READ ME FIRST! IRBNet Quick Reference for RDC

Research and Development Committee
William. S. Middleton Memorial Veterans Hospital
Madison, WI

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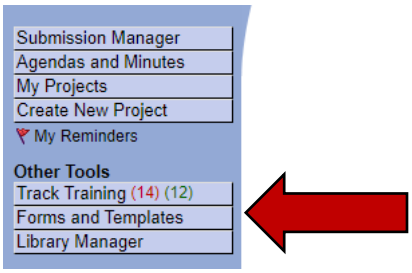
The following is a quick reference guide only.

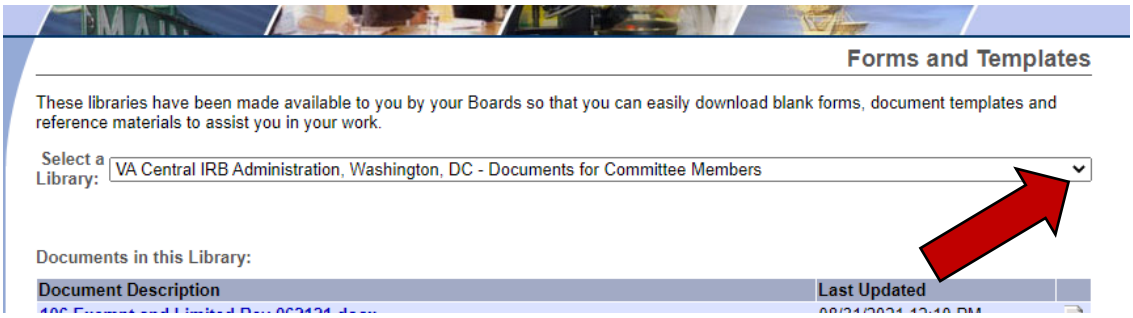
If more detailed information is needed regarding project submission, please see the "*RDC Submission Guidelines*" as well as the "*RDC Workflow to Approve HSR Projects – [UW/NCI CIRB/VA CIRB] IRB*" in IRBNet. These can be found in the Madison R&DC document library.

NOTE: This is a "living" document and will be updated as needed. Please continue to check IRBNet for the most current version of submission guidance as well as forms & templates. Thanks!

WHERE TO FIND VA FORMS AND INFORMATION IN IRBNET (GOV.IRBNET.ORG)

Unless otherwise noted, all documents and templates discussed in the following guidelines can be found in the "**Forms and Templates**" menu of VAIRRS/IRBNet. Be sure to use the drop-down menu to then select the appropriate document library for the form you need. A list of VA forms and their corresponding document library is below.





- ***Library: VHA ORPP&E, Washington, DC – Documents for Human Subjects Researchers***
  - VA ICF template
    - For UW IRB, please also see "Required Consent Language for UW IRB" in the WSMMVH R&DC library
  - VA Protocol template
  - ERDSP (ISSO review form) and User Guide
  - VA 10-250 (PO review form)
  - Request for Waiver of HIPAA Authorization form

- ***Library: WSMMVH R&D Committee, Madison, WI – Documents for Researchers***
  - Read Me First! IRBNet Quick Reference for RDC
  - Meeting Dates for RDC, IACUC, and SRSS
  - RDC Workflow to Approve New HSR Projects (UW IRB, VA CIRB, NCI CIRB)
  - RDC Submission Guidelines for RDC Review
  - Consent - Required Consent Language for UW IRB
  - Consent – VA Form 10-3203 Picture or Voice
  - Consent – VA Form 10-5345 ROI for Voice Recordings (transcription)
  - HIPAA Authorization Template, VA Form 10-0493
  - Pharmacy Impact Form, Pharmacy Investigational Drug Information Record (VA Form 10-9012)
  - ISSO/PO Required Elements for Project Review (tips & tricks on required language to include in your IRB application and study protocol)
  - NCI CIRB Consent Form Template – letterhead only
  - NCI CIRB Consent Form Addendum for VA
  - Page 18 – Investigator Profile (for new VA investigators only) **Return via email to RDC Coordinator**
  - RDC-MSN Application for Annual Review or Project Closure (for RDC-only studies: IRB-Exempt or Non-HSR)

- ***Library: WSMMVH SRS, Madison, WI – Documents for Researchers***
  - SRS Safety Survey 2022 (required for all projects)
  - 2021 SRS Annual Review or Closure Report

- ***Library: VHA ORPP&E, Washington, DC – Documents for Research and Development Researchers***
  - RDC Non-Veteran Application (if enrolling non-Veterans, civilian caregivers, including VA staff or providers, etc.)
  - RDC Amendment Application (for RDC-only studies: IRB-Exempt or Non-HSR)

- ***Library: VA Central IRB Administration, Washington, DC – Documents for Researchers***
  - All forms and templates for the VA CIRB

- ***Documents Not Currently Available on IRBNet – Please Email*** (VHAMADRDCoordinator@va.gov) ***to Request:***
  - Financial Conflict of Interest (COI) OGE Form 450 Alt-VA
  - Data Use Agreement (DUA)
  - Material Transfer Agreement (MTA)

NEW PROJECT SUBMISSION FOR RDC REVIEW IN VAIRRS/IRBNet

The following is a general overview of the steps to submit a new project for RDC review in VAIRRS/IRBNet. For detailed information on any of the steps below, refer to the relevant section(s) of the *RDC Submission Guidelines* as well as the detailed checklists and submission/review workflows for the RDC.

NEW PROJECT SUBMISSION

1. Log in to VAIRRS/IRBNet gov.irbnet.org
2. To submit a new project – Click "**Create New Project**"
3. Enter the project title, PI name & degree(s), and sponsor (if no sponsor, enter "None". Enter the IRB Project ID# (e.g., 2022-9999, 22-99, EA2299) as a required keyword
4. Enter a "**Package Note**" at the top of the **Designer** page to describe the submission (e.g., "New Project")
5. Click "**Start a Wizard**" and choose "**VA – Project Cover Sheet**" and answer all questions
6. Click "**Start a Wizard**" and choose "**VA – IRB Information Sheet**" and answer all questions
7. Upload all required and relevant project documents (e.g., IRB application, protocol, consent forms, scripts, etc.). Click "**Attach New Document**" to select individual documents or drag and drop directly onto the Designer page. Select the appropriate document type form the drop-down next to each file name
   a. The documents required for RDC review vary depending upon which IRB is reviewing the project. See the *RDC Submission Guidelines* for details, but a general rule of thumb is every document that is submitted to the IRB for review must also be submitted to the RDC
8. Click "**Share this Project**" to share the project with all other study team members (this is to include ALL named personnel in the Project Cover Sheet, as well as any admin-only personnel). If a staff member has created a project submission on the investigator's behalf, the project must be shared with the PI

   Note: Each team member must register for their own individual VAIRRS/IRBNet account to be shared on a project

9. Make sure all personnel named on the project have **current VA training.**

a. There is a required training for admin-only personnel. These personnel are not listed on the Project Cover Sheet but must be shared on the project. Email VHAMADRDCoordinator@va.gov with questions on required VA training for all personnel

10. Click "**Sign this Package**". **This must be the project PI**
11. Click "**Submit this Package**". Confirm the Board you are submitting to is "WSMMVH Research Admin". Submission type = **New Project**. You will receive confirmation when the project is sent to Research Admin

PROJECT AMENDMENT SUBMISSION FOR RDC REVIEW or ACKNOWLEDGEMENT IN VAIRRS/IRBNet

The following is a general overview of the steps to submit a project amendment for RDC review (IRB-exempt or non-human subjects research) or RDC acknowledgement (projects under the oversight of an IRB) in VAIRRS/IRBNet. For detailed information on any of the steps below, refer to the relevant section(s) of the *RDC Submission Guidelines* as well as the detailed checklists and submission/review workflows for the RDC.

PROJECT AMENDMENT SUBMISSION

1. Log in to VAIRRS/IRBNet gov.irbnet.org
2. Click on the project name from the "**My Projects**" list
3. Click "**Create a New Package**"
4. Enter a "**Package Note**" at the top of the **Designer** page to briefly describe the reason for the submission (e.g., "project amendment", "update personnel", etc.)
5. Amend document(s) currently approved by the RDC (e.g., "Documents from previous packages that you can revise" at the bottom of the page), including the online SMART forms: "**VA – Project Cover Sheet**", for changes in funding or personnel (if applicable) and "**VA – IRB Information Sheet**" (if applicable)
   i) Click the **pencil icon** on the right side of the document(s) you wish to amend/upload revisions
   ii) Upload the revised version (with tracked changes) of the document or amend the relevant area(s) of the online SMART form wizard(s)
   iii) Include relevant version dates in the "Description" field for documents. If uploading a new version of a document, you can delete the pre-filled "Description" field and it will default to the file name being uploaded
6. Add any additional document(s) not yet reviewed/approved by RDC
   i) Click "**Attach New Document**" to select individual documents or drag and drop directly onto the Designer page. Select the appropriate document type form the drop-down
7. If adding personnel, click "**Share this Project**" to share the project with all new study team members
   Note: Each team member must register for their own individual VAIRRS/IRBNet account to be shared on a project
8. Click "**Sign this Package**".
   i) If the amendment has already been approved by an IRB and the documents are only being provided for acknowledgement, a study team "Designee" is permitted to sign the package for submission
   ii) If the amendment is for an RDC-only project (e.g., IRB-exempt or NHSR) requiring RDC review and approval, **the project PI must sign the package**

a) Click "**Submit this Package**". Confirm the Board you are submitting to is "WSMMVH Research Admin". Submission type = **Amendment/Modification**. You will receive confirmation when the project is sent to Research Admin.

RESPONDING TO A REQUEST FOR MODIFICATIONS FROM THE RDC

- ❒ Following review of your project, the RDC will issue a decision in VAIRRS/IRBNet, both with a "system alert" and publish a separate decision memo. This memo can be found on the "**Project Overview**" page by clicking on "**Review Details**" for the RDC and look under "**Board Documents**". A copy of all published board documents can also be found by clicking on the "**Reviews**" menu on the left side of the screen. The RDC memo will state that the project application was reviewed and that either the project is approved, disapproved, or the RDC requires modifications to secure approval.

- ❒ If the decision is to grant contingent approval or modifications are requested, requirements to obtain final RDC approval will be outlined in the RDC decision memo or in a separate ***PI Response to RDC Review*** form. The study team can download the PI Response Form as described above for the RDC memo. There is a space to provide a response or comments to each of the contingencies or modifications requested by the RDC for approval.

- ❒ When ready to submit a response to RDC:
  - In VAIRRS/IRBNet, go to the "**My Projects**" page.
  - Open the project for which you will submit modifications and click "**Create a New Package**" from the left panel menu.
  - Near the top of the **Designer** page, click on the line next to the yellow sticky note icon to add a package description. Type something such as "*Response to RDC Review*" to describe why the package is being submitted. This helps document that the current package is a subsequent submission to seek final approval for a previous package that has been reviewed.
  - If modifications must be made to any of the individual documents previously submitted for review, go to the table of "**Documents from Previous Packages that you can Revise**" and locate the document to be updated.
  - Click on the **pencil icon** on the right side of the table. This allows you to upload an amended version of the document and will properly track the revision history and keep the old copy intact.
  - If there is a new document to be submitted with your response, (e.g., an IRB approval letter, the PI Response to RDC Review form, etc.), click "**Attach New Document**" to select individual documents to add to your amendment application in VAIRRS/IRBNet. You can also "drag and drop" documents directly onto the Designer page. After attaching the document, you must select the most appropriate "Document Type" for each file.
  - When all required documents have been amended/uploaded to the project package, the PI should click "**Sign this Package**" from the menu on the left of the screen. Any study team member who has been granted "Full access" to the project by the PI can create new project packages for review in VAIRRS/IRBNet.
    - If the amendment requires RDC review, the PI MUST SIGN THE PROJECT PACKAGE TO BE ACCEPTED FOR REVIEW
    - If the amendment did not require RDC review and the IRB-approved amendment documents are being submitted for RDC acknowledgement, a designee may sign in lieu of the PI
  - After the PI has signed the package, click "**Submit this Package**". Make sure the correct review board is selected "William S. Middleton Memorial Veterans Hospital Research Administration, Madison, WI"

- Certify that the required PI signature has been added to the package. Click "**Continue**"
- Select the appropriate Submission Type from the list of choices for Human Subjects Research, usually "**Response/Follow-up**". Add comments if applicable and click "**Submit**".

HELPFUL HINTS & INFORMATION FOR VAIRRS/IRBNet

- **File Description** – the "description" field defaults to the file name when a new file is uploaded. When a revised version is uploaded using the pencil icon, you must delete the description to re-enable this feature, otherwise the new file will be uploaded with the name of the previous older file version. Also, please update the file description if there isn't sufficient detail in the file name as to what the document is. Use a clear description of the document as well as a version date whenever possible, e.g., "Protocol v01.01.2020" or "Consent v01.01.2020 tracked". This will help keep the project tracking history clear.

- **Package Signatures** – packages can be created, assembled, and even submitted by other approved study personnel with the appropriate access (e.g., "write" or "full" access), but each package being submitted to the RDC for review must be signed by the project's PI for some types of project reviews.

  IRBNet package submissions where a PI signature is *required*:

  1) New Projects
  2) Project amendments that require RDC review (e.g., IRB-exempt projects, non-human subjects research projects)
  3) Packages submitted in response to RDC review at a convened meeting

  IRBNet package submissions where a designee signature would be accepted in lieu of PI signature for human subjects research:

  1) Administrative Updates (e.g., personnel changes)
  2) Submission of IRB approval of project amendments
  3) Submission of IRB approval of continuing review
  4) Submission of project closure reports

- **Project vs. Package** – in VAIRRS/IRBNet, the overall study is a "project" while any submission made to the R&DC to modify the project is called a "package". The system allows submission of more than one package at a time for review, but this is discouraged whenever possible unless submitting to separate review boards (e.g., RDC & SRSS).

- **Delete Packages** – after submission to Research Administration, a package cannot be deleted. If a package is submitted in error, or if circumstances change and a PI wants to withdraw a package from review, contact the Research Office so the package can be assigned to the "Cornfield Agenda" for Research Administration and/or RDC.

- **Package Notes** – a "Package Note" is a note that would be specific to a given package that has details specific to that submission, e.g., "Update protocol and consent form to update risks/benefits". This helps keep a clear audit trail as well as making it easy to find older changes in a long list of package submissions.

- **Project Mail** – these messages can be sent to study team members and/or Research Admin and are tracked in IRBNet. *Be aware that messages sent via Project Mail are visible to anyone with access to the project, including research administrators and R&DC reviewers!* Helpful uses for Project Mail are to remind personnel of training that is due or when a package signature is required by the PI.

- **Tags** – tags can be either "global" or "single submission" and multiple tags can be added to a project. A **global tag** is one that will carry through with the project on each package within your workspace. A **single submission tag** is one that is specific to that package. **Note**: Tags created by researchers are not visible to Research Administration or RDC reviewers when packages are submitted for review.

- **My Reminders vs. Messages & Alerts** – there are two ways to track notifications in VAIRRS/IRBNet. The "My Reminders" area is more of a global message area that tracks information on all active projects. The "Messages & Alerts" area is specific to each project and only tracks information relevant to that project.

- **Archive a Project** – if you no longer wish to see a project in your "active projects" list, you can archive it to remove it from view (you can un-archive a project at any time). To the right of the project title, click the folder icon with the down arrow to archive. You will be asked to confirm this action. **Note**: If there are any active notifications (red flags), the project will remain on the active project list until those notifications are removed. You can click "show archived projects" above the table of active projects to view the archive list.

- **Lock Status of Packages** – when a package is submitted for review, the package is immediately "locked".
  Grey padlock icon – a package is locked upon submission and cannot be modified while locked. If revisions to a package are needed prior to review (e.g., missing or incorrect documents), the Research or RDC Administrator will unlock the package with a message stating what must be done. This message is automatically sent to the study team.
  Red padlock icon – this indicates a package has been unlocked by Research or RDC Admin and will show "revisions pending". Click on the red padlock in the My Projects list and then "view history" next to the padlock icon in the Designer page to view the comments indicating why the package was unlocked. Once revisions are complete, click "Mark Revisions Complete", and a message is automatically sent to Research Admin.
  Green padlock icon – this indicates a package has been revised and the study team member has marked revisions complete. Once verified, the lock status must be changed to "locked" by Research Admin and the icon will revert to the gray padlock.

DIRECTORY OF VA RESEACH OFFICE and ANCILLARY STAFF:

If you are unsure of who to contact for questions, please email VHAMADRDCoordinator@va.gov for assistance.

Name	Title	Questions Regarding:	Email
Nasia Safdar	ACOS/Research	VA investigator responsibilities	Nasia.Safdar@va.gov
Jake Lindheimer	Deputy ACOS/Research	Human Subjects Research Support, Clinical Trials Task Force	Jacob.Lindheimer@va.gov
Aaron Heneghan	Administrative Officer (AO)	Budgets, CARES (VA non-profit), personnel & hiring	Aaron.Heneghan@va.gov
Jamie Swanlund	R&DC Coordinator	RDC and IRB protocol submission, human subjects research	Jamie.Swanlund@va.gov
Karen Hoffman	Research Administration	Research and VAIRRS/IRBNet administration, staff training requirements	Karen.Hoffman@va.gov
Jenna Quinto	Grants Manager/Technical Writer	VA grant opportunities & applications submission, manuscript prep	Jenna.Quinto@va.gov
Jacque Bohrmueller	Staff Onboarding Specialist	WOC Onboarding/Renewals, Badging	Jacqueline.Bohrmueller@va.gov
Mina Herreman	Training Specialist	Requirements for VA training, COI submission	Mina.Herreman@va.gov
Dan Aughey	Purchasing Assistant	Ordering equipment and supplies	Daniel.Aughey@va.gov
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Amy Reeder	SRS and IACUC Coordinator	Safety Survey, SRS committee	Amy.Reeder@va.gov
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Brian Rothermel	VA Information System Security Officer (ISSO)	Information security, data sharing	Brian.Rothermel@va.gov
Dyan Lesnik	Data Specialist	Data from CPRS, VISTA, VINCI, etc.	Dyan.Lesnik@va.gov
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Jennie Piccolo	Research Pharmacist, hematology/oncology	Oncology clinical trials	Jennifer.Piccolo@va.gov
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