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CHAPTER 9. COOPERATIVE STUDIES PROGRAM

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9.01 GENERAL

Cooperative studies enable investigators from two or more VA medical centers to study collectively a selected problem in a uniform manner, using a common protocol with central coordination. The multi-center approach of VA cooperative studies facilitates the accumulation of patient samples that are sufficiently large to provide valid and significant findings regarding medical technologies. For medical conditions that are relatively rare, cooperative studies may be the only feasible approach; for other more common conditions, these studies enable accumulation of data more rapidly by pooling observations at several hospitals.

9.02 DEVELOPING AND CONDUCTING A COOPERATIVE STUDY

a. A cooperative study begins with the submission of a planning request by a VA researcher to the Chief, CSP (Cooperative Study Program), through the ACOS for R&D and Director at the originating medical center. The request includes the following: objectives of the proposed research; importance of the study to VA and its feasibility within VA; a brief description of the study design including the patient population to be studied; treatments to be compared, type of data collection (retrospective or prospective); randomization or observational approach; end points to be evaluated; number of patients and medical centers required; duration of the study in years; and curriculum vitae of Principal Proponent. To be eligible for planning support, the Principal Proponent must be at least a 5/8 VA salaried employee or must have applied for and received approval for eligibility to receive R&D funds from the Eligibility Committee in VA Central Office (M-3, pt. II, ch. 3).

b. Proposals are reviewed by three or more consultants chosen by the Chief, CSP. At the recommendation of the Chief, a proposal may be sent to one of the Coordinating Centers for planning, rejected, or rewritten to incorporate reviewers' assessments, and then submitted for a second review.

c. The culmination of the planning process is a fully developed protocol which is reviewed by the CSEC (Cooperative Studies Evaluation Committee). If a preliminary pilot study is developed, it must be reviewed by CSEC.

d. The recommendation of CSEC and the approval of the Director, Medical Research Service, are required to activate a study.

e. The study is administered by the CSPCC (Cooperative Studies Program Coordinating Center) that designed the protocol. Conduct of the study is a cooperative effort of the study chairperson, principal investigator, Coordinating Center Chief, Study Biostatistician and their respective staffs. If drugs and/or devices are involved, the Chief, CRP, (Clinical Research Pharmacy) and study pharmacist have responsibilities for administration of drugs and/or devices. The Chief, CSP, has overall responsibility for all cooperative studies.

f. Active studies are reviewed by CSEC at 3-year intervals or when an extension of patient intake is requested.

g. A cooperative study is terminated when the objective has been attained or when it is not feasible or ethical to continue the study.

9.03 REVIEWING AND MONITORING A COOPERATIVE STUDY

a. The CSEC reviews proposals'for new cooperative studies, recommends approval for funding using a priority score rating from 10 to 50, or defines reasons for disapproval. The CSEC also reviews the progress of each cooperative study every 3 years, or more frequently if requested. Committee members include experts in biostatistics, in the experimental design of large-scale multi-hospital clinical trials, and in relevant biomedical fields. At least one member is a full-time VA employee, but none is from the staff of the Cooperative Studies Program Coordinating Centers.

b. The R&D Committee at the participating medical center reviews the protocol and determines that the medical center can provide the necessary space and services to conduct the study.

c. The Subcommittee on Human Studies at each participating medical center reviews the protocol and informed consent material to ensure that the rights and welfare of patients are protected.

d. The CSP Coordinating Center's Committee on Human Rights reviews the protocol during planning and meets annually with the Data Monitoring Board during the course of the study. At least one time during the course of the study, the committee will visit a selected facility where the research is being performed.

9.04 ONGOING PLANNING AND REVIEW BY COMMITTEES

a. The Study Group reviews progress, discusses problems, and provides suggestions for improving the study. The members consist of the Study Chairperson, all participating investigators, and any permanent consultants to the study.

b. The Executive Committee makes changes in the study and in subprotocols, determines the use of study data and publications of study results, and recommends action in the case **of** unsatisfactory performance at participating centers. The members consist of the Study Chairperson, Study Biostatistician, Clinical Research Pharmacist, two or three principal investigators, and consultants when appropriate.

c. The Data Monitoring Board provides evaluation of the study's progress and formulates operational policy. It may make recommendations regarding the participation of a medical center and may recommend terminating the study when necessary. The members consist of experts in the field of the study, an independent biostatistician, and other appropriate consultants. Non-voting members are the Study Chairperson Biostatistician, Chief CSPCC, and Chief, CSP.

d. All major decisions regarding the conduct of a cooperative study are reviewed and confirmed by the Chief, CSP.

9.05 COOPERATIVE STUDY CENTERS

a. There are three Cooperative Study Program Coordinating Centers that serve all cooperative studies during the planning and conduct of the study, and reporting of

the research. The centers provide biomedical statistical advice and assistance, facilities for data collection and evaluation, administrative management, and supportive services such as those of a Human Studies Subcommitte.

b. The Cooperative Studies Program Clinical Research Pharmacy provides administration and management of all drugs and medical devices that are involved in a cooperative study.