North Florida/South Georgia Veterans Health System Research Service

CHARTER

Research and Development Committee

April 4, 2011

I. Purpose. The purpose of the Research and Development Committee (R&DC) is to optimize the research performed at the North Florida/South Georgia Veterans Health Service (NF/SGVHS); to assure the infrastructure necessary to optimize research; to facilitate the conduct of research by investigators; to assure protection of human and animal research subjects; to assure personnel and laboratory safety; and to assure regulatory compliance of research activity.

II. Roles. The R&DC is responsible, through the Chief of Staff (COS) to the Medical Center Director, for advising and assisting the Medical Center Director in providing oversight, planning, and execution of the local research Program; and assisting the Medical Center Director in maintaining high standards throughout the R&D Program. Those standards include ensuring the scientific and ethical quality of VA research projects; protection of human subjects in research; safety of personnel engaged in research; welfare of laboratory animals; security of VA data; and security of VHA research laboratories.

The R&DC is assisted by the Associate Chief of Staff (ACOS) for Research and the Administrative Officer (AO) for Research in carrying out its duties.

III. Purview. The purview of the R&DC includes research performed by any investigator at the NF/SGVHS that is funded by the VA, whether or not it actually takes place at a VA facility, and research, funded or unfunded, that involves use of VA facilities or resources or more than incidental recruitment of veterans. All such research must obtain the complete approval of all appropriate non-research entities and R&DC subcommittees, and written notification from the ACOS for Research prior to initiating a research project. Additionally, continuing review and studies exempt from IRB review are also reviewed and approved initially and annually by the R&DC and relevant subcommittees with written approval by the ACOS for Research prior to initiating a research project.

IV. Authority. Authority is vested in the R&DC through the Department of Veterans Affairs as stipulated in Veterans Health Administration (VHA) Handbook 1200.01 (June 16, 2009). Charters of the R&DC and its subcommittees shall be in full compliance with all relevant VHA Handbook. The R&DC is responsible, through the Chief of Staff, to the Facility Director.

V. Subcommittees.

1) The R&DC has the following standing subcommittees, all of which report to the R&DC on a regular basis:

i. Institutional Review Board (IRB).

a. University of Florida (UF) IRB-01. NF/SGVHS has a Memorandum of Understanding (MOU) with the University of Florida relative to the designation of UF IRB-01 as a NF/SGVHS IRB of Record. The UF IRB-01 is charged with the oversight of all research activities involving the use of human subjects at NF/SGVHS except those select multi-site projects covered under the provisions of the MOU with VA Central IRB. Refer to R&DC SOPs for additional information regarding UF IRB-01.

b. VA Central IRB. NF/SGVHS has a MOU with VHA Central Office relative to the designation of the VA Central IRB as a NF/SGVHS IRB of record. The VA Central IRB authorities, roles and responsibilities are described in VHA Handbook 1200.05, the NF/SGVHS HRPP Manual and the MOU. Refer to VA Central IRB SOPs for additional information on VA CIRB policies and procedures.

ii. Scientific Projects Committee (SPC). Authority is vested in the SPC through the R&DC to make recommendations regarding specific VA research projects; keep the R&DC informed on research areas within the SPC domain and make recommendations for changes in policy and process. Additional information regarding the SPC can be found in the SPC Charter.

iii. Research Facilities and Space Utilization Sub-Committee (RFSUS). The Research Facilities and Space Utilization Subcommittee (RFSUS) is an advisory group to the R&DC for the allocation and use of common facilities and research space. Refer to the RFSUS Charter regarding the authority and responsibility of this subcommittee.

iv. Research Budget Sub-Committee (RBS). Authority is vested in the RBS through the R&DC. The RBS reports on a routine basis (at least quarterly) to the R&DC, as requested by the Chair of the R&DC. The RBS is charged with apprising the R&DC of the state of the Research Service budget and budget accountings at regular intervals, to be determined by the R&DC. Refer to the RBS Charter regarding the authority and responsibility of this subcommittee.

v. Committee on Research Support (CRS). The CRS is charged with advising the R&DC regarding investigator mentorship, investigator recruitment, and University research liaison with the general aim of improving the quality of research at NF/SGVHS, developing its investigators, facilitating VA research, and potentiating synergies with the University of Florida. Refer to the CRS Charter regarding the authority and responsibility of this subcommittee.

vi. Institutional Animal Care and Use Committee (IACUC). The IACUC is charged with protection of animal subjects and assuring compliance with VA ORD requirements bearing on animal research. The R&DC may not approve projects involving animal research that have not been reviewed or have been disapproved by IACUC. Refer to the IACUC Charter regarding the authority and responsibility of this subcommittee.

vii. Subcommittee for Research Safety (SRS). The SRS is charged with assuring high standards of safety of research protocols and within NF/SGVHS research laboratories. The R&DC may accept SRS certifications of research laboratory safety without further review but may also investigate specific issues or laboratories on an ad hoc basis. The R&DC may not certify laboratories that have not passed SRS inspection. The R&DC may accept SRS conclusions regarding project safety but may also review specific projects on an ad hoc basis. The R&DC may not approve projects that have not been reviewed or have been disapproved by SRS. Refer to the SRS Manual regarding the authority and responsibility of this subcommittee.

viii. Oversight Committee for Clinical Research (OCCR). OCCR is charged with monitoring human subject research practices of local VA investigators and applicable research committees in an effort to promote compliance with applicable laws, regulations and guidance. The R&DC will review Quality Assurance recommendations from OCCR and may accept the proposed recommendations, or may provide alternate recommendations or modification to the proposal. Refer to the OCCR Charter regarding the authority and responsibility of this subcommittee.

VI. Minutes

The R&DC is authorized to convene other committees, standing or ad hoc, and time limited, to address its mission.

1) Minutes of all subcommittees, standing and ad hoc, are reviewed, approved by the R&DC, and preserved according to the Records Retention Schedule.
2) ACOS-R is responsible for ensuring R&DC and its subcommittees, including those from subcommittees at VA facilities or at the affiliate, are sent to the Medical Center Director and Chief of Staff (COS) for review and appropriate action.

VII. Membership.

1) The members of the R&DC are appointed by the Medical Center Director and must reflect the types and amount of research being conducted at the facility.
2) Nominations for membership may be from current R&DC members, subcommittee members, and the facility's staff.
3) R&DC receives written verification from the AO-R that all individuals nominated for membership to the R&DC and/or appointed by the Facility Director to the R&DC meet the requirements outlined in VHA Handbook 1200.01 prior to obtaining membership to the Committee.
4) The R&DC must consist of at least five voting members.
5) All voting members must be compensated full-time or permanent part-time Federal employees.
6) All members of the R&DC must fulfill the educational requirements specified by VHA's ORD and other applicable requirements found on ORD's Website at: http://www.research.va.gov/programs/PRIDE/.
7) Membership roster includes:
   i. The Chair of the R&DC.
   ii. The Vice-Chair of the R&DC.

iii. At least two voting members from the VA facility's staff who have major patient care or management responsibilities.
iv. At least two voting members who are VA investigators actively engaged in major R&D programs or who can provide R&D expertise.
v. At least one voting member who holds an academic appointment.
vi. A representative from the investigational pharmacy or Pharmacy Service as either an ex officio nonvoting member, or a voting member due to the facility conducting research that involves the use of investigational drugs.
vii. Ex officio (non-voting) members are the Medical Center Director, the COS, the ACOS for R, the AO for R, and research compliance officers (or those who are responsible for compliance) of the facility. The ACOS for R functions as Executive Secretary of the R&DC.

VIII. Meetings

1) The R&DC meets at least monthly, for a minimum of eleven times during the calendar year; and if it appears that a quorum (i.e. a simple majority of voting members) cannot be obtained a meeting will be rescheduled as needed.
2) If physical presence is not possible, a member may be considered present if participating through teleconferencing or videoconferencing. In that case, the member will have received all pertinent material prior to the meeting and shall participate actively and equally in all discussions.
3) Minutes will meet the guidelines as stipulated in VHA Handbook 1200.01.
4) When the R&DC holds unscheduled meetings in response to emergent issues
a quorum must be present to conduct business and must be present for each vote.
5) R&DC members must comply with the Standards of Ethical Conduct for Executive Branch Employees and the Federal Criminal Code as stated in VHA Handbook 1200.01.
6) The R&DC may require attendance by R&D subcommittee members, but subcommittee members who are not also members of the R&DC must recuse themselves from voting.

IX. Quality Assurance

1) Review of R&DC subcommittee operations must be conducted as an ongoing function of the R&DC. The review must be conducted at least annually and must be accomplished in part by: reviewing the minutes of each subcommittee that reviews VA research studies (whether those of the VA or non-VA institutions when allowed); by close communication with the subcommittees; and through Quality Assurance and Quality Improvement activities. The R&DC will provide oversight through reports from the ACOS for R, AO for R, or other research staff members, facility reports or activities, and other appropriate sources.

2) The ACOS for R is responsible for providing an annual Quality Assurance review of research employees involved in human subject research to ensure the employees are working within their scopes of practice and their privileges allowed by the Facility's by-laws and granted to them by the Facility.

3) The ACOS for R is responsible for providing an annual Quality Assurance review of Cooperative Research and Development Agreements (CRADAs) and other agreements in support of the research program or specific research projects and an assessment of the impact of these agreements on the research program, when applicable. Additional information

regarding Quality Assurance reviews can be found in the R&DC and subcommittees SOPs and policies.

X. Charter Approval and Revision

1) This Charter must be approved by a simple majority of the R&DC to become active.
2) Revisions to this Charter can be made by a simple majority vote of the R&DC. This Charter and any SOPs developed for the purposes of this Committee will be reviewed by the R&D Chair and members annually and revised as needed.

Initial Approval: November 10, 2008
Revised: February 1, 2010
Revised: April 4, 2011