



# VA Innovation and Research Review System (VAIRRS)

Monthly Webinar

July 19, 2022





- ✓ A recording of this session and the associated handouts will be available on ORPP&E's Education and Training website approximately one-week after the webinar
- ✓ An archive of all ORPP&E webinars can be found here:  
<https://www.research.va.gov/programs/orppe/education/webinars/archives.cfm>
- ✓ 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"
- ✓ Complete the post-webinar evaluation survey that pops up once you exit the webinar.
- ✓ Experiencing sound issues? You can call in using the number included on the handouts and on your registration confirmation email.

# Contents

- Welcome
- Announcements
- VAIRRS Ambassador Highlight  
*William S. Middleton Memorial Veterans Hospital*



# Important Announcements

## Project Cover Sheet Wizard

As of July 8, 2022, we have completed 11,775 Project Cover Sheets, accounting for 68.8% of the 17,116 active projects.

## Document Finder Tool (DFT)

In September 2022 ORPP&E will launch the Document Finder Tool, which will serve as a one-stop shop to quickly search, browse, filter and view the most current VA research policy and document content.

## VA Electronic Determination Aid (VAEDA)

If your facility is interested in participating in the soft launch of VAEDA, please email [VAEDAsupport@va.gov](mailto:VAEDAsupport@va.gov)

*Subscribe to the **VAIRRS Newsletter and Program Update** to keep up with important announcements and program updates: [https://public.govdelivery.com/accounts/USVHA/subscriber/new?topic\\_id=USVHA\\_1952](https://public.govdelivery.com/accounts/USVHA/subscriber/new?topic_id=USVHA_1952)*



# VAIRRS Ambassador Highlight

William S. Middleton Memorial Veterans Hospital



Choose **VA**

VA



U.S. Department of Veterans Affairs  
Office of the Secretary  
Secretary's Center for Strategic Partnerships

VA



U.S. Department of Veterans Affairs  
Veterans Health Administration  
Office of Research & Development

VA



U.S. Department  
of Veterans Affairs

# Presenters



## *William S. Middleton Memorial Veterans Hospital*

**Aaron Heneghan**

*Administrative Officer*

Email: [Aaron.Heneghan@va.gov](mailto:Aaron.Heneghan@va.gov)

**Jamie Swanlund, BA, CCRC**

*R&DC Coordinator*

Email: [Karen.Hoffman@va.gov](mailto:Karen.Hoffman@va.gov)

**Karen Hoffman**

*Program Support Assistant*

Email: [Karen.Hoffman@va.gov](mailto:Karen.Hoffman@va.gov)



Choose **VA**

**VA**



U.S. Department  
of Veterans Affairs

# Overview

- **Challenge 1** – Integrating IRBNet When Working With an Affiliate IRB
- **Challenge 2** – Managing Study Team Personnel
- **Challenge 3** – Managing Team Training Requirements
- **Challenge 4** – Reviewers’ Confusion Over Packages With Combined IACUC & SRS Documents
- **Challenge 5** – Triennial Reviews: New Project vs. New Package
- **Challenge 6** – Project Report Due Dates

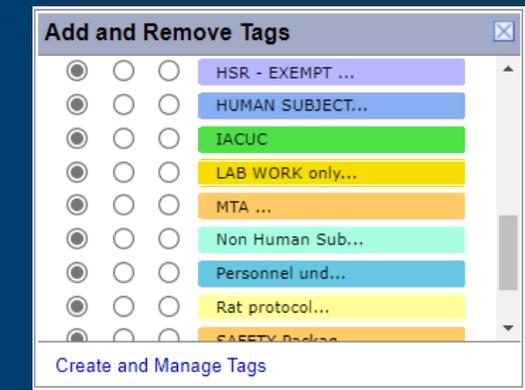
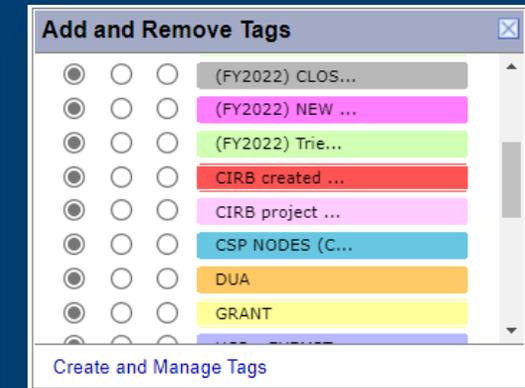


# Challenge 1

## Integrating IRBNet When Working With Affiliate IRB

### Solution

- Set up a **daily** morning meeting with research office staff
  - Review submissions and documents required
  - Review timelines
  - Determine how to route for reviews and how to process through IRBNet
- Employ Guidance materials available for PIs and study teams\*
- Utilize project tags to keep organized (see examples of tags used by research admin to the right)



\*described in detail on next slide

# Developed Guidance Materials

- RDC submission guidelines and flowcharts
- “How To” guides for IACUC and SRS
- MS Teams or in-person meetings for individualized assistance with submissions
- Demo videos available:
  - Registration, Linking CITI, and Uploading Training Certificates (5m 23s)
  - Forms and Templates (1m 43s)
  - Sharing the Project (2m 13s)
  - Using Project Tags and Archiving Projects (3m 8s)
  - Creating a New Package (4m 11s)
  - Package Revisions (Unlock/Lock) (2m 51s)\*
  - Finding Board Documents after Committee Reviews (1m 30s)
  - Creating a New Project (3m 51s)
- Recently started “office hours”

Select a Library: William S. Middleton Memorial Veterans Hospital R&D Committee, Madison, WI - Documents for Researchers

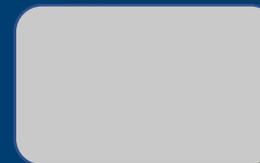
Documents in this Library:

Document Description	Last Updated
**Read Me First! IRBNet Quick Reference for RDC v02.27.2022.pdf	02/27/2022 05:32 PM
*2022 Meeting Dates & Deadlines for RDC, IACUC, and SRSS v2	02/27/2022 05:36 PM
*New Project Support Information for VA Human Subjects Researchers v01.18.2022.pptx	01/19/2022 01:05 PM
*RDC Submission Guidelines v.02.27.2022.pdf	02/27/2022 07:42 PM
*RDC Workflow to Approve HSR Projects - NCI CIRB v11.30.2021.pdf	11/30/2021 05:17 PM
*RDC Workflow to Approve HSR Projects - UW HS-IRB v2.5 2022_final	07/07/2022 06:08 PM
*RDC Workflow to Approve HSR Projects - VA CIRB v02.27.2022.pdf	02/27/2022 07:55 PM

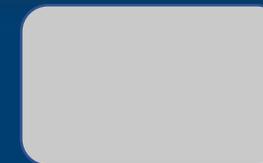
Select a Library: William S. Middleton Memorial Veterans Hospital IACUC, Madison, WI - Documents for Researchers

Documents in this Library:

Document Description	Last Updated
**HOW TO GUIDE: Creating a Continuing Review (ACORP) Package .docx	05/03/2022 03:20 PM
**HOW TO GUIDE: Creating a New (ACORP) Project .docx	05/03/2022 03:20 PM
**HOW TO GUIDE: Creating a Project Amendment (ACORP) Package.docx	05/03/2022 03:21 PM
**HOW TO GUIDE: Creating an IACUC Response Package .docx	05/03/2022 03:21 PM
**HOW TO GUIDE: Creating Triennial Renewal Packages .docx	05/03/2022 03:20 PM



Read Me First!  
doc



RDC/CIRB  
Workflow doc



New ACORP  
Project doc

\*video on next slide



# Challenge 2

## Managing Study Team Personnel

### Solution

- Review study team personnel at **daily** morning meetings
  - Verify that VA appointments are in place or in process (WOC)
  - Verify that all team members are listed on the VA Project Cover Sheet and match the affiliate roster and protocol
  - All team members must be registered in IRBNet and shared on the project
  - Utilize **project notes**: e.g., note if staff are admin only or national study personnel
  - Utilize **package notes** for amendments to personnel

Pkg #	Submission Type	Submission Date	Review Type	Board Action	Effective Date	
4	Work in progress (Not submitted) Adding Researcher D					
3	Amendment/ Modification Removing Researcher A; Adding B and C	07/20/2021		Pending Review		

#### Project Notes

Project Notes provide a project-level scratch pad that is accessible from any submission within the project. Project Notes can only be viewed and edited by users with Admin access.

See 'Project Overview' page for details on national study personnel who are shared on the project but are not tracked by local boards.

# Challenge 3

## Managing Team Training Requirements

### Solution

- Review team training progress at **daily** morning meetings
  - Developed “Training by PI Groups” Spreadsheet\*
  - Revised Research Scope of Practice and Training Sheet\*
  - Developed “Monster” Master Spreadsheet\*
  - All team members enter their training completion certificates into IRBNet
  - All team members are shared on the project so training tracks with the project\*

*\*described in following slides*

# Developed “Training by PI Groups” Spreadsheet to Assign Team Training

Group	**One person may belong to more than one group	Trainings in each group						
0	All Personnel /Admin Only/Other	VA TMS #10176: VA Privacy and Information Security Awareness & Rules of Behavior						
1	Human Subjects	VA TMS #10203: Privacy & HIPAA Training	CITI VA Human Subjects Protection					
2	BBP exposure	UW Biosafety 102 Bloodborne Pathogens (or VA equivalent: TMS 4503950)						
3	Lab Work (on-site)	TMS Laboratory Safety 4503945	UW Biosafety Required Training	CITI - VA ORD Biosecurity Training (ID 13479)	TMS Staff Incident Response Matrix and Emergency Management Response Guide for	TMS General Lab Rules for Research (MAD 272)	TMS Accident Reporting in Research (MAD 272)	TMS Chemical Hygiene Plan (MAD 272)
4	Lab Work (off-site)	TMS Laboratory Safety 4503945	UW Biosafety Required Training					
5	Animal work	UW Animal Contact Risk Questionnaire (ACRQ)	CITI- Working with species (Mice, rats) in Research settings	CITI Working with the IACUC	RARC Animal User Orientation	RARC Biomethodology of the species studied		
6	Formaldehyde exposure	TMS Formaldehyde 3877758						

PI	Training Groups							
Alpha	0, 1	1 - Human Subjects						
Bravo 1 (HS)	0, 1	1- Human Subjects						
Bravo 2 (ACORP)	0, 2, 3, 5, 6		2 - BBP exposure	3 - Lab Work (on-site)		5 - Animal work	6 - Formaldehyde exposure	
Bravo 3 (Lab only)	0, 2, 3, 6		2 - BBP exposure	3 - Lab Work (on-site)			6 - Formaldehyde exposure	
Charlie 1 (HS)	0, 1	1- Human Subjects						
Charlie 2 (ACORP)	0, 2, 4, 5, 6		2 - BBP exposure		4 - Lab Work (off-site)	5 - Animal work	6 - Formaldehyde exposure	
Delta	0, 1	1- Human Subjects						
Echo	0, 2, 3, 5, 6		2 - BBP exposure	3 - Lab Work (on-site)		5 - Animal work	6 - Formaldehyde exposure	
Foxtrot	0, 2, 4, 5		2 - BBP exposure		4 - Lab Work (off-site)	5 - Animal work		
Golf	0, 1, 2	1- Human Subjects	2 - BBP exposure					
Hotel	0, 1	1- Human Subjects						

# Revised Research Scope of Practice and Training Sheet

- WOCs are assigned training, based on the “Training by PI Groups,” during onboarding

REQUIRED RESEARCH TRAINING	
Employee Name:	Date Completed:
PI Name:	Supervisor (if not PI):

**Instructions:**

- Each Employee must complete all training as assigned below and record all completion dates. Additional training may be required based up duties assigned in the Employee’s individual Scope of Practice.
- It is the responsibility of the Employee to keep all required training current. Failure to do so can result in removal from the affected research project(s).

	Required	Name of Training	Training Details	Date Completed
Group 0	<input checked="" type="checkbox"/>	VA Privacy and Information Security Awareness and Rules of Behavior	TMS 10176	
Group 1	<input type="checkbox"/>	Privacy and HIPAA Training	TMS 10203	
		VA Human Subjects Protection	CITI Program (VA)	
Group 2	<input type="checkbox"/>	Bloodborne Pathogens Awareness (VA) or Biosafety 102 Bloodborne Pathogens (UW) <i>*See below</i>	TMS 4503950 UW	
		VA ORD Biosecurity Training	CITI	
Group 3	<input type="checkbox"/>	Biosafety Required Training	UW	
		Laboratory Safety	TMS 4503945	
		Staff Incident Response Matrix and Emergency Management Response Guide for Research (MAD 272)	TMS 4542005	
		General Lab Rules for Research (MAD 272)	TMS 4542014	
		Accident Reporting in Research (MAD 272)	TMS 4542003	
		Chemical Hygiene Plan (MAD 272)	TMS 4542007	
Group 4	<input type="checkbox"/>	Biosafety Required Training	UW	
		Laboratory Safety	TMS 4503945	
Group 5	<input type="checkbox"/>	Animal Contact Risk Questionnaire (ACRQ)	UW	
		Working with the IACUC	CITI	
		Working with Species in Research Settings	CITI	
		Animal Biotechnology Course	RARC	
Group 6	<input type="checkbox"/>	Animal User Orientation	RARC	
		Formaldehyde	TMS MAD-310 (3877758)	
As Assigned	<input type="checkbox"/>	Essentials for IACUC Members	CITI	
		Non-Survival Surgery Course	RARC	
		Lab Animal Surgery Course ( <i>competency required, see page 2</i> )	RARC	
		Radiation Safety	VA in-person training	
		Risk Group 2 Organisms	CITI	
		Human or Nonhuman Primate Materials	CITI	
		Biosafety for Work with Infected Animals	CITI	
		Transporting & Shipping Biological Specimens	TMS 3874637	
		Biosafety 205: Bio Hazmat Shipping Training	UW	
	<input type="checkbox"/>			

*\*For questions while reviewing the Bloodborne Pathogens training, you may email ([vhamadsrcoordinator@va.gov](mailto:vhamadsrcoordinator@va.gov)) for a face to face meeting or call (608-256-1901x17802). The VA Employee Health contact is 608-256-1901x17915. In addition, researchers exposed to human blood or other potentially infectious materials must have hepatitis B vaccine OR sign a hepatitis B declination form showing that they were offered the vaccine.*

TRAINING GROUPS:	
Group 0 – Required for all personnel on VA projects	Group 3 – Lab Work (on-site)
Group 1 – Human Subjects Research	Group 4 – Lab Work (off-site)
Group 2 – Bloodborne/ Airborne Exposure	Group 5 – Animal Subjects Research
	Group 6 – Formaldehyde Exposure



Choose VA

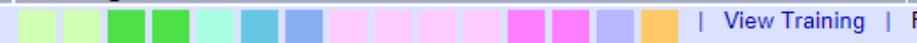
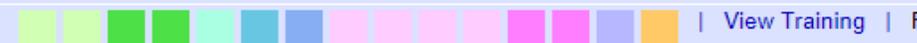


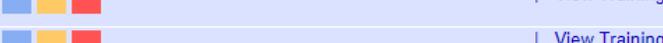
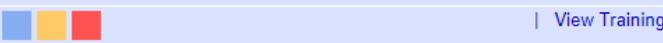
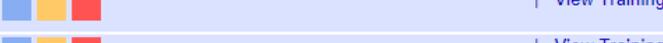
# Developed “Monster” Master Spreadsheet to Track Training outside of IRBNet

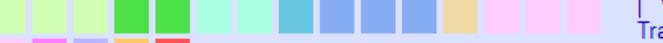
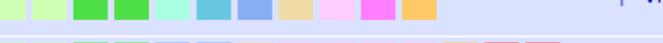
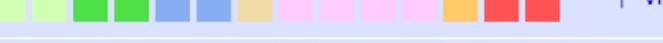
Training Group	VA Information Security & ROB (Group 0)	VA Human Subjects Course (Group 1)	VHA Privacy & HIPAA (Group 1)	Biosafety 102 Bloodborne pathogens (Group 2)	VA ORD Biosecurity Training (Group 3)	MAD-272: Staff Incident Response Matrix and Emergency Management Response Guide for Research (Group 3)	MAD-272 General Lab Rules (Group 3)	MAD-272 Accident Reporting in Research (Group 3)	MAD-272 Chemical Hygiene (Group 3)	Lab Safety 4503945 (Group 3 and 4)	Biosafety Required Training (Group 3 and 4)	ACRQ (Safety for Personnel w/ Animal Contact) (Group 5)	Working with Species in Research Settings (Group 5)	Working with the IACUC (Group 5)	
	TMS	CITI	TMS	UW or TMS	CITI	TMS	TMS	TMS	TMS	TMS	UW	UW	CITI	CITI	
	1 Year (Last Checked 6/30/2022)	2 Years (Last Checked 7/5/2022)	1 Year (Last Checked 7/6/2022)	1 Year (Last Checked 7/6/2022)	One Time Training (Last Checked 7/6/2022)	1 Year (Last Checked 7/6/2022)	1 Year (Last Checked 7/6/2022)	1 Year (Last Checked 7/6/2022)	1 Year (Last Checked 7/6/2022)	One Time Training (Last Checked 7/6/2022)	5 Years (Last Checked 7/6/2022)	1 Year (Last Checked 7/6/2022)	3 Years (Last Checked 7/6/2022)	3 Years (Last Checked 7/6/2022)	
Researcher 1	0,1	6/6/2022	5/31/2022	6/6/2022											
Researcher 2	0,4,5,6	3/10/2022									5/28/2019	1/22/2022	mice-1/4/2022 rats-12/14/2018	1/4/2022	
Researcher 3	0,2,3,5,6	11/19/2021		8/24/2021	4/23/2021	11/19/2021	11/19/2021	11/19/2021	11/19/2021	4/23/2021	7/30/2018	12/2/2021	mice- 11/30/2020 rats-7/27/2020	7/27/2020	
Researcher 4	0,2,3,5	2/9/2022		2/14/2022	12/21/2018	2/7/2022	2/7/2022	2/7/2022	2/7/2022	Assigned 6/10/2022		VA Employee Health 2/24/2022	rat- 2/18/2020 ; mice - 02/18/2020	6/25/2019	
Researcher 5	0,2,3,5,6	12/30/2021		12/28/2021	1/14/2022	1/19/2022	1/19/2022	1/19/2022	1/19/2022	1/19/2022	12/28/2021	1/22/2022	Mice - 1/14/2022	12/30/2021	
Researcher 6	0,1	12/31/2021	10/20/2021	12/31/2021											
Researcher 7	0,1,2,3	8/5/2021	5/9/2021	8/5/2021	2/16/2022	6/16/2019	2/28/2022	2/28/2022	2/28/2022	2/28/2022	2/28/2022	3/1/2021			
Researcher 8	0,1,2,3	4/26/2022	5/21/2021	4/25/2022	5/6/2022	8/6/2021	4/26/2022	4/26/2022	4/26/2022	4/26/2022	6/25/2021	4/12/2021			
Researcher 9	0,2,3,5,6	2/6/2022			3/16/2022	3/15/2022	4/19/2022	4/18/2022	4/18/2022	4/18/2022	3/15/2022	3/16/2022	4/22/2022	Mice - 3/15/2022	3/15/2022
Researcher 10	0,2,3,6	11/12/2021			11/16/2021	11/15/2021	4/18/2022	4/18/2022	4/18/2022	4/18/2022	4/30/2021	10/18/2019			
Researcher 11	0,2,3,5,6	1/26/2022			8/15/2021	3/13/2021	5/11/2022	5/11/2022	5/11/2022	5/11/2022	3/10/2021	9/5/2019	12/7/2021	Rat - 08/16/2021	8/16/2021

- All team members **enter their training completion certificates** into IRBNet
- All team members are **shared on the project** so training tracks with the project
  - We use the “Training by PI Groups” and “Monster” spreadsheets to make sure that training is complete in IRBNet

- Project Team Tracking in IRBNet:

Training & Credentials	Access Type
   View Training   Full	Full
   View Training   Full	Full

Training & Credentials	Access Type
   View Training   Read	Read
   View Training   Full	Full
   View Training   Read	Read
   View Training   Read	Read
   View Training   Read	Read
   View Training   Read	Read
   View Training   Read	Read
   View Training   Read	Read

Training & Credentials	Access Type
   View Training   Full	Full
   View Training   Full	Full
   View Training   Full	Full
   View Training   Read	Read
   View Training   Read	Read
   View Training   Full	Full
   View Training   Full	Full

# Admin Gatekeepers

Before the package is sent to committee:

- **Required documents** are in the package and revised documents are stacked
  - *Input about documents is often provided by coordinators during morning meetings*
- **Study team personnel** have VA appointments - they are congruent across documents and are shared on the project
- **Team training** is complete and current in IRBNet

# Challenge 4

## Reviewers' Confusion Over Packages with Combined IACUC & SRS Documents

### Solution

- Implemented a 1:1 safety protocol per project (vs. previous umbrella)
- Initially, we had teams submit one package with IACUC and SRS documents
  - The package was sent to both committees for review
- Now, we split IACUC and SRS documents into separate packages

Documents in this Package:

Document Type	Description
Conflict of Interest - Other	COI Acknowledgement - [REDACTED] 0903_afh.pdf
Other	[REDACTED] ERDSP Template V 2.4 (1) 09JUN2021_SIGNED.pdf
Other	Risk and mitigation Table example.docx
Other	Chemical Inventory_example.xlsx
Other	BioSafety UWAarrow_6.14.21.pdf
Protocol	[REDACTED] VA Animal Protocol_6.27.2021.docx
Questionnaire/Survey	Fillable Safety Survey_6.1 [REDACTED].pdf
VA - Project Cover Sheet	VA - Project Cover Sheet

Combined IACUC & SRS documents

Documents in this Package:

Document Type	Description
Conflict of Interest - Other	COI Acknowledgement Letter [REDACTED] 2022_afh.pdf
Other	ERSDP Template [REDACTED] Signed.pdf
Protocol	ACORP v4 rev1 [REDACTED].docx
VA - Project Cover Sheet	VA - Project Cover Sheet

IACUC documents

Documents in this Package:

Document Type	Description
Other	Risk and mitigation Table Aug 202 [REDACTED].docx
Other	[REDACTED] Chemical Inventory3-2022.xls
Protocol	B0000061 [REDACTED] VA-3-17-22.pdf
Questionnaire/Survey	Safety Survey 2022-[REDACTED].docx

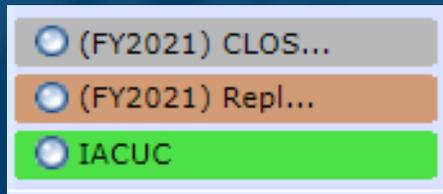
SRS documents

# Challenge 5

## Triennial Reviews: New Project vs. New Package

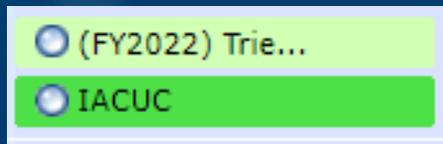
### Solution

- Started a new project for triennials
  - Had to close the old project and document with **package note** and **tags**, and replaced by the new IRBNet number. Teams had to upload documents into a new project.



(FY2021) Replaced by Triennial

- Made more sense to create a new package, with a submission option for Triennial Review



(FY2022) Triennial Renewal



# Challenge 6

## Project Report Dates

### Solution

- Added 90-day report alerts through IRBNet for IACUC and SRS to ensure time for admin review, committee pre-reviews and reviews prior to due dates.
  - We've customized the 90-day report due and 90-day expiration emails from IRBNet to include:

Report Due: October 2, 2022

\*\*All project materials must be submitted into IRBNet 60 days before the report due date in order to be reviewed and approved by applicable VA Committees. Failure to do so may risk temporary suspension of the protocol. For additional information please contact the William S. Middleton Memorial Veterans Hospital SRS.

- Coordinators will reply to the IRBNet report due or expiration email with submission guidance for the PI and study team. Our training specialist is cc'd so she can check that team training is complete and current.\*

*\*described on next slide*



Choose **VA**



VA



U.S. Department  
of Veterans Affairs

- Sample guidance letter from RDC Coordinator (shown at right)
- We've also started using a whiteboard to monitor:
  - Projects with upcoming due dates – report due or expirations
  - Team trainings coming due

RE: [EXTERNAL] IRBNet 60-Day Report Due Reminder

Good morning,

Your project detailed below is coming due for annual review with the VA R&D Committee:

<b>Project ID:</b>	
<b>IRBNet ID:</b>	
<b>Project Title:</b>	
<b>RDC Approval Expiration Date:</b>	<b>September 6, 2022</b>
<b>Note:</b> The submission deadline is three weeks prior to the RDC project approval expiration date. Failure to submit a continuing review application prior to the expiration date may result in suspension and/or termination of the project with the VA R&DC.	

Please submit the required documents into the project review system, VAIRRS/IRBNet ([gov.irbnet.org](http://gov.irbnet.org)):

- "RDC-MSN Application for Annual Review or Project Closure" – attached; also found in the R&DC document library in IRBNet
- "VA OGE Form 450 Alt-VA" – attached; the study PI, as well as any personnel serving in the role of an investigator, must complete a financial Conflict of Interest (COI) form annually.
  - The COI forms are submitted by email to the RDC [Coordinator](#) and a letter is returned to you. You must upload this annual **Financial COI determination letter** to IRBNet.

**\*\*DO NOT upload the COI form OGE 450 Alt-VA into IRBNet\*\***

Required VA research training must be current for each study team member to receive approval.

**If you do not intend to renew this project, a Project Closure Report must be submitted instead.** You must also submit documents from the IRB of record confirming study closure.

There are detailed "RDC Submission Guidelines" to help you if needed in the "Forms and Templates" menu in VAIRRS/IRBNet. Select the R&DC library for researchers for our hospital (WSMMVH). If you have any questions just reach out.

Thank you,  
Jamie

Jamie Swanlund, BA, CCRC

R&DC Coordinator

Madison VAMC

[Jamie.Swanlund@va.gov](mailto:Jamie.Swanlund@va.gov)



Choose VA



# Questions?



Choose **VA**



**VA**



U.S. Department  
of Veterans Affairs

# Contact Information

**Aaron Heneghan**

*Administrative Officer*

Email: [Aaron.Heneghan@va.gov](mailto:Aaron.Heneghan@va.gov)

**Jamie Swanlund, BA, CCRC**

*R&DC Coordinator*

Email: [Karen.Hoffman@va.gov](mailto:Karen.Hoffman@va.gov)

**Karen Hoffman**

*Program Support Assistant*

Email: [Karen.Hoffman@va.gov](mailto:Karen.Hoffman@va.gov)

*For general VAIRRS support, please contact [VAIRRS@va.gov](mailto:VAIRRS@va.gov)*

