

RESEARCH SERVICE

March 30, 2008

## RESEARCH STANDARD OPERATING PROCEDURES (SOP)

### Procedures for Submission, Review and Approval of Research Proposals

1. **PURPOSE:** The purpose of this SOP is to describe the procedures for submission of research protocols to the Research and Development (R&D) Office, administrative processing by the R&D Office, and review and approval of research protocols 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 is assisted by the Associate Chief of Staff (ACOS) for R&D, the Administrative Officer (AO) for R&D, and the Research Office staff in carrying out its duties. The R&D Committee, as described in VHA Handbook 1200.1 and STVHCS Policy Memorandum 151-08-02, is responsible for reviewing all research protocols 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 Proposals.**
    - (1) **Submission of new proposals to the R&D office.**

(a) An R&D proposal submission consists of the following forms, as applicable, depending on the type of research proposed. The original packet and 6 copies are due to the Research office by the first Monday of the month to be included on the VA R&D Committee agenda for the corresponding month.

1. Request to review research proposal;
2. Abstract;
3. Copy of IRB application;
4. IRB approval memo;
5. IRB approved VA research consent form 10-1086;
6. Animal Component of Research Protocol (ACORP);
7. Research protocol safety survey;
8. Personnel List;
9. Statement of clinical research impact on VA hospital services;
10. Conflict of interest form;
11. Commercial sponsor human research protection surcharge memo;
12. Budget;
13. Commercial sponsor funding memo;
14. Copy of General Clinical Research Center (GCRC) application
15. VA Form 10-5368, Investigator Data Sheet;
16. VA data security checklist;
17. Offsite tissue banking application;
18. VA radiation safety approval letter; and
19. Copy of cover memo verifying proposal was sent to the Union.

(b) Information, instructions, forms, and deadlines for preparing research proposals 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 210-617-5300 x.15523 for further assistance.

(d) The R&D Committee reviews research protocols monthly on the fourth Wednesday of each month (except for December), 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 proposals by the R&D Office**

(a) Upon receipt of the protocol 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.

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- (b) Upon receipt of the research application from the Principal Investigator, the R&D office will forward to the appropriate subcommittee(s) the documents necessary for the subcommittee review.
- (c) Within one week of receipt of the application the R&D Office will communicate to the Principal Investigator and/or his/her designated staff, by email any stipulations that must be met prior to review by the R&D Committee or one of its subcommittees.
- (d) At least one week prior to the R&D Committee meeting the R&D Office will provide the submission documents to the R&D Committee member who is responsible for the review.

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

- (a) In conducting an initial review, the R&D Committee evaluates:
  - 1. The scientific quality and design of the research;
  - 2. The relevance to both VA's mission and the facility's research program;
  - 3. The ability to conduct and complete the research;
  - 4. The use, storage, and security of VA data and VA sensitive information including VA protected information (VAPI);
  - 5. The budget;
  - 6. The requirements for space, personnel, equipment and supplies
  - 7. The impact of the research on clinical, laboratory, and pharmacy services, with the availability of such resources determined by approval by the respective service chief on the *Statement of Clinical Research Impact on VA Hospital Service* form.
  - 8. The review and findings of its subcommittees; and
  - 9. Other information deemed relevant by the R&D Committee.
- (b) In conducting the initial review, the R&D Committee considers the findings and recommendations of the Financial Conflict of Interest (FCOI) Administrator. The R&D Committee may not approve a submitted protocol until the FCOI has been reduced and/or managed to the committee's satisfaction.
- (c) In conducting the initial review, the R&D Committee will consider the review, stipulations, and approval by the relevant subcommittees.
  - 1. **The University of Texas Health Science Center at San Antonio (UTHSCSA) Institutional Review Board (IRB).** The STVHCS has established UTHSCSA IRB, through a Memorandum of Understanding as its IRB of records. The R&D Committee oversees the IRB in this responsibility. The IRB Standard Operating Procedures detail the procedures, ethical principles, and regulations by which the IRB abides in

the review and oversight of research involving human research subjects: <http://research.uthscsa.edu/irb/sop.shtml>. The use of a commercial IRB is prohibited. The R&D Committee may not engage the services of another IRB for the purposes of avoiding the rulings of the IRB of record.

- 2. Institutional Animal Care and Use Committee (IACUC).** The R&D Committee has charged the IACUC with review of proposals that involve animal subjects to ensure compliance with animal research regulations. The R&D oversees the IACUC in this responsibility. Research Service Standard Operating Procedures 08-11 contains the procedures and principles by which the IACUC abides in the review and conduct of research involving animal research subjects.
- 3. Subcommittee for Research Safety.** The R&D Committee has charged the Subcommittee on Research Safety (SRS) with review and oversight of all research activities involving safety hazards and ensuring compliance with all applicable regulations, policies, and guidelines pertinent to biological, chemical, physical, and radiation hazards. The R&D Committee oversees the SRS in this responsibility. Research Service Safety Program Standard Operating Procedures No. 2 describes the Research Safety Subcommittee's service level program which adheres to the policies in VHA Handbook 1200.8.
- 4. Non-research committee(s) or subcommittee(s), such as the Radiation Safety Committee.** This review is conducted independent of the R&D Committee oversight, but the research may not be initiated until the non-research committee has approved it.

**(4) Approval of new research proposals by the R&D Committee.**

- (a) The R&D Committee will vote to approve, approve with conditions, or disapprove a research protocol, 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.
- (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

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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 R&D Committee. The approval letter will include any conditions on which the approval is based, such as specific requirements for management of a FCOI.

- b. **“Just-In-Time” Proposals.** “Just-In-Time” procedures allow research projects to be submitted to a funding agency for consideration prior to receiving final R&D Committee approval to conduct the research. Research proposals that are submitted by the STVHCS to VA, other Federal agencies, or other entities for funding consideration must undergo a preliminary review and receive concurrence from the R&D Committee prior to submission of the proposal under a “Just-In-Time” procedure.

- (1) **Submission of “Just-In-Time” proposals.** “Just-In-Time” research proposals are prepared and submitted as instructed by the funding agency. These research proposals do not need to contain the normal Research Proposal submission paperwork or Subcommittee forms. Research staff may be contacted at 210-617-5390 for further information and deadlines for submitting a “Just-In-Time” research protocol.

- (2) **Processing of “Just-In-Time” proposals by the R&D Office.**

- (a) Upon receipt of the “Just-In-Time” protocol by the R&D Office, the administrative staff will conduct an administrative review of the documents to ensure the documents are adequate for review.

- (b) Within one week of receipt of the application, the R&D Office will communicate to the Principal Investigator and/or his/her designated staff, by email, any stipulations that must be met prior to review by the R&D Committee.

- (c) Within one week of receipt of the application, the R&D Office will provide the submission documents to an assigned peer reviewer.

- (d) At least one week prior to the R&D Committee meeting the R&D Office will provide the submission documents and peer review to the R&D Committee member who is responsible for the review. The peer review will also be forwarded to the Principal Investigator at this time.

- (3) **Review of “Just-In-Time” proposals by the R&D Committee.** The R&D Committee will assess the appropriateness of the following items at a regular convened meeting.

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- (a) The scientific quality and design of the research;
- (b) The relevance of the research to VA's mission and the STVHCS research program;
- (c) The qualifications of the investigator(s) who will conduct the research;
- (d) The budget; and
- (e) The adequacy of the resources available to conduct the research

**(4) Approval of "Just-In-Time" proposals by the R&D Committee.**

- (a) The R&D Committee will vote to approve or disapprove the submission of the "Just-In-Time" proposal. The R&D Committee will communicate its decision in writing to the Principal Investigator.
- (b) Approval by the R&D Committee for submission of the research proposal to the funding agency does not give the Principal Investigator final approval to initiate research. The application will need necessary subcommittee approvals before final approval can be granted by the R&D Committee.
- (c) Upon receiving funding notification, the Research Office will send the Principal Investigator a list of additional Subcommittee approvals and forms required to obtain final R&D Committee approval.
- (d) The Subcommittee(s) approval will be sent back to the R&D Committee at a regularly convened meeting for final approval. The R&D committee will also review information on the use, storage, and security of VA data and VA sensitive information including VAPI and other information deemed relevant by the R&D Committee.
- (e) The Principal Investigator will receive a final approval letter from the R&D Committee. Research may be initiated only after receipt of a signed approval letter from the R&D Committee.

- c. **Continuing Review.** Each research project, including research programs and research centers, must be reviewed and approved at least annually.

**(1) Submission of Continuing Review documents to the R&D Office.**

- (a) Two months prior to the expiration date, the Research office will send the Principal Investigator a Continuing Review form.

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- (b) The Continuing Review form must be completed and returned to the R&D Office to enable review and approval by the R&D Committee prior to the protocol's expiration.
- (c) The R&D Office will provide copies of the relevant review materials to the appropriate subcommittee(s) and R&D Committee reviewer to conduct the Continuing Review.

**(2) Processing of Continuing Review applications by the R&D Office.**

- (a) Upon receipt of the Continuing Review form (and any supporting documents) by the R&D Office, the administrative staff will conduct an administrative review to ensure the documents are complete and adequate for review.
- (b) Within one week of receipt of the Continuing Review application, the R&D Office will communicate to the Principal Investigator and/or his/her designated staff, by email, any stipulations that must be met prior to review by the R&D Committee.
- (c) At least one week prior to the R&D Committee meeting, the R&D Office will provide the Continuing Review application documents listed below to the R&D Committee member who is responsible for the review.
  - 1. VA continuing review form with applicable Subcommittee approval(s); and
  - 2. IRB continuing review form and continued approval letter, if applicable.

**(3) Review of Continuing Review application by the R&D Committee.**

- (a) Continuing review of research will occur during a convened R&D Committee meeting at which time the designated reviewer will present his/her review and recommendations to the committee.
- (b) The Continuing Review will assess:
  - 1. The research activities that have occurred;
  - 2. The progress of the research;
  - 3. An evaluation of subcommittee continuing approvals;
  - 4. Research personnel safety issues;
  - 5. Relevancy to VA's mission;
  - 6. Data security issues; and
  - 7. Any other issues that may impact on the progress of the research including compliance issues.

**(4) Approval of Continue Review application by the R&D Committee.**

- (a) The R&D Committee will vote to approve or disapprove the continuing review of the proposal.

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(b) The Principal Investigator will be notified in writing of the decision of the R&D Committee.

d. **Modifications and amendments**

- (1) Upon receipt of the approved subcommittee(s) minutes containing modifications or amendments, the R&D Office will conduct an administrative review of the subcommittee minutes and update the protocol files as appropriate.
- (2) The R&D Office provide a copy of the minutes to the R&D Committee members for review and approval at least one week prior to the next regularly convened R&D Committee meeting.
- (3) Review of subcommittee(s) minutes containing modification or amendments will occur during a convened meeting. The R&D Committee will vote to approve or disapprove the subcommittee minutes, which include modifications and amendments.
- (4) If the R&D Committee requires additional conditions or disapproval of an amendment or modification already approved by the appropriate subcommittee, the R&D Committee will inform the subcommittee (and PI) in writing of its determination.

**5. REFERENCES:** VHA Handbook 1200.1, dated March 2, 2007.

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

**7. RESCISSION:** Research Service Policy Memorandum 04-20, dated May 28, 2004.

**8. RECERTIFICATION:** March 2011.

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PETER MELBY, M.D.  
ACOS for Research and Development