

GUIDE FOR REVIEWER'S WRITTEN COMMENTS

Institutional National Research Service Grant Applications (T32)

The goals of NIH-supported research training are to help ensure that a diverse pool of highly trained scientists is 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 address and consider each of the criteria below in assigning the application's overall score, weighting them as appropriate for each application. Reviewers will first determine the quality of the proposed research training program and then consider whether the requested number of trainee positions is appropriate for the program. Refer to the NIH program announcement on the enclosed CD for more detail about the award. The format outlined below should be followed in preparing your comments for each T32 application assigned to you to review. Include additional headings when they seem appropriate to the review. If this is an amended application, address progress, changes, and responses to the critique from the previous review, indicating whether the application is improved, the same as, or worse than the previous submission. However, you are not constrained to address only the points identified in the previous review. These comments on progress and/or responsiveness to previous critiques may be provided either in a separate paragraph and/or under the appropriate criteria. The application does not need to be strong in all categories to receive a high priority score. These criteria are listed in logical order and not in order of priority.

The Primary (1) and Secondary (1) reviewers should each address all of the review criteria outlined below. The Secondary (2) or Discussant reviewer will prepare a brief written critique. A short paragraph highlighting the strengths and weaknesses of the application or bulleted lists of strengths and weaknesses are both examples of acceptable critiques written by the Secondary (2) or Discussant reviewer. If you prefer to prepare a full critique equivalent to a Primary (1) or Secondary (1) reviewer, you also have that option.

Overall Evaluation: Please provide a brief paragraph indicating in a few sentences: 1) the major thrust of the training program; 2) the major strengths and weaknesses of the program; and 3) the relative importance of the favorable and unfavorable aspects of the application which influenced your recommendation.

Training Program: Are the objectives, design and direction of the proposed 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? Are inter- and multi-disciplinary and inter-professional research training opportunities or novel concepts, approaches, methodologies, or technologies appropriately utilized?

Training Program Director: Does the Program Director have the scientific background, expertise, and experience appropriate to direct, manage, coordinate, and administer the proposed research training program? Does the Program Director plan to commit adequate time to the program?

Preceptors/Mentors: Is the caliber of preceptors/mentors as researchers, including successful competition for research support in areas directly related to the proposed research training program appropriate for their role in the training program? Is there a sufficient number of experienced mentors with appropriate expertise and funding available at the applicant institution to support the number of trainees and levels of trainees being proposed?

Past Training Record: Is the past research training record of the program, the Program Director, and designated preceptors/mentors appropriate? How successful are former trainees in seeking further career development and in establishing productive scientific careers? Is there evidence of successful completion of programs, receipt of subsequent fellowships and/or career awards, further training appointments, and similar accomplishments? Is there evidence of a productive scientific career, such as a record of successful competition for research grants, receipt of special honors or award, a record of publications, receipt of patents, promotion to scientific positions, and any other measure of success consistent with the nature and duration of the training received. What is the track record of proposed mentors in similar research training programs? Is there a record in retaining health-professional postdoctorates (i.e., individuals with the M.D., D.O, D.D.S. D.N.Sc., etc.) for at least 2 years in research training or other research activities, if appropriate?

Institutional Training Environment, Commitment, and Resources: Is the quality of the research environment for the proposed research training program appropriate? Is the level of institutional commitment, quality of available facilities, courses, research and research training support suitable? Is the proposed program to be an integral component of the applicant institution's overall research program/mission?

Trainee Recruitment, Selection, and Retention Plan: Are the quality of the applicant pool and plans for the selection and retention of individuals appointed to the training program appropriate? Specifically, what is the size and

quality of the applicant pool? Are the recruiting procedures, trainee selection criteria, and retention strategies 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 and retain individuals from diverse underrepresented populations?

Evaluation and Tracking Plan: Is the evaluation plan adequate and sufficiently detailed to track career outcomes of trainees and determine if the program is successful? Does it include a system for tracking participants following program completion, such as publications, grant proposals and awards, and career trajectory of supported trainees?

For competing renewal applications: Are there plans to make changes that improve program performance and the assessment of outcomes? Competing renewal applications must describe the program accomplishments to date.

Short-Term Research Training Positions: In addition to the above criteria, applications that request short-term research training positions will also be assessed using the following criteria:

- Is the quality of the proposed short-term research training program appropriate? Are the commitment and availability of the participating faculty, program design, availability of research support, and training environment well suited for short-term training?
- 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?
- Does the research training program include features that might be expected to persuade short-term trainees to consider careers in health-related research?
- What is the effect of the short-term training program on the quality of the regular research training program or any existing, stand-alone short-term research training program? Are the number of short-term positions, and the plan to integrate the short-term training program into the regular research training programs appropriate?
- Is there a plan to follow the careers of short-term trainees and to assess the effect of the training program on subsequent career choices?
- For competing continuation applications, what is the success in attracting students back for multiple appointments?

Protection of Human Subjects from Research Risks: Typically the T32 grant itself does not contain research projects involving human subjects. It may support trainees on projects involving human subjects. Prior to the involvement of human subjects in activities supported by this training grant, the specific project(s) must have been certified and approved by the Institutional Review Board and certification submitted to the awarding institute. The T32 application is not required to enumerate these approvals during the review phase.

If human subjects are directly used in the application you should explain any 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. For additional information, refer to the "NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects in Grant and Cooperative Agreement Applications" which is included on the CD.

Inclusion of Women, Children, and Minorities Plans: Typically the T32 grant itself does not contain research projects involving human subjects. It may support trainees involved in projects involving human subjects. Populations, by definition, must contain women, minorities, and children whenever human subjects are used in clinical trials or other research investigations. Without a justifiable rationale based upon the study protocol, any study populations involved in investigations supported in whole or in part by the application must include women, minorities, and children.

If human subjects are directly used in the application, 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 (**individuals under 21 years of age**) have been included in the research and if their inclusion or exclusion has been explained adequately to justify the code to be assigned.

Data Safety Monitoring Plan: If a data and safety monitoring plan is required, indicate if it is adequate.

Vertebrate Animals: Typically the T32 grant itself does not contain research projects involving vertebrate animals. Prior to the involvement of live vertebrate animals in activities supported by this training grant, the specific project(s) must have been reviewed and approved by the Institutional Animal Care and Use Committee, and an approved animal welfare assurance must be on file with the Office for Protection from Research Risks at the National Institutes of Health. The T32 application is not required to enumerate these approvals during the review phase.

Vertebrate 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. The five items described under Section F of the PHS Form 398 research grant application instructions should have been addressed by the candidate. This includes (a) a detailed description of the use of animals in the proposed research including the identification of the species, strains, ages, sex, and numbers of animals required; (b) the rationale for using animals and the appropriateness of the species and numbers of animals to be used for the proposed research; (c) a complete description of the veterinary care of the animals being used; (d) an assurance that discomfort, distress, pain, and injury to animals will be limited to that which is unavoidable in the conduct of scientifically sound research and that analgesic, anesthetic, and tranquilizing drugs will be employed where appropriate to minimize discomfort, distress, pain, and injury; 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.

Biohazards: Typically the T32 grant itself does not contain research projects. However if applicable, describe any potentially hazardous materials and procedures and whether the protection to be provided will be adequate.

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 plan 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 a revised, acceptable plan. The relevant NIH staff will judge the acceptability of the revised plan.

Budget: The reasonableness of the proposed budget and the requested period of support will be assessed in relation to the proposed research training program and the number of proposed trainees at the requested levels. The priority score should not be affected by the evaluation of the budget.