

REVIEWER GUIDELINES

NIDDK PROGRAM PROJECTS

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GENERAL INSTRUCTIONS FOR PREPARATION OF P01 CRITIQUE

Please consider bringing a laptop and your critiques on a disc to the meeting. Should you need to make some minor edits to your critiques you will be able to do so before the meeting concludes. You may transfer these edits to the Scientific Review Administrator using a flash drive or on a diskette or CD before you leave the meeting. Alternatively, you can upload any final edits into the Internet Assisted Review System after the meeting. Each reviewer is expected to read the complete application in addition to their assigned review components.

You will all comment on the merit of the entire Program Project as a whole and will need to be familiar with the entire application. A key point to remember is that beyond the scores assigned to each project and core, a single score is assigned to the entire Program Project as a whole. It is this "Overall Score" that will be used to guide the Program staff of the NIDDK and our National Advisory Council in their funding decisions. The Overall Score is not just an average of the scores assigned to the projects and cores - you must factor in whether there is synergy and cohesiveness between the individual components. Is the whole greater than the sum of its parts? Are the projects simple stand-alone R01-type applications or together will they achieve something more by being combined with each other in a program? Does the Principal Investigator have sufficient experience and skill to lead a program of this size and complexity?

Introduction - General Review Considerations

For a program project application to be assigned a priority score, at least three component projects must be judged to have sufficient scientific merit to receive priority scores. At least three projects must extend for the duration of the program project. The NIDDK is interested in supporting only the best research; individual research projects that are relatively lower in merit may not be funded under the "umbrella" of the program project mechanism. It is primarily for this reason that each project will be assigned a separate priority score, taking into consideration only its merit as an individual research project. It is important that each project fits and contributes to the theme of the overall program project, but this factor should be judged separately and have no bearing on a project's individual priority score. Instead, these considerations will be addressed later with respect to the merit of the overall program project.

It is expected that individual components, in order to receive funding, will not represent significantly poorer research than is being funded by the R01 mechanism. A project whose score is somewhat poorer than currently funded R01 grants may benefit greatly from inclusion in the overall program project, whereby synergism with other components and use of core facilities significantly enhance its value. Conversely, such a project might provide certain elements that greatly enhance other projects in the overall program project. Such considerations would be expected to have impact on the overall priority score assigned by the reviewers to the program project.

Requested core budgets may need to be adjusted downward if it is recommended that some of the individual projects utilizing their services are reduced in scope or if they are recommended for no further consideration. Therefore, it is important for both the applicant and the reviewer to address the contribution of the cores to each project in both scientific and budget terms.

All applications except supplements must request and be reviewed for 5 years of project period support. While one or more projects may be recommended for less than 5 years, only in very unusual circumstances may the entire program project be recommended for less than 5 years.

In the case of the review of a competing continuation (renewal) application, the progress made during the past period of funding is also an important consideration in the review of projects and cores.

Scientific or budgetary overlap, if identified in an application, should be noted in a statement separate from the critique and should not be considered in the evaluation 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.

Review of Individual Projects

1. **Overall Evaluation** Briefly summarize the most important points of your critique, weighting the review criteria as you feel appropriate. Evaluate the overall impact on the field.
2. **Description** This section is prepared by the SRA after the meeting using the abstract provided by the applicant.
3. **Critique** For each research component judged to have sufficient scientific merit, a priority score is assigned, based on the criteria for the review of individual research projects. Please address each review criteria in a separate section using the individual headings shown below.

The review criteria for individual research projects are:

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? Is the timeline appropriate in relation to the scope of the proposed research?

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?

Protection of Human Subjects from Research Risk: Explain concerns regarding the proposed use of human subjects, including any possible physical, psychological, or social injury individuals might experience while participating as subjects in the research. Indicate whether their rights and welfare will be protected adequately or whether they may be subjected to ethically questionable procedures.

Inclusion of Women, Minorities and Children in Research: Determine if an appropriate balance of gender and minority representation in the study population will be sought, if this is scientifically acceptable, and justify the gender and minority codes to be assigned. Determine whether children have been included in the research and if their inclusion or exclusion has been explained adequately to justify the code to be assigned. Assign an appropriate Minority, Gender, and Children code to the project.

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.

Careful scrutiny also should be given to treatment of animals in experimental protocols. The following five points shall be addressed in the application: (a) the identification of the species and approximate number of animals required; (b) the rationale for using animals and the appropriateness of the species and numbers indicated for the work proposed; (c) a complete description of the anticipated use of the animals;

(d) an assurance that discomfort and injury to animals will be limited to unavoidable situations and that analgesic, anesthetic, and tranquilizing drugs will be employed where possible to minimize discomfort and pain; and (e) a description of any euthanasia method to be applied. 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.

Model Organism Sharing Plan: All NIH applications that plan to produce new, genetically modified variants of model organisms and related resources are expected to include a sharing plan or to state 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 will 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 will not be factored into the priority score of the application; your comments will be captured in an administrative note.

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

Budget: If any changes are recommended, provide a justification along with a specific dollar amount. The budget is not considered when you evaluate the scientific merit of the application and does not contribute to the priority score.

Recommendation: Unless recommended for no further consideration, assign a priority score.

Review of Individual Cores

Please address each review criteria in a separate section using the individual headings shown below. The review criteria for the individual cores are given below (cores receive merit descriptors rather than numeric scores):

Utility of the Core to the Program Project: Each core must provide essential facilities or service for two or more projects judged to have substantial scientific merit.

Quality of the Core Facilities or Services: Assess the quality of the facilities or services provided by the core. Consider procedures, techniques, quality control, and criteria for prioritization of usage.

Core Personnel: Evaluate the qualifications, experience, and commitment of the core director and personnel involved in the core.

Involvement of Human Subjects: Evaluate human subjects as described above under the review of Individual Projects if they are being used within the core.

Animal Welfare: If animals are to be used in the core, discuss if their use is justified and if they will be given proper care as described above under the review of Individual Projects.

Core Budget: If any changes are recommended, provide a justification along with a specific dollar amount. The budget is not considered when you evaluate the scientific merit of the core and does not contribute to the merit.

Recommendation: Unless recommended for no further consideration, assign a merit descriptor term.

Review of the Administrative Core

The Chair of the review panel will prepare the review of the Administrative Core.

The review will assess:

1. The academic environment and resources in which the research will be conducted, including availability of space, equipment, human subjects, animals, or other resources as required, and the potential for interaction with scientists from other departments;
2. The Institutional commitment to the requirements of the program, including fiscal responsibility and management capability of the institution to assist the principal investigator/program director and his or her staff in following DHHS, PHS, and NIH policy.
3. The administrative planning and leadership capability to provide for internal quality control of ongoing research, allocation of funds, enhancement of internal communication and cooperation among the investigators involved in the program, and replacement of the principal investigator/program director if required on an interim or permanent basis.
4. The appropriateness of the budget in relation to the proposed program project.

Review of the Principal Investigator

The Chair of the review panel will prepare the critique of the Principal Investigator of the Program Project. 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)? Does the Principal Investigator have sufficient experience and skill to lead a program of this size and complexity?

Review of Overall Program Project

The Chair of the review panel will prepare the Overall Critique after the meeting concludes using the reviewer critiques for the projects and cores and notes taken during the group discussion of the overall scientific merit of the Program Project. Once all Projects and Cores have been discussed and scored, the entire review committee will participate in a discussion of the overall scientific merit of the application. The Chair will initiate the discussion by summarizing points heard during the evaluations of each project and core. Next, the discussion will be open to the group and each reviewer can add points of emphasis or disagreements to the discussion.

The relationship and contributions of each research component and core (excluding those recommended for no further consideration) to the overall theme of the program project are discussed and evaluated; these points must be clearly and specifically outlined in the summary statement. This will be a separate consideration which is not determined exclusively by the priority scores of the individual projects. Although projects that are not scored are removed from consideration as part of the overall program project, the inclusion of such projects will reflect on the leadership capabilities of the principal investigator/program director.

The overall program project application is evaluated considering the priority-scored projects, supporting cores, and the administrative structure. For a Program Project to receive a priority score, it must consist of at least three priority-scored individual projects for the duration of the proposed Program Project period. Each core must provide essential functions or services for at least two of these projects.

1. Specific factors to be evaluated in the consideration of the overall program project are as follows:

- a. Scientific merit of the program as a whole, as well as that of individual projects, and its potential impact on the field;
 - b. The evaluation of the overall program in terms of significance, approach, innovation, investigators, and environment;
 - c. Scientific gain of combining the component parts into a program project (beyond that achievable if each project were to be pursued separately). Is the whole greater than the component parts;
 - d. Cohesiveness and multidisciplinary scope of the program and the coordination and interrelationship of all individual research projects and cores to the common theme;
 - e. Leadership and scientific ability of the principal investigator/program director and his or her commitment and ability to develop a well-defined central research focus (including request of support for a sufficient percent effort to provide effective oversight and administration of the program will be a specific review criterion); and
 - f. Past accomplishments of the program or a demonstrated ability in mounting similar programs.
2. Additional criteria that are only applicable for competing continuation (renewal) applications include:
- a. Progress and achievements specific to this program project since the previous competitive review and the evidence through publications, conferences, etc., that collaboration has occurred. The application must state clearly when publications have resulted from support through more than one funding source.
 - b. Evidence that the previous specific aims have been accomplished and that the new research goals are logical extensions of ongoing work;
 - c. Previous performance and estimated use of the core(s); and
 - d. Justification for adding new projects or cores or for deleting components previously supported.
3. Additional criteria that are only applicable for supplemental applications include:
- a. Carefully conceived and explained rationale for extension of currently funded projects; and
 - b. Progress made through the program to warrant the extension.

Final Recommendation

If the overall program project is judged to have sufficient merit, a priority score will be assigned based on the application's merit as a program project. This score is not the average of the priority scores assigned to the individual components. If a component project lacks sufficient scientific merit, it will receive neither a priority score nor a budget recommendation, and it will not be considered in the assignment of an overall priority score.

It is possible that one or more of the components will have excellent scientific merit but fit poorly, or not at all, within the program project. Such projects may be deleted from the program project and thus would be omitted from consideration when assigning the final priority score to the overall program project. Conversely, components with relatively poorer scientific merit may contain parts that would strengthen or bridge other proposed projects. Therefore, the review committee specifically should address the value of each project to the overall program project and the resultant synergy.