GUIDELINES FOR REVIEWERS' WRITTEN COMMENTS
NIDDK MENTORED RESEARCH SCIENTIST AWARD (K23)

The K23 award is intended to provide three to five years of support to research-oriented clinicians to allow them to develop independent research skills and gain experience in experimental methods and approaches that will allow them to conduct patient-oriented research. 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 K23 application assigned to you. 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 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. 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.

Overall Evaluation: In a brief paragraph, indicate the major strengths and weaknesses of the proposed program as a means of enhancing the candidate's research career and how these factors determine your overall merit rating of the application.

Candidate: Describe and evaluate the candidate's qualifications, prior scientific training and experience, commitment to a career in patient orientated research, and potential to become a successful, independent investigator in patient orientated research. For individuals having little prior research exposure, evaluate his/her quality and extent of past education and clinical training experience. For individuals having more research background, assess his/her quality and extent of past education, scientific training, and clinical research experience; and the quality of any independent research publications.

Consider the letters of reference from three well-established scientists evaluating the candidate's potential to pursue an independent research career. Also consider the letters of reference submitted by mentor(s)/co-mentor(s) in addition to the three required reference letters.

Career Development Plan: Describe and evaluate the career development plans content, scope, phasing, and duration when considered in the context of the candidate's goals and prior experience. Is there a need for additional training? Assess how this plan will contribute to his/her likelihood of achieving scientific independence. For individuals with limited or no prior research experience, the didactic component, proposed during the first year or two, must be integrated fully into the training program and justified on the basis of their needs. If course work is proposed for candidates with greater research experience, it must be integrated adequately into the training program. Consider the adequacy of plans for evaluating the candidate's research and career development progress.

Research Plan: Reviewers recognize that an individual with limited research experience is less likely to be able to prepare a research plan with the breadth and depth of that submitted by a more experienced investigator. Nevertheless, a fundamentally sound research plan must be provided. For candidates who require substantial didactic training as part of their program, the research plan may cover less than the full period of the award. Assess the research plan outlined, including the specific aims, background and significance, progress report/preliminary studies, and research design and methods for feasibility, scientific soundness, and potential to achieve the goal of this award. Determine the appropriateness of this project to the candidate at his/her stage of development, and as a vehicle to acquire research skills necessary for independence in a career focused on patient orientated research. Consider the relevance of the planned research to the NIDDK's mission. If plans for inclusion and protection of human subjects are inadequate, this should be considered a research design flaw.

Mentor: Evaluate the mentor's research qualifications in the area of the project, extent and quality of his/her

proposed role in guiding and advising, previous experience in training researchers in patient orientated research, and history of research productivity and support. Adequacy of active/pending support for the proposed research project. Consider the strength of the mentor's statement. If more than one mentor is identified, the qualifications, role, and commitment of each must be discussed.

Environment And Institutional Commitment to the Candidate: Evaluate the institution's commitment to the candidate's career development. Indicate the adequacy of research facilities, resources, and training opportunities to be made available to the candidate, including the assurance that 75 percent of his/her full-time effort will be protected for this program.

Training in the Responsible Conduct of Research: All applicants must receive instruction in the responsible conduct of research, and the proposed subject matter, format, frequency, and duration of instruction must be detailed. This component must be included in the application.

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.

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 appropriateness and justification of the budget request within the context of the goal of the award. The candidate's salary must be based on a full-time, 12-month appointment and may not exceed $90,000 per year. $25,000 (up to $50,000 with justification) per year is allowed for tuition, fees, and books related to career development; research expenses such as supplies, equipment, and technical personnel; travel to research meetings or training; and statistical services including personnel and computer time. Justify any proposed changes.

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.