

Guidelines for General Clinical Research Center Advisory Committee Function August 23, 2002

The following guidelines describe the functions of the GCRC Advisory Committee:

1. The Dean, as the Principal Investigator of the GCRC grant, will appoint GCRC Advisory Committee members. Committee members will serve three-year appointments that are renewable at the discretion of the appointee and the Dean. In addition to regular Committee members, the Dean will solicit basic science and clinical faculty as ad hoc reviewers.
2. The Advisory Committee will consist of 8 to 12 voting members who are responsible to the Dean. Committee membership will be composed of a cross-section of the faculty members who are familiar with the broad elements of the GCRC research activities. The Program Director (PD) or the Associate Program Directors may not chair the Committee and individuals in Program Directorship positions shall not be voting members of the Committee.
3. The Committee will supervise and review the operation of the GCRC, its Core Laboratories, and Informatics Core; set general policies; delineate common needs of the GCRC investigators; establish admission policies; and evaluate projects for GCRC use. Studies on the GCRC must have Advisory Committee approval prior to initiation, except when the PD or his/her designee and the Human Investigation Committee give temporary approval for urgent studies.
4. The Associate Dean for Research will assign a primary and secondary reviewer to each new protocol and a primary reviewer for each proposed amendment. Both of these reviewers will provide a written review of the protocol in an electronic format compatible with Microsoft Word to the PI one week prior to the Advisory Committee meeting and to the GCRC Secretary by noon on the day before the meeting. The primary reviewer will present a summary of the project with brief background, rationale and design, along with activities. The secondary reviewer will prepare only a succinct set of comments and questions. (See Appendix.)

The Associate Dean for Research will assign Ad Hoc reviewers who are not regular members of the Committee who have special expertise related to specific protocols. This will encourage individuals who are not directly connected with the GCRC to participate. One of the two assigned reviewers for each protocol will always be a permanent member of the Committee.

5. The Advisory Committee should prospectively prioritize projects for GCRC use to assist the PD in allocating resources. In all cases, NIH-funded clinical research must be given preference. The Committee is responsible for assuring implementation of existing NIH policy on the inclusion of women, minorities, and children as study subjects and the policy regarding approval of data and safety monitoring plans for Phase I, II, and III clinical trials. The Committee must also

designate for each protocol, the category of inpatient research days and outpatient visits as Category A, B, or D. For appropriate classification of industry-related projects, the Committee must review copies of the research agreement between the investigator and industry, an itemized budget, and other relevant correspondence, detailing the drug or other therapeutics or devices supplied. All these reviews should be summarized appropriately in the minutes of the Committee's meetings.

Reviewers should use the following priority scores:

- A-1 Investigator-initiated, NIH-funded
- A-2 Investigator-initiated, peer reviewed foundation-funded (for example: AHA, ACS, ADA)
- A-3 Investigator-initiated, industry-funded
- A-4 Investigator-initiated, no sponsor

6. Upon the recommendation of the primary reviewer or the Committee Chair, the individual PI may give a five-minute presentation at the meeting. The Committee will strive for rapid turn around of reviews and expedited reviews for minor changes.
7. The Committee will periodically review GCRC operations to ensure that GCRC resources are used for the most scientifically justified and relevant projects. The Committee should encourage junior faculty members to perform clinical research and assist them in applying appropriate concepts and methods. Meetings of the full Committee will be held at least quarterly and the Administrative Director will keep detailed records. The Committee may form subcommittees to carry out some of its functions, including the review of biostatistical design of projects, ethical concerns, or the assignment of priority scores based on scientific merit as well as the protocols need for GCRC resources.

APPENDIX

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GENERAL CLINICAL RESEARCH CENTER

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ADVISORY COMMITTEE PROTOCOL REVIEW FORM (Last Revision Date: 3/31/2003) _____.

Advisory Committee Meeting Date:

GAC Primary / Secondary Reviewer Name:

Number and Title of Proposed Protocol :

Principal Investigator's Name:

Brief Summary of Protocol Hypothesis, Methodology and/or Background:

Comments to the Investigator - *Significant Scientific Issues*:

Comments to the Investigator - *Minor Issues*:

Comments to the Advisory Committee:

Decision: (Approved: No changes /Approved: With changes /Not Approved) -

Recommended Categorization and Prioritization:

- A-1 Investigator-initiated, NIH-funded**
- A-2 Investigator-initiated, peer reviewed foundation-funded (for example: AHA, ACS, ADA)**
- A-3 Investigator-initiated, industry-funded**
- A-4 Investigator-initiated, no sponsor**
- B**
- C**
- D Industry initiated, industry funded**
