VA R&D Committee

Submission Guidelines for RDC Review in VAIRRS/IRBNet

William S. Middleton
Memorial Veterans Hospital
Madison, WI 607

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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!

DIRECTORY OF VA RESEARCH OFFICE and ANCILLARY STAFF

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

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INTRODUCTION

All research at the Madison VA is conducted under the purview of the Madison VA R&D Committee (RDC) and its subcommittees (e.g., IRBs, IACUC, SRSS) on behalf of the Medical Center Director (MCD) and Chief of Staff. A Principal Investigator (PI) may not initiate a study until the VA RDC and all relevant subcommittees have granted final approval (or exemption) of the project, and the PI has received written documentation of approval from the VA Associate Chief of Staff for Research (ACOS/R).

All research at the Madison VA is reviewed and approved using the VA Innovation and Research Review System (VAIRRS), the VA's enterprise-wide instance of IRBNet (gov.irbnet.org). You must register for an account in the VAIRRS/IRBNet system and affiliate with the William S. Middleton Memorial Veterans Hospital (WSMMVH). Details on registration in VAIRRS/IRBNet as well as VA training requirements can be found in Appendices 1 and 2.

Contact the Madison VA RDC Coordinator (VHAMADRDCoordinator@va.gov) prior to initiating a research project if you need help determining whether your study falls under VA purview. See separate guidance for information on submitting non-human subjects research (e.g., animal, data- or laboratory-only) protocols for IACUC and/or SRSS committee review and subsequent RDC approval.

Projects requiring submission to the VA RDC may be:

- **Human Subjects Research (HSR)** – this is a project that meets the regulatory definition of research under the Common Rule (VA: 38 CFR 16; DHHS: 45 CFR 46 Subpart A) and an IRB has determined to be one of the following:
    - More than Minimal Risk (MMR) – these projects receive initial review and approval by the IRB and VA RDC, with annual reviews conducted by the IRB and RDC (NOTE: The RDC does not conduct a separate continuing review if such is required by the IRB of record; however, the approved continuing review application and IRB approval letter must be reported to the RDC by submission of these documents in IRBNet, along with an annual updated Conflict of Interest form for all relevant investigators).

      Project modifications determined by the IRB (or RDC) to require RDC approval must be submitted in IRBNet for review. Modifications determined to not require RDC review are to be reported to the RDC by submission of the amendment documents in IRBNet following IRB approval.
    - Minimal Risk (MR) – these projects are reviewed similarly to MMR projects with the exception that in some cases under the revised Common Rule, initial and/or annual reviews conducted by the IRB can be done under expedited procedures. In some instances, continuing review may not be required by the IRB; however, an annual report and updated Conflict of Interest is still required to be submitted to the RDC in IRBNet for such projects annually by the anniversary date of initial IRB approval.

      Project modifications determined by the IRB (or RDC) to require RDC approval must be submitted in IRBNet for review. Modifications determined to not require RDC review are to be reported to the RDC by submission of the amendment documents in IRBNet following IRB approval.
    - Exempt– these are MR projects that are determined by an IRB to be exempt from further IRB review (with a few notable exceptions such as changes in PI, funding, reportable events, etc. that may affect exemption status). After a determination of IRB exemption has been made, these projects then fall under the purview of the VA RDC for initial *and* annual review and approval.

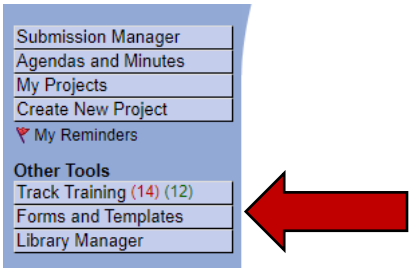
Project amendments to IRB-exempt projects are reviewed and approved solely by the RDC unless there is a change as noted above that may affect the project's exemption status. See section **RDC-ONLY PROJECTS: EXEMPT and NON-HUMAN SUBJECTS RESEARCH (NHSR)** for further details.

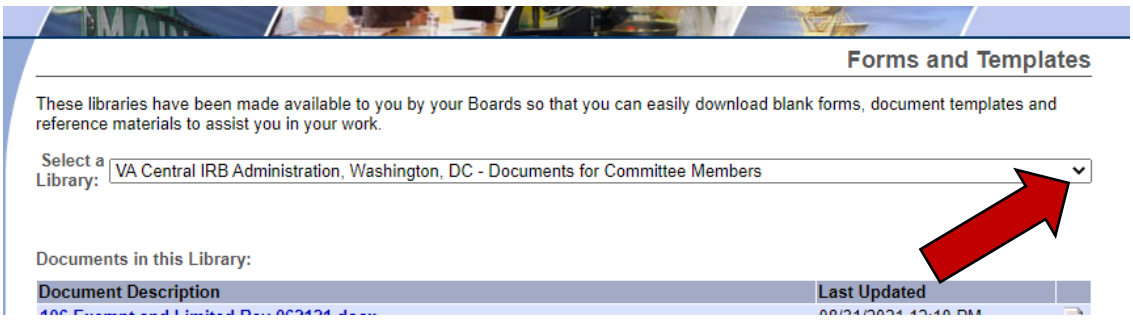
- **Non-Human Subjects Research (NHSR)** – this is a project that meets the regulatory definition of research, but does not involve human subjects and subsequently, does not require review by an IRB. NHSR projects at the VA fall solely under the oversight of the RDC for initial approval and annual reviews. An example is a study using de-identified tissue from a commercial source or de-identified data from a database (e.g., VINCI, CDW, etc.) or laboratory studies that do not involve animals or human subjects. See section **RDC-ONLY PROJECTS: EXEMPT and NON-HUMAN SUBJECTS RESEARCH (NHSR)** for further details.
- **Quality Improvement/Quality Assurance (QI/QA) or Program Evaluation** – these are projects that do not meet the regulatory definition of research. The project PI can use the QI/QA "Self-Certification Tool" provided by our IRB of record (UW Health Sciences IRB) to help make this determination. More information on QI/QA and program evaluation projects, as well as the *UW Self-Certification Tool*, can be found on the UW Health Sciences IRB website.
    - If the project is determined to be QI/QA, a copy of the PDF "determination" from the IRB Self-Certification Tool must be sent by email to VHAMADRDCoordinator@va.gov for recordkeeping. These projects are tracked in collaboration with the Madison VA's Privacy Officer (PO) and Information System Security Officer (ISSO) to ensure all data security and privacy concerns are addressed.

If you are an eligible VA investigator and would like to schedule a brief meeting to discuss your project and its submission into the VA project review system (VAIRRS/IRBNet), contact VHAMADRDCoordinator@va.gov.

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)

REQUIRED DOCUMENTS FOR NEW VA PROJECTS

THE FOLLOWING DOCUMENTS ARE REQUIRED FOR ALL RESEARCH SUBMISSIONS TO THE VA R&D COMMITTEE
(This includes projects determined to be exempt from further IRB review under The Common Rule: VA - 38 CFR 16; DHHS – 45 CFR 46)

See **Appendix 3** for "*Submission Checklists*" for project applications (New/Initial Project and Project Amendments) for each of the IRBs approved for use at the Madison VA (UW Madison HS-IRB, VA CIRB, and NCI CIRB) and non-human subjects research projects. These checklists provide a summary of the required documents to be submitted to the RDC. Please contact VHAMADRDCoordinator@va.gov if you are considering submission to a commercial or alternative IRB.

❒ **Complete and return the following by email to the RDC Coordinator:**

- **Research Financial Conflict of Interest (COI) Form (OGE Form 450 Alt-VA)** – A separate COI form must be completed and signed by the Principal Investigator (PI), *as well as each additional study team member serving in the role of an investigator* on the research project. This form is reviewed & approved by the local Conflict of Interest Administrator; if there is a financial conflict of interest for any investigative team member, the final determination must be made by the VA Office of General Counsel (OGC).
  - Complete the personnel and study information on page 2, then answer the COI questions on pages 3-4. If any of these questions were answered "yes", complete all required follow-up questions on pages 5-6. If all questions on pages 3-4 were answered "no", skip to page 7.
  - On page 7, enter initials x3 and sign with a digital signature. Please do not print/sign/scan this form!
  - Email the completed COI form(s) to the RDC Coordinator. A determination letter will be sent to you and must be included with your project application when submitted to the RDC in VAIRRS/IRBNet.

  Upload the determination letter only - DO NOT UPLOAD THE OGE Form 450 into VAIRRS/IRBNet!

- **Page 18 – Investigator Profile (IF APPLICABLE)** – This form is required for new VA investigators only. A copy of your CV/biosketch is required for all new investigators submitting a Page 18.

❒ **ISSO & PO Review for Privacy and Information Security in Research** – Review by the VA Information System Security Officer (ISSO) and VA Privacy Officer (PO) is required for all projects. Note: Review of non-HSR protocols is subject to ISSO review; the PO must review if there is a HIPAA waiver or may choose to review any project at their discretion.

There is a "cheat sheet" (**ISSO_PO Required Elements for Project Review**) in the "*WSMMVH R&DC – Documents for Researchers*" Forms and Templates library in VAIRRS/IRBNet that provides details on what information must be incorporated into the study protocol and/or IRB application to satisfy the ISSO and PO review requirements.

*Projects reviewed by the UW IRB, VA CIRB, or NCI CIRB: Complete the **Enterprise Research Data Security Plan (ERDSP)** and **VA 10-250** forms. For the VA CIRB, these forms are required to document local context information for the project; do not submit the ERDSP/10-250 reviewed by the national ISSO/PO for the PI_SC project application. Templates and instructions are available in the "Forms and Templates" of VAIRRS/IRBNet in the "*VHA ORPP&E, Washington, DC – Documents for Human Subjects Researchers*" library.

*Projects to be reviewed by WCG (WIRB), Advarra, or other pre-approved commercial IRB: Complete a local version of the **ERDSP and VA 10-250** forms to document local context information for the project, even if the project has already been reviewed by the national VA ISSO and/or PO. Contact the RDC Coordinator when planning to submit a project application to a commercial IRB.

Once your project application and materials have been submitted in VAIRRS/IRBNet for review, a teleconference may be scheduled with the VA ISSO, PO, RCO, and members of the study team to go over the ISSO and PO forms, ask & answer questions, and identify any areas that remain to be addressed so final ISSO & PO signatures can be obtained. Note: A copy of the final approved and signed ERDSP and 10-250 forms will be emailed to you and must then be uploaded to the application package in VAIRRS/IRBNet for final RDC approval.

- ❒ **VA Safety Survey** – The VA Subcommittee on Research Safety and Security (SRSS) must review all VA research projects or grant an exemption of review. SRSS approval/exemption is required to receive final approval from the VA RDC. You will need to complete and submit any additional forms as required or requested by the SRSS.
  - **SRSS Safety Survey (Form 10-0398)** – Complete the "SRS Safety Survey 2022" form and submit as a separate package in VAIRRS/IRBNet for review. This can be found in the document library "*WSMMVH SRS – Documents for Researchers".*

- ❒ **IRB Application** – Submit an application for review to an appropriate IRB of record. If you are unsure which IRB is most appropriate, contact the RDC Coordinator to help make this determination.
  - **UW IRB:** The UW Health Sciences IRB is the local IRB of record for the Madison VA. You will need a UW NetID to submit an online application into their online protocol review system, ARROW.
    - Complete and submit a VA project application in ARROW for review.
    - Work with the IRB review staff to complete pre-review. This involves answering any questions they may have and making modifications to the IRB application and/or project materials as requested to meet regulatory requirements.
    - You will receive an email notification from ARROW when the project has cleared the initial IRB pre-review process and requires "Ancillary Review" (i.e., endorsement by the VA RDC) before being scheduled at a convened IRB meeting or receiving IRB approval via expedited review procedures.
    - When the project is ready for review by the RDC, a PDF of the IRB application and all supporting project documents (e.g., protocol, consent form, HIPAA form, etc.) must be submitted into IRBNet. See detailed instructions on submission below (new projects – page 11; amendments – page 15; instructions on how to download the IRB application from ARROW are in **Appendix 4**).

  - **VA Central IRB (CIRB):** The VA CIRB is an approved IRB of record for the Madison VA. The study team should initiate and remain in contact with the RDC Coordinator as soon as site selection is confirmed and a Local Site Investigator (LSI) in Madison is named. Study teams will work closely with their lead PI/SC study site to prepare the LSI Application (CIRB Form 104) and other required VA CIRB forms and supporting documents. Forms and guidance for the VA CIRB can be found in the "*VA Central IRB Administration, Washington, DC – Documents for Researchers*" library in IRBNet. If there are questions regarding local context considerations during this process, contact the RDC Coordinator.

    Once the VA CIRB has approved the PI/SC application, local sites are then permitted to submit applications for review. These LSI applications must first be submitted to the VA RDC for endorsement. Upon endorsement by the RDC Chair or convened committee, the RDC Coordinator will route the package to the VA CIRB for review. The study team is not to submit documents directly to the VA CIRB for initial review of a project.

- **NCI CIRB:** The NCI CIRB is an approved IRB of record for the Madison VA. The study team must submit the most current version of the national project application approved by the NCI CIRB (initial application or project amendment) in VAIRRS/IRBNet, along with all other required documents for review. See detailed instructions on VAIRRS submission below (new projects – page 11; amendments – page 15). Also see "*Review and Approval of Protocols from the NCI CIRB*" in Appendix 5 for details on the approval process for NCI protocol submissions.

- **Commercial IRBs**: At this time, WCG IRB (formerly WIRB) and Advarra are approved commercial IRBs of record for the Madison VA. Detailed guidance is pending for commercial IRBs. Please contact the RDC Coordinator.

- **Other**: Submission to an IRB not listed above requires pre-approval by the Madison VA Research Office and Medical Center Director (MCD), as well as the VA Office of Research and Development (ORD). VA ORD will make a final determination whether the Madison VA could be allowed to enter into a reliance agreement with the IRB in question. If the project sponsor is requesting an IRB other than one above, contact the VA Research Office at VHAMADRDCoordinator@va.gov immediately.

❒ **IRB Determination Letter for Exempt or Non-HSR Projects (if applicable)** – If an IRB has issued a determination that your project is to be exempt from further review or was determined to not be human subjects research (NHSR) or does not meet the definition of research at all, the IRB determination letter must be submitted in VAIRRS/IRBNet with project documents for RDC review.

❒ **Pharmacy Documents** – If the study involves the use of an investigational drug or device, the following forms are required:

- **Pharmacy Impact Form** – This is required for all studies in which an investigational drug/biologic will be used, regardless or source or sponsor.
- **Investigator's Brochure (IB) or package insert** is required for all products in which one is available.
- **VA Form 10-9012 – Investigational Drug Information Record** – This is required for all studies in which an investigational drug/biologic will be used, regardless of source or sponsor, to document all approved authorized prescribers for the project.
  - Once completed, the Principal Investigator must sign in Box 20.
  - IRB Chair signature is not required (a current IRB approval memo on file is accepted in lieu of signature).
  - RDC Chair signature is required in Box 21b ("Approved By"). This will be obtained by the RDC Coordinator upon final project approval. A copy will be sent to the pharmacy & published as a Board Document to VAIRRS/IRBNet.
- A copy of either the **FDA IND Application** approval or **IND letter of exemption** (when applicable)
- A copy of the **FDA Form 1572** Statement of Investigator is required (when applicable)

  When applicable, a copy of these documents may be requested by the pharmacy and can be submitted via email. Even if copies of documents are requested by the VA pharmacy by email, you must still upload copies of all relevant documents with your application package in VAIRRS/IRBNet.

NEW PROJECT APPLICATION SUBMISSION IN VAIRRS/IRBNet

Submit an application "package" for RDC review into the VAIRRS/IRBNet project review system (gov.irbnet.org). If you do not yet have an account, you can click "Register Now". You must affiliate your account with the "*William S. Middleton Memorial Veterans Hospital*". Contact the RDC Coordinator for assistance or to receive guided instruction on project submission.

1. Click "**Create New Project**" in the menu on the left side of the screen.

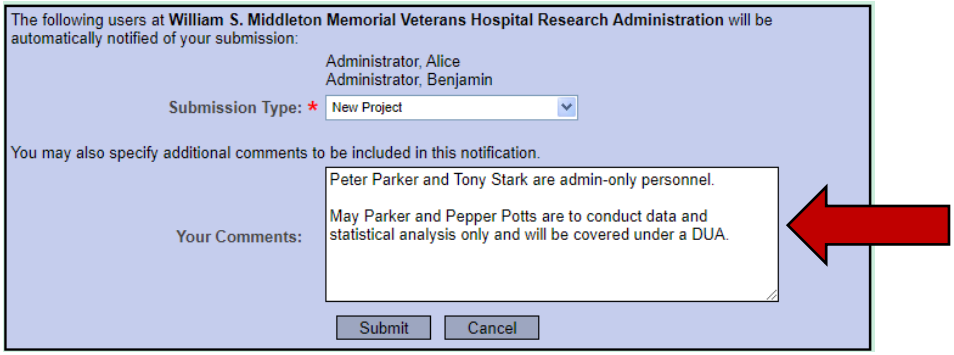
2. Enter the project title, PI name & degree(s), and sponsor (if no sponsor, enter "None". Enter the IRB Project ID# (e.g., 2022-9999, 22-99, EA2299) as a required keyword. If there is no sponsor, enter "None" in this field. The Internal Reference Number is optional and is for use by you and your team and is not visible to Research Admin or committees. Click "Continue" to go to the Designer page.

3. Enter a "**Package Note**" (yellow sticky note icon) at the top of the page to describe the submission (e.g., "New Project for RDC Review".

4. Click "Start a Wizard" and choose "**VA – Project Cover Sheet**".
   - If you have not yet submitted a project in VAIRRS you will "***Create a new wizard from scratch***". Complete all sections and save. ALL personnel who are engaging in the project or submitting documents in IRBNet must also be listed on the Project Cover Sheet with the following exceptions:
     i. Personnel who have an administrative-only role on the project (i.e., preparing and submitting study documents for regulatory review).

     ii. Personnel named on the IRB application and/or protocol who do not have a VA appointment but will be involved in the project only via a Data Use Agreement (DUA) or Material Transfer Agreement (MTA) such as statisticians, data analysts, etc.

     When ready to submit the package in IRBNet, admin-only personnel or those covered under a DUA or MTA should be identified in the comments box on the submission screen:



   - If you have previously submitted projects in VAIRRS, you can also choose to "***Clone one of my existing wizards***". This will let you choose a project from which to import study information that may be similar to your current project. You must amend and update relevant information for the new project and save.

5. Click "Start a Wizard" and choose "**VA – IRB Information Sheet**". Complete all sections and save (Note: This SMART form is not required for non-human subjects research projects).
   - If you have not yet submitted a project in VAIRRS you will "***Create a new wizard from scratch***". Complete all sections and save.

- If you have previously submitted projects in VAIRRS, you can "***Clone one of my existing wizards***". This will let you choose a project from which to import study information that may be similar to your current project. Amend and update relevant information for the new project and save.

6. Upload all required and relevant project documents. Click "**Attach New Document**" to select individual documents. You can also "drag and drop" documents directly onto the Designer page. For any documents uploaded to VAIRRS, you must select the most appropriate "Document Type" for each file (suggestions for each are indicated below). The document "Description" field defaults to the file name upon upload, but you can amend this if desired.

Unless otherwise noted, all documents and templates discussed in the following guidelines can be found in the "Forms and Templates" menu of VAIRRS/IRBNet. See section "**WHERE TO FIND VA FORMS and INFORMATION IN IRBNet**" above for details on where specific documents are located within the online libraries.

The following is a list of documents commonly submitted for new project applications:

- **IRB Application (required)** – this is required for all HSR protocols as **the VA RDC is *not* an IRB**. Upload a searchable (not scanned) PDF of the IRB application form. Document Type = "Application Form". For UW IRB protocols, see ***Appendix 4*** for details on how to download a PDF of the application from ARROW. If unsure of which application is appropriate for an IRB of record, contact the RDC Coordinator.

- **IRB Approval or Determination Letter (required)** – this will be submitted with the follow-up response package following the initial RDC review for endorsement. Document Type = "Letter".

  NOTE: For the VA CIRB, the approval letter does not need to be submitted in your response package as it is available to administrators and RDC members in the project "Reviews" menu of IRBNet.

- **Study Protocol (required*)** – there is a VA template available in the "Forms and Templates" of VAIRRS/IRBNet if there is no protocol available from a sponsor or lead site. Unless otherwise specified (e.g., for grant applications) the VA also accepts the UW ICTR protocol format for local projects. Document Type = "Protocol"

  *All non-human subjects research (NHSR) projects and projects determined to be exempt from IRB review are required to submit a stand-alone protocol in IRBNet (even if not required by the IRB).

- **VA Consent Form** – currently it is required to use the VA consent form template for all VA studies unless an exception is granted. Per local policy, the consent form and HIPAA Authorization must remain separate unless otherwise pre-approved by the Research Office in consultation with the VA Privacy Officer. Document Type = "Consent"

  - **Studies reviewed by the UW IRB**: There is local language that must be added to the consent form when applicable to a project:
    i. When any study procedures occur at the UW Hospital, UW Medical Foundation sites, and/or sites under UW-Madison purview
    ii. If data, images, and/or samples from the research study will be shared with other researchers outside the Madison VA
    iii. If data from this study will be stored on a UW-Madison database system (e.g, OnCore, REDCap)
    iv. Contact information for the UW IRB office

    Please see "***Required Consent Language for UW IRB***" in the "WSMMVH R&DC" document library for details on the language that must be added to the consent form.

- **HIPAA Authorization, VA Form 10-0493** – it is required to use the VA HIPAA Authorization template for all studies in which written HIPAA authorization is required. Even though VHA Directive 1200.05 permits inclusion of HIPAA language in the ICF when permitted by the revised Common Rule, local policy still requires a standalone HIPAA authorization form unless otherwise pre-approved by the Research Office in consultation with the VA Privacy Officer. Document Type = "HIPAA Consent/Authorization"

- **VA Request for Waiver of HIPAA Authorization** – this is required for full or partial HIPAA waiver requests made at the Madison VA. Document Type = "HIPAA Waiver"

- **Consent for Picture or Voice, VA Form 10-3203** – this form may be required for protocols in which a picture or voice recording of a research participant will be obtained *and the information cannot be disclosed in a consent form*. A final determination will be made by the VA Privacy Officer whether this form is required. Document Type = "Consent" then amend the Description field to state "10-3203 Picture/Voice" and indicate version date.

- **Release of Information – Voice Recordings, VA Form 10-5345** – this form may be required when audio recordings (regardless of whether the research participant is identified in the recording and/or whether any other PHI/PII is used/collected) are sent to an outside service for transcription. A final determination will be made by the VA Privacy Officer whether this form is required. Document Type = "Consent" then amend the Description field to state "10-5345 ROI" and indicate version date.

- **Recruitment & Screening Materials, pre- and post-enrollment (Phone/Email/Text Scripts)** – all materials for recruitment and/or direct pre-screening of participants must be submitted for review. Additionally, all scripts, templates, letters, etc. used to recruit and/or communicate with enrolled participants must be submitted for review. Document Type = "Advertisement", "Letter", "Publication Materials", "Other", etc.

  Note: Local policy does not currently permit the use of email to recruit participants; however, email can be used to communicate with enrolled participants if they have agreed (via properly executed informed consent) to be contacted in such a way.

- **Questionnaire, Assessment (clinical or self), Survey Materials, etc.** – all materials used to survey or assess a participant must be submitted for review. Document Type = "Questionnaire/Survey"

- **Investigational Drug/Biologic/Device Information** – if the project involves an investigational drug/biologic/device, all information pertaining to the approval of such as used within the scope of the research project are to be submitted for review. This includes, but is not limited to, the Investigator's Brochure (IB) or package insert, any FDA-related materials for an IND/IDE (e.g., IND/IDE application/approval or letter of exemption), or FDA Form 1572.

  i. All studies using an investigational drug/biologic/device must submit the ***VA Pharmacy Impact Form*** and the ***VA Form 10-9012*** (Investigational Drug Information Record)

- **All Other Materials** – any other materials that are relevant to project approval must be submitted. A general rule is that if a document was submitted to the IRB, it should also be submitted to the RDC for review.

7. Share the project with ALL personnel listed in the Project Cover Sheet and admin-only personnel **(required)**:

- Click "**Share This Project**" in the menu of the left side of the screen, then click "**Share**" in blue.

- Verify the correct organization is selected (WSMMVH). Click "Select Organization".
- Search for the name(s) of personnel to whom you will provide access to the project (only those who have registered for an account will show up in your search results).
  - To save time, you may share the project with your primary study coordinator/project manager and grant them "Full" access. They can then share the project with the rest of your team and prepare the submission materials on your behalf.
- If a new project is created by a study team member on behalf of the PI, the project must be shared with the PI (granting "Full" access) so they can see the project and sign it before submission.
- You must delegate the level of access for each member (you must grant each user only the minimum level of access necessary to perform their work on this project):
  - **Signature Only (Read)**: Users whose only role is to sign off on project documentation should be granted "Read" access. Users with Read access can view project documentation, communicate with the project team and add their signature. This would typically include advisors, department heads, and other individuals who are required to sign off on the project documentation prior to submission but do not otherwise have a day-to-day role on the project.
  - **Read**: Users that are granted "Read" access can view project documentation, collaborate with other users and add their signature, but may not edit project documents or perform any other administrative functions.
  - **Write**: Users that are granted "Write" access can view and edit project documents, collaborate with other users and add their signature, but may not grant access to other users, submit packages for review or perform any other administrative functions.
  - **Full**: Users that are granted "Full" access can perform all functions without restriction. This includes editing project documents, sharing the project with other users, submitting document packages for review and deleting document packages. Only Project Owners with day-to-day responsibility for the project should be granted Full access. Users with Full access will receive automatic email copies of all project notifications and alerts that are sent to the Project Owners.
- You must update/edit access at any time should personnel and/or project roles change.

8. Make sure all personnel named on the project have **current VA training** as this will be verified upon project submission in VAIRRS/IRBNet. Project applications may not be forwarded to the RDC (or its subcommittees) for review until all personnel are properly credentialed and training completed. See **Appendices 1 & 2** for details on training requirements.

9. When all required documents have been uploaded to the project package and it is ready for submission, 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; however, **THE PI MUST SIGN THE NEW PROJECT PACKAGE TO BE ACCEPTED FOR REVIEW!**

10. 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, "**New Project**". Add comments if applicable (e.g., naming admin-only personnel or personnel to be covered under a DUA/MTA) and click "**Submit**"

❒ **Contracts & Agreements (IF APPLICABLE)**

- The Research Office and RDC Coordinator will work with you to determine whether any agreements would be required for your project. These include, but may not be limited to, the following:
  - Data Use Agreement (DUA)
  - Material Transfer Agreement (MTA)
  - Letter of Understanding (LOU)
  - Off-site Waiver Request
  - Cooperative Research and Development Agreement (CRADA)

Questions? Please contact VHAMADRDCoordinator@va.gov

PROJECT AMENDMENT APPLICATION SUBMISSION IN VAIRRS/IRBNet

❒ Submit an application package for RDC review into the VAIRRS/IRBNet project review system (gov.irbnet.org).

All amendments must be submitted to the RDC in IRBNet. If RDC review is not required, the amendment documents must be uploaded for RDC acknowledgement following IRB approval.

Amendment Review Type:	**When to submit documents to the RDC in IRBNet:**
UW IRB – Full Review	Submit in IRBNet following IRB pre-review; RDC review & approval required before changes are implemented
UW IRB – Expedited Review	Only some changes require RDC review (determined by the RDC and/or the IRB): • If RDC review is required, submit in IRBNet after pre-review is completed by the IRB • If RDC review is not required, submit in IRBNet following IRB approval
VA CIRB – All Amendments	Submit in IRBNet following VA CIRB approval; RDC will acknowledge the change(s)
NCI CIRB – All Amendments	Submit in IRBNet following NCI CIRB approval; RDC review & approval required before changes are implemented
RDC-Only – All Amendments	Submit in IRBNet for RDC review and approval; no IRB review is done except in certain circumstances for exempt projects in which the change(s) may affect the exemption status
WCG cIRB – All Amendments	Submit in IRBNet following WCG approval; RDC will acknowledge the change(s)

If you are unsure whether a project amendment would require RDC review, please contact the RDC Coordinator for assistance.

1. Go to "**My Projects**" in the menu on the left side of the screen. You should see a list of all of your approved projects at the Madison VA.
2. Click on the project title of the study for which you want to submit an amendment. Click "**Create a New Package**" in the menu on the left side of the screen. This brings you to the Designer workspace.
3. Enter a "**Package Note**" (yellow sticky note icon) at the top of the page to describe the submission (e.g., "Project Amendment CP022" or "Update Personnel").
4. Update "**VA – Project Cover Sheet**" (if applicable). This form captures the study PI, personnel, funding, etc. If no changes need to be made to personnel or funding, go to Step 5.
   - Click the **pencil icon** on the right side of the document name. Select the field you would like to "Jump To" to make changes and click "Jump". Alternatively, you can select "Introduction" then click "Jump" and move through each screen by clicking "Next" if you want to be sure all applicable fields are updated appropriately. Click "Save and Exit". You can also preview for accuracy.

5. Update "**VA – IRB Information Sheet**". This form captures the study overview, enrollment and consent procedures, permission to enroll non-Veterans, information on investigational drugs/biologics, etc. If no changes need to be made to an existing *VA – IRB Information Sheet*, go to Step 6.

   - Click the **pencil icon** on the right side of the document name. Select the field you would like to "Jump To" to make changes and click "Jump". Alternatively, you can select "Introduction" then click "Jump" and move through each screen by clicking "Next" if you want to be sure all applicable fields are updated appropriately. Click "Save and Exit". You can also preview for accuracy.

6. Attach all documents relevant to the project amendment.

   Amending a document currently approved by the RDC ("Documents from Previous Packages that you can revise"):

   1. Locate the document you wish to amend (e.g., consent form, protocol, etc.) in the list of documents previously approved at the bottom of the Designer page.
   2. Click the **pencil icon** on the right side of the document name.
   3. Attach the revised version of the document. In the "Description" field, update/include any relevant version date(s). If uploading a revised version of a document already in IRBNet, you can manually update the description information *or* you can delete the pre-filled "Description" field and the system will pre-fill the name of the file after it is uploaded.
   4. The document you made changes to will now "jump up" to the top of the page in a section called "Documents in this Package". This alerts the RDC reviewers to which documents have been changed and which have already been approved in a previous submission.

   Adding a document not yet approved by the RDC:

   1. 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. For any new documents uploaded to VAIRRS/IRBNet, you must select the most appropriate "Document Type" for each file.

   NOTE: A "tracked changes" version of all documents amended or relevant to the project amendment must be submitted for RDC review. If the document cannot be tracked or otherwise annotated to denote changes, the changes must be summarized in the IRB/RDC amendment application or a separate document.

   Unless otherwise noted, all documents and templates discussed in the following guidelines can be found in the "Forms and Templates" menu of VAIRRS/IRBNet. See section "**WHERE TO FIND VA FORMS and INFORMATION IN IRBNet**" above for details on where specific documents are located within the online libraries.

   The following is a list of documents commonly submitted for project amendment applications:

   - **IRB/RDC Amendment Application (required)** – this is required for all project amendments.

     For UW IRB Amendments: A searchable PDF copy of the study's "Modified Application" is required in addition to the "Change Application". See ***Appendix 4*** for details on how to download a PDF of the application from ARROW.

     For IRB-Exempt or Non-HSR Projects: For projects that have been exempted from further IRB review and are under the purview of the VA RDC for amendments & annual reviews, complete and upload form "***3.0 – RDC Amendment Application***". This can be found in the "*VHA ORPP&E, Washington, DC – Documents for Human Subjects Researchers*" library in the Forms and Templates area of VAIRRS/IRBNet.

   - **Study Protocol (if applicable)** – include a "tracked changes" version of the protocol if amended.

- **VA Consent Form (if applicable)** – include a "tracked changes" version of the consent form if amended.
- **HIPAA Authorization, VA Form 10-0493 (if applicable)** – if changes other than updating the version date are made to the study HIPAA form, describe changes in either a separate document or email. As a reminder, even though VHA Directive 1200.05 permits inclusion of HIPAA language in the ICF when permitted by the revised Common Rule, local policy requires a standalone HIPAA Authorization form.
- **Recruitment & Screening Materials, pre- and post-enrollment (Phone/Email/Text Scripts) (if applicable)** – if changes are made to the study materials, a "tracked changes" version of each relevant document is required.

  Reminder: Local policy does not currently permit the use of email to recruit participants; however, email can be used to communicate with enrolled participants if they have agreed (via properly executed informed consent) to be contacted in such a way.
- **Questionnaire, Assessment (clinical or self), Survey Materials, etc. (if applicable)** – if changes are made to the study materials, a "tracked changes" version of each relevant document is required.

7. Make sure all personnel named on the project have current VA training as this will be verified upon project submission in VAIRRS/IRBNet. Project applications may not be forwarded to the RDC (or its subcommittees) for review until all personnel are properly credentialed and training completed. See **Appendices 1 & 2** for details on training requirements.

8. When all required documents have been uploaded to the project package and it is ready for submission, 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; however, **THE PI MUST SIGN THE PROJECT AMENDMENT PACKAGE TO BE ACCEPTED FOR REVIEW!**

9. 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, usually "**Amendment/Modification**". Add comments, if applicable, and click "**Submit**"

Questions? Please contact the VA Research RDC Coordinator, VHAMADRDCoordinator@va.gov

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**".

QUICK REFERENCE – VAIRRS/IRBNet SUBMISSION FOR RDC REVIEW

The following is a general overview of the steps to submitting projects for review in VAIRRS/IRBNet. For details on any of the steps below, refer to the relevant section(s) of these *RDC Submission Guidelines*.

❖ 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

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.

CONTINUING REVIEW

Annual review by the R&D Committee is required for all VA studies. Determine which project type listed below is relevant and submit the required documents accordingly.

FOR PROJECTS THAT COMPLETE AN ANNUAL CONTINUING REVIEW WITH AN IRB:

- IRB Continuing Review Application or Project Closure
- IRB Continuing Review approval letter
- Complete a COI form(s) and submit the financial COI determination letter in IRBNet*

FOR PROJECTS THAT DO NOT REQUIRE IRB CONTINUING REVIEW PER THE COMMON RULE:

- Submit the "*RDC-MSN Application for Annual Review or Project Closure*"
- Complete a COI form(s) and submit the financial COI determination letter in IRBNet *

FOR PROJECTS THAT ARE RDC-ONLY (e.g., IRB-EXEMPT AND NON-HUMAN SUBJECTS RESEARCH):

- Submit the "*RDC-MSN Application for Annual Review or Project Closure*" form in IRBNet
- Complete a COI form(s) and submit the financial COI determination letter in IRBNet *

For RDC-only projects: the study team will receive notification from the VAIRRS/IRBNet system 60, 30, and 0 days before the project expiration date. An application for continuing review must be submitted to the RDC at least 3 weeks prior to the expiration date to avoid a lapse in approval. See details in section RDC-ONLY PROJECTS: IRB-EXEMPT and NON-HUMAN SUBJECTS RESEARCH (NHSR).

SUBMISSION IN IRBNet

- ❒ Upload required form(s) per project type above.
- ❒ 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. These are submitted by email the RDC Coordinator and a letter is returned to you. You must upload the annual **financial COI determination letter** to IRBNet.

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

- ❒ Update the "**VA-Project Cover Sheet**", if applicable (update project personnel or funding).
- ❒ When all required documents have been uploaded to the project package, 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.

  A designee may sign in lieu of the PI for projects still under the purview of an IRB.

  The PI must sign annual review packages submitted for RDC-only projects.
- ❒ After the PI (or designee, if applicable) 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 = "**Continuing Review/Progress Report**". Add comments if applicable and click "**Submit**"

RDC-ONLY PROJECTS: IRB-EXEMPT and NON-HUMAN SUBJECTS RESEARCH (NHSR)

Projects determined by an IRB to be exempt from further IRB review (outside of special circumstances such as a change in the project PI, reportable events, or changes in budget funding that may affect the project's exempt status) or projects determined to be non-human subjects research (NHSR) are reviewed by the VA RDC for initial *and* annual reviews as well as all project amendments. Annual review with the RDC is required to keep the project active and in good standing.

2) IRB-EXEMPT PROJECT REVIEW

You are notified by the IRB of record if your project fits the definition of exempt research, as well as what category(ies) of exemption are cited in their determination under the revised Common Rule. When the RDC grants final approval of a new IRB-exempt research project, the decision letter from the ACOS/Research will outline basic information on how to maintain compliance with VA and other federal regulations.

Notably, you will be given a ***project expiration date*** by which you must both submitted an application for renewal (or project closure) as well as have received RDC review and re-approval of the project or acknowledgement of project closure. Project renewals are usually done annually but the RDC may decide to require review and renewal more frequently should they feel circumstances of the project would require more frequent monitoring. However, the RDC is not permitted to approve a project for a period greater than 365 days.

a) **INITIAL REVIEW OF IRB-EXEMPT PROJECTS** – You must submit an application to the RDC for initial review and approval. This submission will occur either before the IRB of record issues their exemption determination (e.g., UW IRB) or in some circumstances after the IRB exemption determination is made. You must submit a new project application for review by the RDC, which is to include:

- ❒ Project Cover Sheet (online SMART wizard in IRBNet)
- ❒ IRB Information Sheet (online SMART wizard in IRBNet)
- ❒ IRB Project Application
- ❒ Project Protocol (required)
- ❒ Request for Waiver of HIPAA Authorization (if applicable)
- ❒ IRB Exemption Determination Letter (can be in a subsequent response package)
- ❒ ERDSP (VA ISSO review form)
- ❒ VA 10-250 (VA PO review form)
- ❒ VA Safety Survey (submit as a separate package in IRBNet)
- ❒ Financial Conflict of Interest Determination Letter ***DO NOT submit the COI Form OGE-450 in IRBNet!**
- ❒ Any other project documents submitted to the IRB for review

❒ When all required documents have been uploaded to the project package, 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. The PI must sign the project package to be accepted for review!

❒ 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 = "**New Project**". Add comments if applicable and click "**Submit**"

Detailed information regarding the required documents and submission process in IRBNet can be found above in the *Required Documents for New VA Projects* and the *New Project Application Submission in VAIRRS/IRBNet* sections of these guidelines.

b) **ANNUAL RENEWAL OF IRB-EXEMPT PROJECTS** – You will receive notification from the VAIRRS/IRBNet system 60, 30, and 0 days before your project expiration date. You must submit an application for continuing review of the project to the RDC at least 3 weeks prior to the expiration date to avoid a lapse in approval.

- ❒ Complete and upload form "***RDC-MSN Application for Annual Review or Project Closure***". This can be found in the "*WSMMVH R&D Committee, Madison, WI – Documents for Researchers*" library in the Forms and Templates area of VAIRRS/IRBNet.
- ❒ 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. These are submitted by email the RDC Coordinator and a letter is returned to you. You must upload the annual **financial COI determination letter** to IRBNet.
- ❒ Update the "**VA-Project Cover Sheet**" if applicable (update project personnel or funding).
- ❒ When all required documents have been uploaded to the project package, 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. The PI must sign the project package to be accepted for review!
- ❒ 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 = "**Continuing Review/Progress Report**". Add comments if applicable and click "**Submit**"

c) **AMENDMENTS/MODIFICATIONS TO IRB-EXEMPT PROJECTS** – Though exempt from most IRB review and follow-up, all modifications to an IRB-exempt project (including changes/updates to project personnel) must be reported to the RDC in VAIRRS/IRBNet.

Note: If the project modification is one that would require a report/change application be submitted to the IRB, the IRB determination memo and IRB Change Application must also be submitted to the RDC in IRBNet.

- ❒ Complete and upload form "***3.0A - RDC Amendment Application***". This can be found in the "*VHA ORPP&E, Washington, DC – Documents for Research and Development Researchers*" library in the Forms and Templates area of VAIRRS/IRBNet.
- ❒ Update the "**VA-Project Cover Sheet**" if applicable (update project personnel or funding).
- ❒ When all required documents have been uploaded to the project package, 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. The PI must sign the project package to be accepted for review!
- ❒ 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 = "**Amendment/Modification**". Add comments if applicable and click "**Submit**"

Details regarding the required documents and submission process in IRBNet can be found above in the *Project Amendment Application Submission in VAIRRS/IRBNet* section of these guidelines.

3) NON-HUMAN SUBJECTS RESEARCH (NHSR) PROJECT REVIEW

Projects that are data- or laboratory-only, or have been determined by an IRB to be non-human subjects research (NHSR), fall under the sole purview of the VA RDC for initial *and* annual reviews as well as all project amendments.

When the RDC grants final approval of a new NHSR research project, the decision letter from the ACOS/Research will outline basic information on how to maintain compliance with VA and other federal regulations.

Notably, you will be given a ***project expiration date*** by which you must both submitted an application for renewal (or project closure) as well as have received RDC review and re-approval of the project or acknowledgement of project closure. Project renewals are usually done annually but the RDC may decide to require review and renewal more frequently should they feel circumstances of the project would require more frequent monitoring. However, the RDC is not permitted to approve a project for a period greater than 365 days.

a) **INITIAL REVIEW OF NHSR PROJECTS** – You must submit an application to the RDC for initial review and approval. If an IRB issued the NHSR determination, the RDC submission will occur after the IRB determination. You must submit a new project application for review by the RDC, which is to include:

- ❒ Project Cover Sheet (online SMART wizard in IRBNet)
- ❒ IRB Project Application (if an application was submitted to an IRB of record for NHSR determination)
- ❒ Project Protocol (required)
- ❒ IRB NHSR Determination Letter (if applicable)
- ❒ ERDSP (VA ISSO review form)
- ❒ VA Safety Survey (submit as a separate package in IRBNet)
- ❒ Financial Conflict of Interest Determination Letter ***DO NOT submit the COI Form OGE-450 in IRBNet!**
- ❒ Any other project documents relevant for review

- ❒ When all required documents have been uploaded to the project package, 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. The PI must sign the project package to be accepted for review!
- ❒ 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 = "**New Project**". Add comments if applicable and click "**Submit**"

Details regarding the required documents and submission process in IRBNet can be found above in the *Required Documents for New VA Projects* and the *New Project Application Submission in VAIRRS/IRBNet* sections of these guidelines.

b) **ANNUAL RENEWAL OF NHSR PROJECTS** – You will receive notification from the VAIRRS/IRBNet system 60, 30, and 0 days before your project expiration date. You must submit an application for continuing review of the project to the RDC at least 3 weeks prior to the expiration date to avoid a lapse in approval.

- ❒ Complete and upload form "***RDC-MSN Application for Annual Review or Project Closure***". This can be found in the "*WSMMVH R&D Committee, Madison, WI – Documents for Researchers*" library in the Forms and Templates area of VAIRRS/IRBNet.
- ❒ 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. These are submitted by email the RDC Coordinator and a letter is returned to you. You must upload the annual **financial COI determination letter** to IRBNet.
- ❒ Update the "**VA-Project Cover Sheet**" if applicable (update project personnel or funding).
- ❒ When all required documents have been uploaded to the project package, 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. The PI must sign the project package to be accepted for review!
- ❒ 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 = "**Continuing Review/Progress Report**". Add comments if applicable and click "**Submit**"

c) **AMENDMENTS/MODIFICATIONS TO NHSR PROJECTS** – All modifications to your NHSR project (including changes/updates to your project personnel) must be reported to the RDC in VAIRRS/IRBNet.

- ❒ Complete and upload form "***3.0A - RDC Amendment Application***". This can be found in the "*VHA ORPP&E, Washington, DC – Documents for Research and Development Researchers*" library in the Forms and Templates area of VAIRRS/IRBNet.
- ❒ Update the "**VA-Project Cover Sheet**" if applicable (update project personnel or funding).
- ❒ When all required documents have been uploaded to the project package, 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. The PI must sign the project package to be accepted for review!
- ❒ 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 = "**Amendment/Modification**". Add comments if applicable and click "**Submit**"

Details regarding the required documents and submission process in IRBNet can be found above in the *Project Amendment Application Submission in VAIRRS/IRBNet* section of these guidelines.

PROJECT CLOSURE

When you wish to close your project, you must close it with the RDC in IRBNet. You must also close the project with the IRB of record when applicable.

a) Submit a Closure Report to the IRB of record (if applicable). Save a PDF copy of the IRB acknowledgement to submit to the RDC.

b) In VAIRRS/IRBNet, go to the "**My Projects**" page.

c) Open the project you want to close and click "**Create a New Package**".

d) Complete the form "***RDC-MSN Application for Annual Review or Project Closure***". This can be found in the "*WSMMVH R&D Committee, Madison, WI – Documents for Researchers*" library in the Forms and Templates area of VAIRRS/IRBNet.

e) On the **Designer** page, 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.

   Required documents include:

   - ❒ "RDC-MSN Application for Annual Review or Project Closure "
   - ❒ Documentation of project closure with the IRB of record (when applicable)

   After attaching the documents, you must select the most appropriate "Document Type" for each file.

f) When all required documents have been uploaded to the project package, 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. The PI or a Designee must sign the project package to be accepted for review!

g) After the PI/Designee 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*".

h) Certify that the required PI/Designee signature has been added to the package. Click "**Continue**"

i) Select the appropriate Submission Type = "**Closure/Final Report**". Add comments if applicable and click "**Submit**"

j) The protocol closure will be reviewed and reported to the RDC at the next convened board meeting. The RDC will issue a memo to acknowledge the protocol closure and outline any further requirements.

REQUEST TO ENROLL NON-VETERANS IN VA RESEARCH

If you wish to enroll non-Veterans in a project (this includes enrolling VA hospital staff members/providers and family caregivers), you must first have approval from the RDC.

a) The "***3.5A - RDC Non-Veteran Application***" form is required. This can be found in the "*VHA ORPP&E, Washington, DC – Documents for Research and Development Researchers*" library in the Forms and Templates area of VAIRRS/IRBNet.

b) Submit the "*RDC Non-Veteran Application*" form along with all other application package materials (initial or amendment) in VAIRRS/IRBNet for approval.

c) The RDC will evaluate the request, along with the Medical Center Director and/or Chief of Staff as relevant, as the cost of any potential research-related injury must specifically be addressed and is to be considered prior to granting approval.

VAIRRS/IRBNet TERMS AND HELPFUL HINTS

- **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 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.
- **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** – a "Work in Progress" package can be deleted by the investigator/designee at any time; however, after a package is submitted to Research Administration it 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 a "Cornfield Agenda". These will show as "Withdrawn" under the board action.
- **Package Notes** – a "Package Note" is a note that would be specific to a given package that has details specific to that submission or details that can aid project tracking, e.g., "Amendment CP099", "Update Personnel", "Response to RDC Review". This helps keep a clear audit trail as well as making it easy to identify older 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.
- **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-HSR projects)
3) Packages submitted in response to RDC review at a convened meeting

IRBNet package submissions where a Designee signature would be accepted:

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

- **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 cannot be archived and 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 to resolve the issue. 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 the project is automatically returned to Research or RDC 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 will be changed to "locked" by Research or RDC Admin and the icon will revert to the gray padlock.

APPENDIX 1: REGISTRATION INFORMATION FOR VAIRRS/IRBNet

ALL STUDY PERSONNEL MUST REGISTER for a VAIRRS/IRBNet ACCOUNT & ENTER THEIR TRAINING

All personnel named on a research project must register for an IRBNet account. This includes anyone working in an admin-only role but does not include personnel working under a Data Use Agreement (DUA) or Material Transfer Agreement (MTA). This allows the PI to share the project with the entire study team and make their training visible to Research Administration. The PI and all study personnel must enter the required VA training information to their User Profile in IRBNet so training can be tracked & verified (details below).

Registration & training of study personnel is required for project review and approval in all VA committees. Delays in registering study team members and/or completing training will delay review of the project.

- **REGISTER for an IRBNet ACCOUNT**

  You must go to gov.irbnet.org and register for an account. You must affiliate your account with the "*William S. Middleton Memorial Veterans Hospital*" (WSMMVH).

- **ALL PERSONNEL* MUST ENTER CURRENT VA TRAINING DATES & CERTIFICATES in VAIRRS/IRBNet**
  Go to your "User Profile" and click "Add a New Training and Credentials Record".
  - Under "Document Type", scroll down to find required training under the "WSMMVH R&D Committee".
  - Enter training dates and upload a copy of the completion certificate for the following:
    - **VA TMS #10176** – "*VA Privacy and Information Security & Rules of Behavior*"
    - **VA TMS #10203** – "*Privacy and HIPAA Training*"
    - **CITI Program** – Human Subjects Protection (VA Version) **The UW version of CITI training is *NOT* accepted**
      - See instructions below on how to link your CITI training to your IRBNet profile (optional) to have certificates uploaded automatically to IRBNet when you complete them.
  - Back in the "User Profile" page, make sure to submit the training documents by clicking "***Submit***" under each of the Training & Credential files. This allows Research Admin to approve and track your training as is mandated to maintain program compliance. You can update these in the future as needed.
  - VA TMS #10176 and #10203 must be renewed annually. The VA CITI human subjects training must be renewed every two years.

***ADMIN-ONLY PERSONNEL MUST REGISTER AND COMPLETE A MODIFIED DATA SECURITY TRAINING MODULE**
All personnel whose role is strictly administrative and does not constitute engagement must still register for an account, be shared on relevant projects, and complete the following modified training:

- **VA TMS #10176** – VA Privacy and Information Security & Rules of Behavior
  - Admin-only personnel without a VA appointment and/or access to the VA TMS training system can complete a PDF version of this training. Contact the Research Office if you believe your role would qualify you for this training to obtain the current version of the PDF training and signature page.
  - Read the PDF "*FY22 Text-only Course Transcript*" of the #10176 training.
  - A separate PDF signature page must be signed to acknowledge completion of the training. The signed PDF must then be uploaded to IRBNet as your training "certificate" for the 10176 training course.

- **THE PI (or Designee) MUST SHARE THE PROJECT WITH ALL RESEARCH AND ADMIN PERSONNEL**

  Reminder: personnel acting under a DUA or MTA do not need to register for an IRBNet account and hence cannot be shared on projects in IRBNet. Personnel shared on projects are expected to complete required VA trainings.

  - On the "My Projects" page of IRBNet, click on a project title. This opens the "Project Overview" screen.
  - Click "Share This Project" in the menu of the left side of the screen. Click the blue "Share".
  - Verify the correct organization is selected (WSMMVH). Click "Select Organization".
  - Search for the name(s) of personnel to add (only those who registered for an account will show up).
    - A PI may choose to share the project with a primary study coordinator/project manager and grant them Full access. This "Designee" can then share the project with the rest of the study team on the PI's behalf.
  - You must delegate the level of access for each member (you should grant each user only the minimum level of access necessary to perform their work on this project:
    - **Signature Only (Read)**: Users whose only role is to sign off on project documentation should be granted "Read" access. Users with Read access can view project documentation, communicate with the project team and add their signature. This would typically include advisors, department heads, and other individuals who are required to sign off on the project documentation prior to submission but do not otherwise have a day-to-day role on the project.
    - **Read**: Users that are granted "Read" access can view project documentation, collaborate with other users and add their signature, but may not edit project documents or perform any other administrative functions.
    - **Write**: Users that are granted "Write" access can view and edit project documents, collaborate with other users and add their signature, but may not grant access to other users, submit packages for review or perform any other administrative functions.
    - **Full**: Users that are granted "Full" access can perform all functions without restriction. This includes editing project documents, sharing the project with other users, submitting document packages for review and deleting document packages. Only Project Owners with day-to-day responsibility for the project should be granted Full access. Users with Full access will receive automatic email copies of all project notifications and alerts that are sent to the Project Owners.
  - You can update/edit access at any time should personnel and/or project roles change.

- **LINK YOUR CITI ACCOUNT TO IRBNET AND HAVE YOUR TRAINING RECORDED AUTOMATICALLY (optional)**
  You can upload your CITI training certificates manually as described below, or you have the option to link your IRBNet profile to your CITI account (www.citiprogram.org). To link your account:

  Go to your "User Profile" and click "Add an External Account"
  - In the drop-down for *Account Type*, select "CITI Training Program"
  - Enter your CITI Member ID and click "Continue"
  - A confirmation email will be sent to the address you have listed in IRBNet.
  - Click the confirmation link in the email and your status in IRBNet should change to "Verified". Allow 24-48 hours for any CITI training records to be imported and available in IRBNet.

See also "*Appendix 2: Training Requirements for VA Research*" for details on how to access the CITI and TMS training systems.

APPENDIX 2: Training Requirements for VA Research

The VA Office of Inspector General (OIG) continues to actively monitor adherence to credentialing to the (3) training requirements listed below.

- **VA Human Subjects Protection**, (**CITI),** renewed every two years.
  This training is completed on the CITI training website, see instructions below.
- **Privacy and HIPAA Focused Training**, item #10203, renewed annually.
- **VA Privacy and Information Security Awareness and Rules of Behavior***, item #10176, renewed annually**.**
  This training is completed on the VA TMS 2.0 training website. There is a PDF version that can be signed & uploaded to your IRBNet training record for admin-only personnel. Contact the Research Office if you believe your role would qualify you for this training.

Human Subjects Research personnel must complete all three of the training modules listed above.

Animal Research personnel only need to complete the **VA Privacy and Information Security Awareness** module.

VA Human Subjects Protection, (CITI) Training:

You will need a UW NetID to access this training.

- https://research.wisc.edu/compliance-policy/human-research-protection-program/accessing-arrow-and-the-netid-process/
  - From this page, there are further links to find out if you have an active NetID, a link to activate your NetID, and a Help Desk number if needed.

To complete this course, log on at: WWW.citiprogram.org. Click on, **Log in – CITI Program**

Please be sure to Add Institutional Affiliation to the Madison VA Hospital - 607 when taking this training to receive VA credit.

NOTE: The CITI Course used by the University of Wisconsin-Madison is NOT acceptable for VA purposes.

To Complete the Two Privacy Modules in TMS 2.0:

- Using a non-VA (e.g. home or UW) computer **–** www.tms.va.gov/SecureAuth35/
- Enter your email address as your **Username.**
- Click on **Create new non-employee user**.
- Creating Your TMS Account – Follow the step by step instructions in your WOC paperwork packet.

You will be creating a password for logging in to your account. To log into your account, click on **Password Login for New Staff**. Enter your Username and the password you created.

To print a Completion Certificate:

- Under My History, click on View All.
- Click on the printer icon on the left.

If you need assistance with the VA Talent Management System (TMS 2.0) contact the Enterprise Service Desk at 1(855) 673-4357.

Jacqueline Bohrmueller
VA Research TMS Administrator VA Research Office
jacqueline.bohrmueller@va.gov ***Revised 1/2021***

APPENDIX 3: Submission Checklists for RDC Review

The following are available Submission Checklists for VA RDC Review:

- ❒ New/Initial Project Applications
- ❒ Amendments/Updates to Approved Projects
- ❒ Annual/Continuing Review, Project Closure

RDC Submission Guidelines

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

New VA Project Application Checklist for IRBNet (gov.irbnet.org)

Forms (*) required for the IRB of record:

	VA FORMS and GENERAL APPLICATION MATERIALS:	UW IRB	VA CIRB	NCI CIRB	RDC-Only	WCG cIRB
☐	**VA-Project Cover Sheet** (online SMART form wizard in VAIRRS/IRBNet)	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
☐	**VA-IRB Information Sheet** (online SMART form wizard in VAIRRS/IRBNet)	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
☐	**IRB Application** (**UW IRB**: PDF from ARROW; **VA CIRB**: For PI/SC, Form 108 (also Form 108a if Co-PI; For LSI, Form 104 or 104 NSI (also Form 104a if Co-PI); **NCI CIRB**: Most recent approved lead site amendment application; **RDC-Only**: relevant application from IRB of record; **WCG cIRB**: HRP-212 for PI or one form for each Co-PI, and HRP-290-VA Addendum)	**Yes**	**Yes** (5)	**Yes**	**Yes**	**Yes** (6)
☐	**IRB Approval Letter for Lead Site/PI_SC (multi-site projects)** (RDC will retrieve this letter from IRBNet for VA CIRB and WCG cIRB projects)	n/a	RDC Admin	**Yes**	n/a	RDC Admin
☐	**Local ACOS/R&D Review Supplement** (VA CIRB Form 102)	n/a	**Yes** (5)	n/a	n/a	**n/a**
☐	**VA Facility Endorsement Letter for Commercial IRB Submission** (national VHA template)	n/a	n/a	n/a	n/a	RDC Admin
☐	**Protocol** (VA template, UW ICTR template, sponsor template accepted) Additional Reference for local projects: *"ISSO_PO Required Elements for Project Review"*	**Yes** (2)	**Yes** (5)	**Yes**	**Yes** (2)	**Yes** (2)
☐	**Research Financial Conflict of Interest** (COI) Form(s) (OGE Form 450 Alt-VA)	EMAIL**	EMAIL**	EMAIL**	EMAIL**	EMAIL**
☐	**Research Financial COI Determination Letter** (emailed after COI review)	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
☐	**ISSO/PO Review** – ERDSP and VA 10-250 forms	**Yes** (2)	**Yes** (2)	**Yes** (2)	**Yes** (2)	**Yes** (2)
☐	**VA Safety Survey** – for SRSS approval or exemption	**Yes** (4)	**Yes** (4)	**Yes** (4)	**Yes** (4)	**Yes** (4)
☐	**NCI Study Specific Worksheet** (**NCI CIRB**: Submit to NCI *after* RDC endorsement; once approved, submit the SSW and approval letter in your response package to the RDC)	n/a	n/a	**Yes**	n/a	**n/a**
☐	**IRB Approval Letter for PI/LSI/SSW, Exemption Determination, NHSR Determination -** Following RDC initial review/endorsement (RDC will retrieve this letter from IRBNet for VA CIRB and WCG cIRB projects)	**Yes**	RDC Admin	**Yes**	**Yes**	RDC Admin
☐	**RDC Request to Review VA CIRB- or cIRB-Approved New Project** (post VA CIRB or WCG cIRB approval)	n/a	**Yes**	n/a	n/a	**Yes**
☐	**Current Training for Research Personnel** (CITI, TMS #10203, TMS #10176)	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
☐	**CV/Biosketch** (for all Local Study Team Members in an Investigator Role)	n/a	**Yes**	n/a	n/a	**Yes**
☐	**Medical License** (for all Local Study Team Members in an Investigator Role)	n/a	n/a	n/a	n/a	**Yes**
	CONSENT & WAIVERS OF CONSENT:	**UW IRB**	**VA CIRB**	**NCI CIRB**	**RDC-Only**	**WCG cIRB**
☐	VA Informed Consent Form	PRN (2)	PRN (2)	**Yes** (2)	PRN (2)	PRN (2)
☐	VA Informed Consent Form Addendum for NCI CIRB (approved 12.22.2019)	n/a	n/a	**Yes** (1)	n/a	n/a
☐	VA Participant Information Sheet	PRN	PRN (5)	**Yes**	PRN	PRN
☐	HIPAA Authorization (VA Form 10-0493)	PRN (1)	PRN (1)	**Yes** (1)	PRN (1)	PRN (1)
☐	Phone/Email/Text Scripts	PRN	PRN	PRN	PRN	PRN
☐	Waiver of HIPAA Authorization – Full/Partial Waiver Request	PRN (2)	PRN (2)	Not permitted	PRN (2)	PRN (2)
☐	Informed Consent – Use of Picture and/or Voice (VA Form 10-3203)	PRN (1)	PRN (1)	PRN (1)	PRN (1)	PRN (1)
☐	Release of Information (VA Form 10-5345)	PRN (1)	PRN (1)	PRN (1)	PRN (1)	PRN (1)

SUBJECT RECRUITMENT, QUESTIONNAIRES, SCRIPTS, Etc.:		**UW IRB**	**VA CIRB**	**NCI CIRB**	**RDC-Only**	**WCG cIRB**
☐	Recruitment Materials	PRN	PRN	PRN	PRN	PRN
☐	Questionnaires, Assessments (clinical and/or self), Surveys	PRN	PRN	PRN	PRN	PRN
INVESTIGATIONAL DRUG/BIOLOGIC/DEVICE:		**UW IRB**	**VA CIRB**	**NCI CIRB**	**RDC-Only**	**WCG cIRB**
☐	Pharmacy Impact Form	PRN (1)	PRN (1)	PRN (1)	N/A	PRN (1)
☐	VA Form 10-9012 – Investigational Drug Information Record	PRN (1)	PRN (1)	PRN (1)	N/A	PRN (1)
☐	Investigator's Brochure (IB) or Package Insert for each drug/biologic	PRN	PRN	PRN	N/A	PRN
☐	Device Manual (investigational device)	PRN	PRN	PRN	N/A	PRN
☐	FDA Form 1572 Statement of Investigator (if applicable)	PRN	PRN	PRN	N/A	PRN
☐	FDA Letters (IND, IND Exemption, IDE, HUD)	PRN	PRN	PRN	N/A	PRN
MISCELLANEOUS:		**UW IRB**	**VA CIRB**	**NCI CIRB**	**RDC-Only**	**WCG cIRB**
☐	Page 18 – Investigator Profile (for new VA PI only)	PRN (1)	PRN (1)	PRN (1)	PRN (1)	PRN (1)
☐	RDC Non-Veteran Application (requires additional approval from hospital MCD)	PRN (3)	PRN (3)	PRN (3)	PRN (3)	PRN (3)

(*) - The IRBNet document library in which a document can be found for a particular submission/IRB is listed in parentheses. See below for list of documents and their corresponding IRBNet library.

"PRN" = Forms completed "as needed" or "if applicable" to the project

***Forms and Templates Libraries** in VAIRRS/IRBNet for additional information and templates for our site:

(1) "*WSMMVH R&D Committee – Documents for Researchers*"
- "ISSO_PO Required Elements for Project Review"
- Consent – Required language for UW IRB
- Consent – VA Form 10-3203 Picture or Voice
- Consent – VA Form 10-5345 ROI for Voice Recordings (transcription)
- HIPAA Authorization, VA Form 10-0493
- NCI CIRB Consent Form Template (letterhead only)
- NCI CIRB Consent Form Addendum for VA
- Pharmacy Impact Form
- VA Form 10-9012 (Investigational Drug Information Record)
- RDC-MSN Application for Annual Review or Project Closure (for RDC-only studies: IRB-exempt or non-HSR)
- Page 18 – Investigator Profile (for new VA investigators only) **Return via email to RDC Coordinator**

(2) "*VHA ORPP&E, Washington, DC – Documents for Human Subjects Researchers*
- VA Protocol Template (UW ICTR template and protocols from an industry or federal sponsor are also accepted)
- VA ICF Template (For UW IRB, also see "Required Consent Language for UW IRB" in the WSMMVH R&DC library)
- Request for Waiver of HIPAA Authorization
- ERDSP (VA ISSO review form)
- Form 10-250 (VA PO review form)

(3) "*VHA ORPP&E, Washington, DC – Documents for Research & 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)

(4) "*WSMMVH SRS – Documents for Researchers"*
- SRS Safety Survey

(5) "VA CIRB – Documents for Researchers"

- Form 104, 104a (Co-PI) or 104 NSI (No Subject Interactions)

(6) "WCG IRB (formerly WIRB), Puyallup, WA – Documents for Researchers"

- HRP-212 Initial Review Submission Form
- HRP-290 Initial Review Submission Form – VA Addendum

For materials requiring submission via email or to request a copy of the COI/OGE Form 450 Alt-VA form, email the RDC Coordinator: VHAMADRDCoordinator@va.gov.

Have Questions?

Please contact the RDC Coordinator: VHAMADRDCoordinator@va.gov.

VA Project Amendment Checklist for IRBNet (gov.irbnet.org)

Forms (*) required for the IRB of record:

	VA FORMS and GENERAL APPLICATION MATERIALS:	UW IRB	VA CIRB	NCI CIRB	RDC-Only	WCG cIRB
☐	**VA-Project Cover Sheet** (online SMART form wizard in VAIRRS/IRBNet)	PRN	PRN	PRN	PRN	PRN
☐	**VA-IRB Information Sheet** (online SMART form wizard in VAIRRS/IRBNet)	PRN	PRN	PRN	PRN	PRN
☐	**IRB Amendment Application** (**UW IRB**: PDF of Change Application from ARROW pre- or post-IRB approval per guidelines; **VA CIRB**: Form 116; **NCI CIRB**: Most recent lead site amendment application; **RDC-Only**: Form 3.0A RDC Amendment Application; **WCG cIRB**: HRP-201 Form)	**Yes** (pre- or post-IRB approval)	**Yes** (5) (post-CIRB approval)	**Yes** (post-CIRB approval)	**Yes** (3)	**Yes** (6) (post-cIRB approval)
☐	**IRB Modified Application** (PDF from ARROW)	**Yes**	n/a	n/a	n/a	n/a
☐	**NCI CIRB Amendment Review** (reviewer's worksheet/comments)	n/a	n/a	**Yes**	n/a	n/a
☐	**3.0 RDC Amendment Application**	n/a	n/a	n/a	**Yes**	n/a
☐	**Protocol** (submit version with tracked changes)	PRN	PRN	PRN	PRN	PRN
☐	**Research Financial Conflict of Interest** (COI) Form(s) (OGE Form 450 Alt-VA)	PRN	PRN	PRN	PRN	PRN
☐	**Research Financial COI Determination Letter** (emailed after COI review)	PRN	PRN	PRN	PRN	PRN
☐	**ISSO/PO Review** – update ERDSP if data security and/or privacy amended	PRN (2)	PRN (2)	PRN (2)	PRN (2)	PRN (2)
☐	**VA Safety Survey Change of Protocol Form**	PRN (4)	PRN (4)	PRN (4)	PRN (4)	PRN (4)
☐	**IRB Approval Letter for PI/LSI** (if RDC review is required, submit in a separate package following RDC initial review/endorsement)	**Yes**	**Yes**	**Yes**	n/a	**Yes**
☐	**Current Training for Research Personnel** (CITI, TMS #10203, TMS #10176)	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
	CONSENT & WAIVERS OF CONSENT:	**UW IRB**	**VA CIRB**	**NCI CIRB**	**RDC-Only**	**WCG cIRB**
☐	**VA Informed Consent Form** (submit version with tracked changes)	PRN (2)	PRN (2)	**Yes** (2)	PRN (2)	PRN (2)
☐	**VA Informed Consent Form Addendum** for NCI CIRB (approved 12.22.2019) (submit version with tracked changes)	n/a	n/a	**Yes** (1)	n/a	n/a
☐	**VA Participant Information Sheet** (submit version with tracked changes)	PRN	PRN (5)	**Yes**	PRN	PRN
☐	**HIPAA Authorization VA Form 10-0493** (note changes if other than version date)	PRN (1)	PRN (1)	**Yes** (1)	PRN (1)	PRN (1)
☐	Phone/Email/Text Scripts (submit version with tracked changes)	PRN	PRN	PRN	PRN	PRN
☐	**Waiver of HIPAA Authorization** – Full/Partial Waiver Request (submit version with tracked changes)	PRN (2)	PRN (2)	Not permitted	PRN (2)	PRN (2)
☐	Informed Consent – Use of Picture and/or Voice (**VA Form 10-3203**)	PRN (1)	PRN (1)	PRN (1)	PRN (1)	PRN (1)
☐	Release of Information (**VA Form 10-5345**)	PRN (1)	PRN (1)	PRN (1)	PRN (1)	PRN (1)
	SUBJECT RECRUITMENT, QUESTIONNAIRES, SCRIPTS, Etc.:	**UW IRB**	**VA CIRB**	**NCI CIRB**	**RDC-Only**	**WCG cIRB**
☐	**Recruitment Materials** (submit version with tracked changes)	PRN	PRN	PRN	PRN	PRN
☐	**Questionnaires, Assessments** (clinical and/or self), Surveys (submit version with tracked changes)	PRN	PRN	PRN	PRN	PRN
	INVESTIGATIONAL DRUG/BIOLOGIC/DEVICE:	**UW IRB**	**VA CIRB**	**NCI CIRB**	**RDC-Only**	**WCG cIRB**
☐	**Pharmacy Impact Form**	PRN (1)	PRN (1)	PRN (1)	N/A	PRN (1)
☐	**VA Form 10-9012** – Investigational Drug Information Record (submit if adding/removing authorized prescribers)	PRN (1)	PRN (1)	PRN (1)	N/A	PRN (1)
☐	**Investigator's Brochure (IB)** or Package Insert for each drug/biologic	PRN	PRN	PRN	N/A	PRN

☐	**Device Manual** (investigational device)	PRN	PRN	PRN	N/A	PRN
☐	**FDA Form 1572** Statement of Investigator (if applicable)	PRN	PRN	PRN	N/A	PRN
☐	**FDA Letters (IND, IND Exemption, IDE, HUD)**	PRN	PRN	PRN	N/A	PRN
MISCELLANEOUS:		**UW IRB**	**VA CIRB**	**NCI CIRB**	**RDC-Only**	**WCG cIRB**
☐	**RDC Non-Veteran Application** (requires additional approval from VA MCD)	PRN (3)	PRN (3)	PRN (3)	PRN (3)	PRN (3)

(*) - The IRBNet document library in which a document can be found for a particular submission/IRB is listed in parentheses. See below for list of documents and their corresponding IRBNet library.

"PRN" = Forms completed "as needed" or "if applicable" to the project

***Forms and Templates Libraries** in VAIRRS/IRBNet for additional information and templates for our site:

(1) "*WSMMVH R&D Committee – Documents for Researchers*"

- Consent – Required language for UW IRB
- Consent – VA Form 10-3203 Picture or Voice
- Consent – VA Form 10-5345 ROI for Voice Recordings (transcription)
- HIPAA Authorization, VA Form 10-0493
- NCI CIRB Consent Form Template (letterhead only)
- NCI CIRB Consent Form Addendum for VA
- Pharmacy Impact Form
- VA Form 10-9012 (Investigational Drug Information Record)
- RDC-MSN Application for Annual Review or Project Closure (for RDC-only studies: IRB-exempt or non-HSR)
- Page 18 – Investigator Profile (for new VA investigators only) **Return via email to RDC Coordinator**

(2) "*VHA ORPP&E, Washington, DC – Documents for Human Subjects Researchers*

- VA Protocol Template (UW ICTR template and protocols from an industry or federal sponsor are also accepted)
- VA ICF Template (For UW IRB, also see "Required Consent Language for UW IRB" in the WSMMVH R&DC library)
- Request for Waiver of HIPAA Authorization
- ERDSP (VA ISSO review form)
- Form 10-250 (VA PO review form)

(3) "*VHA ORPP&E, Washington, DC – Documents for Research & Development Researchers*"

- 3.5A RDC Non-Veteran Application (if enrolling non-Veterans, civilian caregivers, including VA staff or providers, etc.)
- 3.0A RDC Amendment Application (for RDC-only studies: IRB-exempt or Non-HSR)

(4) "*WSMMVH SRS – Documents for Researchers"*

- SRS Safety Survey Change of Protocol Form

(5) "VA CIRB – Documents for Researchers"

- Form 116 Amendment Request Form

(6) "WCG IRB (formerly WIRB), Puyallup, WA – Documents for Researchers"

- HRP-201 Change in Research Submission Form

For materials requiring submission via email or to request a copy of the COI/OGE Form 450 Alt-VA form, email the RDC Coordinator: VHAMADRDCoordinator@va.gov.

Have Questions?
Please contact the RDC Coordinator: VHAMADRDCoordinator@va.gov.

VA Project Continuing Review Checklist for IRBNet (gov.irbnet.org)

Forms (*) required for the IRB of record:

	VA FORMS and GENERAL APPLICATION MATERIALS:	UW IRB	VA CIRB	NCI CIRB	RDC-Only	WCG cIRB
☐	**VA-Project Cover Sheet** (online SMART form wizard in VAIRRS/IRBNet)	PRN	PRN	PRN	PRN	PRN
☐	**VA-IRB Information Sheet** (online SMART form wizard in VAIRRS/IRBNet)	PRN	PRN	PRN	PRN	PRN
Is annual continuing review required by the IRB/Common Rule?						
☐	**YES - IRB Continuing Review Application** (**UW IRB**: PDF of CR Application from ARROW post-IRB approval; **VA CIRB**: Form 115a (PI/SC) or Form 115b (LSI); **NCI CIRB**: CR application worksheet; **RDC-Only**: n/a; **WCG cIRB**: HRP-251 CR Report Form)	**CR App (PDF) from ARROW**	**PI/SC – Form 115a; LSI – Form 115b** (5)	**CR App**	n/a	**HRP-251 CRRF** (in Connexus)
☐	**NO - IRB Continuing Review Application** (**UW IRB**: RDC-MSN Application for Annual Review or Project Closure; **VA CIRB**: Form 130 Annual Status Report; **NCI CIRB**: n/a; **RDC-Only**: RDC-MSN Application for Annual Review or Project Closure; **WCG cIRB**: RDC-MSN Application for Annual Review or Project Closure;)	**RDC-MSN App for Annual Review** (1)	**Form 130** (5) (post-CIRB approval)	n/a	**RDC-MSN App for Annual Review** (1)	**RDC-MSN App for Annual Review** (1)
☐	**IRB Approval Letter for PI/LSI** (if IRB continuing review is required)	PRN	**Yes**	**Yes**	n/a	**Yes**
☐	**Research Financial Conflict of Interest** (COI) Form(s) (OGE Form 450 Alt-VA)	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
☐	**Research Financial COI Determination Letter** (emailed after COI review)	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
☐	**Any Documents Modified/Submitted with Continuing Review App**	PRN	PRN	PRN	PRN	PRN
☐	**ISSO/PO Review** – update ERDSP if data security and/or privacy amended	PRN (2)	PRN (2)	PRN (2)	PRN (2)	PRN (2)
☐	**VA SRSS Annual Review or Closure Report Form** (unless exempted by SRSS at initial review due to no hazards identified)	**YES** (4)	**YES** (4)	**YES** (4)	**YES** (4)	**YES** (4)
☐	**Current Training for Research Personnel** (CITI, TMS #10203, TMS #10176)	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**

VA Project Closure Checklist for IRBNet (gov.irbnet.org)

Forms (*) required for the IRB of record:

	CONSENT & WAIVERS OF CONSENT:	UW IRB	VA CIRB	NCI CIRB	RDC-Only	WCG cIRB
☐	**IRB Project Closure** (**UW IRB**: PDF of closure submission in ARROW; **VA CIRB**: Form 117a (PI/SC) or Form 117b (LSI); **NCI CIRB**: Study Closure xForm; **RDC-Only**: n/a; **WCG cIRB**: HRP-252 Closure Report Form)	**Yes**	**Yes**	**Yes**	n/a	**Yes**
☐	**IRB Approval Letter/Acknowledgment of Project Closure**	**Yes**	**Yes**	**Yes**	n/a	**Yes**
☐	**RDC Project Closure** (RDC-MSN Application for Annual Review or Project Closure)	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
☐	**VA SRSS Annual Review or Closure Report Form** (unless exempted by SRSS at initial review due to no hazards identified)	**YES** (4)	**YES** (4)	**YES** (4)	**YES** (4)	**YES** (4)

(*) - The IRBNet document library in which a document can be found for a particular submission/IRB is listed in parentheses. See below for list of documents and their corresponding IRBNet library.

"PRN" = Forms completed "as needed" or "if applicable" to the project

***Forms and Templates Libraries** in VAIRRS/IRBNet for additional information and templates for our site:

(1) "*WSMMVH R&D Committee – Documents for Researchers*"

- RDC-MSN Application for Annual Review or Project Closure (for RDC-only studies: IRB-exempt or non-HSR)

(2) "*VHA ORPP&E, Washington, DC – Documents for Human Subjects Researchers*

- ERDSP (VA ISSO review form)
- Form 10-250 (VA PO review form)

(3) "*VHA ORPP&E, Washington, DC – Documents for Research & Development Researchers*"

- None

(4) "*WSMMVH SRS – Documents for Researchers"*

- SRSS Annual Review or Closure Report

(5) "VA CIRB – Documents for Researchers"

- Form 115a (PI/SC) or 115b (LSI) – Continuing Review Application
- Form 117a (PI/SC) or 117b (LSI) – Project or Local Site Closure Report

(6) "WCG IRB (formerly WIRB), Puyallup, WA – Documents for Researchers"

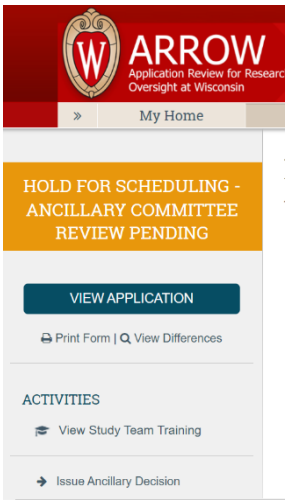
- HRP-251 Continuing Review Report Form (may have to log into Connexus for this form)
- HRP-252 Site Closure Form

For materials requiring submission via email or to request a copy of the COI/OGE Form 450 Alt-VA form, email the RDC Coordinator: VHAMADRDCoordinator@va.gov.

Have Questions?
Please contact the RDC Coordinator: VHAMADRDCoordinator@va.gov.

APPENDIX 4: Downloading Project Applications from the UW IRB

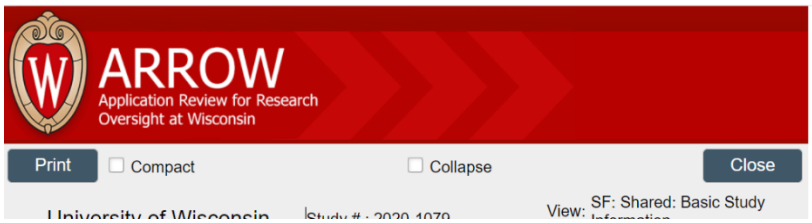
Once your project has completed the pre-review process at the UW IRB, you will receive a message from ARROW stating your project requires "Ancillary Review". Your project home page in ARROW will look similar to the following ➔



1. Click "Print Form" below the *View Application* box: ➔

2. Your full application will open in a new window.

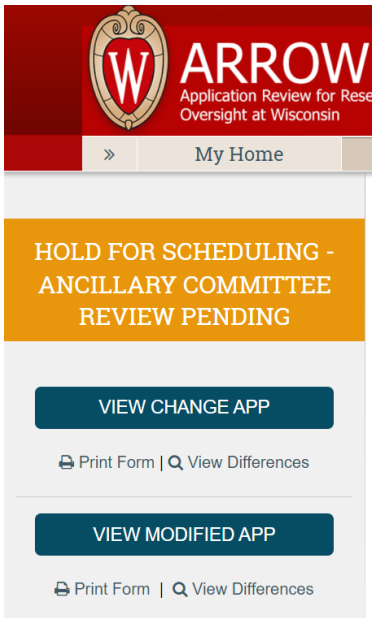
3. Click "Print" in the top left corner: ➔



4. Choose "**Save as PDF**", "**Microsoft Print to PDF**", or "**Adobe PDF**".

5. Save the PDF file along with your other project documents that are ready to be uploaded to VAIRRS.

6. For project amendments, you must download *BOTH* the "**Change Application**" and the "**Modified Application**". Click "Print Form" and follow steps 2-5 above.



APPENDIX 5: Review and Approval of Protocols from the NCI CIRB

NEW PROJECT SUBMISSIONS

NCI CIRB projects must first be approved at the University Hospital site before being eligible for submission to the VA

- ❒ **NCI Annual PI Worksheet** for the Madison VA site must be completed for the PI on a study to be scheduled for RDC review.
- ❒ Complete and submit the following form to the VA R&D Coordinator *by email*: Jamie.Swanlund@va.gov
  - **Financial Conflict of Interest (COI) Form** - required for each staff member serving in the role of an investigator
- ❒ Submit the following required materials to the VA R&D Committee in VAIRRS/IRBNet (gov.irbnet.org). The most current templates and instructions can be found in the "Forms and Templates" libraries in IRBNet:
  - **VA – Project Cover Sheet** – complete the online SMART "wizard" form
  - **VA – IRB Information Sheet** – complete the online SMART "wizard" form
  - **ISSO/PO Review: ERDSP and VA 10-250** – the R&D Coordinator act as liaison between the study team and ISSO/PO
  - **VA SRSS Safety Survey** – this is submitted as a separate package for review and approval by the SRSS committee
  - **VA Pharmacy Application**:
    - **Pharmacy Impact Form**
    - **VA Form 10-9012** – this is required to track the authorized prescribers on the project
    - **Investigational Drug Brochure(s)/Package Insert or IND Exemption Letter** – submit a copy for each investigational drug to be used
    - **Pharmacy P&T Review** – review by the VA hospital's Pharmacy and Therapeutics (P&T) committee will be facilitated and overseen by the lead VA research pharmacist concurrent with RDC review
  - **NCI CIRB Initial/Amendment Application** – attach the most recent version approved by the NCI CIRB that corresponds to the study documents submitted for RDC approval
  - **NCI CIRB Approval Letter of Lead Site/PI_SC** – attach the approval letter for the most recent version of study documents being submitted for RDC approval
  - **Study Protocol** – Submit the most current version approved by NCI CIRB that corresponds to the study documents submitted for RDC approval
  - **NCI Informed Consent Form transferred to VA ICF template** – this must include all required Madison VA boilerplate language approved by NCI using "tracked changes" so the insertions can be verified
  - **VA Informed Consent Form Addendum** – approved by NCI for use 12/22/2019
  - **VA HIPAA Form 10-0493** (Note: HIPAA waivers are not permitted for NCI studies at the Madison VA)
  - **Patient Information Sheet** – required for all NCI trials at the Madison VA
  - **Questionnaires and Interview Documents** – upload any applicable documents that will be in use locally

The PI must sign the application package in VAIRRS/IRBNet prior to it being submitted for RDC review

- ❒ The RDC will review the initial application at a convened meeting and issue a decision memo as a Board Document in VAIRRS/IRBNet. If modifications are requested or the project was approved with contingencies, the items to be addressed will be outlined in the RDC decision memo, or for more substantive changes and/or questions, in an additional **PI Response to RDC Review** document.
  - If needed, the **PI Response to RDC Review** form will be uploaded as a Board Document in VAIRRS/IRBNet. The study team must download this form and enter responses to RDC questions or requests for additional information.
- ❒ Once the RDC endorses the protocol with contingent approval, the **NCI Study Specific Worksheet** should then be submitted to the NCI CIRB by the PI for approval to conduct the trial at the Madison VA site.

❒ Submit the following required materials *in a new package* in VAIRRS/IRBNet for final RDC approval:

- **PI Response to RDC Review** with PI responses to contingencies (if applicable)
- **Study Specific Worksheet submitted to NCI CIRB**
- **NCI CIRB site approval letter**
- **COI Determination Letter** – when all investigator COI forms have been received and reviewed, the COI Administrator will issue a determination letter. This will be emailed by the RDC Coordinator to the PI/team and must be uploaded with the package for final RDC approval
- **ERDSP and VA 10-250 (Final)** – once a final, signed copy are obtained from the ISSO & PO they will be sent to the study team via email from the RDC Coordinator. The final, signed version is to replace the draft version in VAIRRS/IRBNet. Do this by using the pencil icon next to the document name in VAIRRS/IRBNet to "replace" the previous version
- **Modified Documents** - upload updated versions of any study materials for which modifications were requested by the RDC. This is done using the pencil icon next to the document name in VAIRRS/IRBNet

❒ All decision memos can be found in the "Board Documents" area of the *Project Overview* page in VAIRRS/IRBNet. A "fillable" PDF of all the most current approved consent and HIPAA documents will be uploaded, along with the RDC decision memo and approved Information Sheet, superseding all previous versions. All previous versions of consent documents are to be marked "obsolete" by the study team so they are not inadvertently used to consent new participants.

PROTOCOL AMENDMENTS TO NCI CIRB PROJECTS

Timeline for Review (Implementation Deadline)

At the top of the Designer page of a new package submission in VAIRRS/IRBNet, click on the field next to the yellow sticky note icon and clearly indicate the date of the 30-day NCI deadline for local implementation of the protocol change. This can also be added as a comment just prior to submission.

❒ Complete and submit the following form to the VA R&D Coordinator *by email*:

- **Financial Conflict of Interest (COI) Form** – required only if the protocol amendment is adding a new staff member serving in the role of an investigator

❒ Submit the following required materials to the VA R&D Committee in VAIRRS/IRBNet (gov.irbnet.org). Click the pencil icon next to the document name to upload an amended version of the relevant project document(s). If new or updated forms are needed, the most current VA templates and instructions can be found in the "Forms and Templates" library for the WSMMVH R&D Committee:

- **NCI CIRB Approval Letter** – attach the approval letter for the version of study documents being submitted
- **NCI CIRB Amendment Review Application** – attach the CIRB amendment application detailing the change(s)
- **NCI CIRB (Expedited) Amendment Review** – attached the CIRB reviewer's comment worksheet
- **Study Protocol** – submit a tracked version of the most current protocol approved by NCI
- **NCI Informed Consent Form transferred to VA ICF template** – submit a tracked version of the consent form. This must include all required Madison VA NCI boilerplate language
- **VA Informed Consent Form Addendum** – submit a tracked version of the addendum, making sure the version in the document footer matches the version on the consent form
- **VA HIPAA Form** – update when applicable. Best practice is to update the version date and submit for re-approval to keep consent documents congruent
- **Patient Information Sheet** – submit a tracked version; update when applicable to match the current protocol and consent form, making sure to also update the version date in the document footer
- **VA – Project Cover Sheet** – update when applicable (changes in funding, personnel, etc.)
- **VA – IRB Information Sheet** – update when applicable
- **VA Form 10-9012** – update when applicable (e.g., changes to drug information or addition of a new prescriber)

- **Investigational Drug Brochure(s)** – submit when IDB is updated
- **Questionnaires, Interviews, Recruitment Documents** – upload any applicable documents
- **COI Determination Letter** – when new investigator is being added with the amendment

The PI must sign the application package in VAIRRS/IRBNet prior to it being submitted for RDC review

❒ The project amendments will be reviewed by Designated Review whenever possible. If a project amendment is not eligible for Designated Review, or the Chair or Designee feel the change should be reviewed by the convened board, a reasonable effort will be made to convene an *ad hoc* RDC meeting to obtain approval within the NCI 30-day implementation deadline.

❒ All decision memos can be found in the "Board Documents" area of the *Project Overview* page on VAIRRS/IRBNet. A "fillable" PDF of all the most current approved consent and HIPAA documents will be uploaded, along with the decision memo. The approved consent documents supersede all previous versions; these older versions are to be marked "obsolete" in the PI's files so they are not used to improperly consent participants.

CONTINUING REVIEW OF NCI CIRB PROJECTS

At the top of the Designer page of a new package submission in VAIRRS/IRBNet, click on the field next to the yellow sticky note icon and clearly indicate the package submission is for continuing review (e.g., "CR22").

❒ Complete and submit the following form to the VA R&D Coordinator *by email*:
- **Financial Conflict of Interest (COI) Form** – required only if the protocol amendment is adding a new staff member serving in the role of an investigator
  - The forms will be evaluated by the VA COI Administrator and a determination letter will be returned to the study team. This letter must be uploaded in VAIRRS/IRBNet with the rest of the application materials

❒ Submit the following required materials to the VA R&D Committee in VAIRRS/IRBNet (gov.irbnet.org). If this this is the first continuing review in VAIRRS/IRBNet for this project, simply upload the required documents below. If this is a subsequent continuing review in VAIRRS/IRBNet, click the pencil icon next to the document name to upload an amended version of the relevant project document(s). If new or updated forms are needed, the most current VA templates and instructions can be found in the "Forms and Templates" library for the WSMMVH R&D Committee:

- **NCI CIRB Approval Letter** – attach the approval letter for the continuing review application
- **NCI CIRB Continuing Review Application (xForm)** – attach the CIRB Continuing Review Application xForm from IRBManager
- **COI Determination Letter** – upload the COI determination letter to document that annual review of COI has been completed
- **VA – Project Cover Sheet** – update when applicable (changes in funding, personnel, etc.)

A Designee may sign the continuing review package in VAIRRS/IRBNet on behalf of a PI if needed

❒ The continuing review applications will be reviewed by Research and RDC Administration and the submission will be acknowledged. Any concerns will be forwarded to the RDC Chair for review prior to an acknowledgement memo being issued.