GENERAL INSTRUCTIONS FOR PREPARATION OF CRITIQUES

National Institutes of Diabetes and Digestive and Kidney Diseases

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In your written review, you should comment on the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals.

These instructions are general in nature. Depending on the particular grant mechanism or solicitation (i.e., a Request for Applications) you may be evaluating, more precise review criteria may be specified and should be followed.

Please bring a copy of your assigned written critiques to the meeting. Most reviewers also bring their laptop computers for use during the meeting. In addition, if you do not participate in Internet Assisted Review, bring electronic versions of your critiques to be given to the SRA when the meeting concludes. This will facilitate the writing of summary statements. Your written reviews should not bear personal identifiers since comments will be minimally edited before being sent to the investigator.

EVALUATION OF APPLICATIONS

PRIMARY AND SECONDARY REVIEWERS should provide an overall evaluation, briefly summarizing the most important points of your critique, weighting the review criteria as you feel appropriate, and evaluating the overall impact of the research on the field. (Note: 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 merit rating.) In the critique, the five review criteria should be addressed as separate sections. If this is a competing continuation application, evaluate the progress made during the previous funding period either as a separate paragraph or under the individual criteria as appropriate. If this is an amended application, address progress, changes, and responses to the critique from the previous review, indicating whether the application is improved, the same as, or worse than the previous submission. However, you are not constrained to address only the points identified in the previous review. These comments on progress and responsiveness to previous critiques should be provided either in a separate paragraph and/or under the appropriate criteria.

DISCUSSANTS The written critique for a discussant review may be brief; all aspects of the five review criteria do not need to be specifically addressed. A brief paragraph highlighting the strengths and weaknesses of the application (essentially equivalent to an overall evaluation section) or bulleted lists of strengths and weaknesses are both examples of acceptable critiques. If you prefer to prepare a full critique equivalent to a primary or secondary review, you also have that option.

CRITERIA FACTORED INTO PRIORITY SCORE

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?

Investigators: 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)? Do not include descriptive biographical information.

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? Do not describe available facilities and equipment.

Human Subjects: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed (see the Research Plan, Section E on Human Subjects in the PHS Form 398). If exemptions are claimed, express any comments or concerns about the appropriateness of the exemption(s) claimed. If no exemptions are claimed, express any comments or concerns about the appropriateness of the responses to the four required points, especially whether the risks to subjects are reasonable in relation to the anticipated benefits to the subjects and in relation to the importance of the knowledge that may reasonably be expected to result from the research. If a data safety and monitoring plan is required, determine whether the proposed plan is appropriate.

Inclusion of Women, Minorities and Children in Research: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children (individuals under 21 years of age) as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated (see the Research Plan, Section E on Human Subjects in the PHS Form 398). In conformance with NIH policy, the use of women, children, and minority individuals in patient populations is an issue that should be addressed in any application which involves clinical research (for more information, see (http://grants.nih.gov/grants/guide/notice-files/not98-024.html and http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html). Clinical research includes "...human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials". If there is no compelling rationale provided for the exclusion or under-representation of women, children, and minorities from the patient study population, this constitutes a flaw in experimental design and should be reflected in the priority score. Reviewers are asked to inform the Scientific Review Administrator if such concerns exist and to comment specifically on these issues in their critiques. In addition, you will be asked to recommend a code for the application, using categories 1 to 4 as follows. Also determine whether the research is a Phase III clinical trial.

CODE	Minority (M)	Gender (G)	Children (C)
1	minority and non-minority	both females and males	both children and adults
2	only minority	females only	children only
3	only non-minority	males only	no children included
4	representation unknown	unknown	unknown

Evaluate acceptability as "A" (acceptable) or "U" (unacceptable). If you rate the sample as "U", consider this feature a weakness or a deficiency in the design of the project reflected in the overall scoring of the application. NOTE: To the degree that acceptability or unacceptability impacts on the investigator's approach to the proposed research, such comments should also appear under Approach in the five major review criteria above and should be factored into the score as appropriate.

Care and Use of Vertebrate Animals in Research: If vertebrate animals are to be used in the project, the five items described under Section F of the PHS Form 398 research grant application instructions will be assessed.. Express any comments or concerns about the appropriateness of the responses to the five required points, especially whether the procedures will be limited to those that are unavoidable in the conduct of scientifically sound research.

OTHER CONSIDERATIONS

Budget: Evaluate direct costs only. For all years, determine whether all items of the budget are appropriate and justified. Provide a rationale for each recommended modification in amount and/or duration of support. With regard to personnel, do not be concerned with the salary requested but with the percent effort proposed. The priority score should not be affected by the evaluation of the budget.

Scientific/Budgetary Overlap: If it is identified in an application, it should be noted in a statement separate from the critique and should not be considered in the evaluation of the application. Identify of there is an overlap of aims or excessive effort between this application and other active or pending support. Reviewers are asked to focus on the scientific and technical merit of the application. The Scientific Review Administrator will ensure that such issues are documented in the summary statement as an administrative note. Purported overlap must be resolved by NIH staff before an award is made.

Model Organism Sharing Plan: All NIH applications (regardless of budget) where the development of model organisms is anticipated are to include a description of a specific plan for sharing and distributing unique model organism research resources or state appropriate reasons why such sharing is restricted or not possible. Please comment on the adequacy of the sharing plan, taking into consideration the organism, the timeline, and the applicant's decision to distribute the resource or deposit it in a repository. Your assessment of the sharing plan should not be factored into the priority score of the application. Your comments will be captured in an administrative note.

Data Sharing Plan: Investigators seeking $500,000 or more in direct costs in any year must include a brief one-paragraph description of how final research data will be shared, or explain why data sharing is not possible. Applicants are encouraged to discuss their data sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. http://grants.nih.gov/grants/policy/data_sharing/index.htm. Please comment on the adequacy of the sharing plan. Your assessment of the sharing plan should not be factored into the priority score of the application; your comments will be captured in an administrative note.

Biohazards: If biohazardous materials are to be used in the proposed research, the Principal Investigator should address the proper handling of such items. Note any materials or procedures that are potentially hazardous to research personnel and indicate whether the protection proposed will be adequate.

Foreign Institutions: If the applicant organization is foreign, comment on any special talents, resources, populations, or environmental conditions that are not readily available in the United States or that provide augmentation of existing U.S. resources. In addition, indicate whether similar research is being performed in the U.S. and whether there is a need for such additional research. These aspects do not apply to applications from U.S. organizations for projects containing a significant foreign component.

10/06