Criteria Guidance for K Critiques

Definitions of Criteria and Considerations for K Critiques:

K01: Mentored Research Scientist Development Award
K08: Mentored Clinical Scientist Research Career Development Award
K22: Non-mentored career transition award (NIAID Career Transition Award)
K23: Mentored Patient-Oriented Research Career Development Award
K24: Midcareer Investigator Award in Patient-Oriented Research
K25: Mentored Quantitative Research Development Award
K99/ R00: Mentored career transition award (NIH Pathway to Independence Award)

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.

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?

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?
- 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?
K22 (NIH-specific instructions)

- Look at the history, the publications, the reference letters, and whether or not the candidate is ready for independence and has the qualities for a successful independent career. Is the candidate capable of aggressively seeking out his own collaborators, has his career so far been marked by his/her own motivation and innovation. Is he/she self-directed.

K23

- 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 patient-oriented 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?

K24

- Is there evidence of ongoing high quality patient-oriented research, and what is the relationship of that research to this K24 application?
- 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 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/ 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 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

- 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?

K22 (NIH-D-specific instructions)

- The career development plan may contain past coursework to show that the candidate has already taken the grant-writing, manuscript prep, classes necessary for career development or if not, it should contain plans to take these in the future. Remember, the candidate is already independent and should be sufficiently trained by this period.
K23

• What is the likelihood that the plan will contribute substantially to the scientific development of the candidate and lead 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

• 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

- 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?

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

K22 (NIH D-specific instructions)

- The research plan becomes very important in the K22. Will the project be substantial enough and have enough impact to start a career? Unlike the mentored Ks where the research plan will provide the candidate with learning tools - learn the field and techniques - and a good mentor will be watching out for problems - (although these are becoming more and more sophisticated) in the K22, the research plan should be R01-like and the candidate should already have the tools necessary to carry it out.

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), 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?
K08

- Are the mentor's research qualifications in the area of the proposed research appropriate?
- Do(es) 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?

K22 (NIH-specific instructions)

- No mentor is required or should be named. For the mentor criteria only evaluate collaborators, consultants, advisory committees if there are any and if not leave it blank.

K23

- Are the mentor's research qualifications in the area of the proposed research appropriate?
- Do(es) 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(es) 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

- 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?

**K08**

- Is there clear commitment of the sponsoring institution to ensure that the required minimum 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 as an independent investigator?

**K22 (NIAID-specific instructions)**

- For the environment criteria, no institutional commitment is required, the candidate has one foot already out of the institution, but has the current institution provided him with the tools necessary for independence (either in the past or for the one year grant period).

**K23**

- Is there clear commitment of the sponsoring institution to ensure that the required minimum 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 as an independent investigator?
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?

K25

- Is there clear commitment of the sponsoring institution to ensure that the required minimum of the candidate’s effort will be devoted directly to the research and career development activities described in the application, with the remaining 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/ 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

Training in the Responsible Conduct of Research (not included in the overall impact score)

**K01, K05, K08, K18, K22, K23, K25 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](#).

**Note for K22 and K99:** The RCR section may not be described in detail as the applicant may plan to take these courses as an Assistant Professor at the future, unknown institution. However, intent should be described in the application. This is acceptable.

**Resubmissions (Can be included in the overall impact score)**

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.