

GUIDE FOR REVIEWER'S WRITTEN COMMENTS NIDDK EDUCATION PROGRAM GRANTS (R25)

The Education Grant Program at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is a flexible, curriculum-driven program aimed to create educational opportunities that will attract undergraduate and graduate students and postdoctoral fellows to careers in areas of biomedical or behavioral research of particular interest to the NIDDK and to foster their career development. The NIDDK is especially interested in attracting students and postdoctoral fellows from scientific disciplines underrepresented in disease-oriented biomedical research such as engineering, informatics, computer science, and computational sciences, and encouraging them to apply their expertise to research relevant to diabetes and other endocrine and metabolic diseases, digestive and liver diseases and nutrition, obesity research and prevention, and kidney, urologic and hematologic diseases. Refer to the NIH program announcement on the enclosed CD for more detail about the award.

INSTRUCTIONS FOR WRITTEN CRITIQUE AND PRELIMINARY SCORES

Please use the following guidelines when preparing written comments on R25 research project grant applications assigned to you for review.

Written Critiques

- The format of the critiques should follow the structured template provided for each mechanism, which can be downloaded from the Internet Assisted Review (IAR) site and found on the CD.
- Each core criterion and additional review criteria are represented in the reviewer template and should be commented on, listing the strengths and weaknesses of each in a bulleted form.
- The goal is to provide the maximum and most pertinent information in a concise manner.
- After considering all of the review criteria, briefly summarize the strengths and weaknesses of the application in the Overall Impact section of the template.
- Assigned reviewers must upload critiques before entering an overall impact/priority score.
- Criterion scores should be entered in IAR before the review meeting.
- Assigned reviewers may submit criterion scores only after their critiques have been uploaded. At the SRO's discretion, discussants who are assigned to the application and SRG members who are not assigned to the application may submit criterion scores without critiques.
- The criterion scores may be changed during FINAL SCORING on your electronic or paper Voter/Scoring Sheet, or following the review meeting during the EDIT phase.
- Please do not write your criterion scores on the critique template.

Preliminary Scores

- Each core review criterion should be given a score using the nine-point rating scale in accordance with the new Enhanced Peer Review Criteria.
- The criterion scores for the applications should be entered in the meeting Internet Assisted Review (IAR) site in NIH Commons before the review meeting using the same page that is used for submitting the preliminary impact/priority score and 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 had been uploaded into IAR.

- The criterion scores will appear in the summary statement as part of your critique.

Core Review Criteria

Reviewers 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. These individual criterion scores are considered part of your critique and 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 proposed research education program address scientific/education areas and/or topics important to the mission of the NIDDK? How will implementation of the proposed program advance the objectives of this funding opportunity announcement as well as the mission of the NIDDK? Is the justification of the need for the proposed program, relative to other on-going education and/or training/career development activities being sponsored within the institution(s), compelling?

Investigator(s)

Are the investigators appropriately trained and well suited to carry out this work? Is the proposed program appropriate to the experience level of the PD/PI and other researchers? Does the investigative team bring complementary and integrated expertise to the program (if applicable)? Is there evidence that an appropriate level of effort will be devoted by the program leadership to ensure the program's objectives? Is the makeup of the Advisory Committee suitable? Are the members committed to providing oversight and input, and to monitoring and evaluating the overall effectiveness of the program? If appropriate, were institutional curriculum committees involved in the plan for integrating the proposed program into the current established curriculum?

Innovation

Is the research education program 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? Does this program duplicate, or overlap with, existing research education, training and/or career development activities currently supported at the applicant institution or available elsewhere? Adaptations of existing research education programs may be considered innovative under special circumstances, e.g., the addition of unique components and/or a proposal to determine portability of an existing program.

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 there evidence that the program is based on sound research concepts and educational principles? Is the approach feasible and appropriate to achieve the stated research education goals? If the proposed program will recruit participants, are the recruitment, retention, and follow-up activities adequate to ensure a highly qualified and diverse participant pool?

Environment

Does the scientific/educational environment in which the program will be conducted contribute to the probability of success? Does the proposed research education program benefit from unique features of the scientific environment, subject populations, or employ useful collaborative arrangements? Is there evidence of appropriate collaboration among participating programs, departments, and institutions? Is the institutional commitment to the proposed program appropriate? If multiple sites are participating, is this adequately justified in terms of the research education experiences provided? Are adequate plans provided for coordination and communication between multiple sites (if appropriate)? Are the plans to continue the program after the period of grant support ends (i.e. when the program involves curriculum development aimed at strengthening the educational capability of the institution) adequate?

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.

Evaluation Plan

Is the evaluation plan and timeline adequate for assessing the effectiveness (process and outcome) of the program in achieving its goals and objectives?

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.

<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	

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.

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.

Overall Impact

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).

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.

Training in the Responsible Conduct of Research

Assess the applicant's plans for training in the responsible conduct of research on the basis of the appropriateness of topics, format, amount and nature of faculty participation, and the frequency and duration of instruction. The plan is judged either acceptable or not acceptable.

Diversity Recruitment and Retention Plan

Examine the strategies to be used in the recruitment and retention of individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from socially, culturally, economically, or educationally disadvantaged backgrounds. The plan is judged either acceptable or not acceptable.

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.

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