

May 19, 2008

RESEARCH AND DEVELOPMENT COMMITTEE

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 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) **Continuing Review:** Periodic review by the R&D Committee or one of its Subcommittees (e.g. IRB or IACUC) of active research for the purpose of re-approving, requiring modifications, disapproving, terminating or suspending the study. Continuing review must occur at least annually or more frequently if determined by the R&D Committee or one of its Subcommittees.

(2) **Human subject:** The STVHCS oversees and conducts research that is covered by both the Department of Veterans Affairs and Department of Health and Human Services (to include FDA) regulations, therefore, the definition of human subject (also called a research participant) employed by the STVHCS includes both DHHS (and VA) and FDA definitions:

(a) Department of Health and Human Services (DHHS) and Department of Veterans Affairs (DVA) definitions: A living individual about whom an investigator (whether professional or student) conducting research obtains: (1) Data through intervention or interaction with the individual, or (2) Identifiable private information. Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

(b) FDA definition: An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. Under 21 CFR 812 this also includes an individual on whose specimen an investigational device is used.

(3) **Human subject research:** Human subject research includes all research meeting the definition of "research" (see section 3.j) performed with "human subjects" (see section 3.b). VA also defines human subject research to include research involving human biological specimens. A human specimen obtained from a commercial source with no identifying information, when used in research, does not constitute human subjects research.

(4) **Human Research Protection Plan (HRPP):** The systematic and comprehensive approach by an organization to ensure human subject protection in all research. The implementation of any part

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of the program may be delegated to specific committees, individuals or entities, by the organization.

(5) **Institutional Review Board (IRB):** An independent committee comprising scientific and non-scientific members established according to the requirements outlined in Title 38, part 16 (same as Title 45, part 46 and Title 21, part 56) of the U. S. Code of Federal Regulations. The IRB may also be referred to as the Human Studies Subcommittee of the Research & Development (R&D) Committee.

(6) **Investigator:** An investigator is an individual under the direction of the Principal Investigator (PI) who is involved in some or all aspects of the research project, including the: design of the study, conduct of the study, analysis and interpretation of the collected data, and writing of resulting manuscripts. An investigator must be either compensated by VA, be appointed to work without compensation (WOC), or may be an employee assigned to VA through the Intergovernmental Personnel Act (IPA) of 1970. The FDA considers an investigator and a PI to be synonymous.

(7) **Non-compliance:** Conducting research in a manner that disregards or violates federal regulations or institutional policies and procedures applicable to human research (including the requirements of the VA Handbook 1200.5 and other VA policies and regulations, as applicable) which can be characterized by severity of the event and the pattern of like or similar events. Noncompliance with IRB and/or federal requirements may involve a range of issues from relatively minor or technical violations that result from inadvertent errors, inattention to detail, or inadequate training and supervision of research staff to more serious noncompliance. **Serious noncompliance** is defined as noncompliance that adversely affects subject safety or the safety of others, increases the risks to subjects, and/or violates the rights and welfare of participants (any of which may also be an unanticipated problem). Serious noncompliance may affect the subject's willingness to participate in research or may affect the integrity of the data (which may also be scientific misconduct). **Continuing noncompliance** is a pattern of recurring (involving one or more protocols simultaneously or over a period of time) or ongoing instances of actions or omissions (noncompliance), which indicate an underlying deficiency in knowledge of the regulations and IRB requirements, or a possible inability or unwillingness to comply with them. Instances of continuing noncompliance may or may not constitute [serious noncompliance](#).

h. Principal Investigator (PI): Within VA, a PI is an individual who conducts a research investigation, i.e., under whose immediate direction research is conducted, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. The FDA considers a PI and an investigator to be synonymous. The PI is accountable for the proposal and the execution of the research protocol, as designed, by overseeing the performance of research staff to ensure the completion of all research activities.

(8) **Protocol:** A plan that includes, at a minimum, the objectives, rationale, design, methods and other conditions for the conduct of a research study.

(9) **Research:** The STVHCS oversees and conducts research that is covered by both the Department of Veterans Affairs and Department of Health and Human Services (to include FDA) regulations, therefore, the definition of research employed by the STVHCS HRPP includes both DHHS (and VA) and FDA definitions:

(a) DHHS and DVA definitions: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of the STVHCS HRPP, even if they are conducted

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or supported under a program that is not typically considered research. For example, some demonstration and service programs may include research activities.

(b) FDA definition: Clinical investigation (Per FDA Title 21 CFR 50 & 56) means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

(10) **Sponsor:** Any person or entity that takes responsibility for and initiates a clinical study. The sponsor may be an individual, pharmaceutical company, device manufacturer, governmental agency, academic institution, private organization, or other organization.

(11) **Test article:** Any drug for human use, biological product for human use, medical device for human use, or other article used in a clinical investigation involving human subjects or their specimens.

(12) **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.

(13) **VA Protected Information (VAPI).** VAPI is VA sensitive information, Privacy Act Information (PAI), Protected Health Information (PHI), or other VA information that has not been deliberately classified as public information for public distribution. VA information that the VA would have to release under the Freedom of Information Act (FOIA) is not VA protected information. All VA protected information needs to be classified as one of the following: VA Proprietary, VA Restricted, or VA Highly Restricted.

(14) **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.

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(15) **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.

(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. ACTIONS:

a. Activities requiring R&D Committee review

(1) All research that meets the definition of “VA Research” must be reviewed and approved by the STVHCS R&D Committee and its subcommittee(s) prior to initiation of the research.

(2) Research that is being 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 protocol.

(3) 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

(4) If unsure whether an activity or proposed project is research, and therefore requires R&D approval, contact the STVHCS Research Office at (210) 617-5123.

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:

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(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, external monitor visit reports, 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 R&D Committee will consider information from various sources including but not limited to:

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.

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3. A QA review of research employees involved in human subject 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.

5. Ensure compliance with all policies related to personnel as defined in VHA research manuals, Handbooks and Directives.

(i) Providing oversight of the management of Research General Post Funds as directed in STVHCS Policy Memorandum 151-06-01.

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

(2) Initial scientific and programmatic review of all research projects: The R&D Committee is responsible for reviewing all research including research protocols, research grant proposals, and amendments or changes to previously submitted research protocols. In conducting the initial review, the R&D Committee will consider the review and findings of its Subcommittees, as appropriate. 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 review all STVHCS research to ensure:

(a) The maintenance of high scientific standards. The R&D Committee will review all research protocols to ensure that the research design is sound, and capable of producing meaningful results consistent with study objectives. The research should have the ability to answer the proposed questions and contribute to knowledge of the field.

(b) The relevance of the research to the VA mission of enhancing the healthcare of veterans.

(c) The appropriateness of the research to the goals, opportunities, patient population, and resources of the STVHCS.

(d) The resources available for the proposed research are adequate to successfully and safely perform the research. The R&D Committee will evaluate:

1. The requirements for clinical or laboratory service involvement

2. The requirements for space, personnel, equipment, and supplies

3. The role of the investigator at the STVHCS and the investigator's qualifications and ability to perform and complete the research

4. The proposed budget

5. Any other information deemed relevant to assess the feasibility of the study

(e) The protection of human subjects (including privacy and confidentiality) and the implementation of adequate safety measures for research subjects and personnel.

(f) The research is ethical, including if the human subject research exempt from regulation. Exempt human subject protocols will be evaluated to ensure that the subjects are appropriately

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informed of the nature of the research, that it is not more than minimal risk, that it has equitable selection and voluntary participation of subjects, and that there is adequate protection of the privacy of the subjects and confidentiality of the data.

(g) The welfare and appropriate use of animals in research.

(h) The safety of personnel engaged in research.

(i) The security of research laboratories where hazardous agents are stored and utilized.

(j) The security of VA data, VAPI, and VA sensitive information. The R&D Committee will review information on the collection, use, storage, transport, transfer and disclosure of VA data and VA sensitive information including VAPI to ensure that it meets VA data security and privacy standards.

(k) The function of the investigator and integrity of the research is not compromised, nor has the appearance of being compromised, by a Financial Conflict of Interest.

(3) Approval of research projects.

(a) 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. 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.

(b) Per VHA Handbook 1200.5, 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, including the IRB. In such cases, the R&D Committee will inform the subcommittee (and PI) in writing of its determination.

(c) 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.

(d) 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.

(e) 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. 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.*

(4) Continuing Review

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(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.

(e) Continuing approvals from the subcommittees must be 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. 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.

(5) "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 must undergo a preliminary review and receive concurrence from the R&D Committee prior to submission of the protocol under a "Just-in-Time" procedure.

(b) During the preliminary review, the R&D Committee must 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.

(6) **Amendments and modifications:** The R&D Committee will review all protocol amendments and modifications received and approved by its subcommittees. The R&D Committee will be provided with the appropriate subcommittee minutes, which documents the amendment and modification approvals. The Research Office will conduct an administrative review of the subcommittee minutes and up date the protocol files as appropriate. 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.

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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 review and decisions related to research protocols. 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, Assistant Chief for Clinical Research, AO for R&D, a Representative from the Nursing Service, the Research Compliance Officer or designee, a Research pharmacist, the Privacy Officer or alternate Privacy Officer, and the Information Security Officer or alternate Information Security Officer

(3) 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 an R&D Committee meeting, only the primary member may vote and only the primary member counts toward the quorum.

(4) 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 annually 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

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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 1200.5) and 38CFR16 and 38 CFR 17.

(a) The IRB of record for the STVHCS is the UTHSCSA IRBs, governed by a Memorandum of Understanding between the two institutions. The UTHSCSA IRBs are registered with OHRP: IRB 1 (Registration #IRB0000553) provides Full Reviews; IRB 2 (Registration #IIRB00002691) provides Continuing Reviews; and IRB 3 (Registration #IRB00002692) provides Full Reviews.

(b) The IRBs are charged with review, approval, and oversight of all VA-approved research involving human subjects regardless of funding or funding administration. The IRB is responsible for ascertaining the acceptability of proposed research in terms of medical center commitments and policies, applicable law, validity of study design as it relates to risks and benefits, sensitivity to community standards and attitudes, as well as standards of professional conduct and practice.

(c) The R&D Committee oversees the activities of the IRB by review of the IRB meeting minutes, IRB reports and recommendations, and other communications from the IRB regarding human studies. No human research project is granted final approval by the R&D Committee until it has been approved by the IRB.

(d) The determination of exemption from regulations is the responsibility of the IRB Director,

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not the investigator. The IRB Director may delegate this authority to a designated reviewer. Questions about whether research involving human subjects is exempt from regulation should be directed to the IRB Director or his/her designee. For VA research, the R&D Committee will review the exempt determination by the IRB, and has the authority to disapprove the research at the STVHCS if it does not agree with the IRB's exempt determination. In such cases, the R&D Committee will inform the IRB (and PI) in writing of its determination.

(e) IRB review of VA research that involves an FDA-regulated article requires the presence of a licensed physician in the quorum.

(f) IRB review of VA research that involves mentally disabled persons or persons with impaired decision-making capacity requires the IRB membership to include at least one member who is an expert in the area of the research.

(g) The membership of the IRB plays a pivotal role in its ability to fulfill its role and will comply with VA regulations established in VHA Handbook 1200.5:

1. Each IRB must have at least five members with varied backgrounds to promote complete and adequate review of research activities commonly conducted by the institutions (VA and affiliate) for which it reviews research. The IRB members must be sufficiently qualified to review the research through their experience, expertise, and diversity, including consideration of race, gender, cultural backgrounds, and sensitivity to community issues and/or attitudes. The IRB must promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects; and possess the professional competence necessary to review specific research activities (38 CFR 16.107(a)).

2. In the appointment of IRB members, equal consideration must be given to qualified persons of both genders. No appointment to the IRB will be made solely on the basis of gender. Every non-discriminatory effort will be made to ensure that the IRB membership does not consist entirely of men or entirely of women (38 CFR 16.107(b)).

3. No IRB may consist entirely of members of one profession (38 CFR 16.107(b)).

4. Each IRB must include at least one member whose primary expertise is in scientific areas and at least one member whose primary expertise is in non-scientific areas (38 CFR 16.107(c)). These members are to be selected primarily to reflect the values of the research community and the community from which the research subjects are drawn with respect to the rights and welfare of human research subjects.

5. Each IRB that reviews VA research must include at least two VA employees (5/8 salary) as voting members, and at least one of the VA representatives must have scientific expertise. The VA representatives must serve as full members of the IRB and must be involved in the review of both VA and non-VA research.

6. At least one VA voting member must be present during the IRB review of VA research.

7. Each IRB must include at least one member who is not otherwise affiliated with the VA medical center and who is not part of the immediate family of a person who is affiliated with the medical center (38 CFR 16.107(d)).

8. No IRB may have a member participate in the review of any project in which the member has a conflict of interest, except to provide information requested by the IRB (38 CFR 16.107(e)).

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9. An IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB (38 CFR 16.107(f)).

10. R&D Office personnel from the STVHCS including, but not limited to the ACOS for R&D, the Assistant Chief for Clinical Research, and the AO for R&D, may not serve as voting members of the IRB. The ACOS for R&D, the Assistant Chief for Clinical Research, AO for R&D and/or a Research Compliance Officer may serve as non-voting members and must be sensitive to the occurrence or appearance of conflict of interest.

11. Alternate members may be formally appointed to the IRB. The IRB's written procedures must describe the appointment and function of alternate members, and the IRB roster must identify the primary member(s) for whom each alternate member may substitute. The alternate member's qualifications must be comparable to those of the primary member to be replaced. When an alternate member replaces the primary member, the alternate member must receive and review the same material that the primary member received. In addition, the IRB minutes must document instances in which an alternate member replaces a primary member.

12. IRB members and R&D Committee members will forward names as needed for consideration for new IRB members to the Medical Center Director. Other VA personnel may submit names to the IRB or R&D committee to be forwarded to the Medical Center Director for consideration. The Medical Center Director must officially appoint members in writing.

13. Members of VA IRBs and VA representatives to affiliate IRBs must be appointed by the Medical Center Director for a period of 3 years and may be re-appointed indefinitely.

(5) Subcommittee on Research Safety (SRS) is established by the R&D Committee in keeping with VA regulations (VHA Handbook 1200.8) 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) Quality Assurance / Quality Improvement Subcommittee: The day-to-day operations of the various elements of the STVHCS Research Program are subject to periodic assessment for purposes of assuring the protection of human and animal research subjects through compliance and quality improvement activities. This may include such activities as investigator protocol compliance, study documentation, investigational pharmacy operations, R&D Committee documentation, and IRB documentation. Such assessments will determine the extent to which the STVHCS Research Program complies with VA and Federal regulations and local standard operating procedures. The Research Quality Assurance / Quality Improvement Subcommittee is responsible for overseeing the compliance and quality assurance activities involved in the protection of human research subjects, animal subjects, and research personnel, and reporting these findings and the subcommittee's recommendations to the R&D Committee.

(7) Research Resource Subcommittee is established by the R&D Committee to review

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requests for research space or core equipment, reviewing existing space or equipment for utilization, making recommendations on new assignment of space or equipment, making recommendations on acquisition of new core equipment or space needed, and providing advice and assisting in the development of a facility plan for research space or major research equipment.

(8) 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 and AO for R&D, cannot serve as voting members of a R&D subcommittee.

(9) 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 or final reports.
- (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.

(10) 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 make its own determination of serious or continuing noncompliance and how serious and non-serious compliance issues are addressed. 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 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 final review; 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, IRB action and abstract. New protocols from the IACUC should include the IACUC assigned number, title, Investigator name, and IACUC action. All protocols submitted for continuing or final review 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

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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 must be notified in writing 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.

(7) **Suspension or termination of a research protocol:** The STVHCS Director, IRB Chair, R&D Committee Chair, and/or the ACOS for R&D as the designated representative of the STVHCS Director, have the independent authority to suspend or terminate a research protocol at the STVHCS that is not being conducted in accordance with IRB or R&D Committee requirements, or that is associated with unexpected harm to subjects (serious noncompliance). Demonstration of a pattern of repeated failure to comply with reporting or training deadlines by the Principal Investigator or his/her staff will result in suspension of the study based on continuing research noncompliance. Suspensions or terminations are reported to the appropriate oversight agencies.

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 records must include, but are not limited to, the following:

- (1) Copies of research proposals
- (2) Continuing and final reports
- (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 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)

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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 1200.5 Requirements for the Protection of Human Subjects in Research, dated July 15, 2003

e. STVHCS Policy Memorandum 151-06-1, Research General Post Funds, dated November 21, 2006

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 1200.8 Safety of Personnel in Research, dated June 7, 2002

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

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

6. RESCISSION: STVHCS Policy Memorandum 151-05-02 dated May 31, 2005

7. RECERTIFICATION: June 2011

//Signed//

RICHARD J. BALTZ
Director

DISTRIBUTION: A