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.

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 T35 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.

Program Design: Evaluate the quality of the training that can be expected from the proposed program. The evaluation should include consideration of:

- Past accomplishments of the program.
- Scope and nature of the research training to be provided and the importance of these areas of research in terms of the needs of biomedical research.
- Depth of research training, including skills that will be developed and opportunities for scientific cross-fertilization and interdepartmental contacts.
- Degree and desirability of participation in formal course work, seminars, etc., within the framework of the program.

Program Director: Assess the leadership capabilities of the Program Director. Include consideration of his/her background, experience in research training and administration, publications and successful competition for research support.

Training Faculty: Assess the faculty relative to a high-quality training program, including evaluation of:

- Qualifications as basic and clinical researchers,
- Publication records and successful competition for research support,
- Opportunities for research training which parallel the aims of the training program.
- Competence and availability of each trainer to provide research training.
- Faculty stability and cooperation.

Trainees: Assess the trainees with respect to the following:

- Proposed criteria for advertisement, recruitment, selection, and assignment of trainees.
- Whether the program is adequately designed and coordinated to accommodate the number of trainees proposed for each of the years of support requested.
- Availability of well-qualified trainees.
- Evidence that trainees entering the program are likely to pursue careers in biomedical sciences.

Institutional Research Training Environment: Evaluate the following:

- Availability and adequacy of the necessary facilities (equipment, space, etc.) for the proposed research training program.
- The institutional commitment to training students in basic and clinical research.
- Indications that the institution supports the proposed program.
- Availability of appropriate courses and seminars.
- Availability of research support.

Institutional Program Monitoring Plan: Evaluate the following:

- The institution's plan for measuring the effectiveness of the training program including the productivity of the trainees (publications, abstracts, presentations),
- The impact of the training program on the institution, and
- The impact of the program on the career choices, opportunities, and further research activities of the trainees

Training Record: Briefly describe 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, discuss whether this program can be expected to achieve its stated goals.

Protection of Human Subjects from Research Risks: Typically the T35 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 T35 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 T35 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 T35 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 T35 application is not required to enumerate these approvals during the review phase.

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 T35 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.

Minority Recruitment and Retention Plan: The success of efforts to recruit and retain minority trainees is a factor in the assessment of the quality of the trainee pool and thus will be included within the priority score. In addition, peer reviewers will separately evaluate the minority recruitment plan and report (for competing renewals) after the overall score has been determined. Reviewers will examine the strategies to be used in the recruitment of minorities and 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 plan or the record of minority recruitment and retention is judged to be unacceptable, funding will be withheld until a revised plan (and report) that addresses the deficiencies is received.

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.