f 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.

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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?

K02

- Has the candidate demonstrated the capacity to carry out independent research?
- Does the candidate have potential to become an outstanding scientist who will make significant contributions to the field?
- Is there evidence of past and present research productivity as evidenced by contributions to the scientific literature, and success in obtaining independent funding?
- Has the candidate demonstrated the ability to conceptualize and organize a long-term research approach?
- Is there evidence of current independent, peer-reviewed research support?
- Is the candidate's level of training, experience, and competence commensurate with the purposes of the award?

K05

- Has the candidate demonstrated the capacity to carry out independent research?
- Does the candidate have potential to become an outstanding scientist who will make significant contributions to the field?
- Is there evidence of past and present research productivity as evidenced by contributions to the scientific literature, and success in obtaining independent funding?
- Has the candidate demonstrated the ability to conceptualize and organize a long-term research approach?
- Is there evidence of current independent, peer-reviewed research support?
- Is the candidate's level of training, experience, and competence commensurate with the purposes of the award?

K07 (Development)

- Does the candidate show potential to become an outstanding investigator, teacher, resource person, and leader in research, educational and (where appropriate) clinical programs related to the mission of the NIH awarding component?
- Is there likelihood that the award will contribute substantially to the academic and research career development of the candidate?
- Do the letters of reference on behalf of the candidate express the potential and commitment to the planned academic career program and the likelihood that the program will meet the candidate's career goals?

K07 (Leadership)

- Does the candidate show potential to continue as an outstanding investigator, teacher, resource person, and leader in research, educational and (where appropriate) clinical programs related to the mission of the NIH awarding component?
- Is there likelihood that the award will contribute substantially to the academic and research career of the candidate?
- Does the candidate have sufficient and appropriate past experience in teaching, curriculum development and leadership?
- Does the candidate have the ability and commitment to work cooperatively with other scientists to develop innovative curricula, educational materials, and programs?

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 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?

K18

- Has the candidate provided evidence of excellence as an independent investigator, including a record of research support and peer-reviewed publications?
- Does the candidate show evidence of a high level of commitment to meeting the program's career enhancement objectives?
- Does the candidate have high potential for successfully augmenting his/her research career capabilities and in becoming an outstanding contributor to the research field relevant to the proposed research enhancement experience?

K22 (Mentored)

- Does the candidate have the potential for becoming a successful independent investigator who will contribute significantly to a chosen health-related research field?
- Will the research experiences in the mentored phase prepare the candidate to implement successfully the independent phase research project?

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?

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

- 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?

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?

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

- 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?

K25

- 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?

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

- 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?

K43

- Does the candidate have the potential to develop as an independent and productive researcher addressing scientifically significant topics that reflect the health priorities of the Low- or Middle-Income Country (LMIC)?
- Does the candidate have the research experience and skills needed to carry out the proposed research?
- Is there evidence of the candidate's commitment to meeting the program objectives to become an independent researcher?
- Do the letters of reference from at least three well-established scientists address the candidate's potential for becoming an independent researcher?

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?

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

- 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?

K02

- What is the likelihood that the award will contribute substantially to the continued scientific development and productivity of the candidate?
- Are the career goals and objectives consistent with the candidate's career goals?
- Is there evidence that the award will enable the candidate to devote full time (at least the required minimum of 75% of full-time professional effort) to research and related duties by release from teaching, administration, clinical work, and other responsibilities?

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?

K05

- What is the likelihood that the award will contribute substantially to the continued scientific development and productivity of the candidate?
- Are the career goals and objectives consistent with the candidate's career goals?
- Is there evidence that the award will enable the candidate to devote full time (at least the required minimum of 75% percentage of full-time professional effort) to research and related duties by release from teaching, administration, clinical work, and other responsibilities?

K07 (Development)

- Is the candidate's career development plan, including plans for after termination of the award, of high quality and sufficient feasibility?
- Are the content and duration of the proposed didactic and curriculum development components appropriate and reasonable?
- Do the structured activities such as coursework (including course numbers and descriptive titles), seminars or technical workshops, etc., meet the career goals of the candidate?
- Are appropriate timelines planned for the candidate's progress?
- Is there a satisfactory and appropriate relationship of the research plan to the career development goals and the candidate's previous experience?

K07 (Leadership)

- Are any proposed curriculum and educational experiences therein distinct from other curricula and federally funded educational experiences within the existing educational infrastructure and framework of the candidate/participating institution(s)?
- Is it likely that the developed curriculum contributes to an increase in the pool of individuals with academic and research expertise and/or enhances the educational or research capacity at the sponsoring institution?
- Are the plans for enlisting the support of professional and other organizations involved in medical education, as deemed essential, in these efforts appropriate?
- Are the plans and milestones for institutionalizing the curriculum changes feasible and appropriate?
- Are the plans and procedures for evaluating the process, progress, and outcomes of this curriculum development initiative feasible and appropriate?
- Are the plans to share curricula and any education materials developed as a result of this award appropriate and adequate?
- Are any plans for collaboration(s) with other individuals to develop course(s) and curricula adequate and appropriate?

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?

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?

K18

- Is the career development plan appropriate in its content, scope, duration, and phasing for the candidate's stated career development goals?
- Is there a high likelihood that the proposed program will contribute substantially to the advanced research career enhancement of the candidate?

- Is the candidate's academic, clinical (if relevant), and research record of high quality?
- Are the career goals, objectives and scope of the plan appropriate, when considered in the context of prior research experience, and the proposed training experience and research aims?

K22 (Mentored)

- To what extent are the plans for evaluating the 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 independent phase of the award?

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 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 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?

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 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?

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?

K43

- What is the likelihood that the career development plan will contribute substantially to the scientific development of the candidate leading to research 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 mentors to monitor and evaluate the candidate's research and career development progress?
- Does the career development plan demonstrate a clear commitment to a research career in the LMIC setting?

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?

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?

K02

- 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 of high quality, and does it have potential for advancing the field of study?
- Is the scientific and technical merit of the proposed research plan of significance?
- When applicable for the specific candidate and situation, do the letters from consultant(s) and collaborator(s) adequately document their willingness to participate in the independent scientist award program?

In addition, for applications where an independent clinical trial is 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 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?

K05

- Candidates are expected to have 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 of high quality, and does it have potential for advancing the field of study? Is the scientific and technical merit of the proposed research plan of significance?
- When applicable for the specific candidate and situation, do the letters from consultant(s) and collaborator(s) adequately document their willingness to participate in the independent scientist award program?

K07 (Development and Leadership)

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

activities, appropriate and adequate for providing the experience, knowledge, and skills necessary to achieve the objectives of the award?

- 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 scientific and technical merit of the research plan appropriate and adequate for developing new or enhancing existing skills among the targeted faculty and students that are relevant to stated career objectives?

K08

- 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 an independent clinical trial is 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 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?

K18

- 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?
- Are the proposed research question(s), 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 enhancement plan?
- Is the research plan appropriate in developing a rigorous research program that integrates basic behavioral or social sciences?
- Is the proposed research project appropriate for the candidate's stage of research development and as a vehicle for developing the research skills described in the career development plan?
- Is the research plan, including the research question, specific aims, design and methods, of high scientific and technical merit?
- Is the proposed research a novel extension of the research of the candidate? In cases where the candidate and the proposed host laboratory/research program have previous research collaborations, is there sufficient justification as to why this program will facilitate career development that could not be achieved solely through a research grant or current collaborative effort?

K22 (Mentored and Independent)

- Is the proposed research project appropriate for the candidate's stage of research development and as a vehicle for development of the research skills described in the career development plan?
- Is the proposed research relevant to stated career objectives?
- 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?

K23

- 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 an independent clinical trial is 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 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?

K24

- Candidates are expected to have 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.

In addition, for applications where an independent clinical trial is 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 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?

K25

- 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 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?

In addition, for applications where an independent clinical trial is 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 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?

K43

- 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?
- Are the proposed research question, design, and methodology novel, scientifically significant, creative, and of 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?
- If applicable, are there adequate plans for data and safety monitoring of clinical trials?
- Does the research plan address an area of health priority and scientific importance to the LMIC?

K99/R00

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

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 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?

K02 [Consultants and Collaborators]

- Are the proposed collaborations with other active investigators and other opportunities for professional growth appropriate and of high quality?
- Is adequate information provided that clearly documents expertise in the proposed area(s) of consulting/collaboration?

K05 [Consultants and Collaborators]

- Are the proposed collaborations with other active investigators and other opportunities for professional growth appropriate and of high quality?
- Is adequate information provided that clearly documents expertise in the proposed area(s) of consulting/collaboration?

K07 (Development)

- Are the qualifications of the mentor(s) including current and pending research support, prior research experience, and mentoring track record appropriate and adequate for guiding the candidate in meeting the goals of the Development Award?
- Do the mentor(s) adequately address the above review criteria including the candidate's potential and his/her strengths and areas needing improvement?
- Does the mentor's statement demonstrate a strong commitment to the candidate's progression to independent academic investigator?
- Are the combined expertise, roles and responsibilities of any involved co-mentors, consultants, and/or collaborators likely to enhance the candidate's career development?
- Is the mentor's description of the elements of the research career development activities, including formal course work, adequate?

K07 (Leadership)

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

K08

- 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 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 involved:

- 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 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?

K18

- Are the mentor(s) research qualifications, scientific stature, experience, and mentoring track record appropriate for the candidate's research career development needs?
- Does the mentor(s) adequately address the above review criteria in his/her statement?
- Are the nature and extent of mentorship proposed adequate and appropriate, and is the commitment of the mentor(s) to the candidate's advanced research career development appropriate?
- Does the mentor(s) have a history of research productivity and support, and a prior track record in research mentoring?
- Do the mentor and his/her host institution have adequate resources available to the candidate to conduct the proposed research?

K22 (Mentored)

- 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, 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?

K22 Independent [Consultants and Collaborators]

- Is adequate information provided that clearly documents expertise in the proposed area(s) of consulting/collaboration?
- Have the proposed consultant(s) and collaborator(s) provided evidence of commitment to the candidate and the candidate's project?
- Do the proposed consultant(s)/collaborator(s) provide the required expertise for successful conduct of the research project?

K23

- 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 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 involved:

- 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?

K24 [Consultants and Collaborators]

- 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?

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

- 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 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?

K43

- Are the primary U.S. mentor's and the primary LMIC mentor's research qualifications in the area of the proposed research appropriate?
- Do the mentors adequately address the candidate's potential and his/her strengths and areas needing improvement?
- Is there evidence of the mentors' previous experience in fostering the development of independent researchers in the LMIC?
- Is active/pending support relevant to the candidate's proposed research project appropriate and adequate?

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?

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?

K02

- 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?
- Are the quality and relevance of the environment for continuing the scientific and professional development of the candidate and for others pursuing research appropriate and adequate?
- Is the commitment from the sponsoring institution to provide adequate protected time for the candidate to conduct the research program adequate?

In addition, for applications where an independent clinical trial is 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?

K05

- 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?
- Are the quality and relevance of the environment for continuing the scientific and professional development of the candidate and for others pursuing research appropriate and adequate?
- Is the commitment from the sponsoring institution to provide protected time for the candidate to conduct the research program adequate?

K07 (Development and Leadership)

- Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate adequate and appropriate?
- Is there merit to the institution's plan and commitment to strengthening research and education activities beyond the current status of activities and capacities?
- Is there a strong statement of commitment by the institution to the levels of effort required for this career award?
- Are the scope and nature of collaboration among participating schools and departments appropriate and adequate?
- Are the quality of the scientific environment and relevance to the candidate's professional academic and scientific development, including any unique features of the scientific environment beneficial to the candidate, adequate and appropriate?

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?

In addition, for applications where an independent clinical trial is 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?

K18

- Are appropriate and high-quality research resources and training opportunities available to the candidate at the sponsoring institution?
- Is there clear commitment from both the candidate's home institution and sponsoring institution to ensure that the requisite effort of the candidate will be devoted directly to the research career enhancement activities described in the application?
- Is there strong institutional commitment to fostering the advanced research career development of the candidate?
- Are there unique features of the scientific environment of the sponsoring institution and host laboratory that will benefit the proposed research and career development plan (e.g., useful collaborative arrangements, special equipment or analytic methods, unique subject populations)?

K22 (Mentored and Independent)

- Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate, adequate and appropriate?
- Is there clear commitment of the sponsoring institution to ensure that the required 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?
- Is there strong institutional commitment to fostering the career development of the candidate?
- Are there unique features of the scientific environment that benefit the proposed research; e.g., useful collaborative arrangements or subject populations?
- Is the environment of high quality and relevance for scientific and professional development of the candidate?

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?

In addition, for applications where an independent clinical trial is 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?

K24

- Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate adequate and appropriate?
- Is there assurance that the institution intends the candidate to be an integral part of its research program as an independent investigator?
- Is the level of the applicant institution's commitment to the scientific development of the candidate appropriate?
- 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?

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?

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 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 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?

K43

- Is there clear commitment of the LMIC institution to ensure that the required minimum of the candidate's effort will be devoted directly to the research described in the application?
- Are the institutional commitments from the LMIC and U.S. collaborating institutions to the career development of the candidate and for the mentors appropriately strong?
- Are the research facilities, resources and training opportunities at the U.S. and LMIC institutions, 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 LMIC 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?

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.

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.

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.

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.

K07 (Development Award). 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 of the review committee.

K07 (Leadership). Taking into account the circumstances of the candidate, including the more senior level of experience of candidates for this award, 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 that the candidate will participate in? 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 candidate's role in the participation in instruction in RCR? 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 of the review committee.

K02, K24 and K26. 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 – may fulfill the requirement for instruction in RCR by participating as lecturers and discussion leaders; 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 also: NOT-OD-10-019

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; 2) Sharing Model Organisms; and 3) Genome Wide Association Studies (GWAS)/Genomic Data Sharing 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.

[Return to 'Guidance for Reviewers' website]

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