

## **GUIDE FOR REVIEWER'S WRITTEN COMMENTS**

### **Institutional National Research Service Grant Applications (T35)**

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) invites new and competing continuation applications for its ongoing Short-Term Training for Medical Students program. This trans-NIDDK program provides short-term research support for medical students, or students in health professional schools, to expose them to career opportunities in research related to diabetes, obesity, endocrine disorders, metabolic diseases, nutritional disorders, digestive diseases, liver disease, kidney diseases, urologic diseases, and hematologic disorders. These Institutional National Research Service Award (NRSA) grants (T35) provide support for training experiences of eight to twelve consecutive weeks under the supervision of experienced researchers. This exposure to an active research environment may encourage students to pursue a biomedical or behavioral research career. In addition to the research experience, institutions are encouraged to provide seminars, research forums, guest lecturers, student presentations, special courses, or travel to a scientific meeting of interest to the student.

### **INSTRUCTIONS FOR WRITTEN CRITIQUE AND PRELIMINARY SCORES**

Please use the following guidelines when preparing written comments on T35 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.

### ***Training Program***

Are the objectives, design, direction, and quality of the proposed short-term research training program appropriate? Does the proposed program provide suitable training for the levels of trainees being proposed and the area of science to be supported by the program? Is the quality of proposed course contents and training experience appropriate for all levels of trainees to be included in the program? Does the program have access to candidates for short-term research training and the ability to recruit high quality, short-term trainees from the applicant institution or some other health-professional school? For competing continuation (renewal) applications, what is the success in attracting trainees back for multiple appointments?

### ***Training Program Director/Principal Investigator (PD/PI)***

Does the Training PD/PI have the scientific background, expertise, and experience appropriate to direct, manage, coordinate, and administer the proposed research training program? Does the PD/PI plan to commit adequate time to the program? Is the past training record of the PD/PI appropriate? For applications designating multiple PD/PIs, is the leadership approach, including the designated roles and responsibilities, governance and organizational structure consistent with and justified by the aims of the research training program and the expertise of each of the PD/PIs? Does the PD/PI team bring complementary and integrated expertise to the proposed research training program? Does the leadership plan describe how multiple PD/PIs will benefit the program and the trainees?

### ***Preceptors/Mentors***

Are sufficient numbers of experienced preceptors/mentors with appropriate expertise and funding available to support the number and level of trainees proposed in the application? Do the preceptors/mentors have strong records as basic or clinical researchers, including successful competition for research support in areas directly related to the proposed research training program? Do the preceptors/mentors have strong records of training pre- and/or postdoctorates?

### ***Training Record***

Consider the past record of the Program Director and designated preceptors in terms of numbers and types of degrees and the current career status of past trainees (if available in the application). On the basis of this past research training record, consider whether this program can be expected to achieve its stated goals.

### ***Institutional Training Environment, Commitment, and Resources***

Is the quality of the research environment for the proposed short-term research training program appropriate? Is the level of institutional commitment, quality of available facilities, courses and seminars, research and research training support suitable for the short-term training program?

## **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.

## ***Trainee Recruitment and Selection Plan***

Are the quality of the applicant pool and plans for the selection of individuals appointed to the short-term training program appropriate? Specifically, what is the size and quality of the applicant pool? Are the recruiting procedures, and trainee selection criteria, appropriate and well defined? Are there advertising plans or other effective strategies to recruit high-quality trainees?

For competing renewal applications: How successful has the program been in efforts to recruit individuals from diverse underrepresented populations?

## ***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](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](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.

<b><u>Gender Inclusion Code</u></b>	<b><u>Minority Inclusion Code</u></b>	<b><u>Children Inclusion Code</u></b>
<b>G1</b> = Both genders	<b>M1</b> = Minority and nonminority	<b>C1</b> = Children and adults
<b>G2</b> = Only women	<b>M2</b> = Only minority	<b>C2</b> = Only children
<b>G3</b> = Only men	<b>M3</b> = Only nonminority	<b>C3</b> = No children included
<b>G4</b> = Gender composition unknown	<b>M4</b> = Minority composition unknown	<b>C4</b> = Representation of children unknown
	<b>M5</b> = 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](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](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 major thrust of the training program; the major strengths and weaknesses of the program; and the relative importance of the favorable and unfavorable aspects of the application.

## **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***

The reasonableness of the proposed budget and the requested period of support in relation to the proposed short-term research training program. The priority score should not be affected by the evaluation of the budget.

### ***Training Program Evaluation***

Does the application describe an evaluation plan to review and determine the quality and effectiveness of the training program? Are the plans for obtaining feedback from current and former trainees and monitoring trainees' career development and progressions adequate to measure the quality and effectiveness of the research training program?

For competing renewal applications: Are there plans to make changes to improve program performance and incorporate feedback from current and former trainees (e.g., new mentors, changes in courses, recruitment strategies, etc.)?

Does the competing renewal application describe the program accomplishments to date, including information on trainee publications, degree completion, and post-training positions?

### ***Recruitment and Retention Plan to Enhance Diversity***

The NIH recognizes a unique and compelling need to promote diversity in the biomedical, behavioral, clinical and social sciences workforce. The NIH expects efforts to diversify the workforce to lead to the recruitment of the most talented researchers from all groups; to improve the quality of the educational and training environment; to balance and broaden the perspective in setting research priorities; to improve the ability to recruit subjects from diverse backgrounds into clinical research protocols; and to improve the Nation's capacity to address and eliminate health disparities.

Accordingly the NIH continues to encourage institutions to diversify their student and faculty populations and thus to increase the participation of individuals currently underrepresented in the biomedical, clinical, behavioral, and social sciences such as: individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from socially, culturally, economically, or educationally disadvantaged backgrounds that have inhibited their ability to pursue a career in health-related research. Institutions are encouraged to identify candidates who will increase diversity on a national or institutional basis.

Peer reviewers will separately evaluate the recruitment and retention plan to enhance diversity after the overall score has been determined. Reviewers will examine the strategies to be used in the recruitment and retention of individuals from underrepresented groups. The review panel's evaluation will be included in an administrative note in the summary statement. If the diversity recruitment and retention plan is judged to be unacceptable, funding will be withheld until a revised plan (and report) that addresses the deficiencies is received. Staff within the NIH awarding component, with guidance from the appropriate national advisory committee or council, will determine whether amended plans and reports submitted after the initial review are acceptable.

### ***Training in the Responsible Conduct of Research***

Peer reviewers will 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 will be discussed after the overall determination of merit, and the review panel's evaluation of the plan will not be a factor in the determination of the priority score. Plans will be judged as acceptable

or unacceptable, and the result will be described in an administrative note on the summary statement. Regardless of the priority score, applications with unacceptable plans will not be funded until the applicant provides an acceptable, revised plan. Program staff will judge the acceptability of the revised plan. The relevant NIH staff will judge the acceptability of the revised plan.

5/1/2009