

# VA Innovation Research Review System (VAIRRS)

Monthly Webinar

May 24, 2022











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- ✓ Please use the Q&A feature to submit questions.
  - Please do not use Chat to send in questions.
  - Be sure to send questions to "All panelists".
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  - Event Password: ORPP&EWebinars1







## **Contents**



- Welcome
- Announcements
- IRBNet Basics for Investigators

  Presented by Angela Foster, Program Manager, Enterprise Research Data Systems, Office of Research

  Protections, Policy, and Education (ORPP&E)



### **IMPORTANT ANNOUNCEMENTS**



#### **Project Cover Sheet Wizard**



Project Cover Sheets must be completed for <u>all</u> new study applications, when changes to a study require prior PCS submissions to be updated (e.g., change to PI), and for all <u>active studies transitioned</u> to IRBNet.

#### **IRB Information Sheet Wizard**



IRB Information Sheets must be completed for <u>all</u> new study applications submitted to an IRB (internal or external) and for all <u>active human subjects research</u> transitioned to IRBNet.

Subscribe to the VAIRRS Newsletter and VAIRRS Program Update to keep up with important announcements and program updates. <a href="https://www.research.va.gov/programs/orppe/vairrs/default.cfm">https://www.research.va.gov/programs/orppe/vairrs/default.cfm</a>









Angela Foster
Program Manager, Enterprise Research Data Systems

Office of Research Protections, Policy, and Education (ORPP&E)

Tuesday, May 24, 2022











- □ Accessing and Enrolling in IRBNet
- ☐ User Profile
- ☐ My Projects
- □ Project vs Package
- ☐ Creating a New Project/Package
- □ Revising a Package/Response Package







#### What is VAIRRS?

- VA Innovation Research Review System
  - IRBNet: <a href="https://gov.irbnet.org/release/index.html">https://gov.irbnet.org/release/index.html</a>
  - VAIRRS Website: <a href="https://www.research.va.gov/programs/orppe/vairrs/default.cfm">https://www.research.va.gov/programs/orppe/vairrs/default.cfm</a>
  - VAIRRS SharePoint Portal: <a href="https://dvagov.sharepoint.com/sites/VHAORPPE/VAIRRS">https://dvagov.sharepoint.com/sites/VHAORPPE/VAIRRS</a>
  - Power BI Dashboards







VAIRRS
VA Innovation and
Research Review System

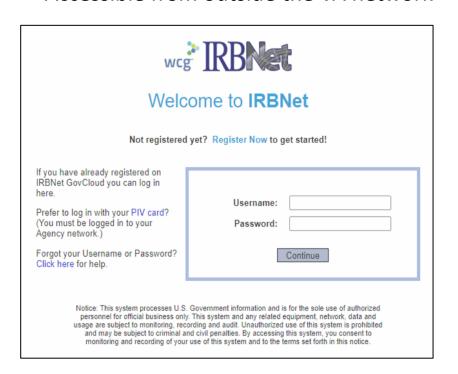
□ Accessing and Enrolling in IRBNet







- Website address: gov.irbnet.org
  - PIV log-in
  - Accessible from outside the VA network









#### **Enrolling in IRBNet**



 All VA facilities are listed in affiliation section First Name: Last Name: **Email Address:** Verify Email Address: wcg IRBNet Phone Number: Your Research Institution or Alaska VA Health Care System, Anchorage, AK Organization: Welcome to IRBNet If you do not see your organization listed you may add a new organization. Not registered yet? Register Now to get started! Choose a Username and Password for your new account. You can use this Username and Password to access all IRBNet GovCloud services. If you have already registered on Username: IRBNet GovCloud you can log in Password: Username: Prefer to log in with your PIV card? Verify Password: (You must be logged in to your Password: Agency network.) Forgot your Username or Password? Continue Continue Cancel Click here for help. Notice: This system processes U.S. Government information and is for the sole use of authorized personnel for official business only. This system and any related equipment, network, data and usage are subject to monitoring, recording and audit. Unauthorized use of this system is prohibited and may be subject to criminal and civil penalties. By accessing this system, you consent to monitoring and recording of your use of this system and to the terms set forth in this notice.







☑Accessing and Enrolling in IRBNet

☐ User Profile





#### User Profile - Add Affiliations



#### Manage Your User Profile

You may access this page at any time to update your account information, change your password, manage your affiliations and external accounts, and manage your Training & Credentials records.

#### User Account Information and Password

Username vacirblocal2

First Name Elizabeth

Last Name Researcher

#### Affiliations

Note that if you add or update an affiliation you will be sent an activation email to your contact email address. You must click on the link in the activation email to confirm your changes.

Add an Additional Affiliation



#### Researcher at Localton VA Medical Center, Localton, LA (6011)

Email vacirblocal2@mailinator.com

#### 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.

Add an External Account

There are currently no external accounts in your profile.

#### **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

IRBNet supports multiple VAMC affiliations

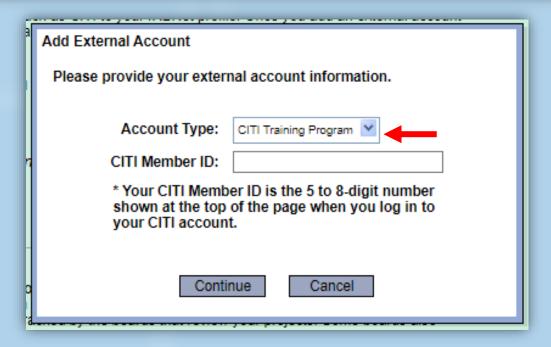




#### User Profile - External Accounts



# 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

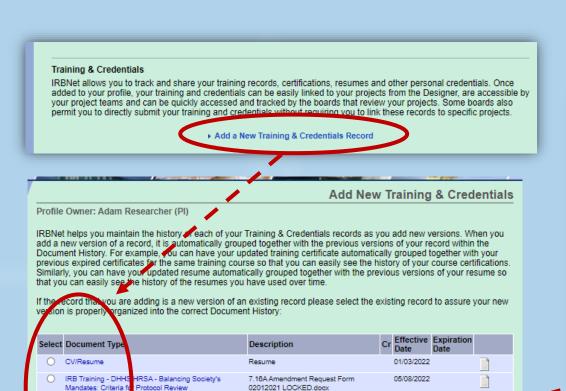




VAIRRS SharePoint – Researcher Energizers

#### User Profile - Training and Credentials





How to open ERDSP form template.docx

20210219 eCMS v7.02d Information Sheet (AAMS KB).docx

Continue

Г		Show all Versio				ersions					
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	22367.1	IRB Training - DHHS HRSA - Balancing Society's Mandates: Criteria for Protocol Review	7.16A Amendment Request Form 02012021 LOCKED.docx		05/08/2022		05/08/2022 09:52 AM	Accepted	1	Submit	<b>¾</b> ☑
ı	22369.1	▼ IRB Training - OHRP - General Informed Consent Requirements	How to open ERDSP form template.docx		05/08/2022	(	05/09/2022 05:34 PM	Not Submitted		Submit	
	22366.1	IRB Training - OHRP - General Informed Consent Requirements	How to open EBDS form template.docx		05/08/2022		05/08/2022 09:37 AM	Accepted		Submit	<b>¾</b> ₩
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You must select

'Submit' to notify the administrator!



O IRB Training - OHR

Requirements
Other

None of these

General Informed Consent





☑Accessing and Enrolling in IRBNet

**☑**User Profile

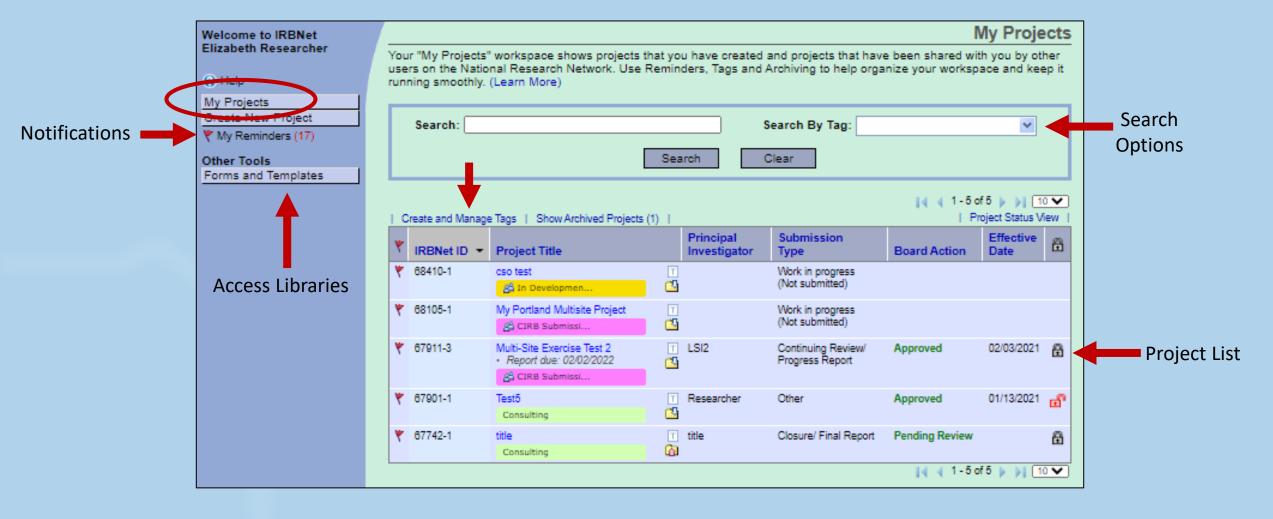
☐ My Projects





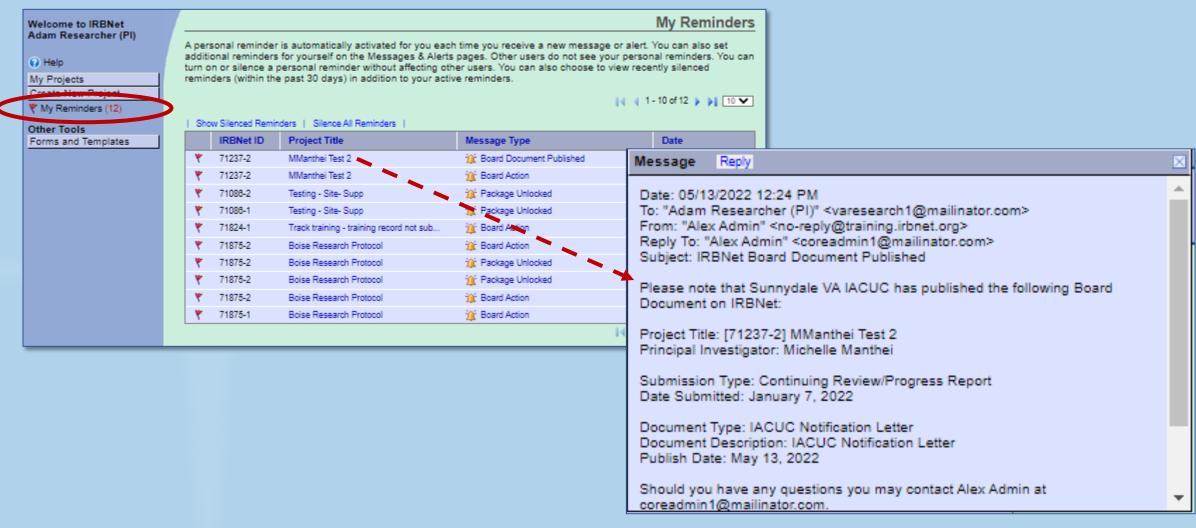
#### My Projects





#### My Projects - Notifications and Reminders

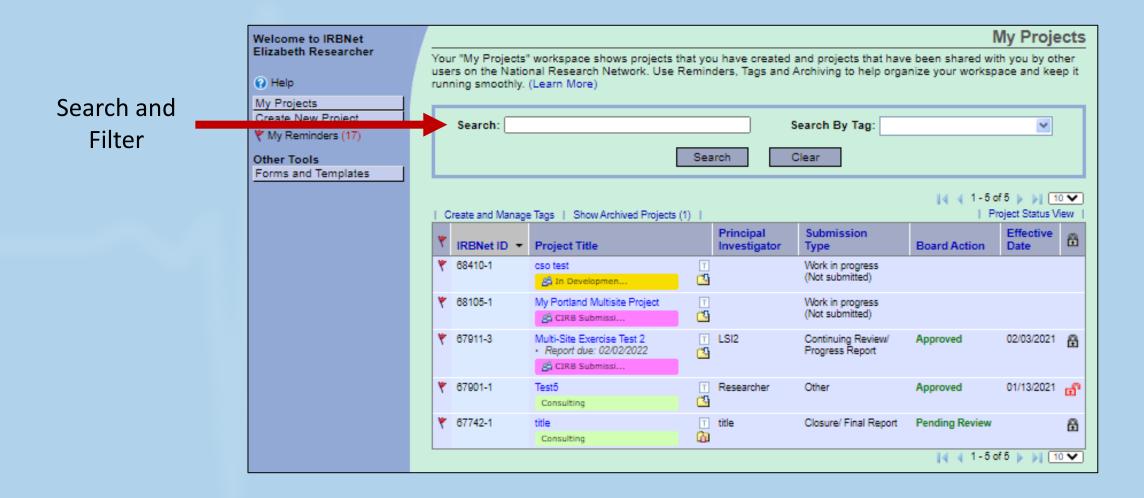






#### My Projects - Search Options

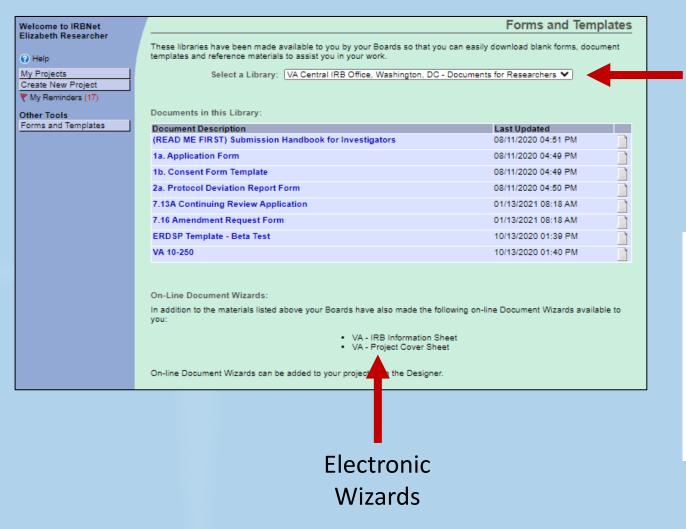




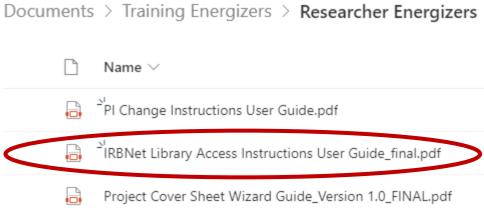


#### My Projects - Forms and Templates





Select the correct library





## My Projects - Tags



	Welcome to IRBNet	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)							
	Elizabeth Researcher								
	My Projects Create New Project  My Reminders (17)  Other Tools	Search:			Search By Tag:		~		
	Forms and Templates	Create and Man	age Tags   Show Archived Projects				f 5     10 V		
Use Tags to		♥ IRBNet ID	▼ Project Title	Principal Investigator	Submission Type	Board Action	Effective Date		
organize your		₹ 68410-1	cso test		Work in progress (Not submitted)				
workspace		<b>*</b> 68105-1	My Portland Multisite Project	T C	Work in progress (Not submitted)				
		<b>₹</b> 67911-3	Multi-Site Exercise Test 2 • Report due: 02/02/2022  gå CIRB Submissi	⊤ LSI2	Continuing Review/ Progress Report	Approved	02/03/2021 🚡		
		<b>♥</b> 67901-1	Test5 Consulting	Researcher	Other	Approved	01/13/2021 🚮		
		<b>♥</b> 87742-1	title Consulting	⊤ title	Closure/ Final Report	Pending Review	≅		
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**△**Accessing and Enrolling in IRBNet

**☑**User Profile

My Projects

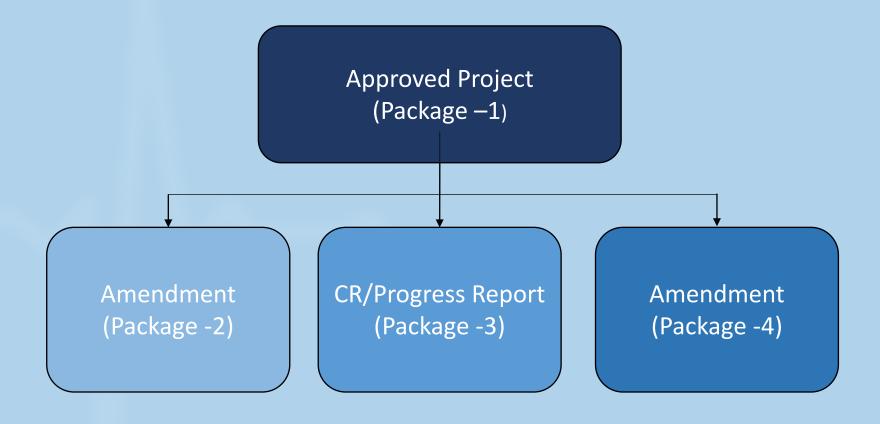
☐ Project vs Package



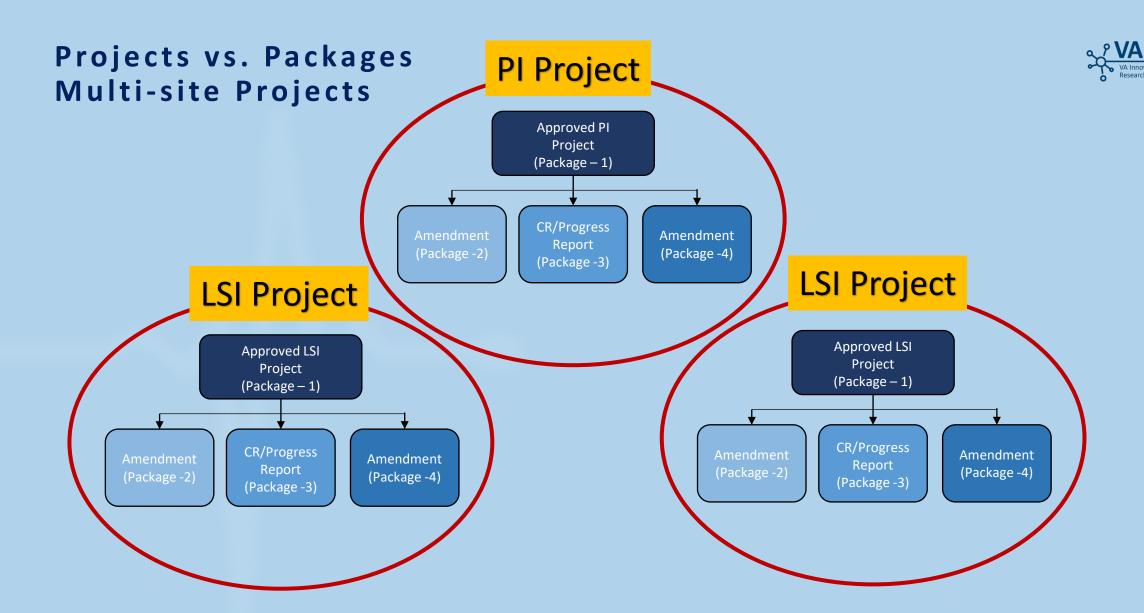


### Projects vs. Packages













## Projects vs. Packages



When submitting a	Create a new			
New Study Application	Project			
New Study Action	Package			
Revised submission	Package (per local guidance)			
New LSI Application	New project created by PI site			

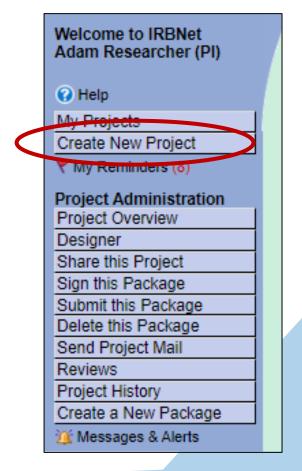


- ✓ Accessing and Enrolling in IRBNet
- **☑**User Profile
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- ☐ Creating a New Project/Package

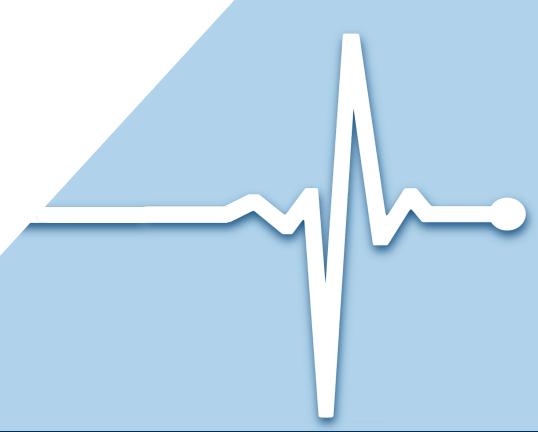


#### **Creating a New Project**

Select <u>Create New Project</u> to create a new study application











## **New Project Details**

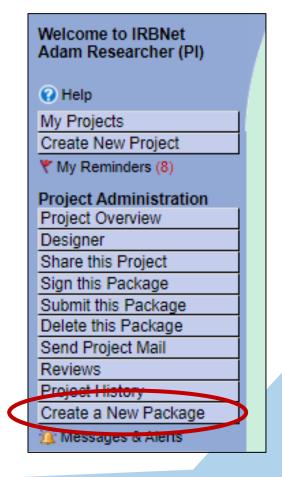


	Project Information						
Create a New Project							
To create a new project, first provide the ba project documentation and share the project	sic project information below. Once your project is created you may attach at with other users.						
Research Institution: *	Sunnydale VA, Washington V						
Title: *							
Local Principal Investigator:	First Name:*  Last Name:*  Degree(s):						
Keywords:							
Sponsor:							
Internal Reference Number:	You may specify an internal account number, billing identifier or reference number for this project.  Continue  Cancel						
* required fields							





Select <u>Create a New Package</u> to create a **new study action** within an IRBNet project



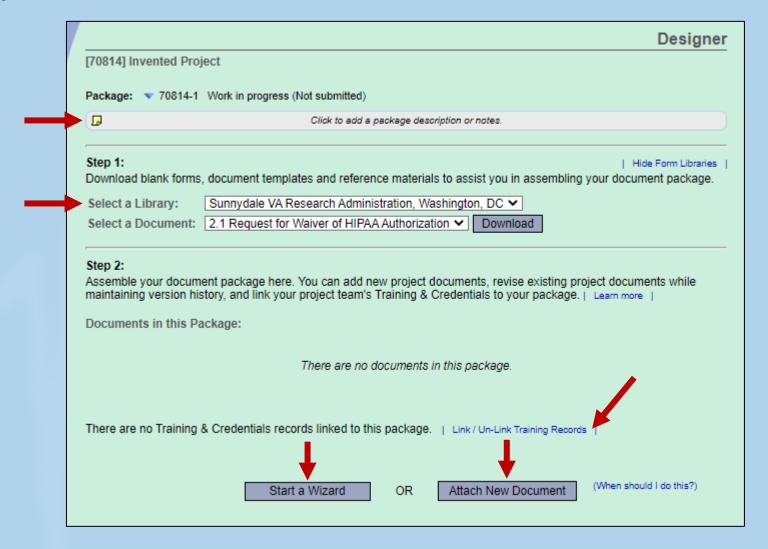






#### Designer









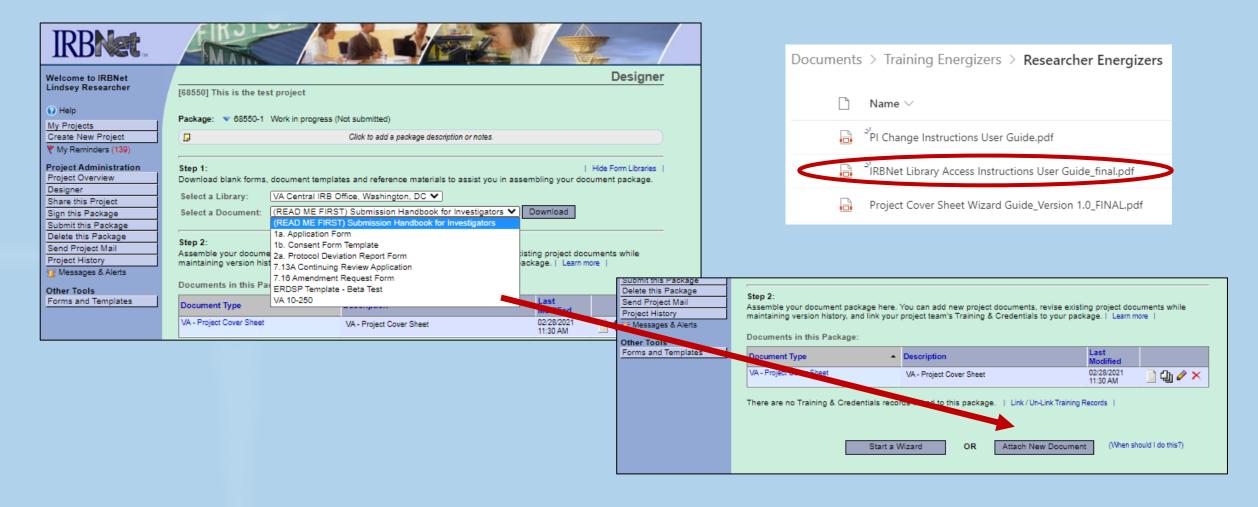
#### Completing and Submitting a Package

- Step 1: Upload completed study documents
- Step 2: Complete applicable wizards
- Step 3: Link Training Records
- Step 4: Share Package with study team members
- Step 5: Sign Package
- Step 6: Submit Package



#### **Step 1: Upload Study Documents**

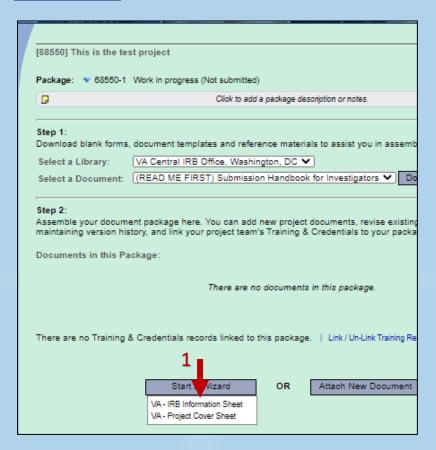


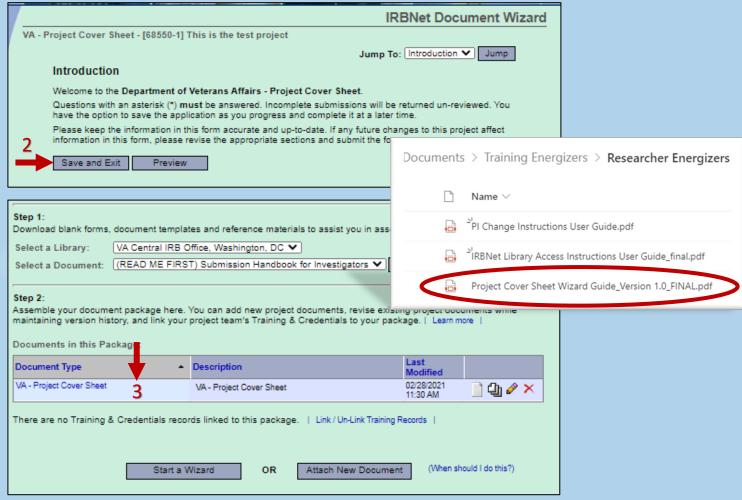




#### Step 2: Complete Applicable Wizards











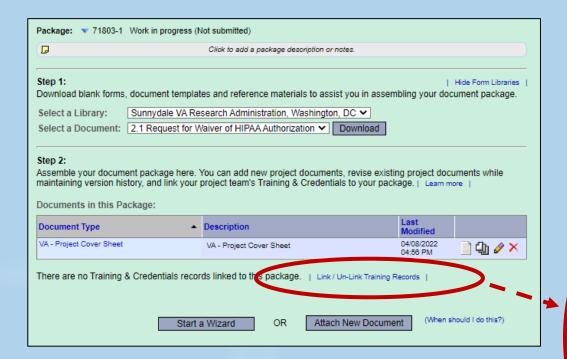
## **Step 2: Document Upload Complete**

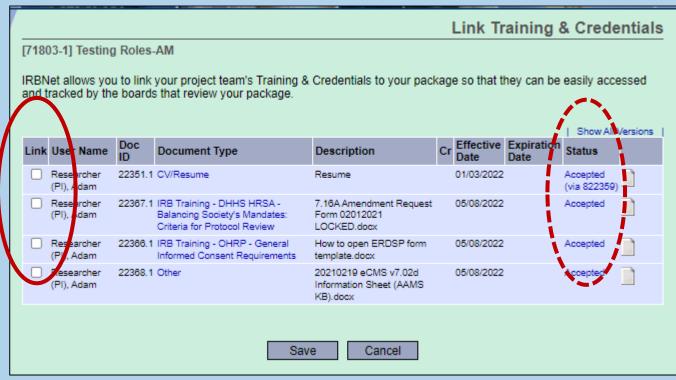


Package: ▼ 71875-2 New Project	A	Locked - Revi	sions Comple	te   View History					
Click to add a package description or notes.									
Get stamped documents, approval letters	stamped documents, approval letters and other board documents, and track reviews for this package: Review details.								
Need Forms? Show Form Libraries									
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						
Application Form	Boise Initial Review Application Revise	tion Revised 2 04/24/2022 10:03 AM							
VA - Project Cover Sheet	VA - Project Cover Sheet		04/24/2022 10:02 AM	ight 🔑 🗙					
There are no Training & Credentials records linked to this package.   View All Links    Start a Wizard OR Attach New Document (When should I do this?)									

#### **Step 3: Link Training Records**



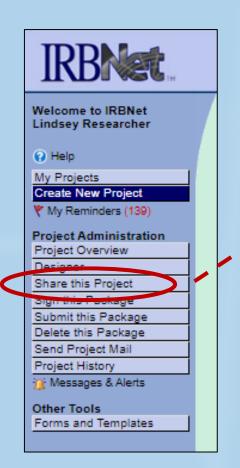




#### Step 4: Share Package



**Share Project** 



[68550-1] This is the test project

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 Spons is 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: Ise 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: ansfer your ownership of this project to another user. In doing so you will relinquish all access to this
  project to the designated user will be granted Full access.
- ☐ Share package with study team members
- ☐ Multi-site share with local site/non-lead site investigator
- ☐ <u>Transfer</u> ownership of project to another investigator

#### Step 5: Sign Package



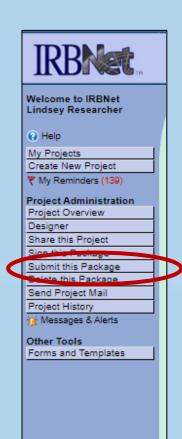


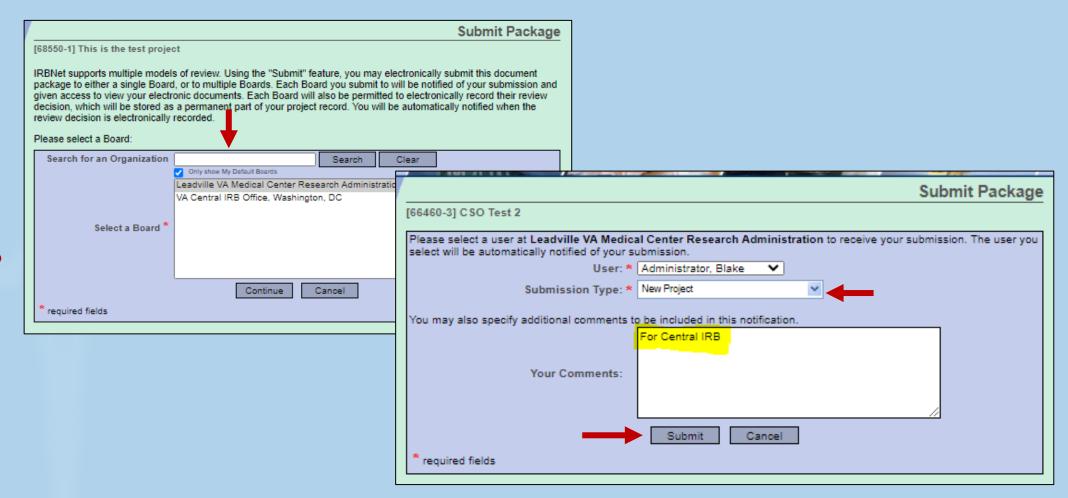




#### **Step 6**: Submit Package









# **IRBNet Basics for Investigators**



- ✓ Accessing and Enrolling in IRBNet
- **☑**User Profile
- **☑**My Projects
- ☑Project vs Package
- ☑Creating a New Project/Package
- □ Revising a Package/Response Package





#### Revised and Response Packages

- All packages are 'locked' upon submission to preserve the audit trail
- Package may be 'unlocked' by administrator and returned to study team if required forms are missing
- Package may receive a board action of 'Information Required' or 'Modifications Required' if additional information or modifications are necessary. A response package is used to respond to the request for more information or modifications

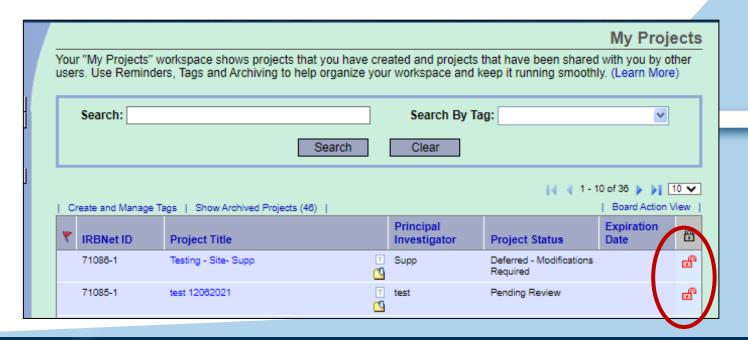






#### Unlocked Package

- 1. Reference unlock message for details and instructions from administrator
- 2. Follow instructions to revise documents or upload missing documents to package
- 3. Mark Revisions Complete

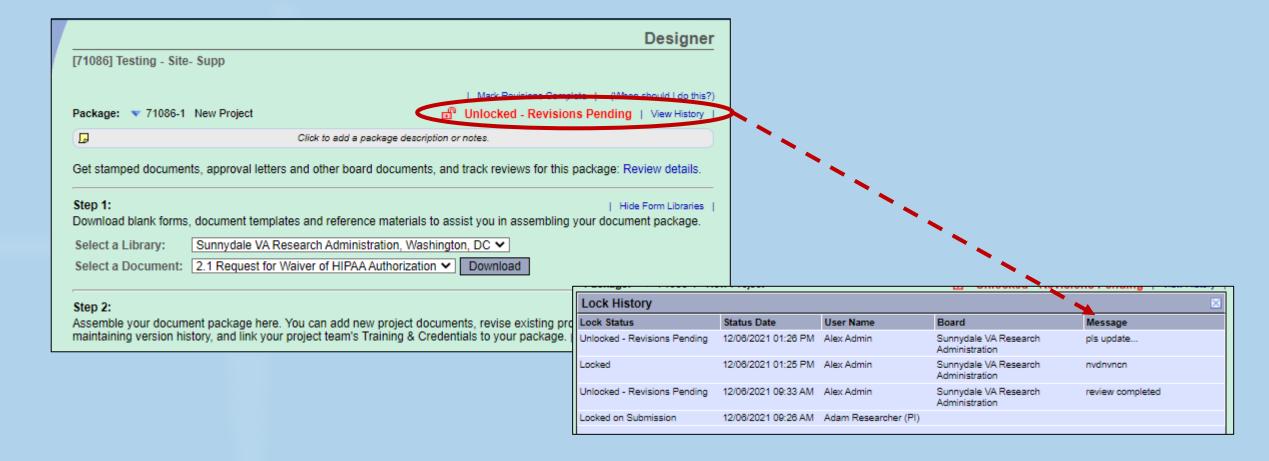






#### Revising Unlocked Package





## Revising Unlocked Package



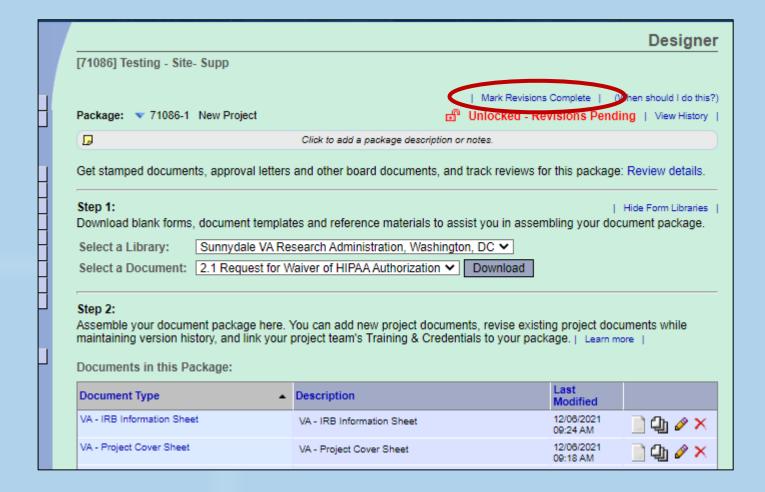
			Designe
[71086] Testing - Site- Supp			
	1	Mark Revisions Complete	(When should I do this
Package: v 71086-2 Other	ლმ სი	locked - Revisions Pen	ding   View History
D .	Click to add a package description or not	es.	
Get stamped documents, approva	al letters and other board documents, and tra-	ck reviews for this packag	e: Review details.
		Need Forms	? Show Form Libraries
		Need Forms:	
Assemble your document package	e here. You can add new project documents	,	oumants while
	e here. You can add new project documents, nk your project team's Training & Credentials	revise existing project do	
maintaining version history, and lir	e here. You can add new project documents, nk your project team's Training & Credentials	revise existing project do	
		revise existing project do to your package.   Learn	
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maintaining version history, and lir Documents in this Package:  Document Type  Protocol  VA - Project Cover Sheet	Description  Protocol version 2.0  VA - Project Cover Sheet  als records linked to this package.   Link/Un	revise existing project does to your package.   Learn of the Last Modified   05/09/2022   05:59 PM   05/22/2022   02:57 PM   0	more

Select to replace an uploaded document or edit a wizard.

Select X to delete document from package.

#### Revising Unlocked Package





You must select
"Mark Revisions Complete"
to notify the administrator!



#### Response Package

- Reference board document for details on additional required information or modifications
- 2. Create new package within project
- 3. Follow instructions to update documents or upload additional information to package
- 4. Submit the new package

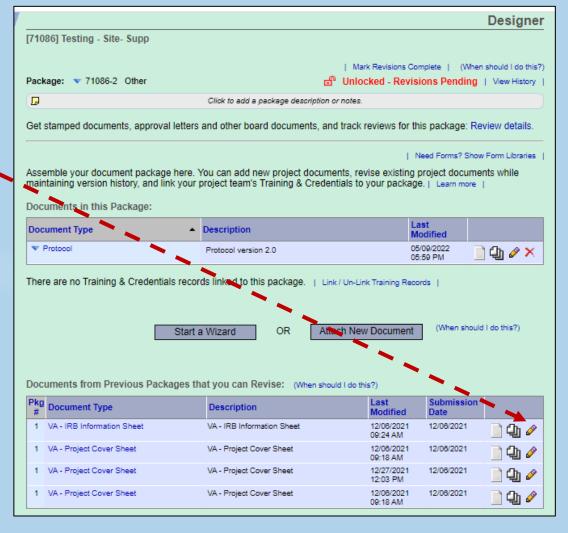




#### Response Package Documents



Updates made to documents from previous packages (using pencil icon) are tracked using version control.



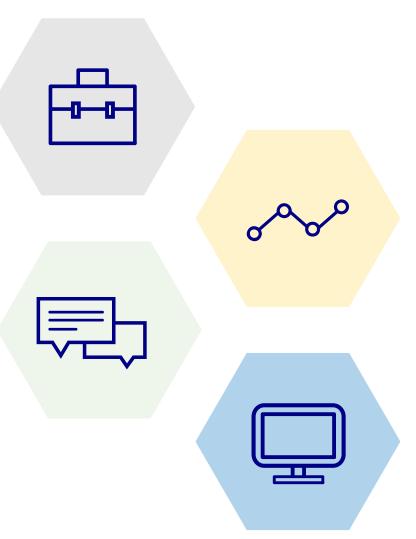




#### **VAIRRS** Resources

VAIRRS
VA Innovation and
Research Review System

- Recorded training videos are available on the VAIRRS SharePoint portal. The training videos are categorized by role (e.g., researcher, administrator, committee member perspectives).
- Training energizers are available on the <u>VAIRRS SharePoint portal</u>. The
  energizers, which serve as guides for the end-user, are also categorized by
  role.
- Answers to Frequently Asked Questions (FAQs) about VAIRRS are available on the VAIRRS website.
- The VAIRRS Newsletter is published bi-monthly. A VAIRRS Program Update is published on the alternative months. Any user can subscribe to the publications. Subscribe <a href="here">here</a>:
- Contact the VAIRRS Support Team at <u>VAIRRS@VA.gov</u>



# QUESTIONS & COMMENTS



## **Contacts**

#### **VAIRRS Support Team**

VAIRRS@va.gov



Questions related to VAIRRS program, resources, training, and VA processes

#### **IRBNet**

govsupport@irbnet.org



Technical assistance, account issues

# References

VAIRRS Website: https://www.research.va.gov/programs/orppe/vairrs/default.cfm

VAIRRS SharePoint: <a href="https://dvagov.sharepoint.com/sites/VHAORPPE/VAIRRS">https://dvagov.sharepoint.com/sites/VHAORPPE/VAIRRS</a>

VAIRRS Webinar Archive: <a href="https://www.research.va.gov/programs/orppe/education/webinars/archives.cfm">https://www.research.va.gov/programs/orppe/education/webinars/archives.cfm</a>

VAIRRS Support Team: <u>VAIRRS@va.gov</u>

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