NIGMS PROGRAM PROJECT AND RESEARCH CENTER GRANT APPLICATIONS

INFORMATION FOR CONSULTANTS

I. CONSULTANT DUTIES: Program Project Grant (PPG) and Research Center Grant (RCG) applications to the National Institute of General Medical Sciences (NIGMS) are reviewed by Scientific Review Groups (SRGs), either standing study sections or special emphasis panels, in accordance with procedures used by the Center for Scientific Review. When deemed necessary, the review may take place in conjunction with a site visit. Consultants are assigned to review specific aspects of the application based on their expertise, but they should be familiar with the entire application in order to participate effectively in all of the review proceedings.

II. CONFIDENTIALITY: Applications and related materials furnished for review purposes, discussions held during the site visit and SRG meeting, and outcomes of the review process are confidential and must be handled appropriately. All communication between applicants and consultants regarding any aspect of the review must be through the scientific review administrator (SRA) or appropriate NIH staff members.

III. CONFLICT OF INTEREST: Even the appearance of possible conflict of interest can be cause for re-review at considerable expense. Consultants should advise the SRA of any present and past associations (e.g., collaboration, mentor-student, or employment) between them or their family members and the personnel or institutions listed in the application, and they must sign the conflict of interest forms provided.

IV. REVIEWS INVOLVING A SITE VISIT:

A. Pre-Site Visit: When a site visit is made, the entire team meets prior to the visit for orientation, to finalize review assignments, to identify questions that need to be asked and information that needs to be gathered on site, and to address procedural details that are essential to the conduct of the site visit.

B. Site Visit: The purpose of a site visit is to gather information needed for the review. This must be done in a way that ensures a fair appraisal and does not convey the reviewers' opinions to the applicants. Direct and forthright questions are encouraged but should be worded so that they cannot be construed as recommendations or judgments. Avoid evaluative comments and inferences. The chairperson moderates the scientific discussions at the site visit and SRG meeting. The team should arrive on site and leave together, and the SRA should be present during all discussions with the applicants.

C. Post-Site Visit: Immediately following a site visit, the team reconvenes (usually at the hotel) to review the information gained, to consider the appropriate actions, and to determine reviewers' levels of enthusiasm for each component and for the application as a whole. The goals are to ensure that all pertinent review issues have been resolved and that each reviewer's report reflects the opinions of the entire team. These deliberations are not binding until the group convenes and takes official actions as an SRG.

V. SRG MEETING: The SRG meeting begins with an orientation by the SRA, and the chairperson conducts the review in accordance with the guidelines delineated below. Written reports for each component and the overall application are read, discussed, and acted upon. Following discussion of each research component, reviewers individually assign priority ratings, recommend/vote on budget levels, and determine whether that component should be included in the PPG or RCG. For each non-research core component, the SRG recommends appropriate budget levels. The overall application is then considered, each reviewer assigns an overall priority rating, and the group recommends overall budget levels. Priority ratings are assigned in increments of 0.1 and range from 1.0 (the most meritorious) to 5.0 (the least meritorious). A motion to "not recommend for further consideration" (NRFC) may be considered if a research component or overall application lacks significant and substantial merit or there are serious concerns regarding the use of human subjects or animals. If the SRG finds that additional information is needed to complete a review, it may consider a deferral. If a motion to NRFC or defer is passed, that component (or the overall application) is not rated, and the budget is not considered. (If there are two or more dissenting votes on a motion to NRFC, at least one of the written critiques must reflect the minority opinion.) Administrative notes (e.g., to address issues such as budgetary overlap) may be added for any component and for the overall application.

VI. REPORTS: Consultants prepare written reports for their assigned portions of the review prior to the conclusion of the review meeting. When there is a site visit, consultants should arrive with preliminary written reports and modify them as needed following the site visit. Consultants must carefully follow the detailed instructions provided below, in the section entitled "Guidelines for Review and Written Reports."

GUIDELINES FOR REVIEW AND WRITTEN REPORTS

Each PPG or RCG application submitted to NIGMS includes an introductory section that describes the overall application and justifies the use of the mechanism, followed by separate, largely self-sufficient sections that present the individual research and core components. In accord with established NIH practice, the SRG first reviews the research components separately as independent, as well as interdependent, research efforts and then reviews the scientific merit and coherence of the overall application as a synergistic and interactive enterprise. The reviews are based on the criteria enumerated below; the individual projects and the application as a whole must meet the same standards of scientific merit required of regular (individual R01) research grants. **In preparing reports, remember that the summary statement (which is sent to the applicant) will normally be compiled using unedited reviewer comments; do not include personal identifiers.**

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, address each the criteria listed in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. The specified criteria will be considered in assigning the individual project and overall scores, weighting them as appropriate for each application. An application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

I. **RESEARCH COMPONENTS** (Consultants): Each research component is individually reviewed, scored, and recommended for inclusion or exclusion. The guidelines for the review of the individual research components reflect the standard NIH review criteria and basis for assigning a priority score. Assessment of the scientific merit and scoring of individual projects is based on the published criteria for regular research grants (NIH GUIDE, Volume 26, Number 22, June 27, 1997), taking into account the additional strength the project gains from interactions with other components of the proposed PPG or RCG and its potential importance to the success of the total effort. In this context, it may be the case that an individual project may be highly meritorious in the context of an entire program project or center but not make sense as a stand-alone research grant.

A. DESCRIPTION: The description will be taken from the application (abstract).

B. CRITIQUE (include as little descriptive information in this section as possible): Address each criterion listed below in a separate section. **For competing continuation (renewal) applications**, include an evaluation of progress over the past project period; **for amended applications**, address progress, changes, and responses to the critiques in the summary statement from the previous review, indicating whether the application has been strengthened or weakened since the previous submission. Comments on progress and response to the previous review may be provided in a separate paragraph or under the appropriate criteria.

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Approach: Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Innovation: Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

Investigator: Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

Interdependence: To what extent are there interactions between this and other components? Does this component contribute in a significant way to the overall application?

Summary: Briefly summarize the most important points of the critique, addressing the strengths and weaknesses that most influence your evaluation of the project.

C. BUDGET: Recommend scientifically appropriate and justified budget levels for each year; provide a rationale for each recommended budget change. Recommend the inclusion or exclusion of the research component in the overall PPG or RCG. The priority score should not be affected by the evaluation of the budget.

D. OTHER CONSIDERATIONS: Refer also to the PHS 398 or the enclosed "Review Procedures for Initial Review Group Meetings." Address each item below in a separate section of your report as appropriate.

Protection of Human Subjects From Research Risks: Under a separate heading, evaluate the application with reference to: (1) risk to subjects, (2) adequacy of protection against risks, (3) potential benefit to the subjects and to others, and (4) importance of the knowledge to be gained. (If the applicant fails to address **all** of these elements, notify the SRA.) If all of the criteria are adequately addressed, and there are no concerns, write "Acceptable Risks and/or Adequate Protections." A brief explanation is advisable. If one or more criteria are not adequately addressed, write "Unacceptable Risks and/or Inadequate Protections" and document the actual or potential issues that create the human subjects concern (the seriousness of a human subjects concern should be reflected in the assigned score). If the application indicates that the proposed human subjects research is exempt from coverage by the regulations, determine if adequate justification is provided. If the claimed exemption is not justified, indicate "Unacceptable" and explain why you reached this conclusion. If a clinical trial is proposed, also evaluate the Data and Safety Monitoring Plan. Indicate if the plan is "Acceptable" or "Unacceptable" and, if unacceptable, explain why. (If the plan is absent, notify the SRA.)

Gender, Minority and Children Subjects: Public Law 103-43 requires that women and minorities must be included in all NIH-supported clinical research projects involving human subjects unless a clear and compelling rationale establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. NIH requires that children (individuals under the age of 21) of all ages be involved in all human subjects research supported by the NIH unless there are scientific or ethical reasons for excluding them. Each project involving human subjects must be assigned codes using the categories "1" to "5" below. Category 5 for minority representation in the project means that only foreign subjects are in the study population (no U.S. subjects). If the study uses both then use codes 1 thru 4. Examine whether the minority and gender characteristics of the sample are scientifically acceptable, consistent with the aims of the project, and comply with NIH policy. For each category, determine if the proposed subject recruitment targets are "A" (acceptable) or "U" (unacceptable). Address each category under a separate heading and explain the reason(s) for the recommended code; this is particularly critical for any item coded "U." A rating of "U" in a category should be considered as a weakness in the research design and reflected in the score.

CATEGORY	Gender (G)	Minority (M)	Children (C)
1	Both genders	Minority and non-minority	Children and adults
2	Only women	Only minority	Only children
3	Only men	Only non-minority	No children
4	Gender unknown	Minority representation unknown	Representation of children unknown
5		Only foreign subjects	

Note: When acceptability or unacceptability affects the investigator's approach to the proposed research, appropriate comments should appear under the criterion "Approach" and may considered in the score.

Animal Welfare: Are the required five points on care and use of vertebrate animal addressed? Are the procedures described appropriate and necessary for the conduct of scientifically sound research? Note any comments or concerns.

Biohazards: Note any potentially hazardous materials or procedures and indicate whether the proposed protective measures will be adequate.

Overlap (an administrative issue, for consideration by NIH staff but not included in the merit rating): Identify any apparent scientific or budgetary overlap with active or pending support.

Sharing Plans: Are there plans for sharing of data and resources (including model organisms, where relevant)? Comment on the adequacy of the plans but don't include in the priority scores.

II. **CORE COMPONENTS** (Consultants): Non-research core components are evaluated but not scored; appropriate budget levels must be determined.

A. DESCRIPTION: Will be taken from application.

B. CRITIQUE: Assess the quality of services and facilities provided, their cost-effectiveness, their utility to the program, and the extent to which they benefit two or more of the research components.

C. BUDGET: Recommend budget levels for each year that are scientifically appropriate and justified by their contributions to the overall application; provide a rationale for each recommended budget change.

D. OTHER: Address Human Subject, Animal Welfare, Biohazard, Sharing, and Overlap issues as appropriate.

III. **OVERALL APPLICATION**: Following review of the individual research and core components, the PPG or RCG application is reviewed as a whole. An overall numerical rating is assigned privately by each consultant. The overall priority score indicates the scientific merit and the synergy of the entire application; it should reflect the interdependence of the components and their potential to contribute to the overall success of the enterprise; it is not an average of the scores assigned to individual components. For example, one or more of the research components may have very high scientific merit but lack relevance or contribute little to the PPG or RCG as a whole; conversely, research components with relatively lower scientific merit may provide necessary strengths to the other components and to the overall application.

A. RESUME (SRA or Chairperson, as assigned): Summarize the bases for the panel's recommendations, indicating the key strengths and weaknesses of the individual components and the application as a whole.

B. OVERALL DESCRIPTION: Applicant's description (abstract) will be used.

C. OVERALL CRITIQUE (Consultants): Provide appropriate background information on the submission of this application--especially for renewal, supplemental, or amended applications. Briefly address the unifying research focus and long-range goals of the PPG or RCG, the chief approaches and disciplines involved in the application, and the rationale for research in this area. The review criteria listed below will apply the overall review of most PPG applications. A specific program announcement (PA) or request for applications (RFA) for PPGs or RCGs may list alternate criteria, in which case, the criteria enumerated in the specific PA or RFA will apply. Use the relevant criteria to address the strengths and weaknesses of the PPG or RCG application as a whole. Evaluate critically the extent of the interactions among the components and among the investigators that lead to the overall assessment and overall priority rating. Explain briefly how the strengths and weaknesses of the individual components impact on the assessment of the overall application.

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project as a whole? What are the advantages of the program project mechanism over a collection of regular research grants (R01s)? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Innovation: Does the proposed program project grant employ novel concepts, approaches or method? Are the overall aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

Investigator: Is the principal investigator appropriately trained and well suited to carry out this work and provide the leadership necessary to ensure success of the entire program? Is the work proposed appropriate to the experience level of the principal investigator and other researchers?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

D. OVERALL BUDGET: Recommend an overall summary budget, including duration. The priority score should not be affected by the evaluation of the budget.

E. ADMINISTRATIVE NOTE(S): If the SRG considers any administrative issues (such as overlap with other funding sources, consortium or consultant arrangements, delegation of management responsibility, or institutional support) sufficiently important to include in the summary statement as advice to NIGMS staff, then one or more consultants will be designated to detail these issues in a short paragraph.