GUIDE FOR ASSIGNED REVIEWERS' PRELIMINARY COMMENTS ON SMALL GRANT MECHANISM (R03)

The R03 mechanism is designed to support discrete, well-defined projects that realistically can be completed in a short period of time with limited resources. The types of projects commonly supported by the R03 mechanism include the following:

- Pilot or feasibility studies
- Secondary analysis of existing data
- Small, self-contained research projects
- Development of research methodology
- Development of new research technology

R03 applications must identify a Funding Opportunity Announcement (formerly called a Program Announcement) for electronic submission. The NIH Institutes and Centers use the R03 mechanism for a variety of purposes within the broad concept of small grants. Reviewers should refer to the identified Funding Opportunity Announcement for specific information about the eligibility criteria, application focus, or specific review criteria as these may vary across FOAs. R03 applications are able to utilize the multiple PI approach.

The NIH Small Research Grant Program (Parent R03) is described in the Program Announcement (PA-06-180). Many other FOAs for R03 grant applications refer to this parent Program Announcement for page limits, budget limitations, and review criteria. The research plan for most R03 applications is limited to 10 pages. Applicants for an R03 generally may request a project period of up to two years and budget for direct costs of up to $50,000 per year. A modular budget should be used (applications from institutions outside the United States must always have detailed budgets). Two resubmissions of an application are allowed and the Introduction for resubmission applications is limited to one page. Refer to the FOA for the specific requirements and limitations. R03s cannot be renewed.

REVIEW GUIDELINES:

Because the research plan is restricted to 10 pages, an R03 grant application will not have the same level of detail or extensive discussion found in an R01 application. Accordingly, reviewers should evaluate the conceptual framework and general approach to the problem, placing less emphasis on methodological details and certain indicators traditionally used in evaluating the scientific merit of R01 applications, including supportive preliminary data. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or from investigator-generated data. Preliminary data are not required, particularly in applications proposing pilot or feasibility studies. Although any preliminary data provided should be evaluated, reviewers should not request new data. Applications should not be penalized for lacking preliminary data.

Please use the following guidelines when preparing written comments on R03 grant applications.

NOTE: Your written reviews should not bear personal identifiers because essentially unaltered comments will be sent to the applicant.

Description: As a reviewer you will need to be prepared to provide members of the Study Section sufficient information on the application so that they can follow the critiques and discussion.

Critique: Include as little descriptive information in this section as possible. Please address, each of the following:

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? For applications designating multiple Program Directors/Principal Investigators (PD/PI)s, is the leadership approach, including the designated roles and responsibilities, governance and organizational structure consistent with and justified by the aims of the project and the expertise of each of the PD/PIs?

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 PD/PI(s) and other key personnel appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the PD/PI(s) and other researchers? Do the PD/PI(s) and the investigative team bring complementary and integrated expertise to the project (if applicable)?

Environment: Do(es) the scientific environment(s) 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(s), or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

Multiple PD/PI Leadership Plan: For applications designating multiple PD/PIs, a new section of the research plan, entitled "Multiple PD/PI Leadership Plan" (section 14 of the Research Plan Component in the SF424 R&R or Section I of the Research Plan in the PHS 398), must be included. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs and other collaborators. If budget allocation is planned, the distribution of resources to specific components of the project or the individual PD/PIs must be delineated in the Leadership Plan. In the event of an award, the requested allocation may be reflected in a footnote on the Notice of Grant Award (NOGA).

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.

Resubmission (formerly "revised/amended" applications): Are the responses to comments from the previous scientific review group adequate? Are the improvements in the resubmission application appropriate?

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 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 issue(s) that create(s) the human subjects concern. If the application indicates that the proposed research is exempt from coverage by the human subjects' 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. Indicate if the plan is "Acceptable" or "Unacceptable", and, if unacceptable, explain why it is unacceptable.

Inclusion of Women Plan:
Inclusion of Minorities Plan:
Inclusion of Children Plan:
Public Law 103-43 requires that women and minorities must be included in all NIH-supported 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" discussed below. Category 5 for minority representation in the project means that only foreign subjects are in the study population (i.e., no U.S. subjects). If the study involves both US and foreign subjects, use codes 1 through 4. Examine whether the minority, gender, and age characteristics of the subject population 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". Gender (G) Minority (M) Children (C) codes are:

- 1 Both genders; Minority and nonminority; or Children and adults

- 2 Only women; Only minority; or Only children
- 3 Only men; Only non-minority; or No children included
- 4 Gender Unknown; Minority representation unknown; or Representation of children unknown
- 5 Only Foreign Subjects

Vertebrate Animals: 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. The Five Points on Vertebrate Animals in the Research Plan are:

- Detailed description of proposed use, species/strains, sex, numbers, etc
- Justification of use and numbers
- Veterinary care
- Limitation of discomfort, distress, pain, and injury
- Method of euthanasia.

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

NOTE: To the degree that acceptability or unacceptability of protection of human subjects, inclusion of women, minorities, and children, animal welfare, or biohazards affects the investigator's approach to the proposed research, relevant comments should also appear under "Approach" in the five major review criteria above, and should be factored into the score as appropriate.

Other comments that may be required, but which do not influence the score are:

Budget: All budgets are modular, except for applications from foreign institutions which must always have full budgets. Evaluate the direct costs only. Do not focus on detail. Determine whether the total budget is appropriate for the project proposed. Provide a rationale for suggested modification in duration or amount of support.

Model Organism Sharing Plan: All NIH applications that will produce new, genetically modified variants of organisms and related resources are expected to include a sharing plan or to state why sharing is restricted or not possible. Assess the sharing plan in an administrative note. You must take into consideration the organism, the timeline, the applicant's decision to distribute the resource or deposit it in a repository, and other relevant considerations.

Data Sharing Plan: Some PAs require inclusion of a data sharing plan. The reasonableness of the data sharing plan or the rationale for not sharing research data will be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or priority score.

PA Goals: Reviewers may comment briefly on whether the proposed studies meet the goals of the PA. However, this matter is considered an administrative comment and should not be used to influence the final score, which should be based solely on the scientific and technical merits of the application.

Foreign: 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.

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