WILLIAM S. MIDDLETON MEMORIAL VETERANS HOSPITAL
Madison, Wisconsin
RESEARCH and DEVELOPMENT COMMITTEE

Review and Approval of New VA Human Subjects Research Projects (v2.5 2022)

1. PI (and/or Designee) Prepares Project Materials

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2. VA Human Subjects Research Consultation

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3. Project Submitted in IRBNet by PI for Initial VA Administrative Review

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9. Project Forwarded to RDC for Review at a Convened Meeting

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10. RDC Approval and UW IRB Release of Administrative Hold

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11. (OPTIONAL) Project Amendment Required to Secure RDC Approval

❒ **Purple = VA** ❒ **Blue = PI/Study Team** ❒ **Red = UW HS-IRB** ❒ Gold = All

1 PI (and/or Designee) Prepares Project Materials

Materials

- Protocol
  - Local IIT ➔ Create study protocol using VA ORD/ORPP&E template
  - Local site with a protocol from a sponsor (e.g., VA CSP, NCI, industry-funded trials) ➔ Create Protocol Addendum on VA ORD/ORPP&E template
- IRB Application in ARROW (completed but not submitted to UW IRB)
- Online SMART form wizards in IRBNet:
  - VA-Project Cover Sheet
  - VA-IRB Information Sheet
- Consent Form, HIPAA Authorization, Information Sheet
- Request for Waiver of HIPAA Authorization (full or partial)
- All other required project documents per *RDC Submission Guidelines*
- VA Financial Conflict of Interest (VA OGE 450 Alt-VA) Form for PI and all other investigators
- Enterprise Research Data Security Plan (ERDSP) and VA Form 10-250 for ISSO and PO review, respectively
- VA Research Pharmacy documents (feasibility form, 10-9012, IDBs, etc.)

Who is involved?

- PI and study team member(s) designated by PI
- VA Regulatory Specialist (TBN) for questions
- UW IRB regulatory specialist for questions and/or confirmation of Non-Human Subjects Research (NHSR) or QA/QI
- As needed – VA RDC Coordinator (Jamie) for questions
- As needed – VA Research Admin (Karen, Aaron) for questions

Benchmarks to clear this step

- PI has created complete and robust project documents per above and has consulted with relevant VA and/or UW IRB resources and personnel to address questions as needed

2 VA Human Subjects Research Consultation

Materials

- VA Feasibility Checklist – Completed by DACOS/R in consultation with PI
- Application materials prepared for submission (see Step 1)

Who is involved?

- PI (and Designee(s) per PI request)
- DACOS/R&D (Jake)
- Research Pharmacist (Emily) – when applicable to the project
- RDC Coordinator (Jamie) for project awareness & questions as needed
- VA Regulatory Specialist (TBN) for project awareness & questions as needed

Benchmarks to clear this step

- PI presents project proposal and addresses questions in real time
- Jake answers all questions that he can from study team; refers others as appropriate. These are recorded in the Human Subjects Research Consultation document for reference.
- DACOS/R&D will present summaries to RDC Chairs at weekly meetings and highlight any concerns (if applicable). Chairs can help troubleshoot and/or refer to full committee for consideration if needed. A project can "fail" after referral to RDC from DACOS/R&D and Task Force and decision of disapproval is made.
- HSR Consultation will have dates of Initial & Revised (post-task force) reviews to show this has been completed.

3 Project Submitted in IRBNet by PI for Initial VA Administrative Review

Materials

- Application materials prepared for submission (see Step 1)
- VA Financial Conflict of Interest Determination Letter
- VA Project Feasibility Checklist (initial or revised)

Who is involved?

- PI (and Designee) – Sign and submit packages (1 for RDC, 1 for SRSS) for review. Respond to all questions from Research Admin in a timely manner
- Research Admin
  - Gatekeeper and Admin (Karen) – confirms role of project personnel and that they are registered in IRBNet and documented appropriately. Works with RDC (Jamie) and SRSS (Amy) Coordinators to make sure all required documents have been submitted
  - Training (Mina) – confirms all required VA training is assigned & completed
  - VA Appointment (Jacque) – works with personnel and VA HR to get appropriate appointments in place
- RDC Coordinator for questions

Benchmarks to clear this step

- All engaged personnel must have a VA appointment (staff, WOC, IPA, Fee-Basis) or must be covered under an agreement such as a DUA (statisticians and data analysts at UW). This process must only be started; final RDC approval will not be granted until completed.
- All engaged personnel must complete required VA training (admin-only personnel must complete VA Privacy & Rules of Behavior). This process must only be started; final RDC approval will not be granted until completed.
- All engaged personnel must have an IRBNet account and be shared on the project
- All required documents for the submission must uploaded
- A separate package for the SRSS must be submitted with the Safety Survey

4 Project Forwarded by VA Research Admin to RDC (and SRSS) for Review

Materials

- Application materials prepared in Step 1 and submitted to Research Admin in Step 3
- VA Project Feasibility Checklist (initial or revised)

Who is involved?

- PI (and/or Designee) – Respond to all questions from RDC Admin in a timely manner
- RDC Admin pre-review
  - RDC Coordinator (Jamie) and RDC Chairs (Chris & Dane)
  - ISSO (Brian) & PO (Lynn)
  - RDC Member Reviewer (assigned per project by Coordinator & Chairs)

Benchmarks to clear this step

- Admin pre-review will be completed and comments from RDC Coordinator, ISSO & PO, and RDC member reviewer will be sent to study team
  - In IRBNet: Assigned “Administrative Review” and comments published as a Board Document with action of “Modifications Requested”. Package unlocked to allow changes
- Study team completes responses and submits any modified documents and responses in IRBNet. Package re-locked by study team to submit back to RDC.
- Coordinator confirms all comments addressed; unlocks package again, if needed.
- A review package & materials will be sent to the ISSO, PO, and RDC Reviewer for concurrence that comments and questions have been addressed appropriately. RDC Coordinator will continue to liaise for relevant reviewers until all questions & issues resolved
- ISSO and PO “Initial” signatures required on ERDSP and 10-250, respectively

5 Project Endorsed by RDC via Designated Review

Materials

- RDC endorsement memo will be published as a Board Document in IRBNet

Who is involved?

- RDC Admin
  - RDC Coordinator (Jamie) will prepare the RDC endorsement memo
  - RDC Chairs (Chris & Dane) will sign the memo

Benchmarks to clear this step

- RDC Coordinator (Jamie) will upload and publish RDC memo as a Board Document
- PI (and/or Designee) – download RDC endorsement memo from IRBNet for submission to the UW IRB in ARROW

6 Project Submitted to UW IRB in ARROW by PI

Materials

- CLEAN VERSIONS (remove all tracked changes!) of RDC-endorsed application materials prepared for submission (see Step 1) and modified per RDC request (see Step 4) must be uploaded to relevant sections of the ARROW application
- RDC endorsement memo (Board Document published in IRBNet) must be uploaded on the VA Status Page in ARROW to submit the application for review

Who is involved?

- PI (and/or Designee)
- VA Regulatory Specialist (TBN)

Benchmarks to clear this step

- PI (and/or Designee) submits a clean and complete project for review in ARROW. The VA Regulatory Specialist will assist with this and make sure all the correct documents are uploaded and the submission is complete.

7 UW IRB Review

Materials

- ARROW application and project documents
- As IRB review occurs, amended project documents uploaded to ARROW must contain tracked changes

Who is involved?

- PI (and/or Designee)
- IRB Staff Reviewer
- IRB Ancillary Review Committees
- IRB Member Reviewer and/or Convened IRB Board
- VA Regulatory Specialist (TBN) – serves as IRB liaison from VA

Benchmarks to clear this step

- IRB issues approval (with Administrative Hold pending RDC approval) or an exemption determination
- Project approval notification is sent to RDC in ARROW stating Ancillary Review is now required
  - If project was determined to be exempt from further IRB review, no notification is sent to the RDC in ARROW. It is the PI's responsibility to ensure submission of the IRB exemption determination in IRBNet to receive final RDC review & approval. (VERIFY WITH UW IRB)

8 Project Submitted in IRBNet by PI for Final VA Administrative Review

Materials

- IRB Approval/Determination Memo from ARROW
- PDF of updated/revised ARROW application (stack versions; do not replace older copies)
- TRACKED VERSIONS of IRB-reviewed application materials
  - Materials that have not been amended since RDC endorsement do not require re-submission in IRBNet

Who is involved?

- PI (and Designee)
- VA Research Admin (Karen)
- VA RDC Admin (Jamie)

Benchmarks to clear this step

- All engaged staff must have a VA appointment or be named as participating as admin-only regulatory staff or covered under an agreement such as a DUA, MTA, or CRADA
- All engaged staff must have completed all required VA training. The project will not be forwarded to the RDC for review until all personnel have completed training.

9 Project Forwarded to RDC for Review at a Convened Meeting

****SUBMISSION DEADLINE**** The RDC meets the first Tuesday of each month. Projects must be forwarded from Research Administration to the RDC in IRBNet three weeks prior to the RDC meeting date. Projects that do not meet this deadline may be pushed to the next RDC meeting so submit materials to Research Admin in IRBNet promptly so any outstanding issues can be resolved.

Materials

- IRB Approval/Determination Memo from ARROW
- PDF of ARROW revised application
- IRBNet SMART Forms (VA-Project Cover Sheet and VA-IRB Information Sheet)
- TRACKED VERSIONS of IRB-reviewed application materials
  - Materials that have not been amended since RDC endorsement do not require re-submission in IRBNet
- RDC Admin Review Form with PI responses included for RDC member/committee review

Who is involved?

- VA RDC Admin (Jamie)
- VA RDC Chairs (Chris & Dane) – for consultation as needed
- VA RDC Member Reviewer(s)
- VA ISSO (Brian) & PO (Lynn)

Benchmarks to clear this step

- Review project modifications subsequent to IRB review to identify any potential issues. Changes must not interfere with any VHA policies or directives.
- ISSO and PO reviews must be completed. Final signed copies of the ERDSP from Brian and VA 10-250 from Lynn must be uploaded in IRBNet.
- SRSS review must be complete and an approval or exemption memo issued in IRBNet
- Potential issues identified during the feasibility review must be resolved or sufficiently addressed
- Pharmacy feasibility (when applicable) must be complete and required forms (e.g., VA Form 10-9012, IDB, etc.) must be submitted in IRBNet
- VA COI forms must be received, reviewed, and a determination letter uploaded in IRBNet
- Required agreements (e.g., DUA, MTA, CRADA) must be initiated with the Research Office

10 RDC Approval and UW IRB Release of Administrative Hold

Materials

- RDC approval memo signed by the VA ACOS/R&D

Who is involved?

- RDC Admin
  - RDC Coordinator will prepare the RDC approval memo
- ACOS/R&D will sign the memo

Benchmarks to clear this step

- RDC Coordinator will publish the RDC approval memo as a Board Document in IRBNet
- RDC Coordinator will upload the RDC approval memo to ARROW
- IRB Staff Reviewer will release the IRB's administrative hold on the project

11 (OPTIONAL) Project Amendment Required to Secure RDC Approval

Materials

- Documents and materials that require revision

Who is involved?

- VA RDC Admin (Jamie)
- VA RDC Chairs (Chris & Dane) – for consultation as needed
- VA RDC Member Reviewer(s)
- VA ISSO (Brian) & PO (Lynn) – when applicable
- VA IRB Staff Reviewer
- VA IRB Member Reviewer (and convened IRB Board when applicable)

Benchmarks to clear this step

- IRB approval of the modifications