K07 GUIDE FOR REVIEWERS

Academic Career Award

EXECUTIVE SUMMARY

Academic Career Award (K07)

- Supported by NIA, NIAAA, NCCAM, and ODS

- Supports individuals interested in introducing or improving curricula in a particular scientific field as a means of enhancing the educational or research capacity at the grantee institution

- Supports two types of activities

    - Development: for more junior candidates who are interested in developing academic and research expertise

    - Leadership: for more senior individuals who are interested in improving the curricula and enhancing the research capacity within an academic institution

Visit parent FOA at http://grants2.nih.gov/grants/guide/pa-files/PA-09-041.html.

INSTRUCTIONS FOR WRITTEN CRITIQUE AND PRELIMINARY SCORES

The mission of the NIH is to support science in pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend healthy life and reduce the burdens of illness and disability. As part of this mission, applications submitted to the NIH for grants or cooperative agreements to support biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

The overall goal of NIH-supported research career development programs is to help ensure that a diverse pool of highly trained scientists are available in adequate numbers and in appropriate research areas to address the Nation's biomedical, behavioral, and clinical research needs.

The Scientific Review Officer (SRO), and in particular the funding opportunity announcement (FOA) for each specific career development award, provide additional guidance for each core and additional review criterion. **Reviewers must become fully familiar with the detailed review criteria provided in each FOA before assessing any K award application in response to that announcement.**

Written Critiques

- The format of the critiques should follow the structured template provided for each mechanism, which can be downloaded from the Internet Assisted Review (IAR) site and found on the CD.

- Each core criterion and additional review criteria are represented in the reviewer template and should be commented on, listing the strengths and weaknesses of each in a bulleted form.

- The goal is to provide the maximum and most pertinent information in a concise manner.

- After considering all of the review criteria, briefly summarize the strengths and weaknesses of the application in the Overall Impact section of the template.

- Assigned reviewers must upload critiques before entering an overall impact/priority score.

- Criterion scores should be entered in IAR before the review meeting.

- Assigned reviewers may submit criterion scores only after their critiques have been uploaded. At the SRO's discretion, discussants who are assigned to the application and SRG members who are not assigned to the application may submit criterion scores without critiques.

- The criterion scores may be changed during FINAL SCORING on your electronic or paper Voter/Scoring Sheet, or following the review meeting during the EDIT phase.

- Please do not write your criterion scores on the critique template.

Preliminary Scores

- Each core review criterion should be given a score using the nine-point rating scale in accordance with the new Enhanced Peer Review Criteria.

- The criterion scores for the applications should be entered in the meeting Internet Assisted Review (IAR) site in NIH Commons before the review meeting using the same page that is used for submitting the preliminary impact/priority score and critique.

- The criterion scores may be changed following the review meeting during the EDIT phase.

- In the READ phase of the meeting reviewers may submit their scores and critiques, but may not edit them. Core criterion scores can be submitted only after your critique had been uploaded into IAR.

- The criterion scores will appear in the summary statement as part of your critique.

Core Review Criteria

Reviewers are asked to consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each. These individual criterion scores are considered part of your critique and will not be discussed at the review meeting. They may be changed in the EDIT phase in IAR.

Candidate

K07 Development Award (Career Development Plan):

- Does the candidate show potential to become an outstanding investigator, teacher, resource person, and leader in research, educational and (where appropriate) clinical programs related to the mission of the NIH awarding component?

- Is there likelihood that the award will contribute substantially to the academic and research career development of the candidate?

- Do the letters of reference on behalf of the candidate express the potential and commitment to the planned academic career program and the likelihood that the program will meet the candidate's career goals?

- Are sufficient additional relevant information/recommendations submitted by mentor and/or others for review consideration?

K07 Leadership Award (Curriculum Development Plan):

- Does the candidate show potential to continue as an outstanding investigator, teacher, resource person, and leader in research, educational and (where appropriate) clinical programs related to the mission of the NIH awarding component?

- Is there likelihood that the award will contribute substantially to the academic and research career of the candidate?

- Is there adequate past experience in teaching, curriculum development and leadership?

- Does the candidate have the ability and commitment to work cooperatively with other scientists to develop innovative curricula, educational materials, and programs?

Career/Curriculum Development Plan

K07 Development Award (Career Development Plan):

- Is the candidate's career development plan, including plans for after termination of the award, of high quality and sufficient feasibility?

- Are the content and duration of the proposed didactic and curriculum development components appropriate and reasonable?

- Do the structured activities such as coursework (including course numbers and descriptive titles), seminars or technical workshops, etc., meet the career goals of the candidate?

- Are there appropriate timelines planned for the candidate's progress?

- Is there a satisfactory and appropriate relationship of the research plan to the career development goals and the candidate's previous experience?

K07 Leadership Award (Curriculum Development Plan):

- Are the proposed curriculum and educational experiences therein distinct from other curricula and federally funded educational experiences within the existing educational infrastructure and framework of the candidate/participating institution(s)?

- Is it likely that the developed curriculum contributes to an increase in the pool of individuals with academic and research expertise and/or enhances the educational or research capacity at the sponsoring institution?

- Is the proposed plan to enhance pedagogical and leadership skills of the candidate of high quality?

- Are the plans for enlisting the support of professional and other organizations involved in medical education, as determined essential, in these efforts appropriate?.

- Are the plans and milestones for institutionalizing the curriculum changes feasible and appropriate?

- Are the plans and procedures for evaluating the process, progress, and outcomes of this curriculum development initiative feasible and appropriate?

- Are the plans to share curricula and any education materials developed as a result of this award appropriate and adequate?

- Are the plans for collaboration(s) with other individuals to develop course(s) and curricula adequate and appropriate?

Research Plan

The reviewer's assessment of the research plan should take into account the scientific significance and merit of the proposed research question, design, and methodology, as well as its relevance to the candidate's research career objectives, and whether the research plan has potential for advancing the field of study.

- Is the research plan appropriate for the candidate's past experience and current academic/research goals?

- Is the scientific and technical merit of the research plan appropriate and adequate for developing new or enhancing existing skills needed to meet the candidate's career goals?

- Is the plan for coupling the research with other planned activities, appropriate and adequate for providing the experience, knowledge, and skills necessary to achieve the objectives of the award?

Mentor(s), Consultant(s), Collaborator(s):

K07 Development Award (Career Development Plan):

- Are the mentor's research qualifications including current and pending research support, prior research experience, and mentoring track record appropriate and adequate for guiding the candidate in meeting the goals of the Development Award?

- Do the mentor(s) adequately address the above review criteria including the candidate's potential and his/her strengths and areas needing improvement?

- Does the mentor's statement demonstrate a strong commitment to the candidate's progression to independent academic investigator?

- Are the combined expertise, roles and responsibilities of any involved co-mentors, consultants, and/or collaborators likely to enhance the candidate's career development?

K07 Leadership Award (Curriculum Development Plan):

- Are the combined expertise, roles and responsibilities of any involved consultants, and/or collaborators likely to enhance the candidate's career development?

Environment and Institutional Commitment to the Candidate:

- Is there merit to the institution's plan and commitment to strengthening research and education activities beyond the current status of activities and capacities?

- Is there a strong statement of commitment by the institution to the levels of effort required for this career award?

- Is the scope and nature of collaboration among participating schools and departments appropriate and adequate?

- Are there adequate research facilities and training opportunities for the award?

- Is the quality of the scientific environment and relevance to the candidate's professional academic and scientific development, including any unique features of the scientific environment beneficial to the candidate, adequate and appropriate?

Additional Review Criteria

As applicable for the project proposed, reviewers are asked to consider the following additional items in the determination of scientific and technical merit, but not to give separate scores for these items.

Training in the Responsible Conduct of Research

Does the application include appropriate and adequate documentation in prior instruction, or plans for training in the responsible conduct of research?

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46 (as described in Human Subjects Protection and Inclusion), reviewers are asked to evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials. If all of the criteria are adequately addressed, and there are no concerns, write "Acceptable Risks and/or Adequate Protections." A brief explanation is advisable. If one or more criteria are

inadequately addressed, write, "Unacceptable Risks and/or Inadequate Protections" and document the actual or potential issues that create the human subjects concern. Also, if a clinical trial is proposed, evaluate the Data and Safety Monitoring Plan. (If the plan is absent, notify the SRO immediately to determine if the application should be withdrawn.) Indicate if the plan is "Acceptable" or "Unacceptable", and, if unacceptable, explain why it is unacceptable.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt, evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. If the claimed exemption is not justified, indicate "Unacceptable", and, if unacceptable, explain why it is unacceptable.

For additional information to assist you in making these determinations, please refer to http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Protection_and_Inclusion.pdf and http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Worksheet.pdf.

Inclusion of Women, Minorities and Children

When the proposed project involves clinical research, reviewers are asked to evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

Public Law 103-43 requires that women and minorities must be included in all NIH-supported clinical research projects involving human subjects unless a clear and compelling rationale establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. NIH requires that children (individuals under the age of 21) of all ages be involved in all human subjects research supported by the NIH unless there are scientific or ethical reasons for excluding them. Each project involving human subjects must be assigned a code using the categories "1" to "5" below. Category 5 for minority representation in the project means that only foreign subjects are in the study population (no U.S. subjects). If the study uses both then use codes 1 thru 4.   Examine whether the minority and gender characteristics of the sample are scientifically acceptable, consistent with the aims of the project, and comply with NIH policy. For each category, determine if the proposed subject recruitment targets are "A" (acceptable) or "U" (unacceptable). If you rate the sample as "U", consider this feature a weakness in the research design and reflect it in the overall score. Explain the reasons for the recommended codes; this is particularly critical for any item coded "U".

Gender Inclusion Code	**Minority Inclusion Code**	**Children Inclusion Code**
G1 = Both genders	**M1** = Minority and nonminority	**C1** = Children and adults
G2 = Only women	**M2** = Only minority	**C2** = Only children
G3 = Only men	**M3** = Only nonminority	**C3** = No children included
G4 = Gender composition unknown	**M4** = Minority composition unknown	**C4** = Representation of children unknown
	M5 = Only foreign subjects	

NOTE: To the degree that acceptability or unacceptability affects the investigator's approach to the proposed research, such comments should appear under "Approach" in the five major review criteria above, and should be factored into the score as appropriate.

For additional information to assist you in making these determinations, please refer to http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Protection_and_Inclusion.pdf and
http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Worksheet.pdf.

Vertebrate Animals

Reviewers are asked to evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

For additional information to assist you in determining if the Vertebrate Animals section is "Acceptable" or "Unacceptable", please refer to:
http://grants.nih.gov/grants/olaw/VASchecklist.pdf.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmission Applications

When reviewing a Resubmission application (formerly called an amended application), please evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewal Applications

This award may not be renewed.

Overall Impact

Reviewers will provide an overall impact critique to reflect their assessment of the likelihood for candidate to maintain a strong research program, taking into consideration all of the criteria above (as appropriate for the application) in determining the overall impact/priority score. Your critique should indicate the most significant strengths and weaknesses.

Additional Review Considerations

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact score.

Budget and Period Support

Is the proposed budget and period of support appropriate in relation to the proposed research and the career development needs of the candidate?

Select Agents

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s). Select agent information is available via http://grants.nih.gov/grants/policy/select_agent/.

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable:

1) Sharing Model Organisms

(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html). All NIH grant applications are expected to include a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. Unlike the NIH Data Sharing Policy, the submission of a model organism sharing plan is NOT subject to a cost threshold of $500,000 or more in direct costs in any one year, and is expected to be included in all applications where the development of model organisms is anticipated.

2) Genome Wide Association Studies

(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-013.html). Applications and proposals that include GWAS, regardless of the requested costs, are expected to include as part of the Research Plan either a plan for submission of GWAS data to the NIH designated data repository or an appropriate explanation for why submission to the repository will not be possible.

Additional Comments to the Applicant

Reviewers may provide guidance to the applicant or recommend against resubmission without fundamental revision.