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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:

   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.
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 in your "My Home" Folder. 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.
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.
Hide/Show Errors

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.

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**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 circle 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.
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 49.
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.
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.

All attachments can be accessed under the **Attachments** tab. This will include all the documents submitted and approved such as the protocol, drug brochures, questionnaires and surveys etc.

**TIP:** Do not print the consent form for enrollment or any other stamped documents under the Attachments tab. 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

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 91st 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:

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

The CR# displayed on the summary page of the Continuing Review indicates the total number of CRs submitted to the IRB to date, not study specific. This 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 doing 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:

If there were enrollments reported on the previous CR, those numbers will show for this CR.

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

Date of 1st and last signed ICF from previous CR will appear here.

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

Note 2: If you were approved for a Waiver of Informed Consent to Enroll subjects, include all subjects enrolled under the Waiver.
You will need to upload your current cumulative adverse event and deviation tracking log tables within the SmartForm.

**If there was a discrepancy between last CR and this CR you can explain it here.**

**Total enrolled to date**

---

Upload your current CAE and Deviation Tables. You will be prevented from continuing to the next smart form page until these tables have been uploaded.
**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”, 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. 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 Experimental 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 Experimental Procedure 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 Experimental 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 Experimental Procedures page will look like:
V. Revising Attached Documents (ex. Protocol, ICF, Flyer)

There are a couple of ways to access documents that need to be revised:

a) Under the Attachment Tab on the Study Summary Page; or
b) Within the Edit Modified Study form on the appropriate smart form page

A screen shot has been provided for locating the document(s) via the Attachments Tab, but for purposes of this revision, the protocol and ICF will be pulled from the Edit Modified Study smart form.

**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: Within the Edit Modified Study, using the ‘Jump To Menu’, click on ‘Upload Informed Consent Documents’

Upload 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 ‘Update’ button to attach the revised document. **NOTE:** If you are adding an entirely different ICF for this study, then you would click on the ‘Add’ button.

**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 ‘Submit a Document’ 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.
You will follow these same steps to upload a revised protocol:

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, or under the ‘Attachments’ tab. **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 RAC office, and you can attach your revised RAC Grid and other documents with this revision, DO NOT SUBMIT separately to RAC.
The 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 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 (e.g., 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 upper left hand side 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.
To copy in Pre-submission, click on the **Copy Study** Activity, before submitting the study, and follow the rest of the steps as described above.
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 6th Ceded submission in myIRB:

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:

```

UF
Institutional Review Board
UNIVERSITY OF FLORIDA

DATE: 5/26/2017
TO: John Wingard
    po box 100278
    gainesville, FL 32610
FROM: Peter Iafrate, IRB Chairman, University of Florida
      Chair IRB-01
IRB#: CED000000006
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 University of Michigan, the IRB of Record.

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

The Foundation of 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.
```
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:
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: 5/30/2017
TO: John Wingard
   po box 100278
   gainesville, FL 32610
FROM: Pelar Iskandar, IRB Chairman, University of Florida
   Chair IRB-01
IRB#: CED000000846
TITLE: How to Submit a Ceded Study Review

Approved as Ceded  Expires on: 5/31/2017

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

Approval Include, but is not limited to:
   Documents as submitted and approved by the IRB of Record
   Consent Waiver Type(s):
      Consent XX with HIPAA
   HIPAA Waiver Type(s):
      N/A

Special notes to 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/irb21/researcher_information/researcherresponsibilities.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:
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.

New Reportable Event

Only submit AEs, SAEs, Deviations, or Miscellaneous Items if the IRB of Record has requested you to do so.

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) at the request of the IRB of Record.
New Continuing Review/Closure

There are only 3 SmartForm pages:

**Continuing Review/Study Closure Determination**

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

1.0
- We wish to:
  - Close this project
  - Continue this project

**Continuing Ceded Review**

*Upload the following attachments*

1.0 Approval Letter from IRB of Record:
   - TEST DOCUMENT FOR MYIRB UPLOADS.docx(0.01) | History

2.0 Current Approved Protocol:
   - TEST DOCUMENT FOR MYIRB UPLOADS.docx(0.01) | History

3.0 Current Approved Consent:
   - Name | Modified | Version
   - There are no items to display

4.0 Current Delegation of Authority Log:

5.0 Miscellaneous additional attachments:
   - Name | Modified | Version
   - There are no items to display
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:

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

There are no items to display

Approval Includes:

Documents as submitted and approved by University of Michigan, the IRB of Record

Consent Waiver Type(s): There are no items to display

HIPAA Waiver Type(s): undefined

Special notes to Investigator (if applicable):

Reviewer Notes: 0 Reviewer Notes

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 includes:

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

UF Study Team:
Create New 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.

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. If you clear the field, there will be an error when you click ‘continue’ or try to save the page.

**TIP:** 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.

![Record](IRB201701249)

**Study Coordinator:**

**UF will serve as the IRB of Record**

**Requested Review Type:** Full Board

**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.

**Single IRB Participating Sites**

To add sites and the relevant information about the institutions/staff engaged in research, click on ‘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**. Please add one entry for each participating site.
NOTE: A site cannot be added until the IRB Authorization Agreement (IAA) is completed and participating institutions have signed off on ceding review. When these two conditions are met, the site can be added with a revision.
**Study Locations**

**TIP:** Select UF and UF Health but do not select ‘other sites in the USA’ because this is a **multi-center study**. Depending on the study, in some circumstances, you’ll need to select VA or SUS.

**Enrollment Details**

**Enrollment Details SmartForm**

Select ‘yes’.
State in Q 1.0 that sites will be added with a revision.

**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 revision and uploading them to myIRB.
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 9/15/2017 by IRB-031. This study is approved as expedited because it poses minimal risk and is approved under the following expedited category/categories:

1. Prospective collection of biological specimens for research purposes by noninvasive means. A sample of hair and nail clippings, if collected in a non-invasive 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; extracts and external secretions (including saliva) unstimulated and collected either in an unstimulated fashion or stimulated by chewing gum and wax or by applying a dilute citric solution to the tongue; placenta removed at delivery amnion fluid obtained at the time of rupture of the membrane before or during labor; suprabulbar subgingival dental plaque and calculus; provide the collection procedures 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 swabbing or swab, skin swab, or mouth washings, epithelial collected after saliva 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 obtained in a non-standard way, e.g., debriefing written informed consent
- HIPAA Waiver Type(s):
  - HIPAA
    - to be defined for the purpose of recruiting potential subjects for the study

Additional 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 approved by the UF IRB, I am responsible for providing a copy of the IRB Authorization Agreement (IAA) to all PI.
- I will provide all IRBs at the relaying site(s) the link to the UF IRB, I am responsible for ensuring that the information is correct and up to date.
- I will inform all investigators of the study at all sites, I have been provided with the IRB's documentation and have instructed them on what needs to be reported and to whom on the UF study team to whom they should be reported.
- If a conflict of interest exists with a site PI, I am required to disclose this information to the UF IRB.
- As an Investigator, I am responsible for providing a copy of the UF IRB approval letter and all applicable documents (i.e., stamped consent protocol, IAA, etc.) to the PI(s) at the relaying site(s).
- As the Study Team, I am responsible for providing a copy of the UF IRB Acknowledgement to the PI(s) at the relaying site(s).
- As the Study Team, I will submit reports of events to the relaying site(s) at the UF IRB per UF policy and procedures.
Revision of a Current myIRB Study into a sIRB Study where UF is the IRB of Record

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

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

d) Complete the New Revision smart form
e) Edit Modified Study
f) Revise necessary documents (ICF, protocol, flyer, etc) to attach with the Modified Study

Revision Application Form
**Edit Modified Study**

Revise Q 1.1 on the Study Title and Staff SmartForm. Additionally revise all SmartForms that are affected by this change as it would be done in a regular Revision (please see Researcher Manual pgs 44-52).

**NOTE:** Revising the study to a single IRB request will change branching and cause new sIRB-specific SmartForms to blow in.

**TIP:** Use the ‘Continue’ button to sequentially move through SmartForms to ensure completion of the new SmartForms.
**Enrollment Details**

Enrollment Details SmartForm

Select ‘yes’.
Enrollment: Multi-Centered Project

1.0  * List the total number of subjects to be included at all participating sites:
     200

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:
We will use holograms.

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

     Add

     Site Name  Attachment Site Approval

     There are no items to display

Multi Center Project: Information and Approvals (Detail Page)

NOTE: List only sites for which UF IRB is not the IRB of record.
Approval Letter

DATE: 5/31/2017
TO: Willard van Orman Quine
2004 Mowry road - 2nd floor
Gainesville, Florida 32610
FROM: Peter Iraff, IRB Chairman, University of Florida
Chair IRB-01
IRB#: Revision 9 for IRB Study #IRB201500369
TITLE: Revision Test

Revision Approved - Expedited/Exempt

On 5/31/2017, the IRB reviewed and approved your revision:

Revision 9 for IRB Study #IRB201500369

Approval Includes, but is not limited to:

- Dated and watermarked IRB-approved Informed Consent Form(s)
- Revised Protocol version #/date

Thank you for keeping the IRB informed about your research project, thereby allowing us to keep accurate files. If the IRB staff can be of any further assistance, please feel free to call.

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 that these can be reviewed.
- As the lead PI, I will maintain 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 the study’s conduct.
- The names of all investigators 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 handled 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, IRB, 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.