GUIDELINES FOR REVIEWERS' WRITTEN COMMENTS
NIDDK MIDCAREER INVESTIGATOR AWARD IN PATIENT ORIENTED RESEARCH (K24)

The K24 award is intended to provide five years of support for clinicians so they may devote protected time to patient-oriented research and to serve as mentors for beginning clinical investigators. The award may be renewed once. 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 K24 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 allowing the investigator to conduct patient-oriented research and to serve as a mentor, and how these factors determine your overall merit rating of the application.

Candidate: Describe and evaluate the investigator's record of independent, patient-oriented research, including publications and relevant active or recent (last five years) grant support; qualifications to serve as a mentor; and commitment (25-50 percent time) to patient-oriented research. Consider how this award will allow the investigator to contribute and devote time to his/her research program and mentoring. In general, the investigator should typically be at the Associate Professor level or equivalent non-academic setting and must have an established record of independent, peer-reviewed patient-oriented research grant funding including at the time of application for this award, and record of publications.

Research Plan: Although it is understood that currently funded research described in K24 applications do not require the level of detail necessary in regular research grant applications, a fundamentally sound research plan must be provided. New research proposed in the K24 application that is not currently funded by a peer-reviewed grant should include a Statement of Hypothesis and Specific Aims; Background, Preliminary Studies and Aims. The application should outline the general goals for the later years and sufficient detail should be provided to permit evaluation of the scientific merit of the plan.

Assess the research plan outlined, including the specific aims, background and significance, progress report/preliminary studies, and research design and methods for its feasibility, scientific and technical soundness, and potential to achieve the goal of this award. Consider the appropriateness of the research plan as a vehicle for developing the skills and capabilities in patient orientated research of prospective mentees. Evaluate the relevance of the research to the candidate’s career objectives, and the availability of resources and adequate plans for continued support during the funding period. Evaluate the adequacy of the investigator's proposed commitment and resources to achieve the goals of the award.

If plans for inclusion of children, women, and minorities, and protection of human subjects are inadequate, this should be considered a research design flaw.

Mentoring Plan: Evaluate the plans to provide mentoring opportunities or supervision to beginning clinical investigators in patient orientated research. Consider the adequacy of plans to integrate appropriate clinical research curricula, such as those offered by existing K30 programs at the institution, into the mentoring plan. Assess appropriateness of the proposed level of effort committed to mentoring.

Progress Assessment: If this is a competing renewal application, evaluate the progress made during the previous funding period funding period. Consider the extent to which the career, research and mentoring objectives of the previous award have been achieved. Is there adequate justification of the need for an additional 3 to 5 years of support. Is there evidence of leadership in patient-oriented research such as through being principal investigator on independent peer-reviewed research grants and providing high quality mentorship .

Environment And Institutional Commitment: Evaluate the applicant institution's commitment to the scientific development of the candidate and assurances that the institution intends the candidate to be an integral part of its research program. Consider the adequacy of research facilities and the availability of appropriate educational opportunities. Evaluate the quality and relevance of the environment for continuing the scientific and professional development of the candidate and for others pursuing patient oriented research. Is there evidence that the institution is committed to provide adequate protected time for the candidate to conduct the research and mentoring program? Is there evidence of the applicant institution's commitment to the career development in patient-oriented research of individuals mentored by the candidate?

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 appropriateness and justification of the budget request within the context of the goal of the award. The investigator's maximum salary may not exceed 50% of the NIH salary cap, commensurate with effort. Up to $50,000 per year is allowed for research expenses such as supplies, equipment, and technical personnel; travel to research meetings or training; and statistical services including personnel and computer time. Any equipment requests must be justified adequately. 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.