

**South Texas Veterans Health Care System (STVHCS)
Audie L. Murphy Division, San Antonio, Texas 78229-4404
Charter – Research and Development Committee**

RESEARCH AND DEVELOPMENT (R&D) COMMITTEE CHARTER

1. PURPOSE: To outline the structure and function of the South Texas Veterans Health Care System (STVHCS) Research and Development (R&D) Committee.

2. POLICY:

a. The R&D Committee is responsible through the Chief of Staff (COS) to the STVHCS Director, for governance and oversight of the research program and for maintaining high ethical and scientific standards in the conduct of research at the STVHCS. The STVHCS Director is the Institutional Official and is responsible for all aspects of the R&D program. The R&D Committee advises the Director on professional and administrative aspects of the R&D program. The R&D Committee is operationally assisted by the Associate Chief of Staff (ACOS) for R&D and the Administrative Officer (AO) for R&D, and the R&D Office Staff to fulfill its responsibilities. No research at STVHCS, whether funded or unfunded, may be undertaken without review and approval by the R&D committee and its appropriate subcommittees.

b. **Definitions**

(1) **VA Data or VA Information.** VA data or VA information is all information that is obtained, developed, or produced by, or for VA or its employees as part of its business activities.

(2) **VA Sensitive Information.** VA sensitive information is all Department data, on any storage media or in any form or format, which requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the information. The term includes information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary information, records about individuals requiring protection under various confidentiality provisions such as the Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, and information that can be withheld under FOIA. Examples of VA sensitive information include:

(a) Individually-identifiable medical, benefits, and personnel information;

(b) Financial, budgetary, research, quality assurance, confidential commercial, critical infrastructure, investigatory, and law enforcement information;

(c) Information that is confidential and privileged in litigation, such as information protected by the deliberative process privilege, attorney work-product privilege, and the attorney-client privilege; and

(d) Other information which, if released, could result in violation of law or harm or unfairness to any individual or group, or could adversely affect the national interest or the conduct of federal programs.

(3) **VA Research.** All research, and all other activities that in part involve research, are considered VA research and is subject to evaluation and approval by the VA R&D Committee and other VA regulation, if any of the following conditions are met:

(a) The research is sponsored by the VA. Note: VA research may be funded by sponsors other than the VA or be unfunded as well.

(b) The research is conducted by or under the direction of VA Investigators including PIs, Co-PIs, and Site Investigators on VA time (serving on compensated, without compensation (WOC), or IPA appointments.

(c) The research is conducted utilizing VA resources (e.g., equipment), or on any property or facility of STVHCS including space leased to, and used by VA.

(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. Activities requiring R&D Committee review

(1) The R&D Committee is responsible for ensuring the effective operation of the research program through oversight of the R&D Committee's subcommittees and making appropriate recommendations, including space and resource needs, to the medical center Director based on the Committee's oversight and evaluation of the research program.

(2) The following activities are not considered research and therefore are not under the purview of the VA R&D Committee:

(a) Quality Improvement projects that are not designed or intended to produce generalizable results.

(b) Meta-analysis of published studies.

(c) Case Reports that are not designed or intended to produce generalizable results.

(d) Literature Searches that are not designed or intended to produce generalizable results.

(3) If unsure whether an activity or proposed project is research, and therefore requires R&D approval, contact the STVHCS Research Office. (<http://www.southtexas.va.gov/Research/Contacts.asp>).

b. Responsibilities and functions of the R&D committee

(1) **Program planning, guidance, and oversight.** The R&D Committee provides oversight to ensure that the STVHCS research program meets all VA, Federal, State, and local regulations, and functions in an effective, responsible, and efficient manner. To accomplish effective program planning, guidance, and oversight the R&D Committee will:

(a) Understand and apply its obligation to protect the rights and welfare of human and animal research subjects in accordance with the applicable laws, regulations, and local policies and procedures.

(b) Assist and make recommendations to the STVHCS Director in fulfilling the responsibility for the facility's research program. The Committee is responsible for planning and developing broad objectives for the R&D Program so that it supports the VA's research mission.

(c) Determine the extent to which the R&D Program has met its objectives, and make recommendations and strategic plans to more effectively accomplish the goals of the program.

(d) Review the resource needs of the R&D Program, including the HRPP, at least annually, and making appropriate recommendations regarding these needs. The review of resources available to the research program will include fiscal resources, personnel, materials and supplies, space, capital equipment, training, and education.

(e) Oversee Quality Assurance and Quality Improvement assessments and activities, including compliance audit reports, reports of research noncompliance, reports of unanticipated problems involving risks to subjects or others (UPIRSO), and other compliance assessments.

(f) Establish, review, and evaluate (at least annually) the effectiveness of all subcommittees, as necessary for the efficient and effective management and oversight of the STVHCS research program. A summary of the reviews and evaluations is sent to the medical center Director.

1. Annual review of the IRB to include membership composition. As part of this review the R&D Committee will evaluate whether the number of IRBs are appropriate to the volume and types of human research reviewed so that reviews are accomplished in a thorough and timely manner. The annual review of the IRB will be incorporated into the annual review of the HRPP (see below).

2. Annual review of the Animal Care and Use Program including inspection reports, IACUC composition, IACUC arrangements, budgets, space, support staff, training, quality improvement activities, compliance issues, and goals for next year.

3. Annual review of the Research Safety and Security Program including planned training, compliance, security issues, etc.

(g) Annually conduct a review of the Human Research Protection Program including the function of the IRB (see above), credentialing and training status report, budget, space, support staff, quality improvement activities, compliance issues, and goals for the next year.

(h) In fulfilling its responsibilities of ensuring effective oversight of the research program at STVHCS and making appropriate recommendations to the medical center Director, the ACOS for R&D will provide the following to the R&D Committee:

1. An annual QA review of publications assessing acknowledgment of VA support and affiliation.

2. A review of information pertaining to requests for WOC appointments for research, ensuring that all have been appropriately justified and the appointments are in compliance with all applicable research, Human Resource Management, and other VA policies.

3. A QA review of research employees involved in research to ensure that they are working within their approved scope of practice and their privileges.

4. An annual QA review of Cooperative R&D Agreements.

(i) Fulfilling such other functions as may be specified by the medical center Director and VHA procedure.

(2) Review and approval of all research projects

(a) The R&D Committee will review the administrative findings of the R&D Office and recommendations of the ACOS for R&D.

(b) The R&D Committee will ensure all research is approved by the appropriate Subcommittees. Scientific review of human studies will be completed by the IRB and animal studies by the IACUC. The R&D Committee will ensure that the review of research by its subcommittees is properly performed without undue influence. The R&D Committee will be provided with the appropriate subcommittee minutes, which documents subcommittee approvals.

(c) Projects not meeting criteria for assignment to any subcommittee will be assigned to a designated reviewer and presented to the R&D Committee for approval.

(d) In conducting the review of research projects 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.

(e) The R&D Committee may approve, approve with conditions, or disapprove a research project, program, or center. The approval of the R&D Committee may only occur after all applicable subcommittees have reviewed and granted approval and the R&D Committee has considered the findings of the subcommittee.

(f) If a subcommittee of the R&D Committee (IRB, IACUC, SRS) does NOT approve a research project, program or center, it may not be approved by the R&D Committee. However, the R&D Committee may disapprove or add conditions for approval of a study that has been approved by one of the subcommittees. In such cases, the R&D Committee will inform the subcommittee (and PI) in writing of its determination.

(g) If a research protocol requires review by a facility's non-research committee(s) or subcommittee(s) such as the Radiation Safety Committee, this review is conducted independently, but the research may not be initiated until the non-research committee has approved it, the R&D Committee has completed its review at a convened meeting, and the investigator is notified of the approval.

(h) The R&D Committee will consider the findings and recommendations of the FCOI Administrator and the IRB FCOI evaluation. No protocol will be approved by the R&D Committee unless all of the concerns of the FCOI Administrator and the IRB FCOI evaluation are satisfied and a management plan is in place.

(i) Once approved by the R&D Committee, the research becomes VA-approved research. The initial approval requires a majority vote of the convened quorum and must include a specific approval period, not to exceed one year or the expiration date of the required subcommittee approvals, whichever comes first. The committee will provide final approval to all proposals prior to the initiation/conduct of research. **Note:** *Research may be initiated only after R&D Committee approval has been obtained.*

(3) Continuing Review

(a) The R&D Committee must assess, through a Continuing Review process, all protocols at least annually, including human subject protocols exempt from regulation. The Continuing Review will evaluate the research activities that have occurred, the progress of the research, and any issues that may impact on the progress of the research and/or protection of research subjects (animal or human) including compliance issues.

(b) Continuing Review is also conducted by the appropriate subcommittees (IRB, Safety, or IACUC) at least annually. For exempt protocols, which are not reviewed annually by the IRB, the R&D Committee will perform the continuing review at least annually.

(c) The continuing approval of research requires a majority vote of the members of the committee conducting the continuing review. A quorum must be present during the vote.

(d) Continuing approval of research must include a specific approval period, not to exceed one year or the expiration date of the required subcommittee approvals, whichever comes first.

(e) Continuing approval dates from the subcommittees and summaries of study status and any concerns are presented to the R&D Committee for concurrence and must be included in the R&D Committee's meeting minutes.

(g) Expiration of research protocol approval: Approval for a research protocol may expire because of failure to meet reporting (e.g. Continuing Review) deadlines for any subcommittee or R&D. In this case, the Principal Investigator will be notified that activities related to the research protocol must immediately cease, with the exception of those activities that are determined by the IRB or IRB Chair, in consultation with the Chief of Staff, to be required to ensure the safety of subjects already enrolled in the protocol. In this case, the IRB will notify investigators to immediately submit a list of participants for whom stopping research activities would cause harm. The expiration in approval of the protocol will be corrected upon receipt and satisfactory review and approval of the required documentation.

(4) **“Just-in-Time” procedures**

(a) Research protocols that are to be submitted by the STVHCS to VA, other Federal agencies, or other entities for funding consideration will be submitted for endorsement by the R&D Committee prior to submission of the protocol under a “Just-in-Time” procedure.

(b) Prior to R&D Committee endorsement a preliminary review will be conducted by the ACOS for R&D or his/her designee, to assess the appropriateness of the scientific methodology, the relevance of the research to the VA's mission, the investigator qualifications to conduct the research, and the adequacy of the resources.

(c) If the study is funded, the R&D Committee, and its subcommittees as appropriate, must review and approve the project prior to the initiation of any research activities.

(5) **Amendments and modifications.** The Research Office will conduct an administrative review of the of amendments and modifications approved by any R&D subcommittees. Amendments and modifications that require special considerations are presented for R&D approval prior to initiation at the STVHCS.

c. **Membership.** Members of the R&D Committee are appointed by the Medical Center Director. The experience and expertise of the members must reflect the types of research being conducted at the facility, and must contribute to the promotion of respect for the committee's responsibilities and functions. Nominations for membership may be from current R&D Committee members, subcommittee members, and the facility's staff. The types and requirements of membership are as follows:

(1) **Voting members.** The Committee must consist of at least five voting members. All voting members must be compensated full-time or permanent part-time Federal government employees. The Committee shall consist of at least two members from STVHCS staff who have major patient care or management responsibilities and at least two members who are STVHCS investigators actively engaged in major R&D programs or who can provide R&D expertise. There should be at least one member who holds an academic appointment with the university affiliate (University of Texas Health Science Center at San Antonio; UTHSCSA) and is either a full-time Federal employee or a part-time permanent Federal employee. A voting member may fill more than one criterion for required membership. Members should have diverse backgrounds with consideration to race, gender and ethnicity.

(2) **Ex-officio (non-voting) members** include the Medical Center Director, Chief of Staff (COS), ACOS for R&D, Deputy ACOS for R&D, AO for R&D, a Representative from the Nursing Service, a Research pharmacist, the Privacy Officer or alternate Privacy Officer, and the Information Security Officer or alternate Information Security Officer.

(3) **The Research Compliance Officer (RCO)** may attend committee meetings to provide information and serve as a subject matter expert on research compliance issues. The RCO may not contribute to quorum or deliberate or vote with the committee. The Committee Chair may elect to exclude the RCO from any or all proceedings of the committee meeting if it is felt, by the Committee Chair, that a conflict of interest exists. The RCO will also evaluate his/her presence at a committee meeting for potential conflict of interest and act accordingly.

(4) **Alternate members** may be appointed to substitute for the primary members if their qualifications are comparable to the primary members they are to replace. They must meet all the same eligibility criteria as the primary member. Terms of appointment, length of service, and duties are the same as for the regular member. If the alternate and primary member both attend a R&D Committee meeting, only the primary member may vote and only the primary member counts toward the quorum.

(5) **Procedures**

(a) Based on the appropriate criteria as indicated, upon nomination by the ACOS/R&D and the committee members, voting and alternate members are appointed in writing by the Director to serve on the R&D Committee. Voting members serve terms of three years and may be reappointed without any lapse in time if the Committee approves. The terms of members must be staggered to provide only partial change in membership annually.

(b) The Chairperson is elected every one to two years from among the voting Committee members and appointed in writing by the Director. The Chair may be reappointed without any lapse in time. The Chairperson may not simultaneously chair a major subcommittee (e.g. IRB, IACUC, SRS).

(c) All members of the R&D Committee must fulfill the education requirements specified by VHA's ORD and other applicable Federal regulations found on the ORD website at: www.research.va.gov. All Committee members are required to complete training of human subject protection by completing the CITI program, "Good Clinical Practices/Human Subjects Protection" training annually.

(d) During the review of research protocols by the Research and Development Committee or any of its subcommittees, members may find themselves in a personal conflict of interest when reviewing research. These instances include when a member is an investigator on the research, when an investigator must report to or is under supervision of a member, when a member competes for grants or contracts in the same/similar field as an investigator whose research is scheduled for review. Members of the R&D Committee and subcommittees having a conflict of interest are prohibited from participating (both in discussion or voting) in the initial or continuing review of research protocols.

d. **Subcommittees.** The STVHCS R&D Committee has established Subcommittees to ensure the protection of human and animal subjects, the safety and security of personnel engaged in research, and for the efficient and effective oversight of research resources.

(1) The R&D Committee and Medical Center Director as the Institutional Official are responsible for ensuring appropriate and adequate support of the review and record-keeping functions of the subcommittees.

(2) The R&D Committee and its subcommittees do not answer to individuals, departments, or units that rely on them for the review of their research. No undue influence may be asserted by any member of the research team toward any review or oversight committee or committee member. Each of the Subcommittees function independently in its review and oversight of research, and one Subcommittee cannot exert undue influence on the independent review and conclusions of another.

(3) Subcommittee on Animal Studies (Institutional Animal Care and Use Committee; IACUC) is established by the R&D Committee in keeping with VA regulations (VHA Handbook 1200.7) and the USDA Animal Welfare Act (9 CFR 1-4). This subcommittee is responsible for reviewing all use of live vertebrate animal subjects in research, including proposed and ongoing studies, as they relate to animal welfare laws, regulations, and policies. The R&D Committee oversees the IACUC by review of the IACUC meeting minutes, IACUC reports and recommendations, and other communications from the IACUC regarding animal studies. No animal research project is granted approval by the R&D Committee until it has been approved by the STVHCS IACUC. No research involving animal subjects may be initiated prior to approval by both the IACUC and R&D Committee.

(4) Subcommittee on Human Studies (Institutional Review Board; IRB) is established by the R&D Committee in keeping with VA regulations (VHA Handbook 1200.05) and 38CFR16 and 38 CFR 17.

(a) The IRBs of record for the STVHCS are the VHA Central Office IRB and the UTHSCSA IRBs, governed by Memorandum of Understandings between the institutions. The IRBs are registered with OHRP: UTHSCSA IRB 1 (Registration #IRB00000553); UTHSCSA IRB 2 (Registration #IIRB00002691); UTHSCSA IRB 3 (Registration #IRB00002692); and VHA Central Office IRB (Registration #00006332).

(b) The IRBs are formulated and function in accordance with VHA Handbook 1200.05.

(5) Subcommittee on Research Safety (SRS) is established by the R&D Committee in keeping with VA regulations (VHA Handbook 1200.08) as well as Federal Statutes and regulations from Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA) the Nuclear Regulatory Commission (NRC) and any applicable state and local requirements. The SRS is charged with protection of all research personnel to ensure safe research practices and physical and biosecurity of the research facility. The R&D Committee oversees the activities of the SRS by review of the SRS meeting minutes, SRS reports and recommendations, and other communications from the SRS regarding safety and security issues. No research project involving potential biohazards, chemical hazards, physical hazards or radiation hazards will be granted final approval by the R&D Committee until it has been approved by the SRS.

(6) Data Security and Privacy Subcommittee is established by the R&D Committee to provide oversight to the data security and privacy aspects of the R&D program. The subcommittee is responsible to evaluate the data security and privacy practices and procedures related to each research protocol that is submitted to the R&D Committee for approval, and to evaluate and make recommendations to the R&D Committee concerning any data security and privacy issue that arises in the course of conduct of research at the STVHCS. The subcommittee provides the venue for review and approval of all research protocols by the STVHCS Privacy Officer and Information Security Officer. The subcommittee is operationally assisted by the administrative staff of the R&D office to fulfill its responsibilities. No research at

STVHCS, whether funded or unfunded, may be undertaken without review by the Data Security and Privacy Subcommittee and concurrence by the STVHCS Privacy Officer and Information Security Officer.

(7) Subcommittee membership: Subcommittee members may be compensated Federal Employees, WOC or IPAs. Members of the subcommittees may serve as members of the R&D Committee. If a subcommittee does not have one of its members serving as a member of the R&D Committee, the subcommittee will designate a member to serve as a liaison with the R&D Committee. Administrative staff from the R&D Office, including the ACOS for R&D, Deputy ACOS for R&D and AO for R&D, cannot serve as voting members of a R&D subcommittee.

(8) Subcommittee records: Each subcommittee must maintain adequate records, which are to be maintained until expiration of the authorized retention period, a minimum of 5 years. Research records may be electronic or paper. When original signatures are required on documents, either a paper copy of the signature sheet must be maintained or an electronic signature must be used. If an electronic signature is used, it must meet all of the requirements of VA, the Office of Human Research Protection, the Food and Drug Administration (FDA), and any other Federal requirements. The records must include the following:

(a) Copies of all research proposals and their amendments reviewed by the subcommittee and any accompanying materials.

(b) All continuing review or inactivation forms.

(c) Minutes of its meetings.

(d) Copies of all written correspondence.

(e) A membership list of all voting, non-voting, and ex officio members including their appointed roles.

(f) Written records documenting actions taken to carry out the subcommittee's responsibilities.

(g) Standard Operating Procedures.

(h) All communications to and from investigators, other committees, subcommittees, and other entities or individuals.

(9) Subcommittee communication with the R&D Committee: Each subcommittee must make available to the R&D Committee a complete, unredacted set of minutes (draft or final) prior to the R&D Committee meeting, at which the protocols listed and other information contained within the minutes are to be discussed. If draft minutes are submitted, formally-approved minutes must be sent to the R&D Committee prior to the following R&D Committee meeting. If the approved minutes differ substantially from the draft minutes, the subcommittee must ensure the R&D Committee considers whether the difference would alter any R&D Committee decisions that were based on the draft minutes. Copies of all written subcommittee correspondence to and from VA investigators must be sent to the R&D Committee or VA Research office at the facility. Each subcommittee (IRB, IACUC, SRS, etc.) will evaluate reports of serious or continuing noncompliance and make recommendations for action to the R&D Committee. Findings and recommendations of the subcommittees are recorded and reported to the R&D Committee.

e. **Operations of the R&D Committee**

(1) **Meeting schedule.** The R&D Committee will meet monthly, except for one month a year if it appears that a quorum cannot be obtained. The R&D Committee may hold unscheduled meetings in

response to emergent issues. The annual schedule of meetings for the R&D Committee and its major subcommittees (IRB and IACUC) will be posted on the STVHCS Research webpage.

(2) **Meeting agenda.** The R&D Committee administrator in conjunction with the chairperson, ACOS for R&D, and AO for R&D prepares the meeting agenda for the R&D Committee meeting. The agenda notes the scheduled date, time and location of the meeting. The agenda includes at a minimum the following categories: approval of R&D Committee and all subcommittee minutes; old business of the Committee; New business of the Committee; research protocols for initial review, continuing review, and inactivation; and other business. The IRB and IACUC administrators submit the lists of approved protocols to the R&D administrator for Committee concurrence. New protocols from the IRB should include the IRB assigned number, title, Investigator name, and IRB action. New protocols from the IACUC should include the IACUC assigned number, title, Investigator name, and IACUC action. All protocols submitted for continuing review or inactivation should include the assigned number, title, Investigator name, and subcommittee action. Agenda copies are distributed to the Committee members 4-5 days before the meeting.

(3) **Attendance requirements, quorum and voting.** Members or their designated alternates are encouraged to attend all regularly scheduled meetings. If physical presence is not possible, a member may be considered present if participating through teleconferencing or videoconferencing. In that case, the member must have received all pertinent material prior to the meeting and must be able to participate actively and equally in all discussions. There must be a quorum present in person, by teleconference, or video conference for any meeting (scheduled or unscheduled). A quorum, i.e. a majority of voting members, must be present to conduct business and must be present for each vote. If a quorum is lost during the meeting, further R&D business must be suspended. Whenever a Committee member recuses himself or herself or leaves the meeting, the number of remaining Committee members must still constitute a quorum (recused members and members not in the room are not counted towards a quorum). Each voting member has one vote with no proxy voting allowed.

(4) **Conflict of Interest for R&D Committee Members.** Members are considered to have a conflict of interest if they are participating in a proposed study as a principal or collaborating investigator, or if they have a financial or other relational interest in the study. Members with a conflict of interest relating to a study under review may not participate in the review, whether the initial, continuing, final deliberations, or in the vote on such studies.

(5) **Minutes.** Minutes for each meeting must be recorded and include the following information:

(a) A list of all voting members and non-voting members, including ex officio members, indicating the category of their membership and whether they are present or absent. If an alternate is present in place of a voting member, the minutes should indicate this fact and name who the alternate member is replacing.

(b) The presence of a quorum.

(c) Actions taken by the Committee to include the type of action, vote on the action including the number voting for, against, and abstaining. In addition, any recused member from the vote should be named, and whether the person was present during the discussion and the vote should be noted. Actions also include the basis for requiring changes to a research project to obtain approval, any required follow-up and which committee, subcommittee, or person is responsible for the follow-up, the basis for disapproving a research project when this occurs, and the action taken on minutes submitted to the Committee if not recorded in other R&D Committee records.

(d) All minutes of the R&D Committee and its Subcommittees must be sent to the medical center Director through the ACOS for R&D and COS for review and appropriate action.

(6) **Notification of Committee findings.** The PI must be notified in writing of the R&D Committee's decision to approve, approve with conditions, disapprove a proposed research activity, or if modifications are required to secure R&D approval. The PI will be notified by email of the results of the R&D Committee's Continuing Review of the project. If the R&D Committee disapproves or requires modifications of the proposed research to obtain approval, the appropriate committees or subcommittees that also approved the protocol must be notified in writing of any modifications related to the area of their purview. If modifications are required by the R&D Committee, the applicable subcommittees must review and approve the modification related to the area of their purview prior to the modified protocol being initiated.

f. **R&D Committee Records.** The adequate documentation of all the activities of the R&D Committee must be maintained. Records are the property of the VA and must be retained for a minimum of 5 years. R&D committee records which are maintained by the R&D Office must include, but are not limited to, the following:

- (1) Copies of research proposals.
- (2) Continuing review and inactivation forms.
- (3) Minutes of R&D Committee and all subcommittees.
- (4) Copies of written correspondence.
- (5) Membership lists for R&D committee and all subcommittees.
- (6) Documentation of committee activities related to the oversight of research program.

4. REFERENCES:

a. Code of Federal Regulations Title 21, Chapter 1 Food and Drug Administration (FDA) Department of Health and Human Services regulations pertaining to rights and welfare of human subjects participating in research involving investigational drugs and devices (21 CFR parts 50, 56, and 812)

b. VA Code of Federal Regulations Title 38, Pensions, Bonuses, and Veteran's Relief, Chapter 1 Department of Veterans Affairs, Part 16, Protection of Human Subjects [38 CFR 16, 16.107(a-f)]

c. VA Code of Federal Regulations Title 38, Pensions, Bonuses, and Veteran's Relief, Chapter 1 Department of Veterans Affairs, Part 17 Medical

d. VHA Handbook 1200.05 Requirements for the Protection of Human Subjects in Research, dated October 15, 2010

e. STVHCS Policy Memorandum 151-10-01, Research General Post Funds, dated May 13, 2010

f. VHA Handbook 1200.7 Use of Animals in Research, dated May 27, 2005

g. Code of Federal Regulations Title 9, Chapter 1-4 Animal Welfare

h. VHA Handbook 1200.08 Safety of Personnel in Research, dated March 6, 2009

i. VHA Handbook 1200.6 Control of Hazardous Agents in VA Research Laboratories, dated October 21, 2005

j. VHA Handbook 1605.1 Privacy and Release of Information, dated May 17, 2006

k. VHA Handbook 1200.01 Research and Development (R&D) Committee, dated June 16, 2009

5. RESPONSIBILITY: Associate Chief of Staff for Research and Development (151)

6. RESCISSIONS: Policy Memorandum 151-2009-02, dated April 22, 2009

7. APPROVED BY:

- Research and Development Committee
- Clinical Executive Board