GUIDELINES FOR REVIEWER'S WRITTEN COMMENTS NIDDK SMALL GRANT (R03) PROGRAM FOR K08 OR K23 RECIPIENTS

The R03 award is intended to provide additional research support as the K08 or K23 recipient transitions to independent investigator status. The scientific directions of the proposed project may not have been anticipated by the project originally outlined in the K08 or K23 application, but instead may reflect the emerging research focus of the investigator as a consequence of that research. Refer to the NIH Guide announcements (PAR-01-066, 3/7/01) for more detail about the award. The format outlined below should be followed in preparing your comments for each R03 application assigned to you. Include additional headings when they seem appropriate to the review. If this is an <u>amended</u> 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.

<u>Resume</u>: In a brief paragraph, indicate the major strengths and weaknesses of the proposed program as a means of enhancing the investigator'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.

<u>Critique</u>: Address each of the following five criteria as separate sections within the context of the stage of the investigator's career.

<u>Significance</u>: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

<u>Approach</u>: Are the conceptual framework, design (including the composition of the study population), methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Is the scope of the project reasonable for the two-year timeframe?

<u>Innovation</u>: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

<u>Investigator</u>: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)? Do not include descriptive biographical information.

<u>Environment</u>: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support? Do not describe available facilities and equipment.

<u>Career Development Plan</u>: Evaluate the accomplishments of the investigator with respect to the original research goals of the K08 grant and the potential of the project to help prepare the investigator for full independence. Recall that the proposed project may represent the evolution of the individual's own research focus.

<u>Mentor</u>: Assess the relationship of the mentor and his/her evaluation of the investigator's progress under the K08 grant.

<u>Action</u>: 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.

<u>BUDGET</u>: Comment on the appropriateness and justification of the budget request within the context of the goal of the award. No salary support is allowed. Up to \$50,000 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.

<u>OTHER CONSIDERATIONS</u>: 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.

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."

<u>Animal Welfare</u>: 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.

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