myIRB

Electronic Submission

Researcher Manual
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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 on myIRB website]

**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.
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.

Pls 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”.

Click to submit your 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:

<table>
<thead>
<tr>
<th>Prior CR</th>
<th>Enrolled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active Subjects</td>
<td>Subjects in Follow Up</td>
</tr>
<tr>
<td>+</td>
<td>+</td>
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</tbody>
</table>

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:
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.

![SmartForm Screen]

**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 (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 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.