

January 09, 2023

**RESEARCH STANDARD OPERATING PROCEDURES (SOP)**  
**Procedures for Submission, Review and Approval of Research Projects**

**1. PURPOSE:** The purpose of this SOP is to describe the procedures for submitting research projects to the Research and Development (R&D) Office, administrative processing by the R&D Office, and reviewing and approving of research projects by the R&D Committee and its subcommittees.

**2. POLICY:** The R&D Committee is responsible, through the Chief of Staff, to the Medical Center Director for oversight of and for maintaining high standards for the research program. The R&D Committee, as described in VHA Directive 1200.01 and South Texas Veterans Health Care System (STVHCS) Research and Development Committee Charter, is responsible for reviewing all research projects submitted to STVHCS. Research that meets the following criteria is defined as VA Research, and may not be conducted without R&D Committee approval:

- a. The research is conducted by VA investigators (serving on compensated, WOC, or IPA appointments) while on VA time or on VA property in space leased to or used by the STVHCS facilities.
- b. The research enrolls subjects at STVHCS or uses STVHCS's nonpublic information to identify or contact human research subjects for research purposes.
- c. The funds for the research activities are managed by STVHCS or its affiliated non-profit corporation, the Foundation for Advancing Veterans' Health Research (FAVHR) of South Texas.

**3. ACTION:**

a. **New Projects**

**(1) Submitting new projects to the R&D office**

- (a) All projects must undergo required R&D administrative review and obtain required subcommittee approvals prior to submission and approval by the Institutional Review Board (IRB) or the Institutional Animal Care and Use Committee that will have jurisdiction or oversight over the research. Administrative review includes: i) Information Security Officer (ISSO) review of studies that involve the collection, processing, storage, and transmission of research data; ii) Privacy Officer (PO) review of studies using human data; iii) safety review; iv) personnel review; and v) if applicable, evaluation of clinical resources, including pharmacy. FCOI Administrator review should occur prior to R&D Committee review and approval.
- (b) An R&D new project submission consists of "smart form" wizards in IRBNet such as the VA Project Cover Sheet (required for all new study submissions) and forms indicated on README guides and/or checklists in the STVHCS R&D Administration library in IRBNet, for New Human Studies, Animal, or Lab only studies, as applicable. All forms must be submitted with signatures if required in the VA Innovation Research Review

System (VAIRRS) instance of IRBNet ([gov.irbnet.org](http://gov.irbnet.org)). The only exceptions are the Financial Conflict of Interest (FCOI) forms, which must be submitted by email to the R&D Service.

- (c) Information, instructions, forms, and deadlines for preparing research projects are in the STVHCS R&D administration library in IRBNet and on the STVHCS' Research Office webpage at: <https://www.uthscsa.edu/vpr/services/va-human-research>.
- (d) Research staff may be contacted at [STXResearchService@va.gov](mailto:STXResearchService@va.gov), [VAHumanResearch@uthscsa.edu](mailto:VAHumanResearch@uthscsa.edu) or at [VHASTXSafetyIACUD@va.gov](mailto:VHASTXSafetyIACUD@va.gov) for further assistance for human and safety/animal studies, respectively.

## **(2) Processing and administrative review of new projects by the R&D Office**

- (a) Upon submission of the project and application documents by the PI/study coordinator in IRBNet, the administrative staff will conduct an administrative review of the documents to ensure the package is complete. This includes administrative review of draft documents that will be submitted to the IRB or IACUC subcommittees that will have jurisdiction or oversight of the human subject or animal protocols.
- (b) The principal investigator is required to list all investigators and research staff who will be engaged in research at the VA (or who have a VA appointment) on the Project Cover Sheet "wizard". R&D administrative staff will also share the package with the R&D WOC/Training Coordinators so that they can: a) check the training database and personnel documentation to ensure all personnel listed have completed all requirements for STVHCS research privileges, and b) document initial findings (and update them as needed) in IRBNet in the R&D administration workspace using the "reviewer" function. Final R&D Committee approval will not be given until training for the principal investigator (PI) has been confirmed. Only personnel who have current training at the time of approval will be allowed to participate in the activities related to the protocol.
- (c) After ensuring that the required forms appear to be complete, the R&D office will forward the new project package to the appropriate subcommittee(s) or share with administrative reviewers (e.g., Information Security or Privacy Officers, Service Chiefs for Evaluation of Clinical Resources) in IRBNet. Subcommittee "board" actions and administrative reviewer approvals will be documented in IRBNet.
- (d) If needed, R&D administrative staff will "unlock" the study package so the PI / study coordinator can make required corrections. When necessary, R&D administration staff will schedule a meeting with the project PI and/or study coordinator to address and finalize administrative issues prior to submission to the R&D Committee.
- (e) After all required administrative and subcommittee approvals (including approval by the IRB or IACUC) have been obtained and all required issues have been resolved, administrative staff will assign new study packages to the monthly R&D Administration "agenda," forward the package to the R&D Committee workspace, and assign package to the next R&D Committee meeting agenda, and at the call of the Chair, as often as necessary to fulfill its functions, by a convened meeting at which there is a quorum consisting of a majority of voting members of the R&D Committee.

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- (f) Administrative staff will: 1) ensure that required FCOIs have been received from all study personnel serving in an investigator role (i.e., PI, Co-Investigators, or Sub-investigators) and contact PIs/study coordinators as needed if any are missing; 2) prepare the “FCOI Acknowledgement” form and bundle with the FCOIs for each study for the FCOI Administrator’s reviews; and c) upload the signed Acknowledgement forms as Board “documents” in the R&D Committee workspace.
- (g) Human Protocol Managers will provide the Associate Chief of Staff for Research (ACOS) or his/her designee with the draft R&D Committee agenda which includes the list of new studies requiring initial R&D Committee approval, noting any special issues that require explicit approval (e.g., enrollment of non-Veterans) 7 days prior to the next scheduled R&D Committee meeting.
- (h) Study packages and reviewer checklists of projects that have not received an initial review or approval from either an IRB or IACUC (i.e., Center infrastructure grants) will be sent to two R&D Committee Members for pre-review 7 days prior to the scheduled R&D Committee so that they can present their recommendations to the Committee.

### **(3) Review of new research projects by the R&D Committee**

- (a) In conducting the initial review, the R&D Committee considers any previous or new findings and recommendations of the Financial Conflict of Interest (FCOI) Administrator that are relevant to the projects being reviewed. The R&D Committee may not approve a submitted project until identified FCOI has been reduced and/or managed to the committee’s satisfaction and a management plan is in place.
- (b) In conducting the review, the R&D Committee will consider the approvals by the relevant research subcommittees and non-research committees as applicable.
- (c) The committee will consider and act on the following information provided by the R&D Office and ACOS for R&D (or his/her designee):
  - 1. The relevance of the research to the VA mission of enhancing the healthcare of veterans.
  - 2. The appropriateness of the research to the goals, opportunities, patient population, and resources of STVHCS.
  - 3. The resources available for the proposed research are adequate to perform the research successfully and safely.
  - 4. Any other information deemed relevant to assess the feasibility of the study.

### **(4) Approval of new research projects by the R&D Committee**

- (a) The R&D Committee will vote to approve, approve with conditions, or disapprove a research project, program, or center. If the R&D Committee finds that it has received insufficient information to review the research, it may defer the review until all required information has been obtained. The R&D administrators will document “Board” actions in IRBNet, prepare the in the minutes the committee’s discussion and decision regarding approval.

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- (b) The final approval of the R&D Committee will only occur after all conditions have been met and applicable subcommittees have granted final approval. Once approved by the R&D Committee, the research becomes VA-approved research.
  - (c) Final approval will be granted for up to one year, not to exceed the IRB or IACUC expiration date (if applicable). Next “report due” and/or expiration dates will be recorded in IRBNet to generate the automated reminder notices the following year
  - (d) R&D administrators will document “Board” actions in IRBNet, prepare approval letters for signature by the ACOS for R&D, and upload these as Board documents in the R&D Committee workspace in IRBNet.
  - (e) The R&D Committee will communicate its decision in writing to the Principal Investigator and all decision letters will be posted as “board” documents in IRBNet. The Principal Investigator may initiate research activities only after receipt of a signed approval letter from the ACOS for R&D. The approval letter will include any conditions on which the approval is based, such as specific requirements for management of a FCOI.
- b. **Continuing Review** Each research project under the sole oversight of the R&D Committee (no SRS or IRB) must be reviewed and approved by the R&D Committee annually. All other research projects will be administratively reviewed in the STVHCS R&D Administration “workspace” annually. Refer to the Research Service SOP for Protocol Management for VA Approved Human Subject Research Projects for additional information on the continuing review process for projects involving human subjects.

**4. REFERENCES:** VHA Directive 1200.01, VHA Directive 1200.05

**5. RESPONSIBILITY:** ACOS for Research and Development (151)

**6. RESCISSION:** Research Service Policy Memorandum 17-43, dated January 14, 2022

**7. RECERTIFICATION:** January 09, 2027

[Signature on File]

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