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

R&DC Review and Approval of New Human Subjects Research Projects – NCI CIRB

Log into VAIRRS/IRBNet (gov.irbnet.org), click on **Forms and Templates**, and select the library for the "*WSMMVH R&DC Committee, Madison, WI – Documents for Human Subjects Researchers*".

The "***Read Me First***" outlines the various document libraries containing VA forms and templates required for submission. You can find more detailed information on how to submit projects in the VAIRRS/IRBNet review system in the "***RDC Submission Guidelines for Human Subjects Protocols***".

PI must have/submit an Annual PI Worksheet approved by the NCI CIRB

The PI named on a VA project must submit (if new) or have a current Annual PI Worksheet approved by the NCI CIRB

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PI submits a VA project for review to the VA R&D Committee in VAIRRS/IRBNet (gov.irbnet.org)

Prepare and submit two packages simultaneously

Package #1:
- VA-Project Cover Sheet (online SMART form)
- VA-IRB Information Sheet (online SMART form)
- ERDSP for VA ISSO review
- VA Form 10-250 for PO review
- COI determination letter
- NCI CIRB approval letter (most recent version corresponding to protocol and consent documents submitted)
- Protocol
- Consent Form *PLUS* VA Consent Form Addendum for NCI CIRB
- HIPAA Authorization
- Patient Information Sheet
- Pharmacy-related documents

Package #2:
- VA SRSS Safety Survey

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SRSS REVIEW

Safety Survey is sent to the SRSS for review or exemption

Respond to this committee directly during their review

ALL PROJECTS:

Submit financial Conflict of Interest (OGE Form 450 Alt-VA) *by email* to the VA R&DC Coordinator (VHAMADRDCoordinator@va.gov)

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COI forms must be submitted for all study team members serving in an investigator role.

The COI Administrator will sign a COI Determination Letter which is sent by email to the PI/designee

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COI determination letter is to be uploaded by the PI/designee to the application package in VAIRRS/IRBNet

or

VA R&D COMMITTEE REVIEW

Projects reviewed at the first eligible convened R&DC meeting
(submission deadline is Noon three weeks prior to the meeting date)

Any questions, modifications, or contingencies required to secure final R&DC approval will be outlined in the "*PI Response to RDC Review*" document published in IRBNet with your determination memo from the R&DC

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PI Submits Application for NCI CIRB REVIEW
(Expedited Review)

Study team completes a Study Specific Worksheet and submits it for NCI CIRB Review.

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PI Submits Response and IRB Approval to the VA R&D Committee in VAIRRS/IRBNet (gov.irbnet.org)

Package #3:
- NCI CIRB approval letter of local site
- NCI CIRB Study Specific Worksheet
- Upload completed "*PI Response to RDC Review*" form (if applicable)
- COI Determination Letter (if not previously submitted)
- Upload final signed copies of the ERDSP and VA 10-250 (emailed by R&DC Coordinator)

Note: The R&DC Coordinator can retrieve the SRSS approval/exemption letter from IRBNet; this does not need to be added to your R&DC package submission

Required for final R&DC approval: IRB approval/exemption, ISSO & PO review (final), COI determination letter, SRSS approval/exemption, VA pharmacy approval (if applicable), resolution of all questions and modification requests, as well as any other RDC contingencies as stated following initial review

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VA R&D COMMITTEE REVIEW
(Convened Meeting or Designated Review)
Projects reviewed for final approval. Memo issued in "Board Documents" in IRBNet

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R&DC Approval

Approved consent documents and patient information sheet published in Board Documents in IRBNet