

Definitions of Criteria and Considerations for K Applications

OVERALL IMPACT

Reviewers should provide their assessment of the likelihood that the proposed career development and research plan will enhance the candidate's potential for a productive, independent scientific research career in a health-related field, taking into consideration the criteria below in determining the overall impact score.

Additional guidance for K01, K08, 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.

Additional guidance for K24:

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.

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. In addition, 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.

Additional guidance for 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.

SCORED REVIEW CRITERIA

Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each.

1. Candidate

K01 and K08:

- Does the candidate have the potential to develop as an independent and productive researcher?
- Are the candidate's prior training and research experience appropriate for this award?
- 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 provide 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 provide evidence that the candidate has a high potential for becoming an independent investigator?

K24:

- Is there evidence of ongoing high quality patient-oriented research, and what is the relationship of that research to this K24 proposal?
- Is there evidence of the candidate's capabilities and commitment to serve as a mentor for new clinical investigators in the conduct of patient-oriented research?
- Does the application demonstrate that the proposed program and protected time will relieve the candidate from non-research patient care and administrative duties and allow him/her to devote additional time and to augment his/her capabilities in patient-oriented research?
- Does the application demonstrate a record of independent peer-reviewed support for patient-oriented research that is likely to continue during the K24 award?

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 candidate's potential for becoming an independent investigator?

K99/R00:

- Based on the candidate's prior research and training experience, track record, referee's evaluations, and the quality and originality of prior research and the current application, what is the candidate's potential to become a highly successful, independent investigator who will contribute significantly to his/her chosen field of biomedical, behavioral, or clinical related research?
- Considering the years of postdoctoral research experience to date, 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, with respect to development of appropriate scientific and technical expertise?
- 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 faculty position within the time period requested for the K99 phase of this award?

2. Career Development Plan/Career Goals & Objectives

K01 and K08:

- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate leading to scientific independence?
- Are the candidate's prior training and research experience appropriate for this award?
- Are 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?

K23:

- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate leading to scientific independence?
- Are 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 evaluating the candidate's research and career development progress?

K24 [Plan to Provide Mentoring]:

- Are the plans to provide mentoring or supervising new clinical investigators in patient oriented research adequate?
- Are plans to integrate appropriate clinical research curricula, such as those offered by available K30 programs at the institution, into the mentoring plans adequate?
- Is an appropriate level of effort proposed for the mentoring component?

K25:

- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate leading to scientific independence?
- Are the candidate's prior training and research experience appropriate for this award?
- Are 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?

K99/R00:

- Are the content and duration of the proposed components of the career development plan appropriate and well-justified for the candidate's current stage of scientific and professional development and proposed research career goals?
- To what extent does the proposed career development plan enhance or augment the applicant's research training and skills acquisition to date?
- Is the proposed career development plan likely to contribute substantially to the scientific and professional development of the candidate, and facilitate his/her successful transition to independence?

- 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 transition to the independent phase of the award appropriate for the candidate's current stage of scientific and professional development, anticipated productivity, and the career development proposed for the K99 phase of the award?

3. Research Plan

K01 and 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 research plan appropriate to the stage of research development and as a vehicle for developing the research skills described in the career development plan?

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?
- Is the research plan appropriate to the candidate's stage of research development and as a vehicle for developing the research skills described in the career development plan?

K24:

- Candidates are expected to have an independent, peer reviewed research support at the time the career award is made. In such instances, reviewers should not re-evaluate the research plan. Rather, the reviewers should evaluate how the research and career development plans together further the candidate's research career.
- Is the research plan an appropriate vehicle for demonstrating and developing the prospective mentee's skills and capabilities in patient-oriented research?
- Are the scientific and technical plans of the proposed research of merit?
- Is the proposed research relevant to the candidate's career objectives?
- Are adequate resources available to conduct the research program? This includes adequacy of plans for continued support of the research during the funding period of the grant.

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?
- Will the proposed research lead to an independent line of research for the candidate? If the proposed research discipline requires team-based approaches, will the candidate develop skills to play a major leadership role in the chosen research field?

K99/R00:

- Is the proposed K99 phase research significant and scientifically sound?

- Are the scientific and technical merits of the K99 research appropriate 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 significant, 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?
- Does the R00 phase 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 foster the career of the candidate as a successful, independent investigator in biomedical, behavioral, or clinical research?

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

K01 and K08:

- Are the qualifications of the mentor(s) in the area of the proposed research appropriate?
- Does 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, and/or collaborator's previous experience in fostering the development of independent investigators?
- Is there evidence of the mentor's current research productivity and peer-reviewed support?
- Is 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?

K23:

- Are the mentor's research qualifications in the area of the proposed research appropriate?
- Does 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 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 and/or collaborator's previous experience in fostering the development of independent investigators?
- Is there evidence of the mentor's current research productivity and peer-reviewed support?
- Is 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?

K24:

- Is there adequate information provided that clearly documents expertise in the proposed area(s) of consulting/collaboration?

K25:

- Are the qualifications of the mentor(s) 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 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?

K99/R00:

- To what extent does the mentor(s) 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?
- Is the supervision proposed for the mentored phase of support adequate, and is the commitment of the mentor(s) to the applicant's career development appropriate and sufficient?
- Does the mentor provide an appropriate plan that addresses the candidate's training needs, and that is likely to foster the candidate's continued development and transition to independence?
- Does the mentor describe an acceptable plan for clear separation of the candidate's research and research career from the mentor's research, including identifying the components of the research plan that the K99 candidate may take to an independent research position?
- Are the consultants'/collaborators' research and/or mentoring qualifications appropriate for their roles in the proposed K99 phase of the award? Do they provide letters of support that affirm their commitment? If applicable, are the Advisory Committee members' qualifications appropriate for their roles in the proposed K99 phase of the award? Do they provide letters of support that affirm their commitment?

5. Environment and Institutional Commitment to the Candidate

K01, K08, K23, and K25:

- Is there clear commitment of the sponsoring institution to ensure that a minimum of 9 person-months (75% of the candidate's full-time professional effort) will be devoted directly to the research and career development activities 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?

K24:

- Is the level of the applicant institution's commitment to the scientific development of the candidate appropriate?
- Is the level of assurance from the institution that they intend the candidate to be an integral part of its patient-oriented research program adequate?
- Are the research facilities, resources and educational opportunities available to the candidate appropriate and adequate?
- Are the size and quality of the pool of clinician investigators to be mentored by the PD/PI adequate?
- Are the quality and relevance of the environment for continuing the scientific and professional development of the candidate and for others pursuing patient-oriented research appropriate and adequate?
- Is there adequate commitment from the sponsoring institution to provide protected time for the candidate to conduct the research and mentoring program?
- Is the level of commitment of the candidate's institution to the career development in patient-oriented research of new clinical investigators mentored by the candidate adequate?

K99/R00:

- To what extent does the institution provide a high quality environment appropriate for the candidate's development during the K99 phase of the award?
- 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?
- Is adequate evidence provided that the K99 sponsoring institution is strongly committed to fostering the candidate's development and preparation for transition to independence?
- Is there adequate assurance that the required minimum of 9 person-months (75% of the candidate's full-time professional effort) will be devoted directly to the research training, career development, and research activities proposed for the K99 phase of the award?

ADDITIONAL REVIEW CRITERIA

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

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 http://grants.nih.gov/grants/peer/guidelines_general/HumanSubjectsProtectionandInclusion.pdf

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.

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 acceptable or unacceptable. If you rate the sample as unacceptable, consider this feature a weakness in the research design and reflect it in the overall score. Explain the reasons for the recommendation; this is particularly critical for any item coded 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.

The reviewer coding of inclusion on the critique template has been simplified to focus on whether the distribution of individuals is scientifically justified for the proposed study(s). Reviewers should assess inclusion according to these guidelines and select the following options for the given categories:

Sex/gender:

- Distribution justified scientifically = Acceptable
- Distribution not justified scientifically = Unacceptable

Race/ethnicity:

- Distribution justified scientifically = Acceptable
- Distribution not justified scientifically = Unacceptable

Children:

- Including ages < 21 justified scientifically = Acceptable
- Including ages < 21 not justified scientifically = Unacceptable
- Excluding ages < 21 justified scientifically = Acceptable
- Excluding ages < 21 not justified scientifically = Unacceptable

For additional information to assist you in making these determinations, please refer to

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 <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), 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

K01, K08, K23, K99/R00:

This award may not be renewed.

K24:

When reviewing a Renewal application (formerly called a competing continuation application), the committee the committee will consider the following questions.

- Has there been adequate progress in achieving the career, research, and/or mentoring objectives of the previous award period? Is the justification provided for an additional 3 to 5 years of support adequate? (This requires that the recipient continue to have independent peer-reviewed research support at the time of submission of the renewal application; and documentation of a continuing need for protected time to expand the program and the mentoring activities supported during the prior funding period of the award).
- Does the PD/PI adequately demonstrate the continuing need for protected time to expand his/her research and mentoring program?
- Is there evidence of the PD/PI’s continuing leadership in patient-oriented research through, for example, being principal investigator on new independent peer-reviewed research grants and providing high quality mentorship?

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

Training in the Responsible Conduct of Research

Reviewers will evaluate plans for instruction in responsible conduct of research as well as the past record of instruction in responsible conduct of research, where applicable. Reviewers will specifically address the five Instructional Components (Format, Subject Matter, Faculty Participation, Duration, and Frequency of instruction), as detailed in [NOT-OD-10-019](#). Plans and past record will be rated as ACCEPTABLE or UNACCEPTABLE.

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.

Sharing Model Organisms: 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.

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>)

Genome Wide Association Studies: 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 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html>)

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?

ADDITIONAL COMMENTS TO APPLICANT

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