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.

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. 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 scientific review group will address and consider each of the following criteria in assigning the application's overall score, weighting them as appropriate for each application. 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.

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?

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?

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.

Investigators: 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?

Environment and Institutional Commitment: 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?

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?

Protection of Human Subjects from Research Risks: Explain 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.

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

Inclusion of Women, Children, and Minorities Plans: 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.

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: Describe any potentially hazardous materials and procedures and whether the protection to be provided will be adequate.

Budget: Comment on the reasonableness of the proposed budget and the appropriateness of the requested period of support in relation to the proposed research education program.

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 and is not factored into the priority score.

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 and is not factored into the applications priority score.

Model Organism Sharing Plan: All NIH applications that plan to produce new, genetically modified variants of model organisms and related resources are expected to include a sharing plan or to state why such sharing is restricted or not possible. Please comment on the adequacy of the sharing plan, taking into consideration the organism, the timeline, and the applicant's decision to distribute the resource or deposit it in a repository. Your assessment of the sharing plan will not be factored into the priority score of the application. Your comments will be captured in an administrative note.