

Definitions of Criteria and Considerations for R03 applications

Small Grant Program for NIDDK K01/K08/K23 Awardees

This R03 award is intended to provide additional research support as the K01, K08, or K23 recipient transitions to independent investigator status. The scientific directions of the proposed project may not have been anticipated by the project originally outlined in the K01, K08, or K23 application, but instead may reflect the emerging research focus of the investigator as a consequence of that research.

Overall Impact

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

Scored Review Criteria

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

1. Significance

- Does the project address an important problem or a critical barrier to progress in the field?
- If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?
- How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
- Are there adequate explanation and justification included that document how the proposed R03 support will affect plans and enhance the progress of the K awardee?
- How likely is it that the proposed work will lead to an independent line of investigation for the applicant, distinct from that of his/her mentor?

2. Investigator(s)

- Is the PD/PI, collaborators, and other researchers well suited to the project?
- If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training?
- How capable does the applicant appear to be with respect to conducting independent research?
- What is the potential of this R03 application to help prepare the applicant to be competitive for funding opportunities at the end of the award?
- Does the mentor's letter adequately discuss the applicant's potential to become an independent investigator? What is the continuing relationship between the applicant and the mentor?

3. Innovation

- Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?
- Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?
- Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
- Have the research goals of the current application diverged sufficiently from the original K01/K08/K23 aims?

- If the original K award goals have been modified, is an explanation of the changes and reasons satisfactory?

4. Approach

- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
- Are potential problems, alternative strategies, and benchmarks for success presented?
- If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?
- How feasible is the research plan for two years of work?
- If the project involves clinical research, are the plans for 1) Protections for Human Subjects, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

5. Environment

- Will the scientific environment in which the work will be done contribute to the probability of success?
- Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?
- Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria

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

Progress on the Career Development Award

- Reviewers will assess the progress to date on the applicant's K award.
- Are the research goals of the K award being met?
- Has the applicant successfully negotiated any difficulties in accomplishing the original aims of the K award?
- If not, has an adequate explanation been provided?
- Is the applicant publishing the work supported by the K award?

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46 (as described in Human Subjects Protection and Inclusion), reviewers are asked to evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria:

- 1) risk to subjects,
- 2) adequacy of protection against risks,
- 3) potential benefits to the subjects and others,
- 4) importance of the knowledge to be gained, and
- 5) data and safety monitoring for clinical trials.

If all of the criteria are adequately addressed, and there are no concerns, write "Acceptable Risks and/or Adequate Protections." A brief explanation is advisable.

If one or more criteria are inadequately addressed, write, "Unacceptable Risks and/or Inadequate Protections" and document the actual or potential issues that create the human subjects concern. Also, if a clinical trial is proposed, evaluate the Data and Safety Monitoring Plan. (If the plan is absent, notify the SRO immediately to determine if the application should be withdrawn.) Indicate if the plan is "Acceptable" or "Unacceptable", and, if unacceptable, explain why it is unacceptable.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt, evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. If the claimed exemption is not justified, indicate "Unacceptable", and, if unacceptable, explain why it is unacceptable.

NOTE: To the degree that acceptability or unacceptability affects the investigator's approach to the proposed research, such comments should appear under "Approach" in the five major review criteria above, and should be factored into the score as appropriate. For additional information to assist you in making these determinations, please refer to http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Protection_and_Inclusion.pdf.

Inclusion of Women, Minorities, and Children:

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. Public Law 103-43 requires that women and minorities must be included in all NIH-supported clinical research projects involving human subjects unless a clear and compelling rationale establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. NIH requires that children (individuals under the age of 21) of all ages be involved in all human subjects research supported by the NIH unless there are scientific or ethical reasons for excluding them. Each project involving human subjects must be assigned a code using the categories "1" to "5" below. Category 5 for minority representation in the project means that only foreign subjects are in the study population (no U.S. subjects). If the study uses both then use codes 1 thru 4. Examine whether the minority and gender characteristics of the sample are scientifically acceptable, consistent with the aims of the project, and comply with NIH policy. For each category, determine if the proposed subject recruitment targets are "A" (acceptable) or "U" (unacceptable). If you rate the sample as "U", consider this feature a weakness in the research design and reflect it in the overall score. Explain the reasons for the recommended codes; this is particularly critical for any item coded unacceptable

NOTE: To the degree that acceptability or unacceptability affects the investigator's approach to the proposed research, such comments should appear under "Approach" in the five major review criteria above, and should be factored into the score as appropriate.

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

Sex/gender:

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

Race/ethnicity:

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

Children:

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

For additional information to assist you in making these determinations, please refer to http://grants.nih.gov/grants/peer/guidelines_general/Review_Human_Subjects_Inclusion.pdf

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points:

- 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used;
- 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed;
- 3) adequacy of veterinary care;
- 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and
- 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

For additional information to assist you in determining if the Vertebrate Animals section is “Acceptable” or “Unacceptable”, please refer to: <http://grants.nih.gov/grants/olaw/VASchecklist.pdf>.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmission Applications

When reviewing a Resubmission application (formerly called an amended application), please evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewal

This award may not be renewed.

Additional Review Considerations

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact score

Select Agents

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

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

(http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm) Applications requesting more than \$500,000 direct costs in any year of the proposed research are expected to include a data sharing plan in their application. Certain Program Announcements may request a data sharing plan for all applications regardless of the amount of direct costs. Assess the reasonableness of the data sharing plan or the rationale for not sharing research data.

2) Sharing Model Organisms

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>). All NIH grant applications are expected to include a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. Unlike the NIH Data

Sharing Policy, the submission of a model organism sharing plan is NOT subject to a cost threshold of \$500,000 or more in direct costs in any one year, and is expected to be included in all applications where the development of model organisms is anticipated.

3) Genome Wide Association Studies

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-013.html>). Applications and proposals that include GWAS, regardless of the requested costs, are expected to include as part of the Research Plan either a plan for submission of GWAS data to the NIH designated data repository or an appropriate explanation for why submission to the repository will not be possible.

Budget and Period of Support

Is the proposed budget and period of support appropriate in relation to the proposed research and the career development needs of the candidate?

Additional Comments to Applicant

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