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

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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)

- Anyone wishing to conduct funded research at the James H. Quillen VA Medical Center must have a minimum of a 5/8ths VA appointment.

- All research studies require a responsible Co-Principal Investigator (PI) and that individual must have a minimum of a 5/8ths VA appointment.

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: www.TMS.va.gov
- Privacy and Information Security Awareness and Rules of Behavior – VA # 10176 and can be found at: www.TMS.va.gov
- VHA CO Compliance and Business Integrity (CBI) Awareness Training – VA # 7318 and can be found at: www.TMS.va.gov

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/ Mike Conway
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/ Janine Olive

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.	Janine Olive (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.	Janine Olive (POC)
Stage 15: Reviewer Stage (conditional stage that displays reviewers are assigned). IRB members serving as reviewers conduct their review.	Janine Olive (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.	Doug Wheeler/ Mike Conway
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

Contacts

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