

P01 GUIDE FOR REVIEWERS

Program Project Grant Applications

EXECUTIVE SUMMARY

NIH Program Project Grant (PPG) Program (P01)

- Supports integrated, multi-project research projects involving a number of independent investigators who share knowledge and common resources.
- Each project contributes or is directly related to the common theme of the total research effort, thus forming a system of research activities and projects directed toward a well-defined research program goal.
- No specific dollar limit unless specified in a Funding Opportunity Announcement (FOA).
- Advance permission required for \$500,000 or more (direct costs) in any year.
- Generally awarded for 3 to 5 years.
- Each Program Project Grant (PPG) application submitted to NIH includes an introductory section that describes the overall application and justifies the use of the mechanism, followed by separate, largely self-sufficient sections that present the individual research and core components.
- In accordance with established NIH practice, the Scientific Review Group (SRG) first reviews the research components separately as independent, as well as interdependent, research efforts and then reviews the scientific merit, impact, and coherence of the overall application as a synergistic and interactive enterprise.
- In some cases, the chair of the SRG, in conjunction with the panel, writes the RESUME AND SUMMARY OF DISCUSSION paragraph at the end of the meeting which focuses on the strengths and weaknesses of the entire project and the meeting discussion. The chair reads this back to the panel for final approval.
- ICs may have specific requirements and review criteria; please refer to the appropriate FOA.

INSTRUCTIONS FOR WRITTEN CRITIQUE AND PRELIMINARY SCORES

Written Critiques

Please use the following guidelines when preparing written comments on the Program Project (P01) grant applications assigned to you for review. This guidance includes templates for writing critiques for the Individual Research Projects, the Administrative Core, the Scientific Cores, and the Overall Program.

- You must format your critiques to follow the structured template provided. This can be downloaded from the files provided by your SRO and/or from the CD.
- Standard criteria and additional review criteria for the Individual Research Project, Administrative Core, Scientific Core, and Overall Program are represented in the reviewer template and should be commented on, listing the strengths and weaknesses of each in a bulleted sentence format.
- The goal is to provide the maximum and most pertinent information in a concise manner.

Critiques for Individual Research Projects

- Assigned reviewers, after considering all of the review criteria prior to the meeting, should:
 - State the strengths and weaknesses of each criterion in the appropriate section on the template.
 - Briefly summarize the strengths and weaknesses of the project in the “Overall Impact” section of the template.
 - Enter a preliminary score in the appropriate box on the Internet Assisted Review (IAR) site for each criterion.
 - Enter a preliminary overall impact/priority score for the project in the appropriate box on IAR.
- **Note:** Assigned reviewers must upload critiques before entering scores.

Critiques for Scientific or Administrative Cores

- Assigned reviewers, after considering all of the review criteria (including review criteria specific to the FOA) prior to the meeting, should:
 - State the strengths and weaknesses of the core in the appropriate template section.
 - Rate the Core either as “Acceptable” or “Unacceptable” within the text of the critique. Support Cores are not scored numerically.

Critiques for Overall Program

- Assigned reviewers, after considering all of the special review criteria, should:
 - State the strengths and weaknesses of the Overall Program in the appropriate template section.
 - Enter a preliminary overall impact/priority score for the entire Program Project application in the appropriate box on IAR.
 - The overall impact/priority score indicates the scientific merit and the synergy of the entire application.
 - It should reflect the interdependence of the components and their potential to contribute to the overall success of the enterprise.
 - It is not an average of the scores assigned to individual components. For example, one or more of the research components may have very high

scientific merit but lack relevance or contribute little to the PPG as a whole; conversely, research components with relatively lower scientific merit may provide necessary strengths to the other components and to the overall application.

Preliminary Scores

- Each scored review criterion for the Individual Research Projects should be given a score using the nine-point rating scale.
- The criterion scores for the applications should be entered in the meeting IAR Web site in the NIH Commons before the review meeting using the same page that is used for submitting the preliminary impact/priority score and critique. Do not enter scores on the critique.
- The criterion scores may be changed following the review meeting during the EDIT phase.
- In the READ phase of the meeting reviewers may submit their scores and critiques, but may not edit them. Core criterion scores can be submitted only after your critique has been uploaded into IAR.
- The criterion scores will appear in the summary statement as part of your critique.
- The overall impact/priority score on a 1 to 9 scale should reflect your assessment of the likelihood for the project or program to exert a sustained, powerful influence on the research field(s) involved, in consideration of the standard review criteria and the additional review criteria (as applicable for the project/program proposed).

Review Criteria

Overall Impact/Priority

NIH peer reviewers are asked to provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria, and the additional review criteria (as applicable for the project proposed). Reviewers also are asked to consider the interactions between the individual research projects and other components, and whether each component contributes in a significant way to the overall application.

Scored Review Criteria for Individual Research Projects

Reviewers often are asked to consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each. However, some FOAs may include additional or special review criteria, so please check the FOA to confirm the scored review criteria listed below.

These individual criterion scores are considered part of your critique, although they are not entered on the critique, and generally will not be discussed at the review meeting. They may be changed in the EDIT phase in Commons. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)

Are the program directors/principal investigators (PD/PIs), collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators (see definitions below), do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Review Criteria for Administrative and Scientific Cores

Cores receive only an Acceptable/Unacceptable rating based on the following criteria:

Administrative Core: Does the application clearly describe and justify the proposed administrative core operational plan and organizational structure? Is the proposed administrative core adequate to support and encourage optimal interactions among participants of the overall program? Do the core leader's administrative, management, and leadership capabilities provide for the following activities: Internal quality control of ongoing research; Management of day-to-day program activities; Management of

contractual agreements; Fair, effective communication and cooperation among program leaders and/or program investigators; Resolution of disputes; Development of scientific meetings; Allocation of funds?

Scientific Core: Is the scientific core necessary? Can it support at least two research projects? How is the core connected to the central focus of the overall program? How good are the facilities or services provided by the core (including procedures, techniques, and quality control)? Are they being used effectively? Are the core leader and key personnel well-qualified to operate the core? Are there any concerns about competence or commitment?

Additional Review Criteria

As applicable for the project proposed, reviewers are asked to consider the following additional items in the determination of scientific and technical merit, but not to give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46 (as described in [Human Subjects Protection and Inclusion](#)), reviewers are asked to evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials. 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. Also, if a clinical trial is proposed, evaluate the Data and Safety Monitoring Plan. (If the plan is absent, notify the SRO immediately to determine if the application should be withdrawn.) Indicate if the plan is "Acceptable" or "Unacceptable", and, if unacceptable, explain why it is unacceptable.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt, evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. If the claimed exemption is not justified, indicate "Unacceptable", and, if unacceptable, explain why it is unacceptable.

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.

For additional information to assist you in making these determinations, please refer to http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Protection_and_Inclusion.pdf and http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Worksheet.pdf.

Inclusion of Women, Minorities and Children

When the proposed project involves clinical research, reviewers are asked to evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

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".

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.

For additional information to assist you in making these determinations, please refer to http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Protection_and_Inclusion.pdf and http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Worksheet.pdf.

<u>Gender Inclusion Code</u>	<u>Minority Inclusion Code</u>	<u>Children Inclusion Code</u>
G1 = Both genders	M1 = Minority and nonminority	C1 = Children and adults
G2 = Only women	M2 = Only minority	C2 = Only children
G3 = Only men	M3 = Only nonminority	C3 = No children included
G4 = Gender composition unknown	M4 = Minority composition unknown	C4 = Representation of children unknown
	M5 = Only foreign subjects	

Vertebrate Animals

Reviewers are asked to evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

For additional information to assist you in determining if the Vertebrate Animals section is "Acceptable" or "Unacceptable", please refer to: <http://grants.nih.gov/grants/olaw/VASchecklist.pdf>.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmission Applications

When reviewing a Resubmission application (formerly called an amended application), evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewal Applications

When reviewing a Renewal application (formerly called a competing continuation application), the committee will consider the progress made in the last funding period.

Revision Applications

When reviewing a Revision application (formerly called a competing supplement application), the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Additional Review Considerations

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact score.

Budget and Period Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

Select Agents

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s). Select agent information is available via http://grants.nih.gov/grants/policy/select_agent/.

Applications from Foreign Organizations

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable:

1) Data Sharing Plan

(http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm)

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.

2) Sharing Model Organisms

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>). All NIH grant applications are expected to include a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. 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.

3) Genome Wide Association Studies

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-013.html>). Applications and proposals that include GWAS, regardless of the requested costs, are expected to include as part of the Research Plan either a plan for submission of GWAS data to the NIH designated data repository or an appropriate explanation for why submission to the repository will not be possible.