

GUIDELINES FOR REVIEWERS' WRITTEN COMMENTS  
**NIDDK MENTORED RESEARCH SCIENTIST AWARD (K01)**

The K01 award is intended to provide research support for a three to five-year transition period between postdoctoral training and a career in independent investigation. Refer to the NIH Guide program announcement (PAR-02-065; released 2/19/02) for more detail about the award. The format outlined below should be followed in preparing your comments for each K01 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.

Resume: 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.

Description: (optional) Briefly describe the research outlined, or use the abstract from the application.

Candidate: Describe and evaluate the candidate's qualifications, prior scientific training and experience, commitment to a career in biomedical or behavioral research, and potential to become a successful, independent investigator. Candidates generally should have between two and five years of postdoctoral work in areas relevant to the NIDDK mission and not have been a principal investigator on a peer-reviewed research project grant or its equivalent.

Career Development Plan: Describe and evaluate the career development plan, incorporating consideration of the candidate's goals and prior experience. Assess how this plan will contribute to his/her likelihood of achieving scientific independence.

Research Plan: 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 NIDDK's mission, for the candidate at his/her stage of development, and as a vehicle to acquire research skills necessary for independence. 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, and history of research productivity and support. If more than one mentor is identified, the qualifications, role, and commitment of each must be discussed.

Environment And Institutional Commitment: Evaluate the institution's commitment to the candidate's career development. Indicate the types of 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.

Action: The application may be recommended for no further consideration, deferred in order to obtain additional information, or given a priority score. If the application is to be scored, indicate the level of scientific merit using the adjectival scale.

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 \$75,000 per year. Up to \$25,000 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.

Other Considerations: If these matters affect the assessment of the scientific merit of the application, they will be considered as part of the critique and the overall score.

Instruction 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.

Involvement of Human Subjects: 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. 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. For applications submitted after October 1, 1998, determine whether children have been included in the research and if their inclusion or exclusion has been explained adequately to justify the code to be assigned. If a data and safety monitoring plan is required, indicate if it is adequate. For additional information, refer to the "NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects in Grant and Cooperative Agreement Applications."

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.

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