

**Department of Veterans Affairs
Charter of the
Cooperative Studies Scientific Evaluation Committee**

1. Official Designation. Cooperative Studies Scientific Evaluation Committee.

2. Authority. The Committee is established by directive of the Secretary of Veterans Affairs (VA) and operates under the provisions of the Federal Advisory Committee Act, as amended, title 5, United States Code (U.S.C.), App. 2.

3. Objectives and Scope of Activity. The Committee provides expert advice on VA cooperative studies, multi-site clinical research activities and policies related to conducting and managing these efforts. Such advice is to ensure that new and ongoing activities are based on scientific merit, mission relevance and quality, and are conducted efficiently, safely and economically. To accomplish these objectives, the Committee reviews proposals and makes recommendations to the Chief Research and Development Officer on funding and administration. The Committee does not consider grants, contracts, or other forms of extramural research for VA.

4. Description of Duties. The Committee reviews proposed and ongoing cooperative studies and multi-site clinical research activities (including clinical trials, epidemiological studies and related efforts) and advises VA on scientific merit; feasibility; the adequacy of the plan of investigation; related activities and requested resources; technical details including the involvement of human subjects; and mission relevance. The Committee evaluates and discusses written materials supplied by the proponents of each project as part of its review process and may hold face-to-face discussions with proponents to further obtain additional information about proposals. Thereafter, the Committee deliberates on the projects and communicates its recommendations to the Chief Research and Development Officer.

5. Official to Whom the Committee Reports. The Committee reports to the Chief Research and Development Officer.

6. Office Responsible for Providing the Support to the Committee. Support for the Committee is provided by the Office of Research and Development, Veterans Health Administration, Department of Veterans Affairs.

7. Estimated Annual Operating Costs in Dollars and Staff Years. The estimated annual cost for operating the Committee is \$50,000 and about 0.2 staff years. All members will receive travel expenses and a per diem allowance in accordance with the Federal Travel Regulation for any travel made in connection with their duties as members of the Committee.

8. Designation Federal Officer. The Designated Federal Officer (DFO), a full time VA employee, will approve the schedule of Committee meetings. The DFO or a designee

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will be present at all meetings, and each meeting will be conducted in accordance with an agenda approved by the DFO. The DFO is authorized to adjourn any meeting when he or she determines it is in the public interest to do so.

9. Estimated Number and Frequency of Meetings. The full Committee meets up to three times annually.

10. Duration. The Committee performs a continuing service, unrestricted as to time except as periodic review of its functions shall indicate that it is no longer needed. The Committee's continued operation is contingent upon renewal of this charter by appropriate action prior to its expiration.

11. Termination Date. Unless renewed by appropriate action prior to its expiration, the Committee will terminate 2 years from the date this charter is signed.

12. Membership and Designation. The Committee is composed of members having experience and expertise in major medical specialties and disciplines, including biostatistics and epidemiology, and selected based on professional expertise and achievement in clinical research. Committee membership shall represent the required technical skills along with diversity in race/ethnicity, gender, religion, disability, geographical background and Veterans of diverse eras and branches to the extent possible. Members will serve 4-year staggered appointments.

The Committee will be composed of approximately 12 members. Members may be Regular Government Employees or Special Government Employees. Committee members will serve as objective advisors, not as representatives of any organizations for which they may otherwise be serving.

13. Subcommittees. With the DFO's approval, the Committee is authorized to establish subcommittees, to perform specific projects or assignments as necessary and consistent with its mission. The Committee chair shall notify the Chief Research and Development Officer, through the DFO, of the establishment of any subcommittees, including its function, membership, and estimated duration. Subcommittees must report their recommendations and advice to the full committee for deliberation by the Committee. A subcommittee must not provide advice or work products directly to VA. A member of one subcommittee may serve as a member of other subcommittees when his or her expertise is required.

14. Recordkeeping. Records of the Committee shall be handled in accordance with General Records Schedule 6.2. or other approved agency records disposition schedules. Those records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. § 552.

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15. Filing date.

Approved. DMC
Denis McDonough
Secretary of Veterans Affairs

4/19/22
Date