

DEPARTMENT OF VETERANS AFFAIRS

CHARTER OF THE CLINICAL SCIENCE RESEARCH AND DEVELOPMENT SERVICE COOPERATIVE STUDIES SCIENTIFIC EVALUATION COMMITTEE

A. OFFICIAL DESIGNATION: Clinical Science Research and Development Service Cooperative Studies Scientific Evaluation Committee.

B. OBJECTIVES AND SCOPE OF ACTIVITY: The Committee's objectives are to provide 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, of high quality, efficiently, safely, and economically conducted and mission relevant. To accomplish these objectives, the Committee reviews proposals and makes recommendations to the Director of the Clinical Science Research and Development Service and Chief Research and Development Officer on their funding and administration. The Committee does not consider grants, contracts, or other forms of extramural research for VA.

C. PERIOD OF TIME NECESSARY FOR THE COMMITTEE TO CARRY OUT ITS PURPOSE(S): 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.

D. OFFICIAL TO WHOM THE COMMITTEE REPORTS: The Committee reports to the Director of the Clinical Science Research and Development Service.

E. OFFICE RESPONSIBLE FOR PROVIDING NECESSARY SUPPORT TO THE COMMITTEE: Office of Research and Development, Veterans Health Administration, Department of Veterans Affairs

F. DUTIES OF THE COMMITTEE: 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: the 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 review process involves evaluations of and discussions on written materials supplied by the proponents of each project. Face-to-face discussions between the Committee and proponents may be held to further obtain information about proposals. Thereafter, the Committee deliberates on the projects. Committee deliberations are communicated to the Director of the Clinical Science Research and Development Service in the form of recommendations.

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 will reflect equitable geographic, ethnic, and gender representation so long as the effectiveness of the Committee is not impaired. Members will serve 4-year staggered appointments, contingent upon renewal of the Committee's charter.

As necessary, standing and ad hoc subcommittees of the Committee may be established to perform specific functions within the Committee's purview. A member of one subcommittee may serve as a voting member of other subcommittees when his/her expertise is required.

The Committee will be comprised of approximately 12 members. Several members may be Regular Government Employees, but the majority of the Committee's membership will be Special Government Employees. Committee members will serve as objective advisors, not as representatives of any organizations for which they may otherwise be serving.

G. ESTIMATED ANNUAL OPERATING COSTS IN DOLLARS AND STAFF-YEARS:

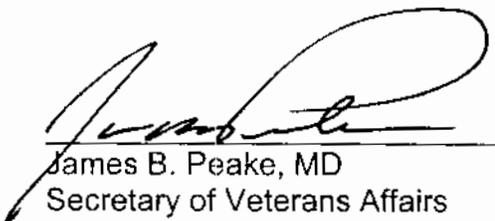
The estimated annual cost for operating the Committee is \$250,000 and about 2.5 staff-years. All members will receive travel expenses and a per diem allowance in accordance with the Federal Travel Regulation for any travel made in connection with their duties as members of the Committee.

H. ESTIMATED NUMBER AND FREQUENCY OF COMMITTEE MEETINGS: The Committee meets two or three times annually. In addition, individual members, task forces, and subcommittees may be called upon periodically for particular advisory services or consultation. The Designated Federal Officer (DFO), a full time VA employee, will approve the schedule of Committee meetings. The DFO or a designee 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.

I. COMMITTEE TERMINATION DATE: Unless renewed by appropriate action prior to its expiration, the Committee will terminate 2 years from the date below.

J. DATE CHARTER IS FILED:

Approved:


James B. Peake, MD
Secretary of Veterans Affairs

Date:

5/20/08