

William S. Middleton Memorial VA Medical Center
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Initial Submission of a VA Protocol

A PI may not initiate a study until both VA R&D Committee and IRB approval or exemption is granted, and the investigator has received the approval or exemption documentation.

NOTE: For each VA protocol submitted, the responsible investigator must be a VA employee. The person need not be a physician nor a full-time employee but must be someone who can bear responsibility for any research outcomes. The VA responsible investigator must be intimately involved in the planning and execution of the research. They will be presumed to be co-authors in any publication resulting from the proposed work. The principal investigator listed on the UW Health Sciences IRB application may be listed as the VA responsible investigator ONLY if he/she holds a VA appointment.

All research at the Madison VA is subject to review and approval by either

1. Health Sciences Institutional Review Board (HS-IRB) or
2. Health Sciences Minimal Risk Institutional Review Board (MR-IRB)

For each new protocol, investigators shall submit to the R&D Committee:

1. The original plus 20 copies of:
 - a. Request to Review Research Proposal form (a federal form)
 - b. VA Application for Initial Review (a local form, see section 1202)
 - c. Investigational Drug Information Record (VA form 10-9012), if applicable
 - d. Informed consent form using VA form 10-1086, if applicable
 - e. Proposed budget
 - f. Completed VA financial conflict of interest (COI) disclosure form for each principal investigator, co-principal investigator, or collaborator
2. The original plus 4 copies of:
 - a. All material submitted to the IRB, including copies of the informed consent documents
 - b. The sponsor's study protocol
3. Any investigator's drug or device brochure, if applicable
4. An Investigator Data Sheet (a federal form) and a curricula vitae (CV) [if this proposal is the first research proposal submitted by the investigator to the VA R&D Committee]
5. The R&D Committee may request one or more copies of the full application to outside funding agencies (i.e. grant proposals).

NOTE: It is the investigator's responsibility to be aware of changes in submission requirements.

Information to be included as part of an initial application to the VA R&D Committee:

1. Title of the study
2. Names of responsible investigator(s) and other staff involved in study
3. VA employment status, and Scope of Work of responsible investigator(s) and other staff
NOTE: Every person involved with the study who has contact with VA subjects, their tissues, or their records must have all of their academic degrees and licenses verified by the VA Research Service. Each person involved with a study, other than the PI, must complete a Scope of Work form that describes his or her role in the research.
4. Study design, including:
 - a. Purpose of the study (\approx 1 paragraph)
 - b. Summary description of program (\approx 1 paragraph)

- c. Specific aim(s) (\approx 1/2 page)
 - d. Background (\leq 1 page)
 - e. Methods and procedures (\leq 5 pages)
 - f. References
 - g. Previous work by applicant (\approx 2 pages)
5. Sponsor of the study/funding sources, if applicable
 6. Supporting statements by service chiefs and collaborator(s) , if applicable
 7. Future plans and impact of research on the VA Hospital
 8. Details of issues concerning the participation of human subjects that shall include:
 - a. Subject inclusion/exclusion criteria.
 - b. Justification for use of any special/vulnerable subject populations.
 - c. Provisions for managing serious adverse reactions, If the research is more than minimal risk.
 - d. Description of consent process that takes into consideration the characteristics of the subject population, or provide justification for waiver of informed consent.
 - e. Procedures for documentation of informed consent, including any procedures for obtaining assent from minors, using witnesses, translators and document storage, unless the IRB waived the requirement to obtain informed consent, or signed consent forms.
 - f. Compensation to subjects for their participation and payment terms (e.g., proration), if applicable.
 - g. Any compensation if research subjects are physically injured as a result of participation in the research study.
 - h. Provisions for the protection of a subject's privacy.
 - i. Potential or known extra costs to subjects for their participation in the study.
 - j. Other issues detailed within the IRB application, e.g., benefits to society, study design (including statistical methodology), risk/benefit analysis, and details on the consent process.

NOTE: The IRB initial application can serve to replace part or all of the required details outlined above.

NOTE: Other subcommittee reviews (e.g., UWCCC Clinical Affairs Committee, UW Cardiology Clinical Research Committee, Radiation Safety Office), must also be completed and submitted to the R&D Committee prior to approval.

b. Additional Submissions to the R&D Committee

When appropriate to their project, investigators shall also submit the following:

1. Use of Radioactive Materials forms
2. Biohazard/Chemical Hazard Information Form
3. Information regarding the use of recombinant DNA or RNA
4. Information for the Diagnostic Radiology Service
5. Information for the Pharmacy Service
6. For studies involving investigational devices, provide information regarding the design and safety data for the device and whether or not the device poses any significant risk to subjects
7. Other study-specific documentation including relevant approvals

NOTE: It is the investigator's responsibility to be aware of changes in submission requirements.