**Definitions of Criteria and Considerations for K Critiques**

*Updated March 02, 2018*

Standard criteria and considerations are shown below. Individual Funding Opportunity Announcements (FOAs) may have additional criteria and considerations.

[**[**](https://grants.nih.gov/grants/peer/reviewer_guidelines.htm)Return to ‘[Guidance for Reviewers](https://grants.nih.gov/grants/policy/review.htm)’ website[**]**](https://grants.nih.gov/grants/peer/reviewer_guidelines.htm)

**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.

**Scored Review Criteria**

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

**In addition, for applications involving clinical trials:**
The reviewers will consider that the clinical trial may include study design, methods, and intervention that are not by themselves innovative, but address important questions or unmet needs. Reviewers should also consider the scope of the clinical trial relative to the available resources, including the possibility that research support provided through K awards may be sufficient to support only small feasibility studies.

**1. Candidate**

**K01**

* 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 address the above review criteria, and do they provide evidence that the candidate has a high potential for becoming an independent investigator?

**In addition, for applications where independent clinical trials are required:**

* Does the candidate have the potential to organize, manage, and implement the proposed clinical trial, feasibility or ancillary study?
* Does the candidate have training (or plans to receive training) in data management and statistics including those relevant to clinical trials?

**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 and lead 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?

**In addition, for applications where an independent clinical trial is not allowed:**

* If proposed, will the clinical trial experience contribute to the applicant’s research career development?

**3. Research Plan.**

**K01**

* Are the proposed research question, design, and methodology of significant scientific and technical merit?
* Is there a strong scientific premise for the project?
* Has the candidate presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
* Has the candidate presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?
* 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?

**In addition, for applications where independent clinical trials are required:**

* Are the scientific rationale and need for a clinical trial, feasibility or ancillary study well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms?
* If proposing a small feasibility study, is the study warranted and will it contribute to planning and preliminary data needed for design of future larger scale clinical trials?
* Is the clinical trial or ancillary study necessary for testing the safety, efficacy or effectiveness of an intervention, or in the case of a feasibility study, necessary to establish feasibility of a future clinical trial?
* Is the study design justified and relevant to the clinical, biological, and statistical hypothesis(es) being tested?
* Are the plans to standardize, assure quality of, and monitor adherence to, the protocol and data collection or distribution guidelines appropriate?
* Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions, if interventions are delivered?
* For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

**In addition, for applications where an independent clinical trial is not allowed:**

* If proposed, will the clinical trial experience contribute to the proposed research project?

**4. Mentor(s), Co-mentor(s), Consultant(s), Collaborator(s).**

**K01**

* 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?

**In addition, for applications where an independent clinical trial is required:**

* Does the mentor or mentoring team have the expertise, experience, and ability to guide the applicant in the organization, management and implementation of the proposed clinical trial, ancillary, or feasibility study and help him/her to meet the timelines?

**In addition, for applications where an independent clinical trial is not allowed:**

* If the applicant is proposing to gain experience in a clinical trial as part of his or her research career development, is there evidence of the appropriate expertise, experience, and ability on the part of the mentor(s) to guide the applicant during participation in the clinical trial?

**5. Environment and Institutional Commitment to the Candidate.**

**K01**

* 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 as an independent investigator?

**In addition, for applications where independent clinical trials are required:**

* Are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?
* Does the application adequately address the capability and ability to conduct the trial, feasibility or ancillary study at the proposed site(s) or centers? If applicable, are the plans to add or drop enrollment centers, as needed, appropriate?
* If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial?

# Additional Review Criteria

**In addition, for applications where independent clinical trials are required:**

**Study Timeline for Clinical Trials**
Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment?  Is the projected timeline feasible and well justified?  Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?  Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

**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, the committee will 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.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section please refer to [Guidelines for the Review of Human Subjects](https://grants.nih.gov/grants/peer/guidelines_general/Guidelines_for_the_Review_of_the_Human_Subjects.pdf).

**Inclusion of Women, Minorities, and Children.**

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to [Guidelines for the Review of Inclusion in Clinical Research](https://grants.nih.gov/grants/peer/guidelines_general/Review_Human_Subjects_Inclusion.pdf).

**Vertebrate Animals.**

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animal Section.](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11150)

**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.

**Resubmissions.**

For Resubmissions, the committee will 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.

**Renewals.**

For Renewals, the committee will consider the progress made in the last funding period.

**Revisions.**

For Revisions, 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.

# Additional Review Considerations

**Training in the Responsible Conduct of Research**

**K01, K05, K08, K18, K22, K23, K25, K43 and K99/R00.** All applications for support under this FOA must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR).  Taking into account the level of experience of the applicant, including any prior instruction or participation in RCR as appropriate for the applicant’s career stage, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) Format – the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable); 2) Subject Matter – the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics; 3) Faculty Participation – the role of the mentor(s) and other faculty involvement in the fellow’s instruction; 4) Duration of Instruction – the number of contact hours of instruction (at least eight contact hours are required); and 5) – Frequency of Instruction – instruction must occur during each career stage and at least once 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. See [NOT-OD-10-019](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html).

**Select Agent Research.**

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).

**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](https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm); 2) [Sharing Model Organisms](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html); and 3) [Genome Wide Association Studies (GWAS)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html)/[Genomic Data Sharing](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html) Plan.

**Authentication of Key Biological and/or Chemical Resources. (NOT applicable for K02, K05 and K24)**

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

**Budget and Period of Support.**

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

**Additional Comments to the Applicant.**

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