GUIDE FOR ASSIGNED REVIEWERS' PRELIMINARY COMMENTS ON RESEARCH GRANT APPLICATIONS (R01)

Please use the following guidelines when preparing written comments on research grant applications assigned to you for review. 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. **NOTE: Your written reviews should not bear personal identifiers because unaltered comments will be sent to the investigator.**

DESCRIPTION: The NIH now scans the abstract on page 2 of an application for use in the Description section of the summary statement. However, as a reviewer you must be prepared to present a summary of the goals of the application to the Study Section so that all members can follow the critiques and discussion. Thus, any description you write (in prose or in bullet form) is for your use in making this presentation.

CRITIQUE: Include as little descriptive information in this section as possible. Please address, in five individual sections, each criterion listed below. In addition: 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 is improved, the same as, or worse than the previous submission. Comments on progress and response to the previous review should be provided in a separate paragraph and/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?

- **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)?

- **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?

OVERALL EVALUATION: In one paragraph, briefly summarize the most important points of the Critique, addressing the strengths and weaknesses of the application in terms of the five review criteria. Recommend a score reflecting the overall impact of the project on the field, weighing the review criteria, as you feel appropriate for each application. An application does not need to be strong in all categories to be judged likely to have a major scientific impact and, thus, deserve a high merit rating. 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.

PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISKS: Evaluate the application with reference to the following criteria: risk to subjects, adequacy of protection against risks, potential benefit to the subjects and to others, importance of the knowledge to be gained. (If the applicant fails to address **all** of these elements, notify the SRA immediately to determine if the application should be withdrawn.) 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 inadequately addressed, write, "Unacceptable Risks and/or Inadequate Protections" and document the actual or potential issues that create the human subjects concern. 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. Also, if a clinical trial is proposed, evaluate the Data and Safety Monitoring Plan. (If the plan is absent, notify the SRA immediately to determine if the application should withdrawn.) Indicate if the plan is "Acceptable" or "Unacceptable", and, if unacceptable, explain why it is unacceptable.

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 a code 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). If you rate the sample as "U", consider this feature a weakness in the research design and reflect it in the overall score. Explain the reasons for the recommended codes; this is particularly critical for any item coded "U".

Category	Gender (G)	Minority (M)	Children (C)
1	Both Genders	Minority & non-minority	Children & adults
2	Only Women	Only minority	Only children
3	Only Men	Only non-minority	No children included
4	Gender Unknown	Minority representation unknown	Representation of children unknown
5		Only Foreign Subjects	

NOTE: To the degree that acceptability or unacceptability affects the investigator's approach to the proposed research, such comments should appear under "Approach" in the five major review criteria above, and should be factored into the score as appropriate.

ANIMAL WELFARE: 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.

BIOHAZARDS: Note any materials or procedures that are potentially hazardous to research personnel and indicate whether the protection proposed will be adequate.

OTHER CONSIDERATIONS: These comments are useful to NIH but should not influence your overall score.

Budget: Evaluate the direct costs only. Do not focus on detail. For all years, determine whether all categories of the budget are appropriate and justified. Provide a rationale for each suggested modification in amount or duration of support.

Sharing Research Data: Applications requesting more than $500,000 direct costs in any year of the proposed research are expected to include a data sharing plan in their application. Certain Program Announcements may request a data sharing plan for all applications regardless of the amount of direct costs. Assess the reasonableness of the data sharing plan or the rationale for not sharing research data.

Sharing of model organisms: A new NIH policy on sharing of model organisms for biomedical research was announced in the May 7, 2004 issue of the NIH Guide (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html). Starting with the October 1, 2004 receipt date, all new and competing-renewal NIH grant applications that plan to produce model organisms will be expected to include a sharing plan. Unlike the NIH Data Sharing Policy, the submission of a model organism sharing plan is NOT subject to a cost threshold of $500,000 or more in direct costs in any one year, and is expected to be included in all applications where the development of model organisms is anticipated.

Foreign: Applications from foreign institutions or international organizations will be evaluated and scored by reviewers using the standard review criteria. In addition, after scoring, they should assess the following:

- Whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing U.S. resources.

- Whether the proposed project has specific relevance to the mission and objectives of the NIH and has the potential for significantly advancing health sciences in the United States.

This requirement does not apply to applications from U.S. organizations containing a foreign component.