

Johns Hopkins Bayview Medical Center

GENERAL CLINICAL RESEARCH CENTER

General Clinical Research Center Advisory Committee: Roles and Responsibilities

Policy No.: 107
Original Date: 09/97
Previous Date: 10/01
Revised Date: 1

Purpose: To delineate the roles, responsibilities and organization of the GCRC Advisory Committee.

Procedure:

1. The GCRC Advisory Committee (GAC) consists of 8 to 12 members appointed by the Principal Investigator/designee, in a rotating basis. The Committee is responsible to the Principal Investigator and/or designee. Membership includes a cross-section of faculty members who are familiar with the broad elements of the GCRC research activities, and shall not be chaired by the Program Director, an Associate, or Assistant Program Director. The Program Director, an Associate, or Assistant Program Director may not be voting members of the Advisory Committee. It is recommended that membership include a biostatistician.
2. Meetings of the full committee are held at least quarterly. Minutes are recorded and circulated among the membership.
3. Committee responsibilities include:
 - A. Supervising and reviewing GCRC operations including the Core Laboratory, and Informatics Core, Exercise and body composition core, Sleep core and Cardiovascular Imaging Core
 - B. Setting general policies
 - C. Delineating common needs of the GCRC Investigators
 - D. Establishing admission criteria and evaluating projects for GCRC use. No study will be undertaken on the GCRC without GAC approval, except when temporary approval may be given by the Program Director or his/her designee and the Institutional Review Board for urgent studies created by an unexpected opportunity to study unusual research participants.
 - E. Prioritizing GCRC projects in order to assist the Program Director in resource allocation. In all cases, NIH- funded clinical research is first priority.
 - F. Assuring implementation of existing NIH policies such as inclusion of women, minorities, and children as study subjects.
 - G. Designating the category (A, B, or D)of inpatient research days and outpatient visits for each proposed project.
 - H. Reviewing copies of the research agreement between the investigator and industry, the related itemized budget, relevant correspondence for appropriate categorization of industry-related projects. Projects may include drugs, therapeutics and/or devices.
 - I. Periodically reviewing GCRC operations (i.e., bed day utilization) to ensure its resources are used for the most scientifically worthy projects
 - J. Encouraging younger faculty members to perform clinical research and assisting them in the application of research concepts and methods.
 - K. As needed, formulating subcommittees to perform GAC responsibilities and functions. These may include review of biostatistical project designs, ethical concerns, priority assignments for research projects.

GAC: roles and responsibilities

- L. Approving scatter-bed inpatient days for Category A patients.
- M. Approving CreFF recipients.
- N. Approving Data and Safety Monitoring Plans for GCRC protocols.
- O. Reviewing data collected from GCRC audits and making recommendations for action to correct or improve protocol and GCRC performance and/or regulation adherence.

Originator: GCRC Clinical Nurse Specialist

References: General Guidelines for the General Clinical Research Centers Program of the National Center for Research Resources National Institutes of Health, November, 2001

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