Guidelines for Reviewer's Written Comments
For
PAR01-056
Small Clinical Research Grants in Digestive Diseases and Nutrition

The format outlined below should be followed in preparing your comments for each application assigned to you. Please feel free to provide additional headings when it seems appropriate to the review.

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? Will a successful outcome from this pilot study lead directly to more extensive studies that would likely advance the digestive disease research?

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

Because the research plan is limited to ten pages, these R03 small grant applications may not have the same level of detail or extensive discussion normally found in a regular R01 research project grant application. Review emphasis will be placed on the conceptual framework and general approach to the problem, with less emphasis on methodological details.

Since pilot/feasibility studies may not include preliminary data, the review will focus on whether the rationale for the study is well developed and whether the proposed research is likely to generate data that will lead to additional studies that could potentially be funded as a regular research project grant (R01).

INNOVATION: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies? Will the project generate a new body of data that provide a foundation for important new research directions?

INVESTIGATORS: Is the investigator 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 (if any)? Is the Principal Investigator an independent researcher?

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?

OVERALL EVALUATION: In a brief paragraph, indicate the major strengths and weaknesses of the planned project.

ACTION: The application may be recommended for no further consideration, deferred in order to obtain additional information, or given a priority score. If the application is to be scored, indicate the level of scientific merit using the adjectival scale.

BUDGET: Comment on the appropriateness and justification of the budget request within the context of the goal of the award.

OTHER CONSIDERATIONS: If these matters affect the assessment of the scientific merit of the application, they will be considered as part of the critique and the overall score.

Protection of Human Subjects From Research Risk: Evaluate 1) Risk to Subjects, 2) The Adequacy of Protection Against Risks, 3) Potential Benefits of the Proposed Research to the Subjects and Others, and 4) Importance of the Knowledge to be Gained. Evaluate the information provided in the application and indicate whether the information is "Absent" or Protection of Human Subjects From Research Risk is Acceptable or Unacceptable. If the Protection of Human Subjects From Research Risk is Unacceptable it should be reflected in the priority score for scientific and technical merit assigned to the application. The negative impact on the score should reflect the seriousness of the human subject concerns that are identified. Reviewers may also recommend limitations on the scope of the work proposed, imposition of restrictions or elimination of objectionable (risky) procedures involving human subjects.

Women, Children and Minorities in Study Populations: Examine whether the minority and gender characteristics of the sample are scientifically acceptable and consistent with the aims of the project, using the categories of 1 to 4 as follows. Determine whether children have been included or appropriately excluded from the study population.

CODE	Minority (M)	Gender (G)	Children (C)
1	minority and non-minority	both females and male	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 project. NOTE: To the degree that acceptability or unacceptability impacts on 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.

Data and Safety Monitoring Plan: Applicants must supply a general description of the Data and Safety Monitoring Plan for all clinical trials as part of the research application. The principles of data and safety monitoring require that all biomedical and behavioral clinical trials be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk.

Animal Welfare: If animals are to be used in the project, discuss if their use is justified and if they will be given proper care and humane treatment so that they will not suffer unnecessary discomfort, pain, or injury.

Hazardous Materials and Procedures: Describe any potentially hazardous materials and procedures and whether the protection to be provided will be adequate.

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 if 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.