

T35 GUIDE FOR REVIEWERS

Ruth L. Kirschstein National Research Service Award (NRSA) Short-Term Institutional Research Training Grants

EXECUTIVE SUMMARY

Ruth L. Kirschstein NRSA Awards for Institutional Research Training Grants (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.

Visit parent FOA at <http://www.grants.nih.gov/grants/guide/PA-files/PA-10-037.html>

INSTRUCTIONS FOR WRITTEN CRITIQUE AND PRELIMINARY SCORES

The goals of NIH-supported research training programs are to help ensure that a diverse pool of highly trained scientists are available in adequate numbers and in appropriate research areas to address the Nation's biomedical, behavioral, and clinical research needs. The scientific review group will determine the quality of the proposed research training program and consider whether the requested number of trainee positions is appropriate for the short-term program.

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.

Overall Impact

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the research training program to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria, and additional review criteria (as applicable for the research training program proposed).

Scored Review Criteria

Reviewers are asked to consider each of the five review criteria below, 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.

Training Program and Environment

- 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?

- Are the research facilities and research environment conducive to preparing trainees for successful careers as biomedical scientists?
- Do the objectives, design and direction of the proposed research program ensure effective training?
- Is the proposed program of training likely to ensure that trainees will be prepared for successful and productive scientific careers?
- Do the courses, where relevant, and research training experiences address state- of-the-art science relevant to the aims of the program?
- Does the program provide training in inter- or multi-disciplinary research and/or provide training in state of the art or novel methodologies and techniques?
- Is a significant level of institutional commitment to the program evident?

Training Program Director/Principal Investigator (PD/PI)

- Does the Training PD/PI have the scientific background, expertise, and experience to provide strong leadership, direction, management, and administration to the proposed research training program?
- Does the PD/PI plan to commit sufficient time to the program to ensure its success?
- Is sufficient administrative and research training support provided for the program?
- For applications designating multiple PD/PIs:
 - is a strong justification provided that the multiple PD/PI leadership approach will benefit the training program and the trainees?
 - Is a strong and compelling leadership approach evident, including the designated roles and responsibilities, governance, and organizational structure consistent with and justified by the aims of the training program and with the complementary expertise of each of the PD/PIs?

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 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?

Trainees

- Are the quality of the applicant pool and plans for the selection of individuals appointed to the short-term training program appropriate?
- Are the size and quality of the applicant pool adequate to support the program?
- 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?

Training Record

- How successful are the trainees (or for new applications, other past students/fellows in similar training) in completing the program?
- How productive are trainees (or for new applications other past students/fellows) in terms of research accomplishments and publications?
- How successful are trainees (or other past students/fellows) in obtaining further training appointments, fellowships, and career development awards?
- How successful are the trainees in achieving productive scientific careers, as evidenced by successful competition for research grants, receipt of honors or awards, high-impact publications, receipt of patents, promotion to scientific leadership positions, and/or other such measures of success?
- Does the program have a rigorous evaluation plan to review the quality and effectiveness of the training?
- Are effective mechanisms in place for obtaining feedback from current and former trainees and monitoring trainees' subsequent career development?
- For programs that provide research training to health-professional doctorates, is there a record of retaining health professionals in research training or other research activities for at least two years?
- What is the success in attracting students back for multiple appointments?
- Are plans presented to follow the careers of short-term trainees and to assess the effect of the training program on subsequent career choices?
- For renewal applications:
 - Does the application describe the program's accomplishments over the past funding period(s);
 - Are changes proposed that would improve/strengthen the training experience?

Additional Review Criteria

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, but will not 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

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

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.

Recruitment and Retention Plan to Enhance Diversity

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 all three underrepresented groups (A, B, and C).

For renewal applications, peer reviewers will evaluate whether the experience in recruitment during the previous award period has been incorporated into the formulation of the plan for the next award period. 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

Reviewers will evaluate plans for instruction in responsible conduct of research as well as the past record of instruction in responsible conduct of research, where applicable. Reviewers will specifically address five Instructional Components (Format, Subject Matter, Faculty Participation, Duration and Frequency), taking into account the characteristics of institutional programs or the unique circumstances for short-term training programs, detailed in [NOT-OD-10-019](#). The review of this consideration will be guided by the principles set forth in [NOT-OD-10-019](#). Plans and past record will be rated as **ACCEPTABLE** or **UNACCEPTABLE**.

Select Agents Research

When applicable, 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).

Budget and Period of Support

The reasonableness of the proposed budget and the requested period of support will be assessed in relation to the proposed short-term research training program and the number of proposed short-term trainees at the requested levels. The overall impact/ priority score should not be affected by the evaluation of the budget.

Additional Comments to the Applicant

Reviewers may provide guidance to the applicant or recommend against resubmission without fundamental revision.