

March 13, 2011

**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 Handbook 1200.01 and STVHCS Research and Development Committee Charter, is responsible for reviewing all research projects submitted to the South Texas Veterans Health Care System (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 sponsored by the VA.
- b. The research is conducted by or under the direction of any salaried or without compensation (WOC) employee of the STVHCS during and in connection with her/his STVHCS responsibilities.
- c. The research is conducted using any property or facility of STVHCS.
- d. The research recruits subjects at the STVHCS or uses the STVHCS's nonpublic information to identify or contact human research subjects for research purposes.
- e. The funds for the research activities are managed by the STVHCS or its affiliated non-profit corporation, the Biomedical Research Foundation of South Texas.

**3. ACTION:**

a. **New Projects.**

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

(a) An R&D project submission consists of the following forms, as applicable, depending on the type of research proposed. The original packet with signatures and an electronic copy are due to the Research office .

1. Request to Review Research Proposal;
2. R&D Checklist for Human or Non-human Studies
3. Animal Component of Research Protocol (ACORP) for animal projects;
4. Research Project Safety Survey;
5. Personnel List;

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6. Evaluation of STVHCS Resources for Clinical Research;
7. Commercial Sponsor Human Research Protection Surcharge Memo;
8. Budget;
9. VA Form 10-5368, Investigator Data Sheet;
10. VA Form 10-9012, Investigational Drug Information Record
11. VA Data Security Checklist;
12. Statement of Commitment and Understanding by the PI
13. Offsite Tissue Banking Application;
14. VA Radiation Safety Approval Letter; and
15. Other documents as requested by the R&D Office

- (b) Information, instructions, forms, and deadlines for preparing research projects are located on the South Texas Veterans Health Care System's Research Office webpage at: <http://www.south-texas.med.va.gov/research/html/protocol.htm>.
- (c) Research staff may be contacted at 210-617-5123 for further assistance.
- (d) Research projects are presented to the R&D Committee monthly in accordance the schedule published on the R&D website, 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.

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

- (a) Upon receipt of the project and application documents by the R&D Office, the administrative staff will conduct an administrative review of the documents to ensure the application is complete. This includes administrative review of the documents submitted to the UTHSCSA IRB.
- (b) Upon receipt of the research project application from the Principal Investigator, the R&D office will forward to the appropriate subcommittee(s) the documents necessary for the subcommittee review.
- (c) The principal investigator is required to submit a list of all investigators and research staff participating in the project. The Research Office will check the training database and documentation to ensure all personnel listed have completed the required training. 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.
- (d) For projects submitted to the R&D Human Protocol Management Staff Assistant an administrative review meeting will be scheduled with the project PI and/or study coordinator to address and finalize administrative issues prior to submission to the R&D Committee.

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- (e) Reminders and deadlines for all administrative issues will be forwarded by the R&D Office to the PI and/or study coordinator to address any outstanding issues prior to submission to the R&D Committee.
- (f) When all subcommittee approvals are in place and all administrative issues have been resolved, the R&D Office will forward the project information and any special requests to the R&D Committee for review.

### **(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 and the IRB FCOI subcommittee that are relevant to the projects being reviewed. The R&D Committee may not approve a submitted project until the 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:
  - 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 the STVHCS.
  - 3. The resources available for the proposed research are adequate to successfully and safely perform the research.
  - 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 Committee Administrator will document in the minutes the committee's discussion and decision regarding approval.
- (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.

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- (c) Final approval will be granted for no more than one year from 1) the IRB continuing review date for human studies; 2) the IACUC continuing review date for animal studies; or 3) the initial R&D approval date for all IRB exempt projects or research projects that do not involve the use of human or animal subjects.
  - (d) The R&D Committee will communicate its decision in writing to the Principal Investigator. 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, including research programs and research centers, must be reviewed and approved at least 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 Handbook 1200.01.
5. **RESPONSIBILITY:** ACOS for Research and Development (151)
6. **RESCISSION:** Research Service Policy Memorandum 08-43, dated March 30, 2008
7. **RECERTIFICATION:** March 2016

  
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