

Guidance in
USING IRBNet
for Barry University IRB

March 22, 2020

Objectives of THIS guidance: *IRBNet*

- How to access IRBNet.org electronic IRB management system
- Define *Project* and *Package*
- How to create a project
- How to upload a package
- How to create a new package associated with your original project
- How to add your CITI certificates to your IRBNet User Profile
- How to link your CITI certificates to your project
- Notification via IRBNet

See posted PowerPoint for guidance for Protocol submission & CITI certification



Innovative Solutions for
Compliance and Research Management

- Electronic submission and management system (IRBNet.org)
- Advantages
 - No more paper copies
 - Sign electronically
 - Two-way automatic email notification
 - Link your CITI certificates to your *User Profile*
 - Permanent archiving of all documents for a project

*Upload all items (e.g., protocol, consents, flyers)
as separate documents.*



Innovative Solutions for
Compliance and Research Management

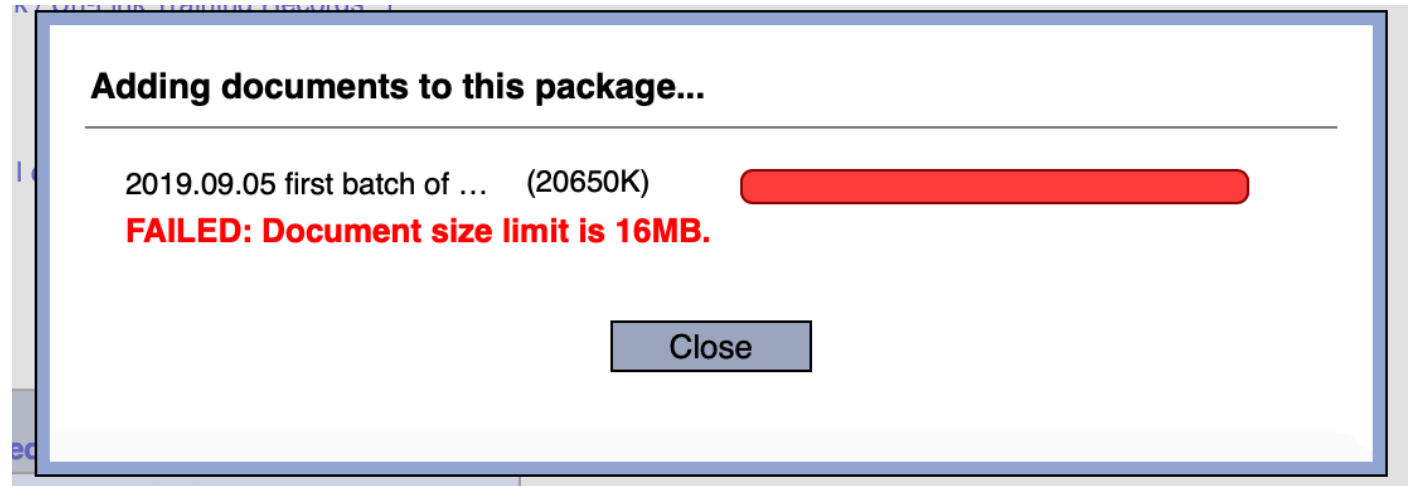
- Definitions

- Project: Your entire research project, including
 - Protocol
 - Ancillary documents (e.g., recruitment documents, consents, instruments)
 - CITI certifications (see Guidance that follows to link certifications to *User Profile*)
- Package--A package can be:
 - New Project documents: e.g., Protocol and ancillary documents
 - Your New Project is your first package.
 - Modifications requested by your reviewer: All modified documents are uploaded as a new package within the original protocol.
 - Should you request a modification to your protocol, your Modification Form and supporting documents should be uploaded as a new package.
 - Annual report should be uploaded as a new package.

Project number: IRBNet ID

- Uploading your New Project generates a unique *IRBNet ID*: xxxx-1 to indicate the first package in this project.
- Uploading a New Package to this project will keep the same unique IRBNet ID, but will increment the package number → xxxx-2


**Document size limit
is 16MB.**





Innovative Solutions for
Compliance and Research Management

Login:

 [New User Registration](#) | [? Forgot Your Password?](#)

- Register at IRBNet.org
 - Create username and password
 - Affiliate with Barry University
 - Use Barry email

Other Tools
[Forms and Templates](#)

- Download and complete forms



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- Next Steps Overview

- Create New Project
- Add CITI certificates to User Profile
- Link CITI certificates to Project
- Upload submission
- IRB Chair and Contact receive immediate notification of any new upload

*Following submission, any subsequent uploads should be made as a **NEW PACKAGE** in the original **PROJECT**.*



Create New Project

Create a 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:	<input type="text" value="Barry University, Miami Shores, FL"/>		
Title: *	<input type="text"/>		
Local Principal Investigator:	First Name: *	<input type="text"/>	
	Last Name: *	<input type="text"/>	
Keywords:	<input type="text"/>		
Sponsor:	<input type="text"/>		
You may specify an internal account number, billing identifier or reference number for this project.			
Internal Reference Number:	<input type="text"/>		
		<input type="button" value="Continue"/>	<input type="button" value="Cancel"/>

* required fields

Student
researchers
MUST
enter your
faculty
sponsor
name.

Project Administration

Project Overview

Designer

Share this Project

Sign this Package

Submit this Package

Delete this Package

Send Project Mail

Project History

 Messages & Alerts Share this project

- *Student **MUST** share with faculty sponsor.*
- *Faculty may share with collaborators.*
 - *Full access*
 - *Read access*
 - *Write access*

Sharing options

- *Share (inside Barry)*
- *Multi-site (outside collaborators)*
- *Transfer (relinquish project to another)*

STUDY TITLE: Expedited/Exempt

If submitting for expedited and/or exempt review:

- Add this information in the textbox message at the time you submit.
- However, you can also indicate exempt and/or expedited in the title, as in the following examples.
 - EXPEDITED-Protocol-StudyTitle
 - EXEMPT-Protocol-StudyTitle
 - ExemptExpedited-Protocol-StudyTitle

Continue...

Step 1 allows you to download forms from Barry University IRBNet library.

[1333287] TestStarratt

Package: ▼ 1333287-1 Work in progress (Not submitted)



Click to add a package description or notes.

Step 1:

| [Hide Form Libraries](#) |

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

Select a Library:

Barry University Institutional Review Board, Miami Shores, FL ▼

Select a

Document:

adverse.doc ▼

Download

Step 2:

Create and submit protocol items *separately*

- Protocol form
- Consents
- Recruitment documents (e.g., flyers, emails)
- Study instruments (e.g., surveys, guiding questions)
- *Do NOT upload CITI certificates:* See previous instructions for
 - Adding your CITI certification to your *User Profile*
 - Linking your CITI certification to your *Project*





Attach New Document > Browse > Select your document from your hard drive

- From the dropdown for each document, select Document Type

Step 2:

Assemble your document package here. You can add new project documents, revise existing project documents while maintaining version history, and link your project team's Training & Credentials to your package. | [Learn more](#) |

Documents in this Package:

Document Type	Description	Last Modified	
<div><div>(please select)</div><div>Other</div><div>Parental Permission Form</div><div>Proposal</div><div>Protocol</div><div>Protocol Deviation/Violation Report</div><div>Publication Materials</div><div>Questionnaire/Survey</div><div>Reportable Event (Non-AE)</div></div>	TEST.docx	10/08/2018 09:13 AM	   

The records linked to this package. | [Link / Un-Link Training Records](#) |

[Attach New Document](#) (When should I do this?)

Continue adding documents, as necessary.

Signing your protocol

- Submitter must sign electronically at the time that they submit the project
- Faculty Sponsor must also sign a student submission
 - With approval of Faculty Sponsor, student may sign electronically for faculty sponsor.
- With approval of the co-researcher, submitter may sign for co-researcher.

Once the student SHARES, the student project will show up on the faculty sponsor's account on IRBNet under MY PROJECTS so the faculty sponsor can sign.

Project Administration

[Project Overview](#)[Designer](#)[Share this Project](#)[Sign this Package](#)[Submit this Package](#)[Delete this Package](#)[Send Project Mail](#)[Project History](#)

Signing electronically

Use dropdown menu to indicate role (e.g. PI, advisor).

Sign Package

[1333287-1] TestStarratt

I Gerene Starratt, as , certify that to the best of my knowledge the information contained in this package is accurate and complete, has been prepared in accordance with all applicable institutional requirements and is ready for submission. I further certify that this electronic signature is intended to be the legally binding equivalent of a traditional handwritten signature.

Sign

To sign on behalf of another person, switch to **Designee Signature Mode**.

This package has not been signed.

Designee Signature Mode

Sign Package

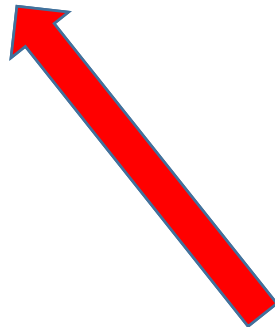
[1333287-1] TestStarratt

I Gerene Starratt, certify on behalf of (enter name) that to the best of this individual's knowledge the information contained in this package is accurate and complete, has been prepared in accordance with all applicable institutional requirements and is ready for submission. I further certify that I have been duly authorized to sign on behalf of this individual and that this electronic signature is intended to be the legally binding equivalent of a traditional handwritten signature.

Sign

Return to [Standard Signature Mode](#).

This package has not been signed.



Add CITI certificates to User Profile and link to project

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

The PI must SHARE the project with faculty sponsor/co-investigators

Faculty sponsor and every co-investigator on a project must:

- 1. Complete two courses of CITI training (see Guidance CITI)*
- 2. Register on IRBNet*
- 3. ADD their CITI certificates to their own USER PROFILE*
- 4. Link both CITI certificates to the new protocol*

Instructions follow

Add CITI certificate to your IRBNet *User Profile*: 2 options

1

External Accounts

You can add your accounts from other organizations such as CITI to your IRBNet profile. Once you add an external account to your IRBNet profile, then external information such as training records can be automatically available to you in IRBNet.

[| Learn More |](#)

► [Add an External Account](#)

When a training certification is added, it will be marked for review and approval.

2

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.

► [Add a New Training & Credentials Record](#)

Add Training Certificates to the User Profile (4 Steps)

Instructions:

1. Log-in to IRBNet and Click on “User Profile” in the top right-hand corner of the screen.

Welcome to IRBNet Mary Researcher

[Help](#)

[My Projects](#)

[Create New Project](#)

[My Reminders \(20\)](#)

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 - 6 of 6

[Create and Manage Tags](#) | [Show Archived Projects \(1\)](#) | [Project Status View](#)

IRBNet ID	Project Title	Principal Investigator	Submission Type	Board Action	Effective Date
62135-4	IRBNet Test Project 4	Researcher	Work in progress (Not submitted)		
59683-1	the lived experience of men with high bl...	reid	Work in progress (Not submitted)		
58284-3	IRBNet Test Project 3	Researcher	New Project	Pending Review	
58156-2	Rocket Man and Nuclear Destruction Expiration Date: 10/16/2018 • Report due: 10/16/2018 animal testin... drugs	Jasmine	Work in progress (Not submitted)		
58154-1	IRBNet Test Project 2 animal testin... drugs memo	Researcher	New Project	Pending Review	
58153-3	IRBNet Test Project 1	Researcher	Closure/ Final Report	Closed	10/23/2017

1 - 6 of 6

2. Scroll down to “Training & Credentials.” Click on “Add a New Training & Credential Record.”

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.

[Add a New Training & Credentials Record](#)

[Show all Versions](#)

Doc ID	Document Type	Description	Cr	Effective Date	Expiration Date	Last Modified	Status	
20238.1	CV/Resume	Resume.docx		10/02/2017		10/16/2017 01:25 PM	Accepted	  Submit  
20802.1	example training	Training.docx		08/28/2019		08/28/2019 01:51 PM	Pending Review	  Submit  
20240.1	example training	Training.docx		10/16/2017	11/16/2018	10/16/2017 02:25 PM	Accepted	  Submit  
20803.1	Other	Example of Not Submitted		08/28/2019	08/27/2020	08/28/2019 02:01 PM	Pending Review	  Submit  
20221.1	Other	Training.docx		09/25/2017	10/25/2017	09/25/2017 02:13 PM	Accepted	  Submit  

3. Mark “**None of these**” (if you had previously uploaded other documents) and click “Continue.” *Do not mark an existing document. Doing so, you will add your current document as a new version of an existing document. In this case, if the expiration dates are overlapped, IRBNet will not allow us to accept your certificate.*

IRBNet™

Welcome to IRBNet
Mary Researcher

Help

My Projects

Create New Project

My Reminders (20)

Other Tools

Forms and Templates

USER PROFILE LOGOUT

Add New Training & Credentials

Profile Owner: Mary Researcher

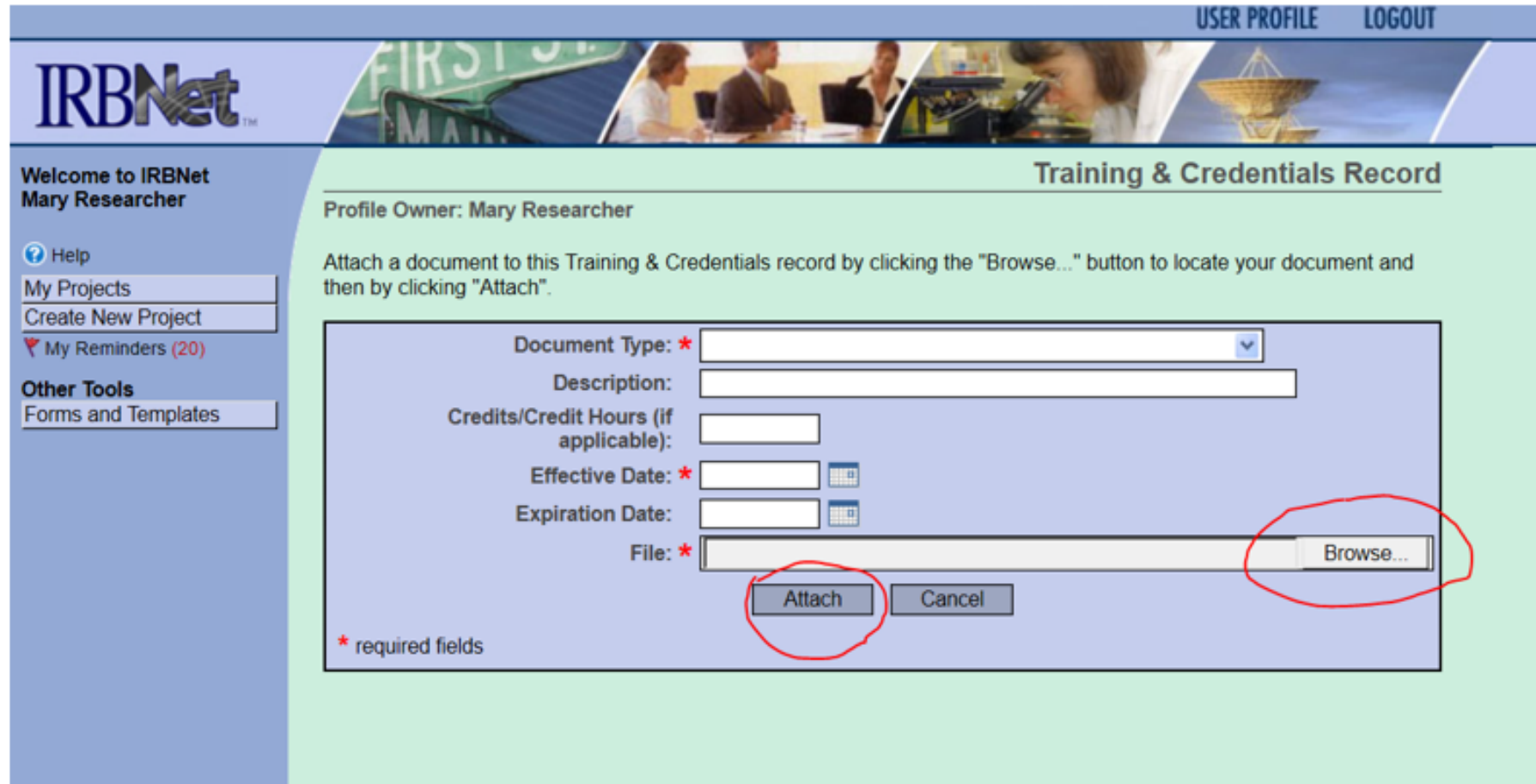
IRBNet helps you maintain the history of each of your Training & Credentials records as you add new versions. When you add a new version of a record, it is automatically grouped together with the previous versions of your record within the Document History. For example, you can have your updated training certificate automatically grouped together with your previous expired certificates for the same training course so that you can easily see the history of your course certifications. Similarly, you can have your updated resume automatically grouped together with the previous versions of your resume so that you can easily see the history of the resumes you have used over time.

If the record that you are adding is a new version of an existing record please select the existing record to assure your new version is properly organized into the correct Document History:

Select	Document Type	Description	Cr	Effective Date	Expiration Date	
<input type="radio"/>	CV/Resume	Resume.docx		10/02/2017		
<input type="radio"/>	example training	Training.docx		08/28/2019		
<input type="radio"/>	example training	Training.docx		10/16/2017	11/16/2018	
<input type="radio"/>	Other	Example of Not Submitted		08/28/2019	08/27/2020	
<input type="radio"/>	Other	Training.docx		09/25/2017	10/25/2017	
<input type="radio"/>	None of these					

Continue Cancel

4. Fill-out the required information, locate your PDF training certificate by browsing your hard drive, and click “Attach.”



USER PROFILE LOGOUT

IRBNet™

Welcome to IRBNet
Mary Researcher

Help
My Projects
Create New Project
My Reminders (20)
Other Tools
Forms and Templates

Training & Credentials Record

Profile Owner: Mary Researcher

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

Document Type: *

Description:

Credits/Credit Hours (if applicable):

Effective Date: *

Expiration Date:

File: *

* required fields

Project Administration

Project Overview

Designer

Share this Project

Sign this Package

Submit this Package

Delete this Package

Send Project

Messages & Alerts

Link your CITI certificates to your project in the Designer

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

Link	User Name	Document ID	Document Type	Description	Cr	Effective Date	Expiration Date	Status	
<input checked="" type="checkbox"/>	Starratt, Gerene	541926.1	Other	CITI - IRB Chair		11/24/2019	11/23/2022	Pending Review	
<input checked="" type="checkbox"/>	Starratt, Gerene	541923.1	Other	SBR-Social & Behavioral Research Basic/Refresher		11/23/2019	11/22/2022	Accepted	

Save

There are 2 Training & Credentials records linked to this package.

Select Barry University

Submit this package

The screenshot displays the IRBNet web application interface. At the top, there is a search bar labeled "Search for an Organization" with a "Search" button. Below the search bar, a checkbox labeled "Only show My Default Boards" is checked. A dropdown menu is open, showing a list of boards. The first item in the list is "Barry University Institutional Review Board, Miami", which is highlighted. To the right of the main content area, there is a sidebar titled "Project Administration". This sidebar contains a list of links: "Project Overview", "Designer", "Share this Project", "Sign this Package", "Submit this Package", "Delete this Package", "Send Project Mail", and "Project History". The "Submit this Package" link is highlighted. At the bottom of the main content area, there are two buttons: "Continue" and "Cancel". In the bottom left corner, there is a red asterisk followed by the text "* required fields".

Search for an Organization

Search

☒ Only show My Default Boards

Select a Board *

Barry University Institutional Review Board, Miami

Continue

Cancel

* required fields

Project Administration

- Project Overview
- Designer
- Share this Project
- Sign this Package
- Submit this Package
- Delete this Package
- Send Project Mail
- Project History

Certify electronic signatures

1) After you have signed your package your name will appear here.

In order to submit this package you must certify that the signatures have been added to this package in accordance with Barry University Institutional Review Board, Miami Shores, FL signature requirements. The following signatures have been added to this package:

- Terene Starratt (Principal Investigator)

If you are unsure of the electronic signature requirements you should check with your board before you submit.

☐ I certify that all required electronic signatures have been added to this package.

Continue

Cancel

2) Only if all names appears above, then click here.

Submit project

Note requests for expedited and/or exempt review here.

The following users at **Barry University Institutional Review Board** will be automatically notified of your submission:

Azevedo, Estela
Perez, Fernando
Starratt, Christopher
Trana, Jasmine

Submission Type: *

You may also specify additional comments to be included in this notification.

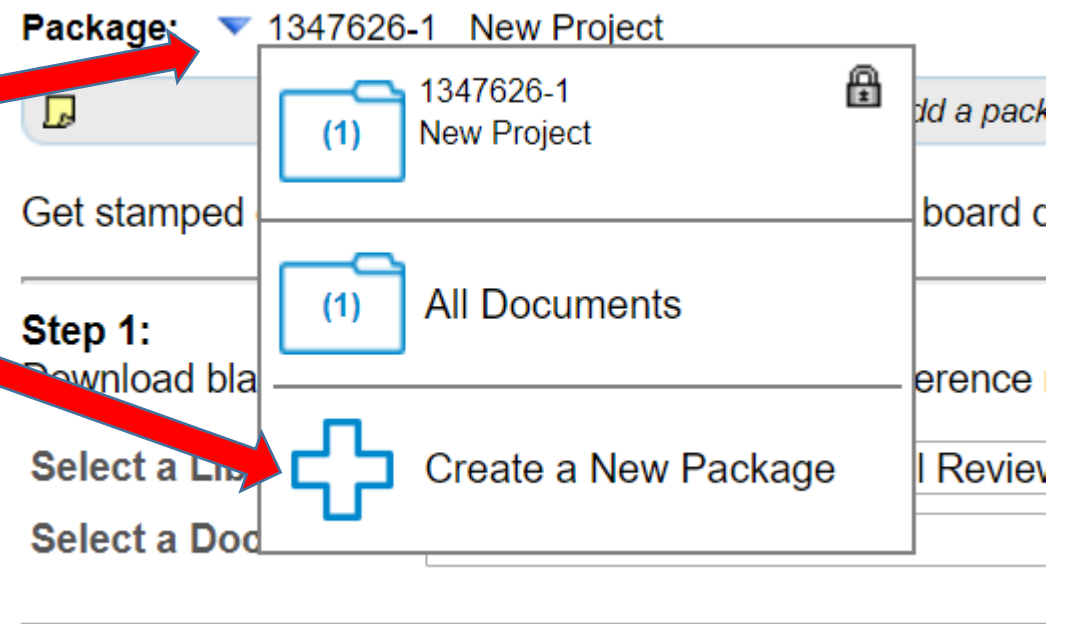
Your Comments:

New Project

To submit a new PACKAGE to your original PROJECT (modifications, etc.)

- Go to your original protocol
- Click the Designer link
- Click the dropdown menu by your package number
- Click *Create a New Package*
- Upload your new documents
 - Modifications
 - Modification Request
 - Annual Report

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



- ***SIGN*** & submit: Every new package must be signed (see slide 21)

Notification

- When you submit a *project* or *package*, the Barry IRB Contact and IRB Chair automatically receive email notification.
- IRBNet will automatically notify the PI, identified co-researchers, and faculty sponsor (for student projects) when an IRB response to your submission has been posted to IRBNet.

*All materials must be uploaded to IRBNet.
No materials will be accepted via email.*

Additional Guidance

- IRBNet Resources for **Researchers** can be accessed at <http://www.irbnetresources.org/tresources/training.html>
 - Login: barry; Password: training
- The *IRBNet Sandbox* is available for training/practice at <http://training.irbnet.org>
 - Login: barryresearch1; Password: training
- Additional guidance available on *IRBNet > Forms & Templates*
 - For guidance on Barry University IRB procedures, download the most current version of the Powerpoint **IRBGuidance PROTOCOL PROCESS**
 - For guidance on CITI certification, download the most current version of the Powerpoint **IRBGuidance CITI**

Questions?

- IRB Contact
 - Jasmine Trana
 - jtrana@barry.edu
 - 305-899-3020
- IRB Chair: irbchair@barry.edu