



FLORIDA AGRICULTURAL AND MECHANICAL UNIVERSITY

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Institutional Review Board (IRB)

Guide to IRBNet:

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## Introduction

*Effective November 8, 2014, Florida A&M University Institutional Review Board (IRB) will only accept new submissions electronically through IRBNet. The next step is to utilize IRBNet for IRB protocol amendments and extensions and we anticipate requiring use of IRBNet for such activities by December 2, 2014 (see [Guide for Submitting Amendments and Extensions for Old Projects in IRBNet](#))*

Web Address:  
[www.irbnet.org](http://www.irbnet.org)

The purpose of this document is to provide guidance for processing IRB submissions electronically through IRBNet. Step-by-step instructions as well as snapshots are provided for each IRBNet transaction. Additionally, each instruction will include a list of required study documents and forms to be attached with a submission in IRBNet. These documents are necessary to facilitate your IRB reviewers' knowledge of your study. Finally, this document will also provide some instructions on how to complete each of the FAMU IRB forms.

Additional guidance, forms and information can also be found on the FAMU IRB website.

### **The following transactions are to be submitted electronically through IRBNet:**

- New Study
- Continuing Review/Extension
- Modification/Amendment
- Close/Final Report
- Reportable Events
- Response/Follow-up to IRB requests

### ***IRBNet User Registration***

To register as a new user, open the above IRBNet webpage. This is what the homepage will look like:



Login:

Username

Password

Login



New User Registration



Forgot Your Password?

## Comprehensive Solutions



### The Industry's Most Complete Solution

IRBNet's unmatched suite of electronic solutions drives compliance and productivity for your Administrators, Committee Members, Researchers and Sponsors. These powerful research design, management and oversight tools support your IRB, IACUC, IBC, COI and other Boards with a unified solution.

### Flexible, Intuitive and Easy to Use

Your own forms. Your own processes. Your own standards. Powerful reporting and performance metrics. The data you need. From electronic submissions to form wizards, to agendas, minutes, and more. Our easy to use, web-based tools are rapidly launched and backed by our best practices expertise and the industry's leading support team.

### Secure, Reliable and Cost-Effective

IRBNet's secure web-based solution is accessible to your research community anytime, anywhere. Our enterprise-class technology is cost-effective and designed to accommodate institutions of any size.

[Try the demo and see for yourself!](#)



### Test Drive IRBNet

See for yourself...

Demo

### Satisfied Members

"Our first electronic meeting went so smoothly! It was over so fast the members didn't know what to do. They just sat there for a few minutes in disbelief."

- Bruce Day

Director, Office of Research Integrity  
Marshall University

Next

### 2011 Events - Join Us

- [PRIM&R Annual IACUC Conference](#)  
Chicago IL, March 31 - April 1
- [AAHRPP Annual Conference](#)  
Washington DC, April 6 - 8
- [NAIM Annual Conference](#)  
Atlanta GA, April 28 - 29
- [HCCA Research Compliance](#)

Click on the "New User Registration" icon located below the login at the top right corner of the page. The link is circled in red in the image above. Complete the registration information. A registration email will be sent to the email address you provided.

### IRBNet ID Number

IRBNet will automatically assign a 6-digit ID number to each new project. The number following the dash is the package number for that project. Therefore, a newly created project will always be 6 digits then a dash and the number 1. The 1 refers to package 1 of the project.

For each subsequent package submitted for that project in IRBNet, the last digit following the dash will go up one. However, the 6 digit project number before the dash will not change. For example, a new project might be #123456-1. Revisions to that project would be #123456-2.

## **Training and Credentials**

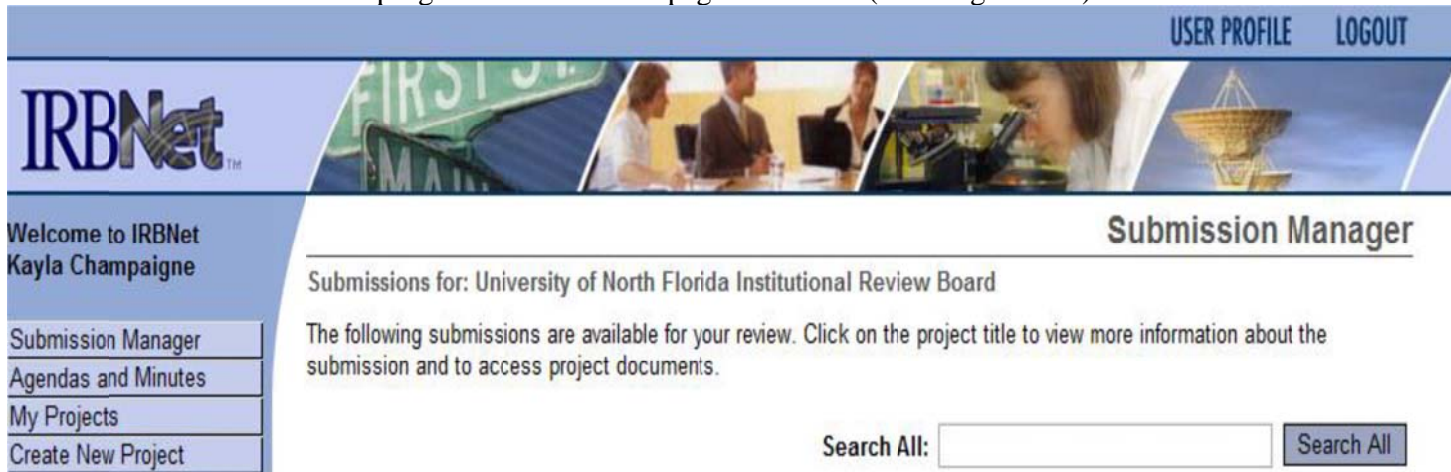
Please note that all PIs, Co-PIs, data collectors, and personnel who interact or intervene with participants and personnel who have access to identifiable information must be CITI certified in the protection of human subjects. If you or any of your study personnel have not completed CITI training, you can do so by following this link: [www.citiprogram.org](http://www.citiprogram.org) and completing either basic course in “Group 1 Biomedical Research Investigators and Key Personnel” or the “Group 2 Social Behavioral Researcher Investigators and Key Personnel” CITI training depending on your discipline. For more information about the CITI training requirements, please feel free to review the FAQs on FAMU IRB CITI Training. After you have completed the required CITI training, please save a copy of your completion report so that it can be uploaded into IRBNet. It will be necessary to save the CITI completion reports for all project personnel to your computer as they will need to be submitted with your project package.

### **There are two ways to document your CITI within IRBNet:**

1. Document the CITI training in your IRBNet User Profile (only needs to be done once every 3 years and will make your CITI training visible for all your projects)
2. Include a copy of your CITI completion report as attachment on the Designer page for your project (if you choose, this option you will need to submit a copy of your CITI completion report each time you submit a new project).

### **Documenting CITI on your IRBNet User Profile:**

1. Complete the required CITI training ([www.citiprogram.org](http://www.citiprogram.org))
2. Save a copy of your CITI completion report on your computer (directions in the FAQs on FAMU IRB CITI Training documents)
3. Log into IRBNet ([www.irbnet.org](http://www.irbnet.org))
4. Click User Profile on the top right hand side of the page in IRBNet (see image below)



The screenshot shows the IRBNet Submission Manager interface. At the top right, there are links for "USER PROFILE" and "LOGOUT". The main header area features the IRBNet logo on the left and a banner image on the right. Below the banner, the text "Submission Manager" is displayed. The main content area shows "Submissions for: University of North Florida Institutional Review Board" and a message: "The following submissions are available for your review. Click on the project title to view more information about the submission and to access project documents." At the bottom right, there is a search bar with the text "Search All:" and a "Search All" button.

5. Scroll down to the training & credentials section,

6. Click Add a New Training & Credentials Record

7. Document the information about your study (i.e., document type, effective date, expiration date). The effective date is the date you passed CITI. All information can be found on the CITI completion report. The description and credits/credit hour's sections can be left blank.

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## Training & Credentials Record

---

Profile Owner: Kayla Champaigne

Attach a document to this Training & Credentials record by clicking the "Browse..." button to locate your document and then by clicking "Attach".

The screenshot shows a form titled "Training & Credentials Record" with the following fields and controls:

- Document Type:** A dropdown menu with a red asterisk indicating it is a required field.
- Description:** A text input field.
- Credits/Credit Hours (if applicable):** A text input field.
- Effective Date:** A date input field with a red asterisk and a calendar icon.
- Expiration Date:** A date input field with a calendar icon.
- File:** A file upload control with a "Choose File" button and the text "No file chosen".
- Buttons:** "Attach" and "Cancel" buttons.
- Legend:** A red asterisk followed by the text "\* required fields" in the bottom left corner.



8. Select "Choose File" after filling in the other applicable fields. Then find the file on your computer and click open on the pop-up once it is selected. After all the required fields are completed, click "Attach" to upload the CITI completion report to your User Profile.

9. Scroll down until you see the training you just added to your User Profile and then click "Submit" to send it to the FAMU IRB to approve (see image below).

## Training & Credentials

IRBNet allows you to track and share your training records, certifications, resumes and other personal credentials. Once added to your profile, your training and credentials can be easily linked to your projects from the Designer, are accessible by your project teams and can be quickly accessed and tracked by the boards that review your projects. Some boards also permit you to directly submit your training and credentials without requiring you to link these records to specific projects.

[| Show all Versions |](#)

Doc ID	Document Type	Description	Cr	Effective Date	Expiration Date	Last Modified	Status	
33797.1	CITI Training: Group 1 Biomedical Research Basic Course	Champaign Group 1 CITI completion report 10 01 11.pdf		10/01/2011	10/01/2014	01/11/2012 06:12 PM	Not Submitted	   <a href="#">  Submit  </a> 
34747.1	CITI Training: Group 2 Social Behavioral Basic Course	Champaign Group 2 CITI completion report 12 17 09		12/17/2009	12/17/2012	01/23/2012 12:23 PM	Not Submitted	   <a href="#">  Submit  </a> 

[Add New Record](#)

10. Select the Florida A&M University as the institution with which you are sharing your CITI training. There is no need to write a message. After you

Click submit, an email will be sent to the IRB with information about your training. It will be necessary to click submit for *each* training/credential that

Want connected to your profile.

## IRB Meetings and Submission Deadlines

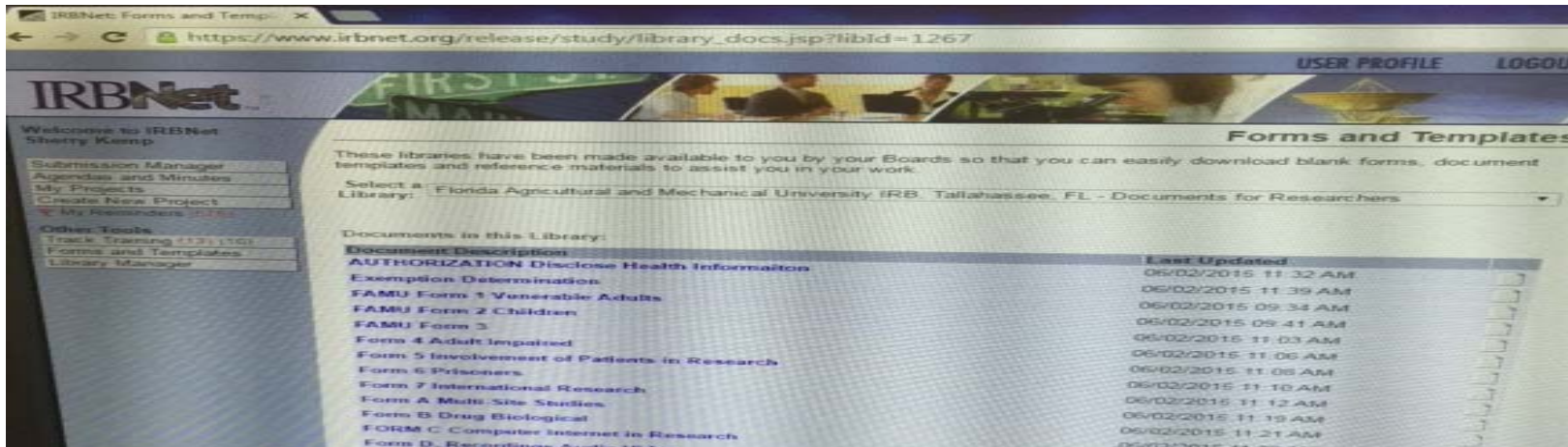
The convened FAMU IRB meets at various times throughout the year. Please refer to the Schedule on the FAMU IRB Website for a list of the meeting dates and deadlines. The deadline for submitting for review at a convened meeting is generally two weeks prior to a convened meeting. However, it is strongly suggested that you submit your documents more than 2 weeks prior to a scheduled meeting in case documents are missing that could delay the review of your project. Only full board projects must be reviewed at a convened IRB meeting.

## IRB Approval Letters and Other Board Documents

IRB approval letters and board documents can only be accessed via IRBNet. You can find the board documents by clicking the Reviews button on the left hand side of your package in IRBNet (see the IRBNet FAQs for more information). You will receive an email notification of the IRB's determination but it is the responsibility of the research team to log into IRBNet to address any modifications requested and/or verify the Approval Letter and approved document(s) are accessible. Approved documents will contain a stamp and date to indicate approval.

## IRB Forms, Templates, and Guidance

Some FAMU IRB forms are available on IRBNet for download and use. The FAMU – IRB Protocol application is available in this library and must be completed and adjusted on the Designer page in IRBNet (see the IRBNet FAQs for more information). More information about new submissions is included below. If you would like to access the forms and templates library, you can do so at any time by clicking on “Forms and Templates” option on the left-hand side of your screen under “Other Tools.”



Please note that the information in the picture shows multiple documents available when you access the library through IRBNet. You can access any document on the list by clicking the name of the document or the paper icon for each document.

If you do not access the forms and templates library prior to beginning your submission, you will have another opportunity to download documents when you create a New Project.

## IRBNet Actions

This section will describe each IRBNet function.

## My Projects



IRBNet will automatically open to the My Projects page after you have logged in. This section allows you to view all studies that you have created or to which you have been shared access. You may sort the list of submissions by clicking on any of the heading options (e.g., Study Title, Status, IRBNet ID).



Welcome to IRBNet  
Charlie Researcher

- My Projects
- Create New Project
- My Reminders (18)
- Other Tools
- Forms and Templates

## My Projects

Your "My Projects" workspace shows projects that you have created and projects that have been shared with you by other users on the National Research Network. Use Reminders, Tags and Archiving to help organize your workspace and keep it running smoothly. ([Learn More](#))

Search:  Search By Tag:  ▼

1 - 1 of 1 10

[Create and Manage Tags](#) | [Show Archived Projects \(0\)](#)

IRBNet ID	Project Title	Principal Investigator	Submission Type	Status	Effective Date
46298-1	smartform application test 1	Researcher	New Project	Pending Review	

1 - 1 of 1 10

### Create New Project

A new project is created in IRBNet using the "Create New Project" menu option. This function only creates new studies. It does not start a new package. To create a new project, follow the instructions in the section entitled [New Study](#).

A package is a bundle of documents (e.g., protocol application, consent forms, measurement tools, training & credentials). The term "project" is a blanket term for all of the packages that make up a submission. If you need more information, please contact the Office of Animal Welfare and Research Integrity 850-412-5246.

## Project Overview

The Project Overview page appears once a project is created and allows a research team member to get general information regarding the status of the project as well as quick links to other functions within IRBNet. You can get to the project overview page only after you have begun work on at least one submission. From the My Projects page you can reach the project overview page by clicking on a desired project title.

**Welcome to IRBNet**  
John Researcher

**Project Overview**

[137618-1] Motivations of Research Subjects: A Mixed Methods Study

**You have Full access to this project. (Edit)**

Research Institution: Zanzibar University, Frederick, MD

Title: Motivations of Research Subjects: A Mixed Methods Study

Principal Investigator: Researcher, John, PhD

Keywords: Incentive, Extra Credit

Sponsor: National Research Foundation

The documents for this project can be accessed from the **Designer**.

Project Status as of: 03/20/2013

Reviewing Board	Board Ref #	Initial Approval Date	Project Status	Expiration Date
Metropolitan IRB, Frederick, MD	09-497			04/03/2013

My Projects  
Create New Project  
My Reminders (3)

**Project Administration**  
Project Overview  
Designer  
Share this Project  
Sign this Package  
Submit this Package  
Delete this Package  
Send Project Mail  
Reviews  
Project History  
Messages & Alerts (3)

The project overview page lets members of the research team view information regarding the project, such as:

- Personal level of access to the project
- The status of the current transaction
- Lock status
- Status of previous transactions (if applicable)
- Shared access permissions of other users


Additionally, the project overview page allows you direct access to other administrative menu pages, including:

- Designer
- Share this project
- Sign this package
- Submit this package (unless package is already submitted)
- Delete this package (only available for those with “full” access)
- Send project mail
- Previous package(s) (if applicable)
- Review details for the current package

## Designer

The Designer is used to access FAMU IRB forms, view attached documents for the current package, add new documents, and access review details for IRB documents.

When you initially access the designer it will be to attach documents for your submission package. After you have submitted a package, that package is “locked” and cannot be revised. After the IRB has reviewed your package and made a determination (e.g., modifications required, project approved), you may be asked to revise your existing package or you may be asked to submit a new package with revised documents. If you are revising documents for your submission, the designer page also allows you to revise your existing project documents or add entirely new documents to your package. Always revise a previous document submitted if you have a choice – this maintains the document history properly in the system. More information about submitting a [New Study](#) is included below. After the IRB has made a determination, you may be required to make changes to an existing document or to upload a new document for review. The following details and examples are directly from IRBNet:

**Revise an Existing Document:** Use this option when you want to add or create a new version of an *existing* project document. IRBNet creates a new version of your document and retains all historical versions as part of your Document History. The new version will be automatically tied to the Document History. You may view the historical versions of a document by clicking on the Document History icon. Please note that if you have not uploaded multiple version of the same document, you will not see the document history icon (.

1. From the list of Documents from Previous Packages at the bottom of the page, download the document to be revised by clicking on the name of the document under the heading “Document Type” or on the paper icon.

Documents from Previous Packages that you can Revise: (When should I do this?)


Pkg #	Document Type	Description	Last Modified	Pkg Submission Date	Pkg Status		
1	Consent Form	IC doc sample template.rtf	01/24/2012 10:23 AM	01/12/2012	Pending Review		
1	North Florida - IRB Protocol	North Florida - IRB Protocol	01/24/2012 10:17 AM	01/12/2012	Pending Review		

2. Make any necessary changes to the downloaded document, and **save** the revised document to your computer.

3. Click on the pencil icon for the document you are updating in the Designer. This will allow you to replace the previous version with the newly revised version of the document.

4. You will then be prompted to attach a document. Browse your computer and select the revised version of the document to upload, make changes to Document Type and Description as appropriate, and click the Update button. The page will look like this:

IRBNet ID: 95621-2 USER PROFILE LOGOUT



Welcome to IRBNet  
Charlie Researcher

**Attach Document**

[95621-2] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenan  
You are updating an attachment. To help you identify the file that was attached:

- This attachment was loaded from the file **IC doc sample template.rtf**
- It was attached on **09/06/2008**.
- It has a size of **361131** bytes.

Document Type \*

Description

File \*  No file chosen

\* required fields

My Projects  
Create New Project  
My Reminders (25)

**Project Administration**  
Project Overview  
Designer  
Share this Project  
Sign this Package  
Submit this Package  
Delete this Package  
Send Project Mail  
Reviews  
Project History  
Messages & Alerts (7)

5. When you click Update, the revised document will appear in the current document package (New and Revised Documents in this Package) with a revision history that reflects versions of that document from previous packages.

Designer

Share this Project

Sign this Package

Submit this Package

Delete this Package

Send Project Mail

Reviews

Project History

Messages & Alerts (7)

**Other Tools**

Forms and Templates

**Step 2:**  
Assemble your document package.

New and Revised Documents in this Package:

Document Type	Description	Last Modified		
Consent Form	revised IC	01/24/2012 11:56 AM	new documents	

**Document Revision History**

Pkg #	Document Type	Description	Last Modified	Pkg Submission Date	Pkg Status
3	Consent Form	revised IC	01/24/2012 11:56 AM		Work in progress
2	Consent Form	revised IC	01/24/2012 10:29 AM	01/24/2012	Pending Review

Pkg #	Document Type	Description	Last Modified	Pkg Submission Date	Pkg Status
1	Consent Form	Consent Form	09/06/2008 11:33 AM	09/06/2008	Approved
1	Revised Form	Form			
1	Study Plan	study plan	09/06/2008 11:33 AM	09/06/2008	Approved

**Add a New Document:** Use the "Add New Document" option when the document you are adding is not a revised or updated version of an existing project document. The "new" document will not be tied to the Document History of any existing document, and it will not have any Document History of its own since it is a completely new addition to your project.

- If you will use a template to generate your new document, you must first access the template in the forms and templates library. On the left-hand side of your screen, select "Forms and Templates." Click on the name of the document or the paper icon for the template or form you wish to download. Save the template or form to your computer for completion. Complete downloaded forms or create documents to be submitted. Make sure you save your finished product. After your document is saved, you can now upload it to the package. Back on the designer page in IRBNet, use the "Add New Document" button to upload the completed document into the package. It will not have a revision history (stack of paper icon) at this time because it is new.
- If you have already generated the document and it is saved on your computer, you do not need to download a template from the forms and template library. You can go straight to the "Add New Document" button to upload the new document into the package. It will not have a revision history (stack of paper icon) at this time because it is new.

**What about copies of existing documents?** Committee members and administrators often need to access copies of existing project documents, such the previously approved Consent Form, when reviewing your new or revised documents. You do not need to attach these older, unchanged project documents to your current package. Committee members and administrators can automatically access these older documents as needed from the "Documents from Previous Packages" list. If you are unsure about the documents you are required to submit, you should contact your local research integrity administrator for more information.

**1. You have a modified Consent Form that replaces the current version of your Consent Form from a previous package.**

**What To Do:** Access the designer page for your project by clicking the "my projects" button on the left-hand side of the screen. From there you can click on the title of the project you are revising. This will bring you to the project overview page where you can click "designer." Locate your Consent Form in the "Documents from Previous Packages" list and click the "Revise this Document" icon which will look like a pencil. This will allow you to include a new version of your document in your current package while retaining your complete Document History.

**2. You have a completely new document that is not a revised or updated version of any existing project document.**

**What to Do:** From the designer page, click the "Add New Document" button. This will allow you to add the new document to your current package.

Please note that there are multiple ways that the Designer can be accessed:

1. Clicking on the "Continue" icon when creating a new project
2. Clicking on the "Designer" icon from the Project Administration menu
3. Clicking on the blue "Designer" link while in the "Project Overview" page
4. Clicking on the blue package type hyperlink while previewing the "Project History"

## IRB Documents





IRBNet sends an automatic email after a decision has been made by the FAMU IRB and when IRB documents such as approval letters are published in IRBNet. To access the IRB documents within IRBNet, log into IRBNet, click the title of the project for which you want to see a board document, then click the Reviews Button on the left hand side of the page. Board documents (e.g., acknowledgement letter, modifications required letter, approval letter) can be accessed from the last table “Board Documents”. Click on either the blue hyperlink text **or** the document icon to view and print the document(s).

Board Documents:

Pkg #	Document Type	Description	Last Modified	View
1	<a href="#">Acknowledgment Letter</a>	Acknowledgment Letter	08/27/2013 03:06 PM	
1	<a href="#">Decision Letter</a>	Review Memo 10 01 13	10/01/2013 03:28 PM	

See the section Response/Follow-up to a request from the IRB for instructions on replying to modifications requested by the IRB.

## View/Update/Delete

Icon	Icon Function
	View/download document
	Update/Revise/Edit document
	Delete document
	See document history

Attached documents can be viewed at any time by any shared user. To view attached forms, click on the view icon of the document from the list of project documents. The update function will let you replace the current attached document with a new revised document. The delete function will completely remove a file from IRBNet. The update and delete functions can only be conducted by shared users with Full or Write privileges. These functions should occur before submitting a project package. **Using the update or delete functions after submitting will create a new package instead of updating the one already submitted.**

## Create New Package

Please note that creating a new package is different than creating a new project. Another package may be prepared while a package or multiple packages are pending review. However we strongly recommend that you avoid doing this as it may delay the review of your protocol documents. Only an individual with Full access to the project can create a new package.

### To create a new package:

1. Log into IRBNet
2. Click into your project in IRBNet by clicking the title of the project.
3. Click the “Project History” button the left-hand side of your screen.
4. Click the “Create New Package” button in the middle of the page.
5. Click “Work in progress (Not submitted)” to access the Designer page for your new package (also may be called “New Document Package” in some instances).

**IRBNet** will now default to this package when you re-enter the project. Alternatively, a new package can be created from the “Designer” when you try to add a new document. Simply accept the warning to create a new package.

## Lock Status

The IRB administrator may unlock a package if it is missing documents required for review or if requested by a PI (as long as the package is not already under review by an IRB member) Contact an IRB administrator via email to request the project package be unlocked. Please provide an accurate IRBNet ID and package # and a brief reason for the request in the message.

**Please note:** your project will only be unlocked if no IRB action has occurred and the package is not being reviewed by the IRB at the time of the request. If the package is being reviewed, the package may not be unlocked.

## Permissions

**Full:** User may manage all aspects of the project. The user may give and change permissions associated with the project. *You may have more than one manager to a project.*

**Write:** User may co-edit the project with owner, but not give or change permissions. Any changes a person with "write" access makes to a document using the project designer will automatically transfer across to the owner's copy.

**Read:** User may only access a read-only PDF of the project. All other management features are disabled. Use this level of permission if you only need that person to sign the project.



Although any individual can sign the project, only an individual with **Full access** may submit the project to the IRB. The individual creating a new project will automatically be assigned Full permissions. Shared access for research team members can be changed at any time. Only individuals with full access may share a project with others. New staff should be entered as soon as they have met the FAMU IRB requirements for new research staff conducting research (e.g., CITI training). Departing staff should be removed promptly. The addition/removal of research staff share permissions does not involve review by the IRB if the project is exempt. However, if the project has been approved as expedited or full board, the addition of new personnel will require IRB review and approval. The PI should ensure share permissions are current and accurate to ensure unwarranted access by non-research team individuals.

More information about project sharing is included below in the [New Study](#) section.

## **Sign this Package**

The Principal Investigator must sign the initial package for each new project. If you are a researcher unaffiliated with FAMU, it will be necessary for you to designate a FAMU full time researcher for your project. This researcher will need to sign the package before it can be submitted to the FAMU IRB. If you are a student, it will be necessary for your faculty advisor to sign the package. If the principal investigator is different than the faculty advisor on a student project, both the PI and the faculty advisor must sign the package. Packages that have not received the proper signatures will be returned without review.

More information about project sharing is included below in the [New Study](#) section of this document.

## **Submit this Package**

A research team member with Full share access may submit the transaction to the IRB after the necessary individuals have signed the submission.

### **To submit a project package:**

1. Click on “Submit this Package” from the Project Administration menu options or click on the “here” hyperlink on the Project Overview page.
2. Ensure that the Florida A&M University, Tallahassee, FL IRB, IACUC or IBC is highlighted and then click the “Continue” icon.
3. Select the Submission Type from the drop down menu. If it is an entirely new submission, please select “New Project.” If you are responding with revisions based on a review memo, please select “Revisions” as the submission type.
4. Write a message if you would like to do so. However, there is no need to send comments when you submit.
5. Click on the “Submit” icon.

## Send Mail

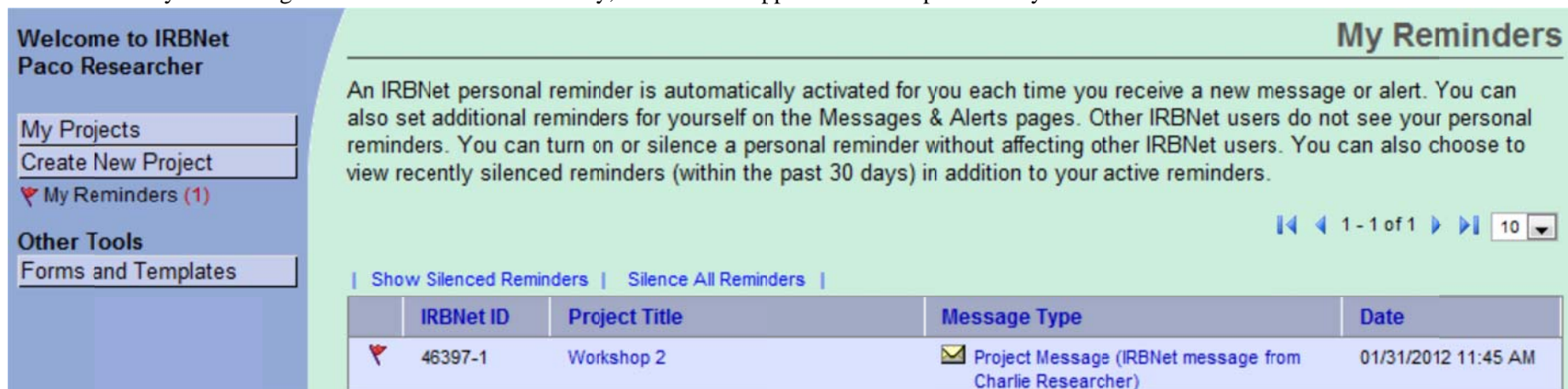
The Send Mail page allows research team members to communicate to each other regarding a *specific* project. In order to use the mail feature, you must open a specific project for which you would like to generate an email.

### Please complete the following steps:

1. Login to IRBNet
2. On the left-hand side of the screen, click the button for “My Projects”
3. From the list of your projects, select the one that you would like to send an email about. You can select a project by clicking the blue link for the project title. This will bring you to the Project Overview page.
4. After you have reached the Project Overview page, click on the “Send Project Mail” button on the left-hand side of your screen.
5. Select the message recipients from the list. If you have not shared the project with anyone, the only people you will be able to send mail to will be the research integrity administrators. Please see the New Study section of this document for specifics about how to share a project with someone. If you would like to send mail to someone who is not shared on a project, you must use your standard email rather than the IRBNet send mail function.

***The sender should include themselves on the email list so they will receive a copy of the email sent through IRBNet for their records.***

The default message requests the recipient to login and view the transaction. The email text may be modified to fit your needs. Within the page, the sender can select any member with share access by checking the box next to that team member’s name. The email can be previewed before sending by clicking on the “Preview” icon. Click the “Send” icon at the bottom of the email to send to the selected team members. The message will be sent to the recipient’s email address that they used to register with IRBNet. Additionally, a notice will appear in the recipient’s “My Reminders” section in IRBNet.



The screenshot shows the IRBNet interface. On the left, a sidebar contains 'Welcome to IRBNet Paco Researcher' and navigation links: 'My Projects', 'Create New Project', 'My Reminders (1)', and 'Other Tools' with a sub-link 'Forms and Templates'. The main area is titled 'My Reminders' and contains a text block explaining reminders. Below this is a table with one row of reminder data.

IRBNet ID	Project Title	Message Type	Date
46397-1	Workshop 2	Project Message (IRBNet message from Charlie Researcher)	01/31/2012 11:45 AM

## Delete this Package

If necessary, anyone with full access to a package can delete a created package; however, any changes made while the package was pending will be lost. After a project has been submitted, the package will be locked and you will be unable to delete or manipulate it. A package can remain open indefinitely and used at the next IRB transaction. It does not necessarily need to be deleted should you no longer plan to submit the intended transaction.

## Submission Types

### New Project

Any individual on the research team may create a new study/project. Therefore, a project *could* be created in IRBNet without your knowledge. If you were not given share access, you would not be able to view the project in the My Projects list. The UNF IRB requests that you contact all other research team members to ensure the project has not yet been created *before* creating a new project. If a project is accidentally duplicated such that one project has two IRBNet ID numbers, please contact an IRB administrator (IRB@famu.edu).

### How to create a new project:

11. After logging into IRBNet, on the left-hand side of the screen you should see an option for “Create New Project.”

The screenshot shows the IRBNet Submission Manager interface. On the left, there is a navigation menu with the following items: "My Projects", "Create New Project", "My Reminders (25)", "Other Tools", and "Forms and Templates". The main content area is titled "Submission Manager" and displays "Submissions for: University of North Florida Institutional Review Board". Below this, there is a search section with a "Search All:" input field and a "Search All" button. A filter section is also present with an "Agenda:" dropdown menu set to "Unassigned", a "Search:" input field, and a "Search By Tag:" dropdown menu. There are two checkboxes: "Only show submissions awaiting Board Action." (checked) and "Only show submissions not marked Review Completed." (unchecked). Below these are "Search" and "Clear" buttons. At the bottom of the page, there is a table with the following columns: "IRBNet ID", "Project Title", "Principal Investigator", "Submission Type", "Review Type", "Action", "Ref #", and "Submission Date". The table currently displays "No Submissions to display." There are also pagination controls at the bottom right showing "0 - 0 of 0" and "10" items per page.

12. Left click on the “Create New Project” button. You will be prompted to enter information about the study: a) title, b) principal investigator name and title, c) key words, d) sponsor, and e) internal reference number. The title information and principal investigator information you include here will be used throughout your submission so make sure you check it for accuracy.

### Create New Project

To create a new project, first provide the basic project information below. Once your project is created you may attach project documentation and share the project with other users.

**Research Institution:**

**Title:** \*

**Local Principal Investigator:** **First Name:** \*  **Last Name:** \*  **Degree(s):**

**Keywords:**

**Sponsor:**

You may specify an internal account number, billing identifier or reference number for this project.

**Internal Reference Number:**

\* required fields

13. The principal investigator (PI) is the individual who will be responsible for the conduct of the project. Although we strongly recommend that the PI be the individual generating the project paperwork, this is not a requirement. If project paperwork is being completed by someone other than the PI (e.g., research coordinator), please "share" this document with the PI so that both parties have full access. Directions on how to share are outlined below. Only faculty, are permitted to be PIs on IRB submissions.

14. In the keywords field, please specify keywords that can be used in a search to find this project. In the sponsor field, list the name of the funding agency sponsoring the project (if applicable) and upload the funding application and approval (when appropriate). If the project is unfunded, leave the sponsor field blank. Finally, we ask that you leave the institutional reference number field blank. After you have completed all the appropriate fields, click “Continue”. Clicking continue automatically saves your data.

15. On the next page (designer page), you will be able to download documents from the UNF documents library (**step 1**). Step 1 is optional and most researchers do not use it because they already completed the documents prior to accessing this page. If you use step 1, be sure to select the University of Florida Agricultural and Mechanical University in the “select a library” field. The documents library contains informational how-to documents, forms, templates, and checklists. Download any document that you will use in your submission. **The Florida Agricultural and Mechanical University – IRB Protocol application cannot be accessed from the documents library.** The application will be available electronically within IRBNet in the next section and outlined in Step 2 below. If you have generated your own supplemental documents (e.g., recruitment, consent, measurement tools), it will only be necessary to download the “Attachment A: Study Details for Expedited or Full Board Projects” document or the “Attachment B: Study Details for Exempt Projects” document for completion. Documents downloaded from the library should be saved to your computer, completed, resaved, and then uploaded into IRBNet.

**Please refer to the guides below for information about what documents are required to be included for a new project:**

- Documents Checklist - For Expedited or Full board projects
- Documents Checklist for Exempt Projects - Use only if you believe your project will be declared exempt from further review

16. after you have completed all of the supplementary documents (e.g., Attachment A or Attachment B, recruitment materials, informed consent documents, permissions

#### [929200-1] IRBNet training test of submission process

##### Step 1:

Download blank forms, document templates and reference materials to assist you in assembling your document package.

Select a Library:

Select a Document :

##### Step 2:

Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link your project team's Training & Credentials to your package.

##### Documents in this Package:

Document Type	Description	Last Modified	
 Consent Form	Consent Letter 016-26.pdf	06/29/2016 11:47 AM	  

There are no Training & Credentials records linked to this package. | [Link / Un-Link Training Records](#) |

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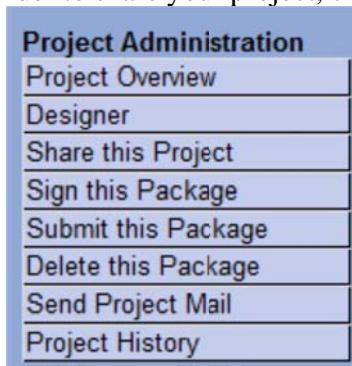
17. On the Attach Document page, you should select the document type you are uploading from the drop down list (e.g., Training/Certification, Consent Form, and Questionnaire/Survey). If you do not see an option that describes your document type, please choose “other” and then add a description of the document to the description field. Additionally, if you are including other personnel (e.g., research assistants, data collectors), it will be necessary to include information about their training and credentials. All Co-PIs, data collectors, personnel who interact or intervene with participants, and personnel who have access to identifiable information are required to complete CITI training. If you will not share the project with these individuals (i.e., give them read or write access to your project documents), you will need to upload their CITI completion reports as supplementary documents. More information about project sharing is included below.

18. Upload the file by clicking “Choose File” and then selecting the document from where it is saved on your computer. After you have selected the correct document file from your computer, click the “Attach” button. You can only add one document at a time.

19. **Sharing a project:** After you have created a new project, you can share your project with relevant personnel. As soon as you share the project with another person, they will have access to the project. We recommend that you share the project with any personnel who will need to read, revise, or sign the submission package.

- If you are a FAMU affiliated faculty or staff member (non-student) who is also the PI on this project and you are not required to obtain signatures from your department chair, you are not required to share the project with anyone else. However, you may choose to share the project with others if you wish (e.g., Co-PI, other personnel, department chair).
- If you are not the PI for this project, it will be necessary for you to share the project with the PI.
- If you are unaffiliated with FAMU, it will be necessary for you to share the project with the FAMU faculty member for your project.
- If you are a student working on a project, it will be necessary for you to share the project with your faculty advisor. If your faculty advisor is different from the PI for your project, you will need to share the project with both your faculty advisor and the PI of the project.

20. In order to share your project, click “Share this Project” on the left-hand side of your screen.



You may share this project with other Researchers, Committee Members, Administrators and Sponsors. You may also send a complete copy of this project to a Principal Investigator at another site if this is a multi-site project. You may also transfer ownership of this project to another individual.

- **Share:** Use this option if you wish to share your project with other Researchers, Committee Members, Administrators or Sponsors at your own institution or any other institution. For example, you may wish to share this project with other members of your research team so that you may collaborate in the design and development of the project, or with a selected Committee Member or Administrator to solicit feedback prior to submitting your project for review. You may provide any individual with **Full**, **Write** or **Read** access.
- **Multi-site:** Use this option only if your project is a multi-site project and you wish to send a complete and independent copy of this project to a Principal Investigator at another site. The local Principal Investigator will be able to obtain project documents from the lead site and may modify their copy of these documents (such as consent forms) to meet the requirements of their local Board. You will be able to monitor the progress of this project at every local site. The other local Principal Investigators will also be able to monitor the progress of this project at every local site (including your own).
- **Transfer:** Transfer your ownership of this project to another user. In doing so you will relinquish all access to this project and the designated user will be granted **Full** access.

21. In most cases, you will choose the “Share” option rather than “Multi-site” or “Transfer.” After you have selected “Share,” (blue text) choose “Florida Agricultural and Mechanical University, Tallahassee, FL” from the drop down list of organizations.

22. Before you can share the study, the person you are sharing it with must:

- **Register with IRBNet (IRBNet.org)**
- **Complete the User Profile**
- **Affiliate with the Florida Agricultural and Mechanical University (unless a Co-PI is located at a different institution)**

23. You can search for an individual by typing in the first letter of the individual’s last name, any letter of their full name, or \* to list all users and click on the “Search” icon.

24. After you have identified the individual to whom you would like to give access, place a mark in the appropriate level of access next to the research team member’s name.

25. If you need the selected personnel to sign the package (e.g., PI, faculty), please include a message to them in the “Your Comments” section at the bottom of this page asking them to sign the package. You might also include instructions as to how they assess and sign the package.

26. Finally, after reviewing all documents and verifying that the submission is just the way you want it, you can sign the package in preparation for submittal.



## Signing the Package:

- Select "Sign this Package" from the Project Administration bar on the left-hand side of your screen. This will allow you to sign the package. Select your role in the study from the drop down list and click "sign."

When you shared the project with other users, you should have specified if you want them to sign the package before it is submitted.

## Who is required to sign the package?

- At a minimum, FAMU's IRB requires that the principal investigator (PI) sign each package before it is submitted. See above for more information about how to sign a package.
- As noted above, if you are a student, it will be necessary for your faculty advisor to sign the package. If the principal investigator is different than the faculty advisor on a student project, both the PI and the faculty advisor must sign the package (Please note that a faculty member must be the PI on non-thesis graduate projects and undergraduate research including honors thesis projects).
- If you are not a FAMU affiliate, it will be necessary for the FAMU sponsor to sign the package before it is submitted.

## Submitting the Package:

- After your project package is complete and signed by all necessary persons, you can submit the package by clicking "Submit this Package" on the Project Administration bar on the left-hand side of your screen.
- Select "Florida Agricultural and Mechanical University, Tallahassee, FL" from the list of organizations and then click "Continue."
- Select the submission type from the drop down menu. If this is a new submission, select "New Project" from the list of options. If you have comments that you would like to send to the research integrity administrators and/or reviewers, please include that information in the "Your Comments" section of the page.

- - Click “Submit” when you are done. IRB Projects generally take between four to six weeks between the time of submission and the time of approval. If you are required to submit multiple revisions or if a large volume of projects have been submitted, the timeline for review and approval may be elongated.

### **Modifications Required: Revising your Project Documents:**

The IRB may request modification(s) to the protocol application or supplementary documents (e.g., attachment A or attachment B, recruitment materials, informed consent documents, CITI training). You will receive an email notification within IRBNet from the IRB informing you that a board document has been published in IRBNet. The board may publish a response to your submission by making a document available for you to review. This letter may ask you to make modifications or it may indicate that your project has been approved or disapproved. It is the responsibility of the research team to log into IRBNet to view these documents and address any modifications requested.

### **To view the IRB’s determination and modification request:**

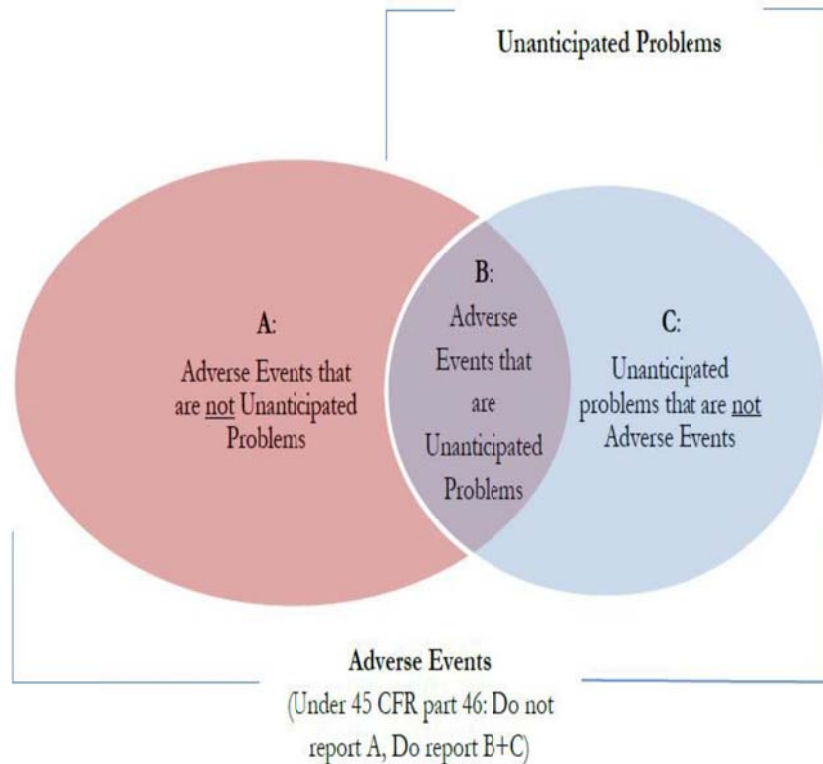
1. Log into IRBNet
2. Select the project (click title of project)
3. Select the “Reviews” from the administrative menu (left-hand side of page)
4. Click on the blue hyperlink for the Decision Letter or other board documents from the IRB. This will download a copy of the letter to your computer.

### **To make revisions:**

1. Complete your revisions as requested. Save the revised documents to your computer.
2. Sign into IRBNet and select the correct project from the My Projects page. Do this by clicking on the title of the project you are revising.
3. On the toolbar on the left-hand side of the screen click on the “Project History” button. This will allow you to see all the packages that have been started for your project.
4. From the project history page, click “Create New Package.”
5. You should see a new entry in the list of packages. This entry should be titled “Work in progress (Not submitted).” Click on the link for “Work in progress (Not submitted)” to begin your new package.
6. Attach a revised document or add new project documents to the new package by following the instructions for adding new documents in the Designer section of this document.
7. Submit the documents to the IRB by following the Submit this Package instructions and designating the submission type as a “Revision.”

## Reportable Event

**Non-Compliance:** any action or activity associated with the conduct or oversight of research involving human subjects that fails to comply with federal or state regulations or institutional policies and procedures governing human subject research or the requirements or determinations of the IRB. Non-compliance reports should be designated as an “Other Reportable Event” when selecting the Submission Type during submission.



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**Protocol Deviation:** An alteration/modification to the IRB approved protocol that is not approved by the IRB prior to its initiation or implementation. Recruitment, informed consent, and data collection are not permitted without final IRB approval. Final IRB approval will be confirmed when the IRB publishes the stamped and dated approval documents within IRBNet. The approval letter will outline the conditions of your approval. If you have not received a stamped and dated approval from the IRB, please contact a research integrity administrator for more information. The PI is responsible for ensuring that the study does not deviate from the IRB-approved protocol, except in such cases where it is necessary to avoid an immediate hazard to the participant. The PI must report any protocol deviations or violations and when possible, should request permission from the IRB to deviate from the protocol prior to conducting the deviation. Non-compliance reports should be designated as an “Other Reportable Event” when selecting the Submission Type during submission.

**Unanticipated Problems Involving Risk:** any incident, experience, or outcome that meets the following criteria:

- a) Event is unanticipated, unforeseen, or unexpected
- b) There is a reasonable possibility that the problem is related or caused by the research, **AND**
- c) Participants or others are at an increased risk of harm

An Unanticipated Problem Involving Risk to Participants or Others could result from a protocol deviation. However, an Unanticipated Problem could also involve the loss of study forms, consents or a participant complaint. An Unanticipated Problem also needs to be reported to the IRB. The submission type for an unanticipated problem involving risk will be “Unanticipated Problem (UP)”.

**To submit a reportable event:**

1. Download the event report form and save the form to your computer for completion.
2. Complete the form and save it to your computer.
3. Sign onto IRBNet and click on My Projects to access the project for which you are reporting
4. Select the correct project by clicking on the project title
5. Create a new package for your project
6. Go to the Designer page of your new package
7. Click the “Add New Document” icon and add the Event Report Form you completed along with any supporting documents, as applicable. Please see the Designer section of this document for more information about navigating through the Designer page. For document type select either “Reportable Event (Non-AE)” or “Unanticipated Problem Report” from the drop down list.
8. Have the PI sign the package by following the Sign this Package instructions
9. Submit the package to the IRB following the Submit this Package instructions, designating the submission type as either a Other Reportable Event or an Unanticipated Problem (UP) as applicable.

In addition to the event report, you may be asked to submit additional documentation. For example, if you will revise any of your protocol procedures, it will be necessary to submit a revised protocol application with your report. If you will make changes to your informed consent documents, it will be necessary to submit those documents for review. Any additional or pertinent information should be submitted with your report as applicable.

**Modification/Amendment**

If your project has been approved and you would like to change your procedures or materials, it may be necessary to submit an amendment before engaging in the revised activities. Any change to an expedited or full board project must be submitted as an amendment. That amendment will need to be reviewed and approved before you begin your revised activities. If you plan to make changes to an exempt project, please note that only substantive changes will need to be submitted for exempt projects. Please refer to the FAMU Standard Operating Procedures for more information about changes to exempt projects that might necessitate an amendment. If you are unsure of whether your project requires an amendment, please contact a research integrity administrator before beginning your revised activities. The investigator is responsible for promptly submitting protocol amendments to the IRB. Amended procedures may not be implemented until the amendment has been reviewed and approved by the IRB unless the change is necessary to reduce or eliminate harm.

1. Download the Amendment Request Form. Save the form to your computer for completion.
2. Complete the form and save it to your computer.
3. Sign onto IRBNet and click on My Projects to access the project that you would like to amend

4. Select the correct project by clicking on the project title
5. Access the designer page for the project
6. Click the “Add New Document” icon
7. Add the required amendment documents (see list below)
8. Have the PI sign the package by following the Package Signing instructions
9. Submit the package to the IRB following the Submit this Package instructions, designating the submission type as Modification/Amendment

**The following documents must be submitted for modification/amendment of expedited or fill board projects. Amendments to exempt projects are not required unless the change could increase risk to participants:**

- Amendment Request Form
- Updated protocol application
- New or revised materials (e.g., informed consent document, measurement tool) – anything that will be affected by the changes you are proposing in your amendment

Additional sections of this guidance document will be added as needed. If you have questions about information in this document or about research integrity in general, please contact one of the research integrity administrators.

### **Research Integrity Contact Information**

**Phone:** (850) 412-5246

**Email:** [IRB@famu.edu](mailto:IRB@famu.edu)

**Mail:** Office of Animal Welfare and Research Integrity  
Florida Agricultural and Mechanical University  
1515 South Martin Luther King  
Room 308H Science Research Center  
Tallahassee, FL 32307

<sup>i</sup> Information in this guide was obtained from many sources including but not limited to the Code of Federal Regulations ([45 CFR 46](#)), the Office for Human Research Protections (<http://www.hhs.gov/ohrp>), the IRBNet forum, and the Anne Arundel Medical Center IRBNet User Manual.

