Definitions of Criteria and Considerations for K Critiques

The edited version for K mechanisms that are supported by NIBIB.

Overall Impact. Reviewers should provide an overall impact critique to reflect their assessment of the likelihood for the candidate to maintain a strong research program, taking into consideration the criteria below in determining the overall impact/priority score. Your critique should indicate the most significant strengths and weaknesses.

Additional guidance for K01, K08, K23, K25, and K99/R00:

K01, K08 and K23. Reviewers should 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.

K08. See K01, K08 and K23 above.

K23. See K01, K08 and K23 above.

K25. Reviewers should 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. Although it is understood that K25 applications do not require the level of detail necessary in regular research grant applications, a fundamentally sound research plan must be provided. In general, less detail is expected with regard to research planned for the later years of the award, but the application should outline the general goals for these years.

1. Candidate.

K01. Does the candidate have the potential to develop as an independent and productive researcher? Is the candidate's academic, clinical (if relevant), and research record of high quality? Is there evidence of the candidate's commitment to meeting the program objectives to become an independent investigator in research? Do the letters of reference from at least three well-established scientists address the above review criteria, and do they demonstrate evidence that the candidate has a high

K08. Does the candidate have the potential to develop as an independent and productive researcher? Is the candidate's academic, clinical, and (if relevant) research record of high quality? Is there evidence of the candidate's commitment to meeting the program objectives to become an independent investigator in research? Do the letters of reference from at least three well-established scientists address the above review criteria, and do they demonstrate evidence that the candidate has a high potential for becoming an independent investigator?

K23. Does the candidate have the potential to develop as an independent and productive researcher focusing on patient-oriented research? Is the candidate's academic, clinical, and (if relevant) research record of high quality? Is there evidence of the candidate's commitment to meeting the program objectives to become an independent investigator focusing on patient-oriented research? Do the letters of reference from at least three well-established scientists address the above review criteria, and do they demonstrate evidence that the candidate has a high potential for becoming an independent investigator?

K25. Does the candidate have the potential to develop as an independent and productive quantitative biomedical, behavioral, bioimaging or bioengineering researcher or to play a significant role in multi-disciplinary research teams? Is the candidate's academic, clinical (if relevant), and research record of high quality? Is there evidence of the candidate's commitment to meeting the program objectives to become an independent investigator in research? Do the letters of reference from at least three well-established scientists address the above review criteria, and do they demonstrate evidence that the candidate has a high potential for becoming an independent investigator?

K99. What is the candidate's record of research productivity, including the quality of peer-reviewed scientific publications? What is the quality of the candidate's pre- and postdoctoral research training experience, including expertise gained? Based on the postdoctoral candidate's experience, track record and prior research training, what is the candidate's potential to become an outstanding, successful independent investigator who will contribute significantly to his/her chosen field of biomedical-related research? To what extent does the application provide evidence of the candidate's research creativity, and does this evidence suggest that the candidate has the potential to develop a creative, independent research program? Evaluate the letters of reference. Are there letters from at least three well-established scientists? Relative to the above review criteria, how do these scientists evaluate the candidate? Do the letters provide strong evidence that the candidate has a high potential to become an independent investigator? Given the candidate's prior training, proposed career development plan, and the referees' evaluations, is it reasonable to expect that the candidate will be able to achieve an independent, tenure-track or equivalent position within the time period requested for the K99 phase of this award?

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring

K01. What is the likelihood that the plan will contribute substantially to the scientific development of the candidate leading to scientific independence? Is the content, scope, phasing, and duration of the career development plan appropriate when considered in the context of prior training/research experience and the stated training and research objectives for achieving research independence? Are there adequate plans for monitoring and evaluating the candidate's research and career development progress?

K08 and K25. What is the likelihood that the plan will contribute substantially to the scientific development of the candidate leading to scientific independence? Is the content, scope, phasing, and duration of the career development plan appropriate when considered in the context of prior training/research experience and the stated didactic and research objectives for achieving research independence? Are there adequate plans for monitoring and evaluating the candidate's research and career development progress?

K23. What is the likelihood that the plan will contribute substantially to the scientific development of the candidate leading to scientific independence? Is the candidate's prior training and research experience appropriate for this award? Are the goals and scope of the plan when considered in the context of prior training/research experience and the stated training and research objectives, appropriate? Are the content and duration of the proposed didactic research activities during the proposed award period clearly stated and appropriate? Are there adequate plans for evaluating the candidate's research and career development progress?

K99. Are the content and duration of the proposed didactic and research components of the career development plan appropriate for the candidate's current stage of scientific and professional development and proposed research career goals? Is the proposed career development plan likely to contribute substantially to the scientific and professional development of the candidate including

his/her successful transition to independence? For individuals currently supported by research training programs, how does the proposed career development plan enhance or augment the applicant's training to date? Is the additional proposed training needed and appropriate for the proposed research plan and the applicant's future career plans? To what extent are the plans for evaluating the K99 awardee's progress adequate and appropriate for guiding the applicant towards a successful transition to the independent phase of the award? Is the timeline planned for the transition to the independent phase of the award appropriate for the candidate's current stage of scientific and professional development and the career development proposed for the K99 phase of the award?

3. Research Plan.

K01. Are the proposed research question, design, and methodology of significant scientific and technical merit? Is the research plan relevant to the candidate's research career objectives? Is the research plan appropriate to the stage of research development and as a vehicle for developing the research skills described in the career development plan?

K08. Are the proposed research question, design, and methodology of significant scientific and technical merit? Is the research plan relevant to the candidate's research career objectives? Is the plan for developing/enhancing the candidate's research skills appropriate and adequate?

K23. Are the proposed research question, design, and methodology of significant scientific and technical merit? Is the research plan relevant to the candidate's research career objectives focusing on patient-oriented research? Is the plan for developing/enhancing the candidate's research skills appropriate and adequate?

K25. Are the proposed research question, design, and methodology of significant scientific and technical merit? Is the research plan relevant to the candidate's research career objectives? Is the research plan appropriate to the stage of research development and as a vehicle for developing the research skills described in the career development plan?

K99. Is the proposed K99 phase research significant? Are the scientific and technical merits of the K99 research question, experimental design and methodology appropriate for the candidate's level of training, an appropriate vehicle for developing the research skills described in the career development plan, and appropriate for developing a highly successful R00 research program? Is the proposed R00 phase research scientifically sound and a logical extension of the K99 phase research? Is there evidence of long-term viability of the proposed R00 phase research plan? Evaluate the innovation and creativity of the proposed R00 phase research, i.e., does the project address an innovative hypothesis or challenge existing paradigms? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies? To what extent is the proposed R00 phase research likely to contribute significantly to our understanding of biomedical problems? To what extent is proposed R00 phase research likely to foster the career of the candidate as an independent investigator in biomedical research?

4. Mentor(s), Consultant(s), Collaborator(s).

K01. Are the mentor's research qualifications in the area of the proposed research appropriate? Do the mentor(s) adequately address the candidate's potential and his/her strengths and areas needing improvement? Is there adequate description of the quality and extent of the mentor's proposed role in providing guidance and advice to the candidate? Is the mentor's description of the elements of the research career development activities, including formal course work adequate? Is there evidence of the mentor's, consultant's, collaborator's previous experience in fostering the development of

independent investigators? Is there evidence of previous research productivity and peer-reviewed support? Is there active/pending support for the proposed research project appropriate and adequate? Are there adequate plans for monitoring and evaluating the career development awardee's progress toward independence?

K08. Are the mentor's research qualifications in the area of the proposed research appropriate? Do the mentor(s) adequately address the above review criteria including the candidate's potential and his/her strengths and areas needing improvement? Is there adequate description of the quality and extent of the mentor's proposed role in providing guidance and advice to the candidate? Is there evidence of the mentor's, consultant's, collaborator's previous experience in fostering the development of independent investigators? Is there evidence of previous research productivity and peer-reviewed support? Is there active/pending support for the proposed research project appropriate and adequate? Is the mentor's description of the elements of the research career development activities, including formal course work adequate? Are there adequate plans for monitoring and evaluating the career development awardee's progress toward independence?

K23. Are the mentor's research qualifications in the area of the proposed patient-oriented research appropriate? Do the mentor(s) adequately address the above review criteria including the candidate's potential and his/her strengths and areas needing improvement? Is there adequate description of the quality and extent of the mentor's proposed role in providing guidance and advice to the candidate? Is the mentor's description of the elements of the research career development activities, including formal course work adequate? Is there evidence of the mentor's, consultant's, collaborator's previous experience in fostering the development of independent investigators? Is there evidence of previous research productivity and peer-reviewed support focusing on patient-oriented research? Is there active/pending support for the proposed research project appropriate and adequate? Are there adequate plans for monitoring and evaluating the career development awardee's progress toward independence?

K25. Are the mentor's research qualifications in the area of the proposed research appropriate? Do the mentor(s) adequately address the above review criteria including the candidate's potential and his/her strengths and areas needing improvement? Is there adequate description of the quality and extent of the mentor's proposed role in providing guidance and advice to the candidate? Is there evidence of the mentor's, consultant's, collaborator's previous experience in fostering the development of independent investigators? Is there evidence of previous productivity and peer-reviewed support in area of basic or clinical biomedical, bioengineering, bioimaging or behavioral research? Is there active/pending support for the proposed research project appropriate and adequate? Is the mentor's description of the elements of the research career development activities, including formal course work adequate? Are there adequate plans for monitoring and evaluating the career development awardee's progress toward independence?

K99. To what extent does the mentor have a strong track record in training future independent researchers? To what extent are the mentor's research qualifications and experience, scientific stature, and mentoring track record appropriate for the applicant's career development needs? Does the mentor(s) adequately address the above review criteria including the candidate's potential as well as his/her strengths and areas needing improvement? Evaluate the nature and extent of the proposed supervision that will occur during the mentored phase of support, i.e. is it adequate, and is the commitment of the mentor(s) to the applicant's continued career development appropriate? Does the mentor have a comprehensive plan to support the proposed K99 phase career development and research plans as well as the candidate's efforts to transition to independence? Is this plan adequate and appropriate? Are the consultants'/collaborators' research and/or mentoring qualifications appropriate for their roles in the proposed K99 phase of the award?

5. Environment and Institutional Commitment to the Candidate.

K01. Is there clear commitment of the sponsoring institution to ensure that a minimum of 75% of the candidate's effort will be devoted directly to the research described in the application, with the remaining percent effort being devoted to an appropriate balance of research, teaching, administrative, and clinical responsibilities? Is the institutional commitment to the career development of the candidate appropriately strong? Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate adequate and appropriate? Is the environment for scientific and professional development of the candidate of high quality? Is there assurance that the institution intends the candidate to be an integral part of its research program?

K08, K23, and K25. Is there clear commitment of the sponsoring institution to ensure that a minimum of 75% of the candidate's effort will be devoted directly to the research described in the application, with the remaining percent effort being devoted to an appropriate balance of research, teaching, administrative, and clinical responsibilities? Is the institutional commitment to the career development of the candidate appropriately strong? Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate adequate and appropriate? Is the environment for scientific and professional development of the candidate of high quality? Is there assurance that the institution intends the candidate to be an integral part of its research program?

K99. To what extent does the institution provide a high quality environment for the candidate's development? To what extent are the research facilities and educational opportunities, including collaborating faculty, adequate and appropriate for the candidate's research and career development goals during the K99 phase of the award? What evidence is provided that the K99 sponsoring institution is strongly committed to fostering the candidate's development and transition to the independent (R00) phase? Is there adequate assurance that the required (minimum of 75%) effort of the candidate will be devoted directly to the research training, career development, and research activities described in the proposed career development and research plans?

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.

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 Human Subjects Protection and Inclusion and Human Subjects Worksheet for Comments.

Inclusion of Women, Minorities, and Children. When the proposed project involves clinical research, the committee will 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 Human Subjects Protection and Inclusion and Human Subjects Worksheet for Comments.

Vertebrate Animals. The committee will 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 Vertebrate Animals checklist.

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. 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.

Revision Applications. This criterion is generally not applicable to K awards. Under rare circumstances, when reviewing a Revision application (formerly called a competing supplement application), the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Training in the Responsible Conduct of Research. NOT-OD-10-019)

K01, K08, K23, K25 and K99/R00. Taking into account the circumstances of the candidate, including level of experience, the reviewers will address the following questions. Does the plan satisfactorily address the format of instruction, e.g. lectures, coursework, and/or real-time discussion groups? Do plans include a sufficiently broad selection of subject matter, such as conflict of interest, authorship, data management, human subjects and animal use, laboratory safety? Do the plans adequately describe the role of the sponsor/mentor or other faculty involvement in the candidate's instruction? Does the plan meet the minimum requirements for RCR, i.e., eight contact hours of instruction every four years? Plans and past record will be rated as **ACCEPTABLE** OR **UNACCEPTABLE**, and the summary statement will provide the consensus rating of the review committee. Applications rated **UNACCEPTABLE** will not be funded until the applicant provides an acceptable, revised plan.

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). For more details, please see 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) Data Sharing Plan; 2) Sharing Model Organisms; and 3) Genome Wide Association Studies (GWAS).

Budget and Period of Support. Is the proposed budget and period of support appropriate in relation to the proposed research and the career development needs of the candidate? For more details, please see Budget Information.

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