLY IF:

   i. Noncompliance: the external IRB determines it is serious or continuing noncompliance and therefore is something we would report to federal oversight agencies.

   ii. Adverse events: the external IRB determines it is an unanticipated problem increasing risk to subjects or others and therefore is something we would report to federal oversight agencies.

New Revision

UF IRB will need to know about all PI and study staff changes. Remember, a new study staff member cannot engage in research activities until this revision is approved.

Only submit other revision(s) if it requires re-review by ancillary committees such as COI, OCR/RAC, IBC, CTSI, HURRC, SRMC etc.

New Continuing Review/Closure

There are only 4 SmartForm pages:
You can now verify study team’s training. If it appears here, then it is current. If training does not appear, that means that it is expired and needs to be updated.

This link can be used to view the required courses.

Note the date that the course is due. This will be the date that the training will expire.
Click “Finish” and remember to have the PI “Submit Continuing Review” to the IRB.

Upon receipt of the CR to the IRB Office, the Ceded Reviewer will look over the submission and if changes are needed, a “Needs Reply” notification will be sent.

If no changes are needed, approve the ceded CR and reset the approval period.
The PI / Coordinator will receive an approval letter:

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**Institutional Review Board**
**UNIVERSITY of FLORIDA**

**DATE:** 8/20/2018  
**TO:** Jim Research  
**PO Box 115500**  
**Gainesville, Florida 326115500**  
**FROM:** Peter Istrate, IRB Chairman, University of Florida  
**Chair IRB-01**  
**IRB#:** Continuing Review for CED000000125  
**TITLE:** How to Submit a Ceded Study Review

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**Approved as Ceded: Continuing Review**  
**Expires on:** 8/8/2010

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/researcher-responsibilities.html](http://irb.ufl.edu/irb01/researcher-information/researcher-responsibilities.html)

Important responsibilities described include:

- I have read and will conduct the IRB 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:**

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*The Foundation for The Gator Nation*  
*An Equal Opportunity Institution*
Create New/Revise Study when UF is the IRB of Record (sIRB)

In the role of PI or Study Staff, you can create a new sIRB study by clicking the New Study button, in the column on the left side of the page. You 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 this order):

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

For simplicity, we’ll use an example of creating a new sIRB study.

Please note the addition of Q 1.1 on the Study Title and Staff SmartForm page. By selecting ‘yes’, the application will default to UF being the IRB of Record.

**TIP:** Do not clear the radio button that states UF will serve as the IRB Record if you have selected ‘Yes’ in response to Q 1.1 If UF will not serve as the IRB of record, simply select ‘no’ in response to Q 1.1.

**NOTE:** Submissions where IRB-01 is the IRB of record have the same nomenclature as regular studies. However, sIRB status of a study is flagged on the Study Workspace.
Working with Smart Forms

Complete the remainder of the SmartForms as usual. Most of the SmartForms will remain the same, including branching.

NOTE: If the overall study is greater than minimal risk, the review type for the study will be Full Board, even though all the procedures done at UF are minimal risk.

Study Locations
**TIP:** Select UF and UF Health but do not select ‘other sites in the USA’ because this is a *multi-center study*.

**Enrollment Details**

Enrollment Details SmartForm

Select ‘yes’.

**Enrollment: Multi-Centered Project**

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.
**TIP:** State in Q 1.0 that sites will be added with a revision, if non sIRB sites are not ready at the time of submitting this study to the IRB. If there are no non-sIRB sites, simply skip Q 2.2.

**Upload Informed Consent**

The consent that needs to be uploaded is the “UF Core” and “UF Addendum.” Additionally, each participating site will send their ICF addenda with the relevant local language to the UF PI, who will be adding them as part of a p-site revision (see instructions later in the manual).

**Submit Study**

The PI is still the only person who can submit the study. Upon submitting the study, the PI agrees to the **IRB of Record Investigator Assurances** language. These assurances are also on the final Approval letter and CR letters.

Once the study is submitted it will be in IRB Assignment state from where it’ll go to IRB Staff Review, and an office pre-reviewer is assigned. The process from here on is the same as for any other Full Board/Expedited study, including meeting deadlines, meeting discussion, addressing contingencies, needs replies, etc.
Approval Letter

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/categorizes:

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: Hair and nail clippings, if collected in a non-disruptive manner, deciduous teeth at time of exfoliation or if routine dental care indicates a need for extraction) permanent teeth, if routine patient care indicates a need for extraction) and external secretions (excluding stool) uncontaminated saliva collected either in an unstimulated fashion or stimulated by chewing gum or ice or by applying a diuretic solution to the tongue, placentas removed at delivery, amniotic fluid obtained at the time of rupture of the membranes before or during labor, suprainfusions of 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 stimulation.

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
- 3 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:

- 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://www.ufl.edu/irb/irb-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 IRB approval letter and any applicable documents (i.e., stamped consent, protocol ID, etc.) to the PI(s) at the relying site(s).
- As the local PI, I am responsible for providing a copy of the IRB Acknowledgement to the PI(s) at the relying site(s).
- As the local 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)

To add a new Participating Site (pSite) go to the study workspace and click “New Revision (Participating Sites Only).”.

NOTE: pSite revision can be open while there is another, regular revision pending in the system. pSite revision cannot be open while there is a continuing review in process. Please do not submit a regular revision to add a p-site.
On the “UF Revision” smartform enter the name of the Institution that you are adding along with the justification for the addition and any requested specific information to include in the approval letter.

Click “Continue” on the top right hand side of the form. This will bring you to the “Revised Single IRB Participating Sites” smartform page where you will be able to add, deactivate, or modify p-sites.
Selecting “Add” will populate a detail page where you insert the relevant information for the participating site.

Once the detail page has been completed select “Continue” to go to the “Revised Local Addenda” smartform page. Select “Add” to upload the local addenda.
NOTE: Please use the recommended naming convention that includes the site name, followed by the PI last name and a word ‘addendum’ (pSite PI_Addendum.docx).

After uploading the pSite addendum, select “Continue” on the top right hand corner to move on to the “Revision: Final Page”.

You will be returned to the Revision workspace where the PI can submit under “My Activities”.
Revising a pSite

To revise a pSite you will follow the steps above to open a new pSite only revision. The previously approved site can be revised on the “Revised Single IRB Participating Sites” smartform page. Select the name of the site you want to revise to open the detail page. This will again open the detail page for you to make your edits. From the detail page you can change the participating sites contacts and attachments.
Once you have updated the “Single IRB Participation Site Detail” smartform page, click “OK”. Once you have saved the changes you will go to the Revision workspace to submit.
Deactivating a pSite

To deactivate a participating site you will follow the steps above to create a revision and modify the “Revised Single IRB Participating Sites” smartform page. Once you have opened the detail page for the pSite that is being deactivated you will modify section 7.0 from “Yes” to “No” and address the new questions 7.1 and 7.2.

Once you have updated the “Single IRB Participation Site Detail” smartform page, click “OK”. Once you have saved the changes you will go to the Revision workspace to submit.