Atlanta VA Submission Process for New Projects

IRBNet and Emory IRB Studies

Goals of this Presentation

- Provide Resources
- Orientation to IRBNet
- Highlight Emory eIRB Submissions
- Clarify Questions

What is IRBNet

Used for ERDSP (Enterprise Research Data Security Plan)

Used for PO/ISSO Pre-Review

Used for VA Submission to R&D Committee

Used for Amendments for Approved Studies when…

- PI Changes
- Risk/Benefit Ratio Changes
- Amendments to Data Repository

Things to Note

- IRBNet=VAIRRS
- WCG IRB = WIRB
- IRBNet is used by some IRBs (WIRB, cIRB), but is a separate submission system for others (Emory eIRB, NCI, Advarra, etc)
- Don’t save local copies of document templates, always download from a library

Available Resources

IRBNet/VAIRRS Guidance

https://www.atlanta.va.gov/services/research/VAIRRS_IRBNet_Guidance.asp

VAIRRS SharePoint

https://dvagov.sharepoint.com/sites/VHAORPPE/VAIRRS

Atlanta VA Health Care System

- Home
- Patients & Visitors
- Become a Patient
- Appointments
- Locations & Directions
- Compare your VA Facility
- Health Care Services
- Health Care Providers
- News & Events
- Jobs & Careers
- About Us
- Contact Us
- Volunteer or Donate
- Operating Status

Veterans Crisis Line 1-800-273-8255 PRESS 1

My healthevet — My Health, My Care: 24/7 Online Access to VA

Research - IRBNet/VAIRRS Guidance

The VA Innovation and Research Review System (VAIRRS) is the VA's enterprise instance of IRBNet. VAIRRS will be used by all VA medical centers with research programs and will provide an enterprise platform to support the management of research oversight committees. Locally, the research office and study teams at the Atlanta VA will use the IRBNet system to submit projects for review through research committees and facility review processes and then manage the studies and study documents throughout the life of the study. Below you will find contact information and guidance for use of this new system.

Login to IRBNet: https://gov.irbnet.org/release/index.html

Local IRBNet Administrators:

- R&D/General Use - Kallie Medbery (Mary.Medbery@va.gov)
- IRB/Human Research Review - Jen Whelan (Jennifer.Whelan@va.gov)
- IACUC/Animal Research - Derek Key (Derek.Key@va.gov)
- SRS/Basic Science Research - Jon Fidler (Jonathan.Fidler@va.gov)

Quick Start Guides for Submissions:

- Preparing a Human Research IRB & RDC Review Package
- Preparing a Non-Human Research (R&D Only) RDC Review Package
- Editing an Unlocked Package
- Submitting an R&D Renewal Form or Close Out for R&D Review
- Completing the IRBNet Wizard Project - **See 08/09/21 Announcement in Table Below**

Form Completion Guidance:

- Project Cover Sheet Wizard
- IRB Information Sheet Wizard
- ERDSP Guide

Energizers Provided by IRBNet:

- IRBNet Training Energizer - New User Registration
- IRBNet Training Energizer - Researcher Part 1
- IRBNet Training Energizer - Researcher Part 2
- IRBNet Training Energizer - Committee Member

USER PROFILE LOGOUT

IRBNet

Welcome to IRBNet
Clayton Carruth

Help
My Projects
Create New Project
My Reminders (70)

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. Use Reminders, Tags and Archiving to help organize your workspace and keep it running smoothly. (Learn More)

Search: **Search By Tag:**

Search Clear

Tour of IRBNet

| Create and Manage Tags | Show Archived Projects (0) | Project Status View |

IRBNet ID	Project Title	Principal Investigator	Submission Type	Submission Status	Effective Date
1647653-1	Applications of Tissue Adhesives in the ...	Blalock	Work in progress (Not submitted)		
1647169-1	Clayton Test	Carruth	Work in progress (Not submitted)		
1634834-1	Targeted intensive case management of Ve...	Rauch	New Project	Modifications Required	09/09/2021
1613091-5	CSP 596, Optimal Treatment for Recurrent... • *Report due: 06/02/2022*	Moanna	Protocol Deviation/ Violation	Pending Review	
1608374-1	VA Diabetes Epidemiology II DATA	Phillips	New Project	Exempt	04/29/2021

IRBNet

Project Overview

[1613091-2] CSP 596, Optimal Treatment for Recurrent Clostridium Difficile Infection

You have Full access to this project. (Edit)	
Research Institution	Atlanta VA Health Care System, Decatur, GA
Title	CSP 596, Optimal Treatment for Recurrent Clostridium Difficile Infection
Principal Investigator	Moanna, Abeer
Internal Reference Number	15-03Atlanta, GA
Multi-Site	Non-Lead Site

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

Project Status as of: 09/10/2021

Reviewing Board	Board Ref #	Initial Approval Date	Project Status	Expiration Date
VA Central IRB Administration, Washington, DC	15-03 Atlanta			
VA Central IRB Panel 2, Washington, DC • Report due: 06/02/2022	15-03 Atlanta, GA	09/02/2015	Active	06/02/2022

Package 1613091-2 is: Locked

Package 2 of 5 | Jump |

Submitted To	Submission Date	Submission Type	Board Ref #	Board Action	Effective Date	

Project Overview

My Projects

Create New Project

My Reminders (75)

Project Administration

Project Overview

Designer

Share this Project

Sign this Package

Submit this Package

Delete this Package

Send Project Mail

Reviews

Project History

Project Overview

[1586163-22] A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety o...

You have Full access to this project. (Edit)	
Research Institution	Atlanta VA Health Care System, Decatur, GA
Title	A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-
Principal Investigator	Moanna, Abeer

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

Project Status as of: 09/20/2021

Reviewing Board	Board Ref #	Initial Approval Date	Project Status	Expiration Date
WCG IRB (formerly WIRB), Puyallup, WA • Report due: 08/31/2022	44970121	09/29/2020	Active	08/31/2022

Package 1586163-22 is: Locked

Package 22 of 22 | Jump |

Submitted To	Submission Date	Submission Type	Board Ref #	Board Action	Effective Date	
WCG IRB (formerly WIRB), Puyallup, WA	09/10/2021	Amendment/Modification	44970121	Approved	09/13/2021	| Review Details |

Shared with the following users:

User	Organization	Access Type
Carruth, Clayton	Atlanta VA Health Care System, Decatur, GA	Full
Moanna, Abeer	Atlanta VA Health Care System, Decatur, GA	Full
Tanukonda, Sridhar	Atlanta VA Health Care System, Decatur, GA	Full
Whelan, Jennifer	Atlanta VA Health Care System, Decatur, GA	Read

Designer

My Projects

Create New Project

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Delete this Package

Send Project Mail

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Create a New Package

Messages & Alerts (39)

Designer

[1586163] A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of A...

Package: 1586163-27 Other **Locked** | View History |

Package 24 - PA6 Study Hub change

Get 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	
Other	PA6 Study Hub change.pdf	10/25/2021 02:49 PM	

There are no Training & Credentials records linked to this package.

Start a Wizard **OR** Attach New Document (When should I do this?)

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

Pkg #	Document Type	Description	Last Modified	Submission Date	
26	Letter	Phone number update letter.docx	10/19/2021 09:28 AM	10/19/2021	
25	Amendment/Modification	Ensemble COV3001 Protocol Amendement 6_tracked changes.docx	10/05/2021 12:03 PM	10/05/2021	
25	Amendment/Modification	Ensemble COV3001 - Protocol Amendment 6.pdf	10/05/2021 12:03 PM	10/05/2021	
25	Consent Form	Consent Form V10.0 8Sep2021-eg	10/05/2021	10/05/2021	

Share this Project

My Projects

Create New Project

My Reminders (75)

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Messages & Alerts (39)

Share Project

[1586163-22] A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety o...

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.

User Name	Organization	Access Type
Sridhar Tanukonda	Atlanta VA Health Care System, Decatur, GA	Full
Abeer Moanna	Atlanta VA Health Care System, Decatur, GA	Full
Jennifer Whelan	Atlanta VA Health Care System, Decatur, GA	Read

Sign this Package

My Projects

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Messages & Alerts (39)

Sign Package

[1586163-22] A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety o…

I Clayton Carruth, 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 been signed by:

Date	Signed By	Role	
09/10/2021 02:37 PM	Sridhar Tanukonda	Research Coordinator	Details

Submit this Package

My Projects

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[1586163-22] A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety o...

IRBNet supports multiple models of review. Using the "Submit" feature, you may electronically submit this document package to either a single Board, or to multiple Boards. Each Board you submit to will be notified of your submission and given access to view your electronic documents. Each Board will also be permitted to electronically record their review decision, which will be stored as a permanent part of your project record. You will be automatically notified when the review decision is electronically recorded.

This document package has been submitted to:

- WCG IRB (formerly WIRB), Puyallup, WA

Please select a Board:

Search for an Organization [ ] Search Clear

☑ Only show My Default Boards

Select a Board *

Atlanta VA Health Care System Research Administration, Decatur, GA

VA Central IRB Administration, Washington, DC

Continue Cancel

* required fields

My Projects

Create New Project

My Reminders (75)

Project Administration

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Share this Project

Sign this Package

Submit this Package

Delete this Package

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Create a New Package

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Delete this Package

WARNING: Deleted packages cannot be recovered.

Delete Cancel

My Projects

Create New Project

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Delete this Package

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Send Project Mail

New Project Message

[1613091-6] CSP 596, Optimal Treatment for Recurrent Clostridium Difficile Infection

Use this page to send communications to the Project Team or to the Board Contacts for any submitted package. Your message will also be automatically posted to the Project Messages & Alerts. Messages sent from this page become part of the project record and can be viewed by the Project Team and other users who have been granted access to this project as well as by Committee Members and Administrators that review this project.

Project Team:

| Select All Project Owners Only | Select All | Un-Select All |

User	User Organization	Send Mail
Carruth, Clayton	Atlanta VA Health Care System, Decatur, GA	☐
Gerding, Dale	Edward Hines VA Hospital, Hines, IL	☐
Jannah, Khadijah	Atlanta VA Health Care System, Decatur, GA	☐
Johnson, Michelle	Edward Hines VA Hospital, Hines, IL	☐
Johnson, Neil	Edward Hines VA Hospital, Hines, IL	☐

Board Contacts:

| Select All | Un-Select All |

Pkg #	Pkg Type	Board	Contact Name	Send Mail
5	Protocol Deviation/Violation	VA Central IRB Administration, Washington, D C	Aulik, Erica	☐
5	Protocol Deviation/Violation	VA Central IRB Administration, Washington, D C	Clarke, Kendra	☐
5	Protocol Deviation/Violation	VA Central IRB Administration, Washington, D C	Eckart, Mary	☐
5	Protocol Deviation/Violation	VA Central IRB Administration, Washington, D C	Foster, Angela	☐

Subject * IRBNet message from Clayton Carruth

Message *

Re: [1613091-6] CSP 596, Optimal Treatment for Recurrent Clostridium Difficile Infection

Please login to IRBNet to review this project.

Regards,
Clayton Carruth

Send Cancel

* required fields

My Projects

Create New Project

My Reminders (75)

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Sign this Package

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Messages & Alerts (39)

Reviews

Reviews

[1613091-6] CSP 596, Optimal Treatment for Recurrent Clostridium Difficile Infection

VA Central IRB Administration, Washington, DC

Reviews:

Pkg #	Submission Date	Submission Type	Agenda	Review Type	Board Action	Effective Date	Project Status	Expiration Date
5	09/09/2021	Protocol Deviation/Violation	12/31/2021 01:00 PM	Administrative Review	Forwarded	09/10/2021		
4	09/02/2021	Protocol Deviation/Violation	12/31/2021 01:00 PM	Administrative Review	Forwarded	09/10/2021		
3	08/10/2021	Response/Follow-Up	12/31/2021 07:00 AM	Administrative Review	Forwarded	08/20/2021		
2	04/02/2021	Continuing Review/Progress Report	04/01/2021 12:00 PM	Administrative Review	Forwarded	04/06/2021		

Board Documents: | Show Current Versions Only |

Pkg #	Document Type	Description	Last Modified	View
2	Decision Letter	00. Amendment Decision Ltr.pdf	04/21/2021 01:43 PM	
2	Decision Letter	00. Initial Review Approval.pdf	04/21/2021 01:43 PM	
2	Other	01. Form 104_031620.pdf	04/21/2021 01:44 PM	
2	Other	02. Form 102_020420.pdf	04/21/2021 01:44 PM	
2	Other	03. ICF_032018.doc	04/21/2021 01:48 PM	
2	Other	04. Form 10-0493_030115.pdf	04/21/2021 01:48 PM	
2	Other	05. 1st Episode Flyer_010719.doc	04/21/2021 01:48 PM	
2	Other	06. Recruit Flyer_040315.doc	04/21/2021 01:49 PM	
2	Other	07. Recruit Letter_012717.docx	04/21/2021 01:49 PM	
2	Other	08. Phone Script_122017.doc	04/21/2021 01:49 PM	
2	Other	09. Palm Card.pptx	04/21/2021 01:49 PM	
2	Other	10. Form 10-9012.pdf	04/21/2021 01:49 PM	

Project History

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Project History

[1613091-6] CSP 596, Optimal Treatment for Recurrent Clostridium Difficile Infection

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Reviewing Board: All Boards

| Project Status View | Expand All |

Pkg #	Submission Type	Submission Date	Review Type	Board Action	Effective Date
6	Work in progress (Not submitted)				
5	Protocol Deviation/ Violation protocol deviation report as required by the the CSP Co...	09/10/2021	Full Committee Review	Pending Review	
4	Protocol Deviation/ Violation Protocol Deviation being report as requested by the CS...	09/10/2021	Full Committee Review	Pending Review	
3	Other	08/20/2021	Administrative Review	Acknowledged	08/21/2021
2	Continuing Review/ Progress Report 2021 Continuing Review	04/06/2021	Expedited Review	Approved	05/07/2021
1	Amendment/ Modification 2021 CR	01/22/2021	Expedited Review	Approved	01/29/2021

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Submission Process

Emory Projects

Approval Process for New Studies

Safety Subcommittees and PO/ISSO Pre-Review (IRBNet)

IRB Submission and Approval

VA R&DC (IRBNet) Submission and Approval

ACOS/R Letter

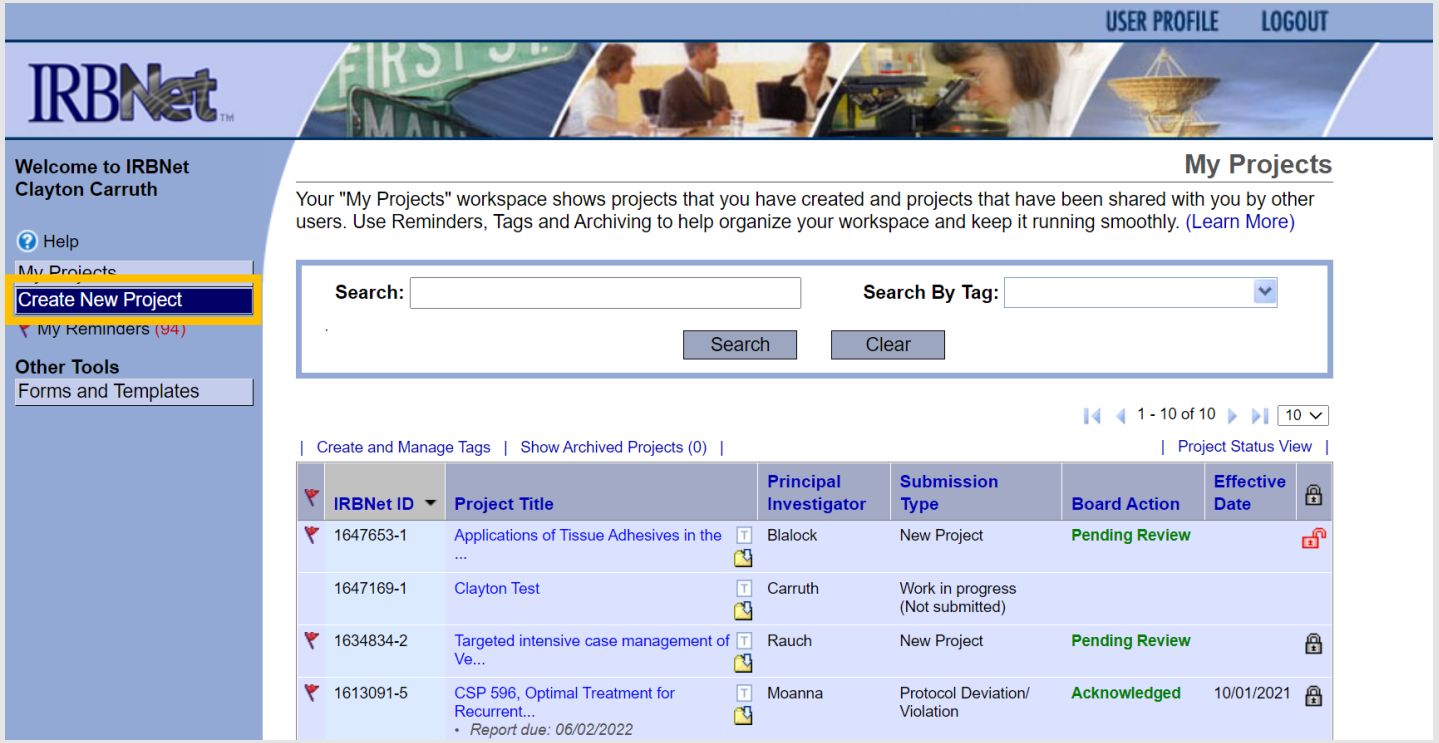
ENROLL

Submission Process

Emory Studies

1. **Create IRBNet Project**
2. **Download the Checklist for the IRB of Record**
3. **Create Emory IRB Application in eRIB – DO NOT SUBMIT**
4. **Add VA required forms to IRBNet package**
5. **Add Emory IRB forms to IRBNet package**
6. **Submit to IRBNet**
7. PO/ISSO Pre Review with edits as needed to Emory documents
8. **Submit to eIRB**
9. Emory IRB Review
10. Emory Approval
11. Project in IRBNet is unlocked by R&D
12. **IRBNet Project is updated with final documents from eIRB**
13. **Submit IRBNet Project**
14. PO/ISSO Post Review
15. R&D Committee Review

First Steps



1

Create your project in IRBNet

FCOI Form and FCOI Concurrence Form

Submission Process

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: Atlanta VA Health Care System Research Administration, Decatur, GA

Select a Document: FCOI Concurrence Form.pdf

Download

- FCOI Concurrence Form.pdf
- Financial Conflict of Interest Form.pdf
- IACUC & RDC Submission Checklist for Animal Studies.pdf
- IRB & RDC Submission Checklist for Human Studies (Advarra).pdf
- IRB & RDC Submission Checklist for Human Studies (Emory IRB).pdf
- IRB & RDC Submission Checklist for Human Studies (NCI IRB).pdf

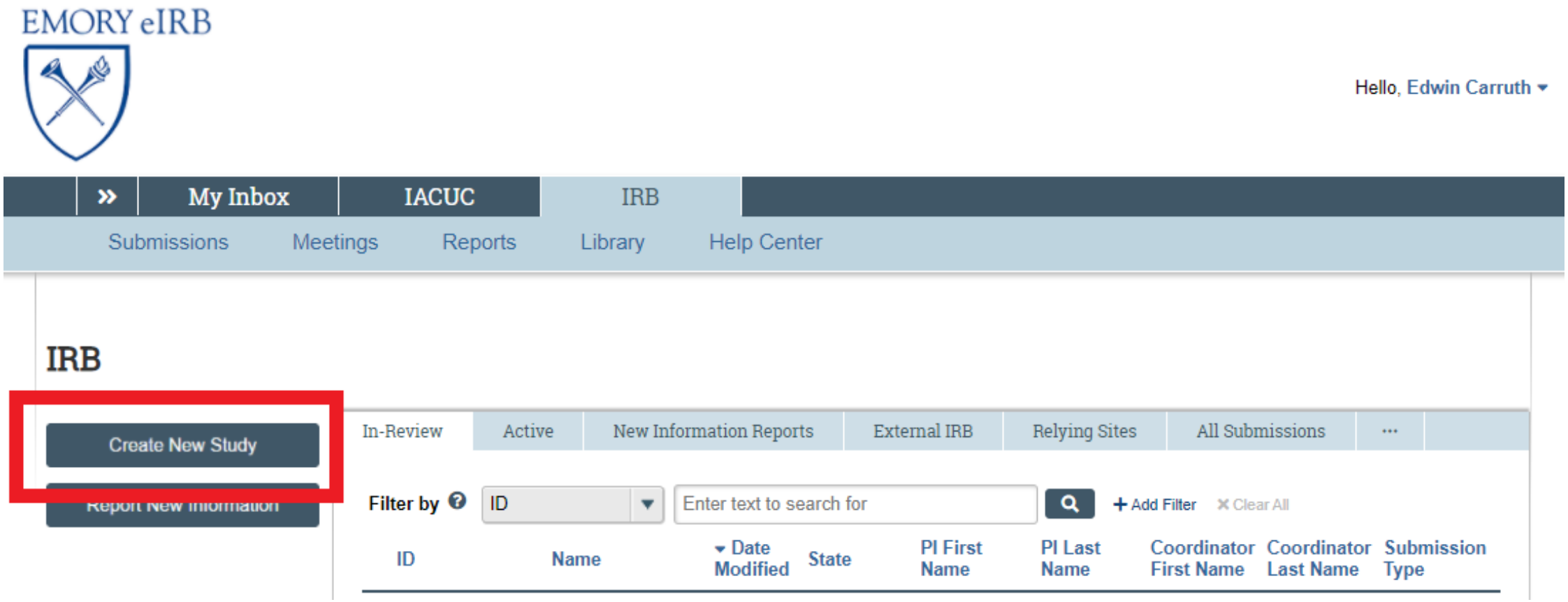
Step 2:

Assemble your docume documents while maintaining version hist n more |

Documents in this Pa

Create Emory IRB Application in eRIB

Submission Process



Submission Process

Add VA required forms to IRBNet package

Always Required For All Emory IRB Studies	
Document	**Where to Find it**
Signed *AVAHCS FCOI Concurrence Form*	You should receive a signed version of this form via email from Brandy.Wade@va.gov after FCOI review is complete for this upload.
Project Cover Sheet Wizard *make sure staff list from eIRB matches staff list on this wizard	Online smart form to be completed in IRBNet
IRB Information Sheet Wizard	Online smart form to be completed in IRBNet
SRS Determination Form	Download from IRBNet AVAHCS R&DC Library
Enterprise Research Data Security Plan (ERDSP) Template Version 2.0	Download from IRBNet AVAHCS R&DC Library
Privacy Checklist Form 10-250	Download from IRBNet AVAHCS R&DC Library
Collaborative Research Worksheet	Download from IRBNet AVAHCS R&DC Library
Assessment of Clinical Impact Form	http://faver.foundation/apps/clinical_impact/
As Applicable:	
Document	**Where to Find it**
If the study is funded upload: *Study Budget*	Study documents or sponsor
If planning to enroll non-veterans: *Non-Veteran Justification Form*	Download from IRBNet AVAHCS R&DC Library
If the study involves ANY drug use: *Assessment of Pharmacy Impact Form*	Download from IRBNet AVAHCS R&DC Library
If the Atlanta VA will be dispensing study drugs: *VA Form 10-9012*	Download from IRBNet AVAHCS R&DC Library
If the study involves Pregnant Subjects/Partners: *MCD Waiver for Pregnant Women/Partners*	Download from IRBNet AVAHCS R&DC Library
If the study involves children: *MCD Waiver for Children*	Download from IRBNet AVAHCS R&DC Library

Submission Process

Add Emory IRB forms to IRBNet package

Always Required For All Emory IRB Studies	
Document	**Where to Find it**
eIRB Study Application	Print to PDF from eIRB
Study Protocol	Pull from eIRB submission
As Applicable:	
Document	**Where to Find it**
If requesting a HIPAA and/or Consent Waiver: *HIPAA/Consent Waiver Request Worksheet*	Pull from eIRB submission
If consenting patients in person: *Draft Informed Consent Form* and stand-alone *HIPAA Authorization Form* OR *Combined ICF and HIPAA Document*	Pull from eIRB submission
If collecting verbal consent or using a script: *Verbal Consent Script*	Pull from eIRB submission
If recruiting: *Recruitment Materials (letters, flyers, etc)*	Pull from eIRB submission
If investigational drug or device: *IND or IDE Approval or Exemption Letter*	Pull from eIRB submission or Sponsor
If conducting a survey: *Survey Materials*	Pull from eIRB submission
If using study drug: *Investigational Brochure*	Pull from eIRB submission or Sponsor

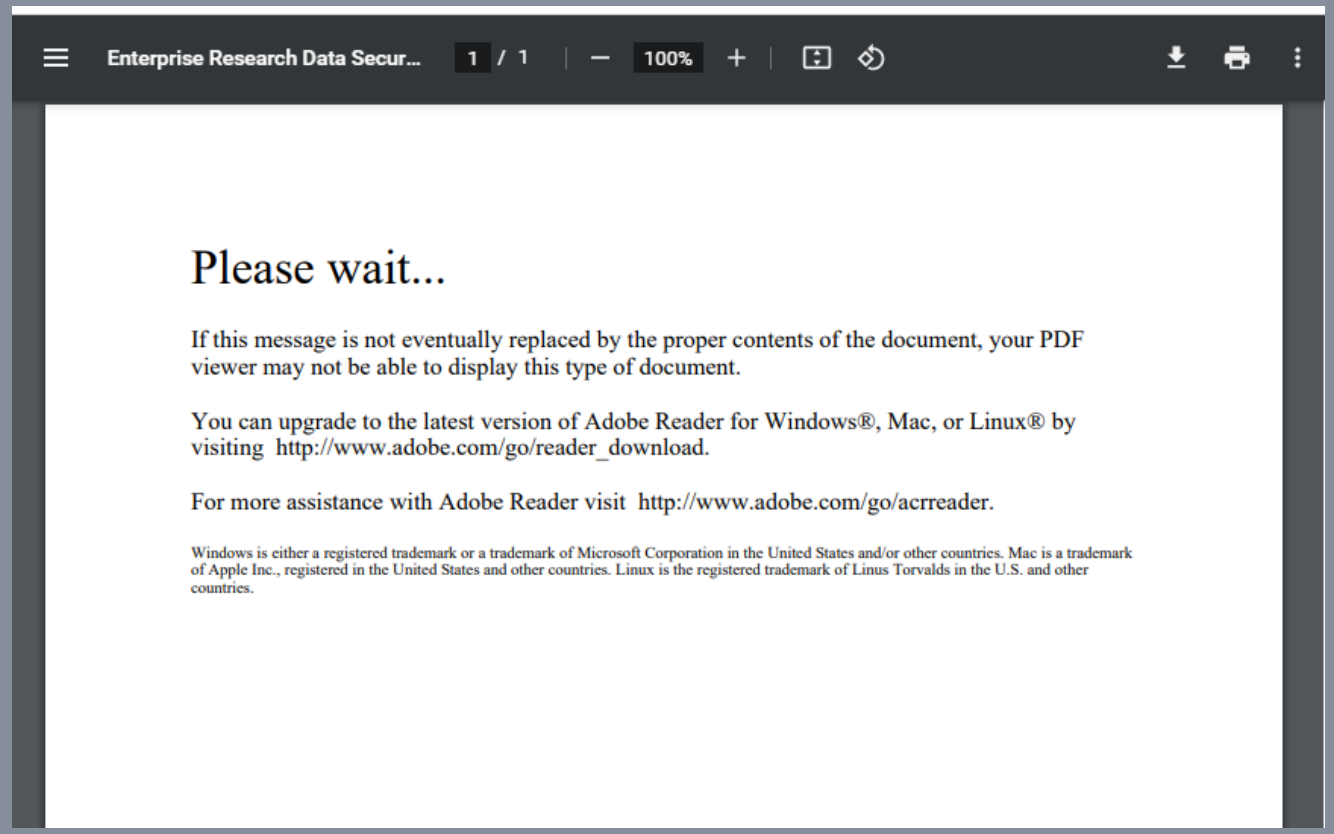
Required Wizards

VA – Project Cover Sheet

FOR HUMAN STUDIES: VA – IRB Information Sheet

Downloading Files

Save to your computer then navigate to the folder where it's saved and open in the specific application (Adobe, Word, etc) or else you'll get this message



REQUIRED R&D APPROVAL

- Risk/Benefit Ratio
- Change in PI
- Amendment to a Data Repository

QUESTIONS?