Guidance in
USING IRBNet
for Barry University IRB

July 1, 2021

Barry University

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 PowerPoints for guidance for Protocol submission & CITI certification

IRBNet 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.
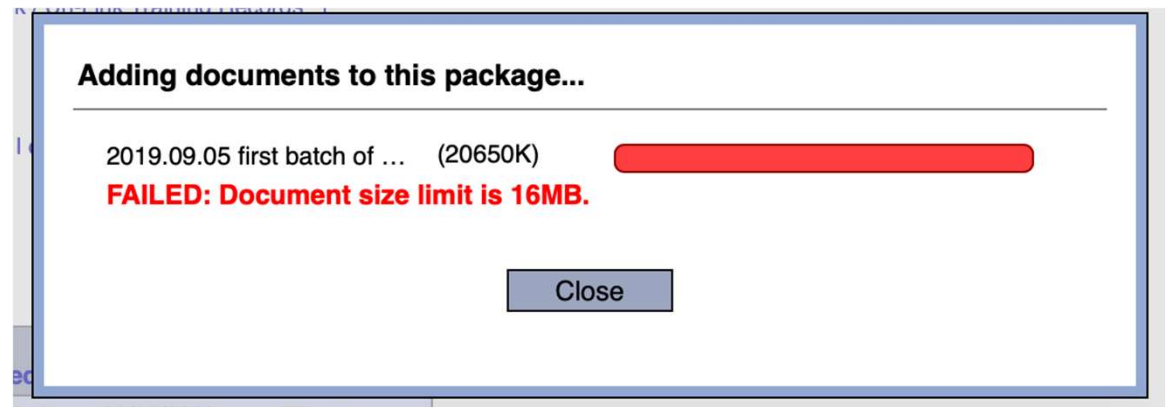
IRBNet
Innovative Solutions for
Compliance and Research Management

- 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.*

Adding documents to this package...

2019.09.05 first batch of …   (20650K)
FAILED: Document size limit is 16MB.

Close

IRBNet Innovative Solutions for Compliance and Research Management

Login: | Username | Password | Login

👤 New User Registration | ❓ Forgot Your Password?

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

Other Tools
Forms and Templates

- Download and complete forms

IRBNet Innovative Solutions for
Compliance and Research Management

- Next Steps Overview
  - o Create New Project
  - o Add CITI certificates to User Profile
  - o Link CITI certificates to Project
  - o Upload submission
  - o 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

IRBNet

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:	Barry University, Miami Shores, FL
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:	

Continue   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
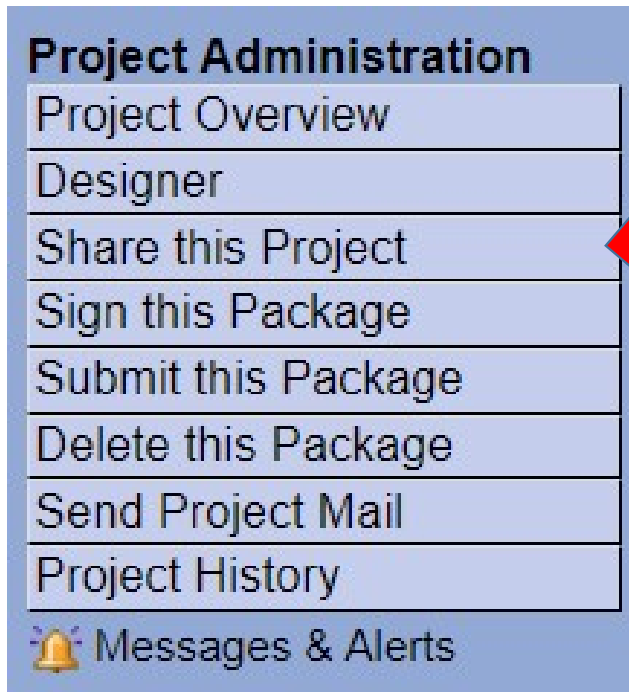
Share this project

- *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…

IRBNet

[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	
▼ (please select)	TEST.docx	10/08/2018 09:13 AM	📄 📑 ✏️ ✖

Dropdown options:
Other
Parental Permission Form
Proposal
Protocol
Protocol Deviation/Violation Report
Publication Materials
Questionnaire/Survey
Reportable Event (Non-AE)

The ...cords linked to this package. | Link / Un-Link Training Records |

Attach New Document   (When should I do this?)

Continue adding documents, as necessary.

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Signing your protocol

- Submitter <u>must</u> might sign electronically at the time that they submit the project

- Faculty Sponsor <u>must</u> also sign a student submission

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.
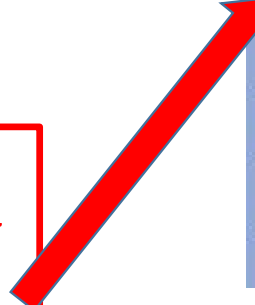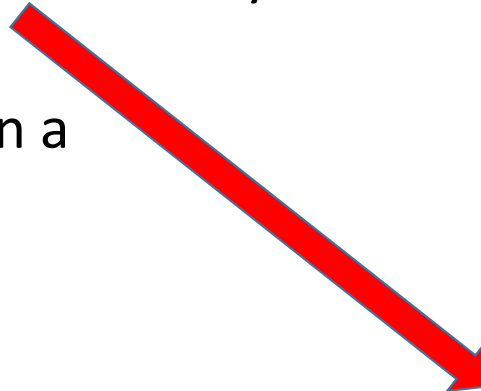
Project Administration

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.

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Designee Signature Mode

[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.
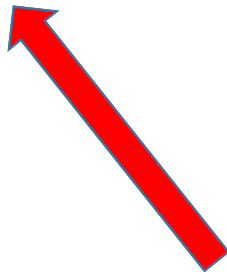
Add CITI certificates to User Profile and link to project

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.

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

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.*

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

Project Administration

Project Overview

Designer

Share this Project

Sign this Package

Submit this Package

Delete this Package

Sen

Proj

🔔 Messages & Alerts

Link your CITI certificates to your project in the Designer

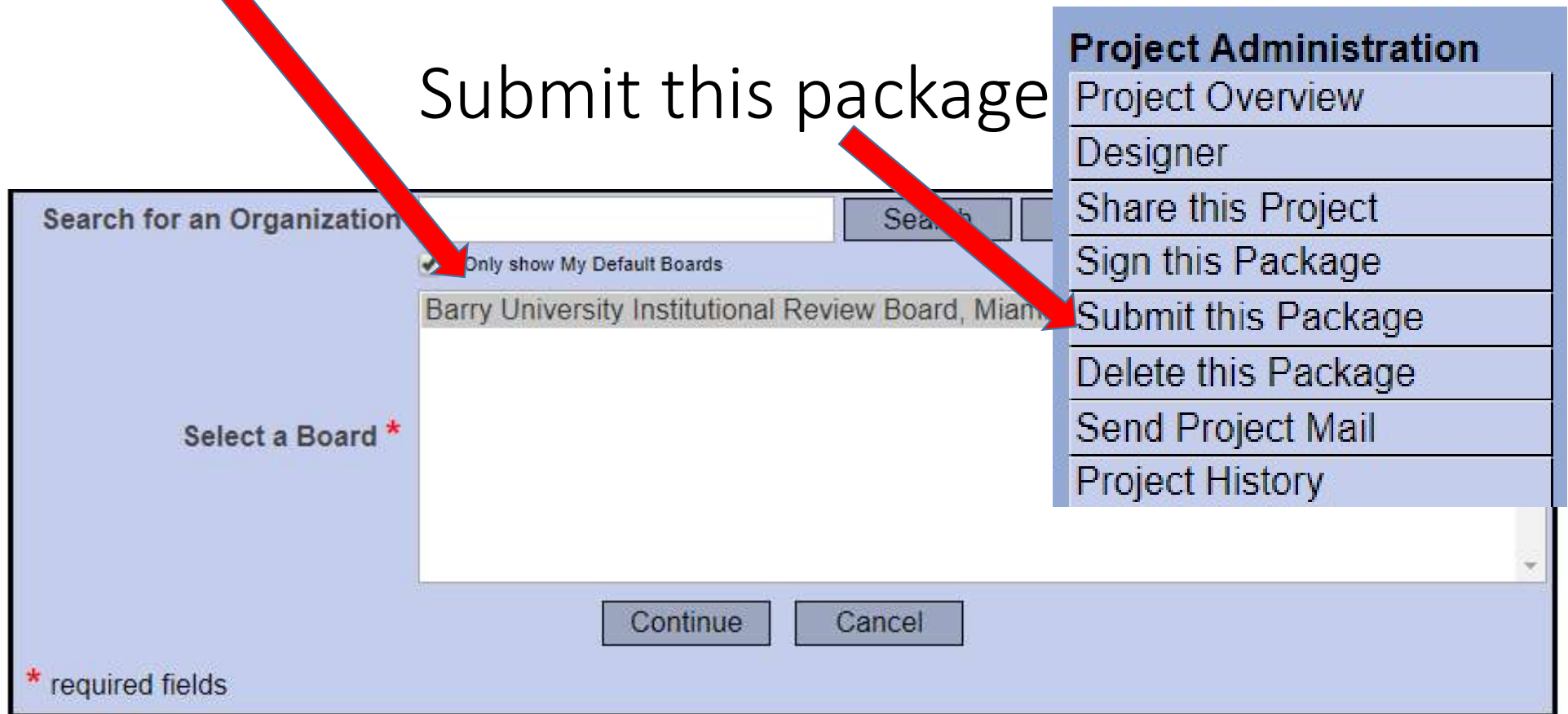There are no Training & Credentials records linked to this package. | Link / Un-Link Training Records |

Link	User Name	D...	...ment Type	Description	Cr	Effective Date	Expiration Date	Status	
☑	...arratt, Gerene	541926.1	Other	CITI - IRB Chair		11/24/2019	11/23/2022	Pending Review	📄
☑	S...ratt, Gene	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

Certify electronic signatures

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

In order to submit this package you m___ ertify th__ signatures have been added to ___ package in acc_____ ___ ___ University Institutional R__ __w Board, Miami Shores, FL signature requirements. The following si_____es have been added to this package:

- ___erene 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.

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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

Submit   Cancel

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

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

Package: 1347626-1 New Project

1347626-1
(1) New Project

Get stamped

(1) All Documents

Step 1:
Download bla

Select a Lis

Select a Doc

Create a New Package
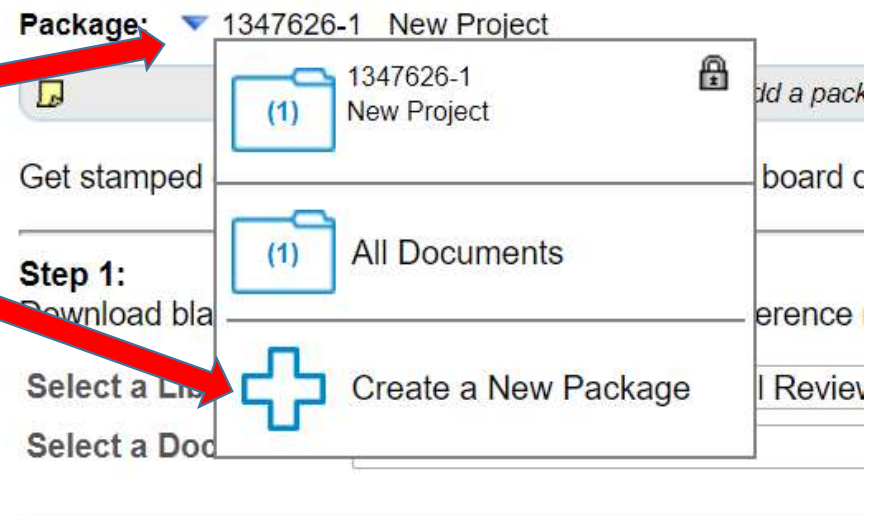
Notification

- 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
  - Anoush McNamee
  - amcnamee@barry.edu
  - 305-899-3020
- IRB Chair: irbchair@barry.edu