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

R&DC Review and Approval of New Human Subjects Research Projects – VA 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***".

NOTE: If submitting a PI/SC Application, contact the RDC Coordinator

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)
- VA CIRB Form 104 or 104 NSI "LSI Application"
- VA CIRB Form 102 "Local ACOS/R&D Review Supplement" signed by ACOS/R&D
- ERDSP for VA ISSO (local context info)
- COI determination letter
- CV/Biosketch for Investigators
- Consent Form/Info Sheet (if applicable)
- HIPAA Authorization (if applicable)
- Recruitment Documents (if applicable)
- Requests for waivers (Forms 103, 112a, 112b)

Package #2:
- VA SRSS Safety Survey
- VA Form 10-250 for PO
- Pharmacy Impact (if applicable)
- Form 10-9012 (if applicable)

SRSS REVIEW

Safety Survey is sent to the SRSS for review or exemption

Respond to this committee directly

ALL PROJECTS:

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

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

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

or

VA R&D COMMITTEE PRE-REVIEW
(Designated Review)

Projects reviewed by the R&DC Chair and Coordinator for endorsement

Any questions, modifications, or contingencies required to secure endorsement will be communicated to the study team by email from the R&DC Coordinator

Once any requested revisions are completed and the project is endorsed by the Chair, the R&DC Coordinator will submit the application package to the VA CIRB for review

VA CIRB REVIEW
(Full or Expedited Review)

Address all questions and/or modification requests from the VA CIRB.

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

Package #3:
- RDC Request to Review VA CIRB-approved New Project
- 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 VA CIRB approval and SRSS approval/exemption letters from IRBNet; this does not need to be added to your R&DC package submission

Required for final R&DC approval: CIRB 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 review

VA R&D COMMITTEE REVIEW
(Convened Meeting)

Project reviewed for R&D approval. Decision memo issued in "Board Documents" in IRBNet

R&DC Contingent Approval or Modifications Required

If the R&DC's determination is something other than approval, respond promptly to all requests for revisions and/or more information

R&DC Approval
(Full or Designated Review)