R&D Overview and Protocol Submission guide
James H. Quillen VA Medical Center
Mountain Home, TN 37684

March 24, 2020

1. Overview

- Research involving human subjects requires first Institutional Review Board/ETSU (IRB/ETSU) approval, then Research and Development Committee (R&D) approval.

- Research involving animal subjects requires first University on Animal Care Committee (UCAC) approval, then R&D approval.

- Research involving human and animal subjects requires IRB/ETSU, UCAC, and R&D.

- Research being performed by a VA employee or using VA facilities, but not involving human or animal subjects, requires R&D approval.

- Any research project that uses any biohazards must be reviewed by the VA Subcommittee on Research Safety (SRS)

- *Unfunded* protocols require that both PI and responsible Co-I have a minimum 5/8th VA appointment UNLESS the protocol is identified as either a chart review or VINCI/DART database review. In these specific instances, the PI must still have a minimum 5/8th VA appointment, but the responsible Co-I need only be a minimum Without Compensation (WOC) employee."

- *Funded* protocols, regardless of risk level, require that both the PI and responsible Co-I have a minimum 5/8th VA appointment (unless there is an approved waiver from VA Central Office).

PLEASE REVIEW RESEARCH AND DEVELOPMENT VA STANDARD OPERATING PROCEDURES MANUAL FOR SPECIFIC INVESTIGATOR REQUIREMENTS AND RESPONSIBILITIES: ETSU IRB Website: http://www.etsu.edu/irb/

2. Important Dates

Institutional Review Board (ETSU/VA IRB):
Meeting dates: First Tuesday of every month.

Research and Development Committee (R&DC):
Meeting dates: Last Wednesday of every month.

Research and Development (R&D) Service Orientation
Meeting: As coordinated with the Principal Investigator and R&D Service

3. Subcommittee dates

VA Subcommittee on Research Safety (SRS):
Meeting dates: Second Wednesday in the months of February, May, August, and November.

University on Animal Care Committee (UCAC):
Meeting dates: Second Tuesday of every month.

4. IRB Manager

- IRB Manager is a web-based system designed specifically for the IRB review process for Initial Review submissions, continuing reviews (CR) and minor modifications. The IRB Manager system allows the submitter to track the process from submission to approval letters. Investigators will be able to sign forms electronically, forward their new submissions to other signatories, such as the Service Chief, other departments for electronic signature, modifications, etc. and then access the current status of the submission at any time.

- New VAMC Principal Investigators (PI) and study staff must register for training by contacting the IRB at 439-6054 or 439-6055 to receive access for submissions.

- Current PIs and study staff must use IRB Manager to enter requirements for continuing reviews, study modifications, etc.

- The VA has specific requirements that are available in and prompted by IRB Manager These forms are available to the PIs and study staff when entering study information. There are some VA specific forms that must be uploaded as attachments.

- When navigating through IRB Manager there will be forms to complete and then upload as an attachment with the appropriate signatures:

- The link to each form is available within IRB Manager. All required VA forms can also be found under the VA portion of the ETSU IRB Website: http://www.etsu.edu/irb/

5. Training and Personnel Requirements

Principal Investigator (s) and study staff personnel requirements should be verified with the R&D Service by calling (423) 979-2859 prior to submitting, Initial and Continuing review and Modifications in IRB Manager.

Training - A copy of ALL training certificates and personnel documentation for each study staff member if not on file in the R&D Service office must be uploaded into IRB manager where prompted.

IRB Manager has a place to enter the personnel participating as staff on the study.

Must include:

- The title of the study
- The name of Study Staff Member
- Role in Study: PI/Co-PI Investigator/Coordinator/Assistant
- Answers to all questions (yes or no) Note: PIs must have at a minimum 5/8ths VA appointment but all other study personnel can be WOC appointees.

Training:

Research - CITI training (with VA affiliation) accomplished every 3 years and can be found at: www.citiprogram.org

VAMC -

- Privacy and HIPAA Training – VA # 10203 and can be found at: https://www.tms.va.gov/SecureAuth35/
- Privacy and Information Security Awareness and Rules of Behavior – VA # 10176 and can be found at: https://www.tms.va.gov/SecureAuth35/
- Technology Transfer Program (TTP) Training – VA # 33534 and can be found at: https://www.tms.va.gov/SecureAuth35/

Personnel Documentation required for all study staff:

- CV that shows current date and VA appointment
- VA Financial Conflict of Interest (FCOI) (Investigator Only and Study Specific) –Access the form in IRB Manager or through http://www.etsu.edu/irb/FCOI%20VA%20Form%20450.pdf
- Intellectual Property Agreement (one-time requirement) – The PI should verify with the R&D Service whether or not there are Agreements on file for all WOC study staff. If not, one will be required to be completed and submitted. The Intellectual Property Agreement can be found at: http://www.etsu.edu/irb/WOC%20Intellectual%20Property%20Agreement.doc
- Scope of Practice (only for study staff who are not credentialed Healthcare providers with research privileges in the VA Medical Center) **Note**: built into manager (mod and initial submission)
- First-Time VA PIs Only (additional required documentation) R&D Information System Investigator Data Form, VA Form 10-5368, also known as "Page 18") and can be found at: http://www.etsu.edu/irb

Protocol Review Stages

Stage	Reviewer
Stage 1: Data entry The PI or other study staff fill out the xform.	N/A
Stage 2: PI Attestation(conditional stage that displays if research staff submit the xform on behalf of the PI)	N/A
Stage 3: VA Instructions This stage is completed by the VA Administrative Officer in the VA R&D Office. The VA AO verifies that all study staff have submitted a VA conflict of interest form and that there is not a conflict, or if there is one, that a management plan has been submitted.	David Hays
Stage 4: VA Education Review This stage is completed by staff in the VA R&D Office. Education on all study staff is checked.	Joe Wilkerson
Stage 5: VA PO Review This stage is completed by the VA Privacy Officer (PO). The Privacy Officer reviews the submission for compliance with rules about protected health information.	Angela Mullins-Allen
Stage 6: VA ISO Review This stage is completed by the VA Information Security Officer (ISO). The ISO reviews the submission for compliance with rules about data security.	Doug Wheeler
Stage 7: VA RCO Review This stage is completed by the VA Research Compliance Officer. The RCO reviews the submission for compliance with VA rules about research. The RCO also reviews any issues identified by the PO and ISO and compiles those to include in his response.	Jesse White
Stage 8: VA AO Approval This "bookend" stage is completed by the VA Administrative Officer in the VA R&D Office. The AO verifies that the study is now ready to submit to the East Tennessee State University/VA IRB (ETSU/VA IRB).	David Hays
Stage 9: IRB Initial Review	Theresia Cannon

The IRB Coordinator or Director reviews the submission for completeness and consistency.	
Stage 10: IRB Coordinator Review The IRB Coordinator prepares the study for review by the ETSU/VA IRB Chair or Vice-Chair.	Theresia Cannon
Stage 11: Create New Protocol Submission and/or Stage 12 IRB Manager system creates a protocol page for the study. Now the steps in the IRB review process are viewable by the PI/study staff.	N/A
Stage 13: Chair Review Stage The IRB Chair or Vice-Chair reviews the study and determines which level of review is needed.	Katie Sellers (POC)
Stage 14: Coordinator Stage to Assign Reviewers (conditional stage that is entered if IRB members are assigned as reviewers). The IRB Coordinator prepares the study for review by assigned reviewers.	Katie Sellers (POC)
Stage 15: Reviewer Stage (conditional stage that displays reviewers are assigned). IRB members serving as reviewers conduct their review.	Katie Sellers (POC)
Stage 16: Final IRB Stage The IRB Coordinator prepares correspondence to PI based on the review.	Theresia Cannon
Stage 17: VA PO Final Review The VA Privacy Officer reviews the submission again.	Angela Mullins-Allen
Stage 18: VA Final ISO Stage The VA Information Security Officer reviews the submission again.	TBD
Stage 19: VA Education Final Check The VA R&D Office reviews to ensure that any educational requirements have been met.	Joe Wilkerson
Stage 20: VA AO Stage Prior to R&D Review The study remains in this stage until the VA Research and Development Committee meeting (monthly, typically the last Wednesday of the month).	David Hays

Publication Requirements

i. VA Investigators. When VA Investigators are the first or primary author for a research publication, they are responsible for: (1) Notifying ORD Communications staff through the PubTracker system at: http://vaww.pubtracker.research.va.gov.

NOTE: *This is an internal VA Web site that is not available to the public.* Notification is required when: (a) Research results are accepted for publication in a scientific journal;

(b) Presentations are scheduled involving a national venue or the media;

(c) Media interviews are scheduled; or

(d) Professional recognition for research accomplishments is scheduled to occur in a national venue or likely to receive local or national media attention.

(2) Acknowledging VA support in publications and presentations using the guidelines set forth in this directive (see paragraph 6).
(3) Making available to the public all peer-reviewed publications and reporting the results of ORD-funded research without restriction, in accordance with this directive (see paragraph 7). This includes: (a) Depositing a manuscript in PubMed Central, operated by the National Institutes of Health's National Library of Medicine (NLM), upon the manuscripts' acceptance for publication. Specific procedures for depositing manuscripts are detailed at: https://www.research.va.gov/resources/policies/guidance/Checklist-for-publishing-VAResearch.pdf; or

(b) Ensuring that the journal posts a free access copy of the accepted manuscript into PubMed at the conclusion of its defined embargo period.

(4) When notification to ORD Communications staff in advance of the activity is not possible (e.g., selection for an interview at a national scientific meeting), providing PubTracker notification at the earliest possible opportunity.
(5) Ensuring that any publishing or copyright agreements concerning submitted articles fully comply with this directive.

GUIDELINES FOR ACKNOWLEDGING VA RESEARCH SUPPORT AND VA EMPLOYMENT a. **Acknowledgment of VA Research Support.** All publications and presentations of VA research results must contain the following acknowledgments: (1) “This work was supported (or supported in part) by (type of award, e.g., Merit Review, Career Development Award, Pilot Project) Award # (award/project number, e.g., I01 RX000123) from the United States (U.S.) Department of Veterans Affairs, (as applicable, Biomedical Laboratory Research and Development Service, Clinical Sciences Research and Development Service, Rehabilitation Research and Development Service, Health Services Research and Development Service, Cooperative Studies Program or Million Veteran Program).” The type of award and the electronic award/project number (e.g., I01 BX123456) must be included in the acknowledgment as indicated above unless prohibited by journal policy.

(2) If VA did not provide direct research funding, but the research was considered VA Research as specified by VHA Directive 1200.01, the publications or presentations must contain a similar acknowledgment. For example, “This material is the result of work supported with resources and the use of facilities at the (name and location of VA medical facility).” If a dually appointed VA Investigator conducts all the work at the academic affiliate and there is no VA Research involved, the VA Investigator should not list the VA affiliation.
(3) Failure to acknowledge VA support or employment may result in discontinuation of current VA R&D funding or ineligibility to apply for future funding for the VA investigator. In extreme circumstances (e.g., the VA Investigator fails on multiple occasions to make the appropriate acknowledgements in publications), such failure may result in the revocation of the privilege to conduct research in VA. ***NOTE:*** *If a journal does not have an acknowledgement section in its published articles, this requirement does not apply.*

b. **Disclaimer Requirement.** Publications or presentations must include a disclaimer stating that the contents do not represent the views of VA or the United States Government.
c. **Acknowledgment of VA Employment.** Authors of research manuscripts, abstracts, books, book chapters, and presentations of VA research results must acknowledge their employment using the following format: “VA title, name of VA medical facility, city, and State.” (1) When the author also holds a faculty appointment, the academic title and school also may be acknowledged.

(2) When the work was solely funded by VA, authors must list their VA affiliation first.

d. **VA Acknowledgment in Media Reports.** News media and other individuals outside VA may not understand the contributions and roles of VA in intellectual advances or VA’s collaborative relationships with universities and other affiliated institutions. Accordingly, when investigators with VA salaries or funding support are presenting or discussing their VA Research results with the news media, they must make a serious and good faith effort to obtain appropriate recognition for VA. A serious and good faith effort requires providing news media, prior to interviews when possible, a document on VA letterhead that: (1) Contains the VA Investigator’s name, VA title, and VA medical facility;

(2) Explains the importance to VA of citing the investigator’s VA employment in any resulting feature (for example, “The Department of Veterans Affairs is committed to ensuring appropriate recognition and acknowledgement of its investigators and the research it supports and makes possible. As such, we at the [VA medical facility] ask that you make every effort to mention the VA affiliation(s) of [investigator’s name] in your coverage.”); and

(3) Expresses a preference that the investigator’s VA title be used when media time or space limitations permit the use of only one professional title.

NOTE: *The media’s failure to acknowledge VA support despite a VA investigator’s good faith effort to comply does not jeopardize the VA investigator’s funding.*

e. **VA Acknowledgment During Other Professional Activities Scheduled to Occur in a National Venue or Likely to Receive Media Attention.** VA support and employment, as appropriate, must be acknowledged during professional activities in which VA Research results are being discussed or recognized. Acknowledgment may be oral or written, in accordance with the nature of the professional activity.

f. **Publications by Contractors.** Publication of research results by firms providing contracted services to VA is governed by the terms of the contract. The contract terms must be consistent with the provisions of this directive with respect to review and acknowledgment of VA support.

g. **Copyright.** Under 17 U.S.C. 105, copyright protection is not available for any work of the United States Government, but the United States Government is not precluded from receiving and holding copyrights transferred to it by assignment, bequest, or otherwise. In 17 U.S.C. 101, a work of the United States Government is defined as work prepared by an officer or employee of the United States Government as part of that person's official duties. Consequently, works prepared by VA employees as part of their official duties are not subject to copyright protection in the U.S. and they cannot assign a copyright in that work to another party. VA employees should decline to sign publishing agreements that do not provide specific language that addresses their contribution as a U.S. government work.

Contacts

Name	E-Mail	Phone Number
David Hays Research & Development Administrative Officer	David.Hays@va.gov	979-4345
Joe Wilkerson Research & Development Budget Analyst	Joseph.Wilkerson@va.gov	979-2859
Chris Makowsky Research & Development Service Secretary	Christopher.Makowsky@va.gov	979-2662
Clyde Johnson Information Security Officer	Clyde.Johnson1@va.gov	926-1171 ext. 1409
Angela Mullins-Allen Privacy Officer	Angela.Mullins-Allen@va.gov	926-1171 ext. 7620
Jesse White Research Compliance Officer	Jesse.White@va.gov	979-4325
April Cheyne IRB Secretary	cheyne@etsu.edu	439-6053
Theresia Cannon Medical IRB Coordinator	Cannontl@mail.etsu.edu	439-6055
Katie Sellers IRB Director	SELLERSKM@mail.etsu.edu	439-6054

John Moorman, M.D., Ph.D. VA IRB Vice Chair	Moorman@mail.etsu.edu Johnathan.Moorman@va.gov	926-1171 ext. 7042
Owen Murnane, Ph.D. ACOS for Research & Development	Owen.Murnane@va.gov	926-1171 ext. 7632