MOUNTAIN HOME VA HEALTHCARE SYSTEM

MOUNTAIN HOME, TN. 37684

May 26, 2016

MEDICAL CENTER MEMORANDUM

151-16-01

**RESEARCH & DEVELOPMENT COMMITTEE**

**1. PURPOSE.** This memorandum is published to establish a Mountain Home VA Healthcare System (MHVAHCS) Research & Development (R&D) Committee with the following subcommittees: Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC) and the Subcommittee on Research Safety (SRS).

**2. SCOPE.** The contents of this memorandum apply to all organizational elements of MHVAHCS.

**3. POLICY**

 a. **The R&D Committee** serves in an advisory capacity to the Medical Center Director (MCD), through the Chief of Staff (COS), on all professional and administrative aspects of Basic Laboratory Research, Clinical Sciences Research, Health Services Research, and the Rehabilitation Research Programs. The committee is responsible for ensuring the scientific and ethical quality of VA research, 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&D Committee advises the MCD providing oversight, strategic planning and execution of the local Research Program.

 b. **All research activities, whether funded or unfunded, which are conducted by VA employees, including part-time employees (on VA tour of duty), involve VA patients or utilize VA facilities and resources,** must be approved by the R&D Committee and its appropriate subcommittees prior to initiation.

**4. ACTION/RESPONSIBILITY**

 a. **The R&D Committee’s role in the VA mission of providing high quality medical care to Veteran patients** is accomplished through the following:

 (1) Ensuring the continuing high quality of the R&D Program.

 (2) Planning and developing broad objectives of the R&D Program.

 (3) Determining the extent to which the R&D Program has met its objectives.

 (4) Critically evaluating the quality, design, desirability, and feasibility of each new R&D proposal, continuing R&D project, application for funding or other reporting activity to ensure maintenance of high scientific standards, protection of human subjects, safety of VA data and research laboratories, adequate safety measures of personnel and proper use and protection of experimental animals.

 (5) Recommending on the basis of such evaluations and after consideration of other needs, the distribution of R&D funds, space, personnel, equipment and supplies and use of animal facilities and other shared resources.

 (6) Review and approving the budgetary requests.

 (7) Recommending policies on recruiting personnel supported by R&D funds.

 (8) Nominating members and chairpersons for appointment by the MCD.

 (9) Ensuring all R&D, IRB members, investigators and key personnel involved in research projects have satisfied the mandated training requirements.

 (10) Oversight and annual review of R&D subcommittees.

 (11) Fulfilling other functions as may be specified by the MCD.

 b. **Membership**

 (1) Qualified potential R&D Committee members will be identified by voting members of the Committee and recommended through ACOS/R&D through the COS to the MCD for official appointment.

 (2) The R&D Committee will have at least five (5) voting members with varying backgrounds to promote complete and adequate review of the research activities conducted at MHVAHCS and approved outpatient clinics. Committee members will be asked to appoint an alternate member in writing and their attendance will be recorded as part of the meeting minutes when applicable. The alternate member’s qualifications shall be comparable to those of the primary member to be replaced. The R&D Committee will meet the following elements of composition:

 (a) At least one (1) member from the affiliated institution, East Tennessee State University (ETSU).

 (b) At least two (2) members from the staff of MHVAHCS selected because they have major patient care or management responsibilities.

 (c) At least one (1) member who is a VA employee selected because they are actively engaged in one of four major Office of Research & Development (ORD) programs or can provide R&D expertise. This expertise will reflect the types of research being conducted at MHVAHCS and affiliated outpatient clinics. All four VA ORD programs including: (1) Biomedical Laboratory Research & Development, (2) Clinical Science Research & Development, (3) Health Services Research and Development, and (4) Rehabilitation Research and Development should be represented, when active programs are ongoing in these areas. Similarly, nursing and allied health professionals should be represented whenever there is research activity in these areas. If applicable, then a representative of a facility Research Enhancement Award Program or Center of Excellence should be a member.

 (d) When possible, one (1) member of the Committee selected according to the criteria listed above, should have expertise in biostatistics and research design.

 (e) Membership should reflect diversity including consideration of race, gender and cultural background.

 (f) Ex-officio (non-voting) members include the MCD, COS, ACOS/R&D, Administrative Officer for Research (AO/R&D), Research Safety Officer (RSO), Information Security Officer (ISO) and Privacy Officer (PO). The Research Compliance Officer (RCO) serves as a non-voting consultant to the R&D Committee. A Union Representative (AFGE Local 2400) will be present when protocols are presented which affect bargaining employees. The ACOS/R&D functions as Executive Secretary of the Committee.

 c. **Meetings**

 (1) The R&D Committee meets monthly and records minutes that will document:

 (a) Attendance (an established quorum with a majority of voting members present).

 (b) Complete record of all items of business brought before the committee.

 (c) Motions presented and actions taken (voting shall be for/against or abstain).

 (d) Any conflicts of interest.

 (e) Any substantive discussion regarding the agenda items.

 (2) Minutes will be recorded for all subcommittees and submitted to the parent R&D Committee for approval. Minutes will be recorded for the R&D Committee including approval of all subcommittee minutes. Minutes will be signed by the Chairperson, ACOS/R&D (Executive Secretary), COS and the MCD. Copies will be forwarded to the Chair/Medical Executive Board, IRB, Principal Investigators, Pharmacy and R&D Committee members (for acceptance/approval at the next convened meeting). Copies of the minutes will be made available to the VA Central office upon request.

 d. **Subcommittees**

 (1) The R&D Committee may establish subcommittees deemed necessary for the efficient and effective management and oversight of the R&D program and may use consultants or advisors who are selected for specific tasks and who do not have a vote.

 (2) All studies undergoing initial review, continuing review or request for changes to the protocol must be approved by the appropriate subcommittee. The R&D Committee conducts continuing review of all studies deemed exempt by the IRB and all studies not reviewed on an annual basis by a subcommittee of the R&D Committee.

 (3) The R&D Committee is the parent Committee within the R&D structure. The following permanent Subcommittees of the R&D Committee have been established at MHVAHCS. These Subcommittees are guided by their specific SOPs available in the R&D office at MHVAHCS.

 (a) ETSU Medical Campus Institutional Review Board (IRB)/ Human Studies Subcommittee: The R&D Committee has delegated the responsibility of the scientific review of all studies to the ETSU Medical Campus IRB. The R&D Committee supports and rigorously abides by the Federal Policy for Protection of Human Subjects of Research (the Common Rule) and the principles outlined in the Belmont Report and the Nuremberg Code. The rights and welfare of all persons participating in research must be vigorously protected. All research involving human subjects must comply with Federal and State regulations and VA requirements that address the protection of human subjects according to the ‘Human Research Protection Program (HRPP) Policies and Procedures for the IRB of ETSU and the MHVAHCS, including Title 38 Code of Federal Regulations (CFR) Part 16 (VA implementation of the Common Rule, also codified by the Department of Health and Human Services as 45 CFR Part 46, Subpart A), and all related policy and procedural documents issued by the ORD(i.e. VHA Handbook 1200.05), Washington, D.C. These regulations and requirements must be met before any research involving human subjects is initiated, and adherence must be sustained throughout the conduct of the research.

 (b) ETSU University Committee on Animal Care (UCAC) (also known as the IACUC): The R&D Committee supports only those animal studies that are designed and performed with the highest degree of attention to the welfare of research animals and supports full compliance with the Association for the Assessment and Accreditation of Laboratory Animal Care international guidelines as established in the SOP for the IACUC Subcommittee.

 (c) Subcommittee on Research Safety (SRS): The R&D Committee supports a safety program consistent with policies, statutes and regulations issued by the VA ORD, the Occupational Safety and Health Administration, Environmental Protection Agency, Nuclear Regulatory Commission, Centers for Disease Control and Prevention and National Institutes of Health. The R&D Committee supports only those studies with the highest standard of protecting personnel against biohazards, chemical hazards, and physical hazards in the research laboratory setting as established in VHA Handbook 1200.08 and associated SOP of the SRS.

**5. REFERENCES**

 a. VHA Handbook 1200.01

 b. VHA Handbook 1200.05

 c. VHA Handbook 1200.08

**6. RESCISSION.** Medical Center Memorandum 151-13-01

**7. RESCISSION DATE.** May 26, 2021

**8. FOLLOW-UP RESPONSIBILITY.** Associate Chief of Staff of Research and Development (151)

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Acting Medical Center Director