

Information to Help You Prepare for the NICHD MOCK STUDY SECTION (REI) August-2011

The purpose of this session is to provide you with the experience of a NIH study section so you will understand how the review process of the grants that you submit to NIH will be reviewed, what the procedures are, the criteria, etc. You need to review the grants enclosed in this packet with the following information in mind.

In this packet are three grant applications. These are actual grant submissions that we have received permission from the applicants to use in this session. You will see that all identifiers (names, institutions, identifying portions of the CV, etc) have been removed to protect their identity. We have included all of the pages so that you can see what a grant application looks like.

For each review session, several of you will be asked to portray the roles of “Primary”, “Secondary” and “Tertiary” reviewers, where you will be expected to give a complete review of the application. You should prepare written comments for the grant that you have been assigned to review. After this, everyone will be asked to add additional comments from your review of the application. We expect that all of you will participate in the review of each application, so please come prepared.

We will be reviewing three grant applications:

- R01 Application (Research Grant Application)
- R03 Application (Small Grant Mechanism)
- K23 Application (Mentored Patient-Oriented Research Career Development Award)

The Scientific Review Officer (SRO) will give an introduction and overview of the administrative aspects of the meeting at the start of the session. General guidelines for review as well as conflict of interest information will be presented in detail

As a general guideline of events for each grant review during the study section, the order is:

- Reviewer 1, 2, 3 all give their scores
- Reviewer 1 gives their critique as per the attached instructions,
please use the guidelines for the correct type of application (i.e. R01, R03, or K23)
- Reviewer 2 gives critique
- Reviewer 3 gives critique
- Statistician gives their critique
- General discussion – go around the table of reviewers (each to give input)
- Opinions from people outside the team/table
- Are there any Human Subjects/animal concerns
- Are the gender and minority issues addressed?
- Are children included/addressed?
- Revote by Reviewers 1, 2, and 3
- Voting around the table
- Everyone in the room votes
- Any budgetary concerns?

**You will find review guidelines for the three types of applications
Please use the correct one for each application**

Reviewers should become familiar with the detailed review criteria provided in each Funding Opportunity Announcement (FOA) before assessing any award application in response to that announcement. Review the complete FOA:

- **R01: PA -10-067:** <http://grants.nih.gov/grants/guide/pa-files/PA-10-067.html>
- **R03: PA-10-064:** <http://grants.nih.gov/grants/guide/pa-files/PA-10-064.html>
- **K23: PA-11-194:** <http://grants.nih.gov/grants/guide/pa-files/PA-11-194.html>

Center for Scientific Review (CSR) Web Sites that will be helpful:

(1) Guidelines for Reviewers

<http://cms.csr.nih.gov/PeerReviewMeetings/ReviewerGuidelines/>

(2) Inside the NIH Review Process Video

<http://cms.csr.nih.gov/ResourcesforApplicants/PolicyProcedureReview+Guidelines/OverviewofPeerReviewProcess/InsidetheNIHGrantReviewProcessVideo.htm>

Research Project Grant (Parent R01)

Program Announcement (PA) Number: PA-10-067

<http://grants.nih.gov/grants/guide/pa-files/PA-10-067.html>

Executive Summary

- **Purpose.** The Research Project Grant (R01) is an award made to an institution/organization to support a discrete, specified, circumscribed project to be performed by the named investigator(s) in areas representing the specific interests and competencies of the investigator(s). The R01 research plan proposed by the applicant institution/organization must be related to the stated program interests of one or more of the NIH Institutes and Centers (ICs) based on descriptions of their programs. All research project grant applications described in this announcement will be assigned to NIH ICs according to standard Public Health Service (PHS) referral guidelines and specific program interests. Investigators are encouraged to consult the participating NIH ICs and their Web sites (see <http://www.nih.gov/icd>).
- **Mechanism of Support.** This FOA will utilize the Research Project Grant (R01) grant mechanism.
- **Funds Available and Anticipated Number of Awards.** Awards issued under this FOA are contingent upon the availability of funds and the submission of a sufficient number of meritorious applications.
- **Budget and Project Period.** Costs appropriate for the project and a project duration of up to five years may be requested.
- **Application Research Strategy Length:** The R01 application Research Strategy section of the PHS398 may not exceed 12 pages, including tables, graphs, figures, diagrams, and charts. See [Table of Page Limits](#).
- **Eligible Institutions/Organizations.** Institutions/organizations listed in [Section III, 1.A.](#) are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.
- **Number of PDs/PIs.** More than one PD/PI (i.e., multiple PDs/PIs) may be designated on the application.
- **Number of Applications.** Applicants may submit more than one application, provided that each application is scientifically distinct.
- **Resubmissions.** Applicants may submit a resubmission application, but such application must include an Introduction addressing the previous peer review critique (Summary Statement). See new NIH policy on resubmission (amended) applications ([NOT-OD-09-003](#), [NOT-OD-09-016](#)).
- **Renewals.** Applicants may submit a renewal application.
- **Application Materials.** See [Section IV.1](#) for application materials.

- **General Information.** For general information on SF424 (R&R) Application and Electronic Submission, see these Web sites:
 - SF424 (R&R) Application and Electronic Submission Information:
<http://grants.nih.gov/grants/funding/424/index.htm>
 - General information on Electronic Submission of Grant Applications:
<http://era.nih.gov/ElectronicReceipt/>
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (301) 451-5936

Application Review Information

Review Process

Applications submitted for this funding opportunity will be assigned on the basis of established PHS referral guidelines to the ICs for funding consideration.

Applications that are complete will be evaluated for scientific and technical merit by (an) appropriate scientific review group(s) in accordance with NIH peer review procedures (<http://grants.nih.gov/grants/peer/>) using the review criteria stated below.

As part of the scientific peer review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific and technical merit, generally the top half of applications under review, will be discussed and assigned an impact/priority score;
- Receive a written critique; and
- Receive a second level of review by appropriate national advisory council or Board.

The mission of the NIH is to support science in pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend healthy life and reduce the burdens of illness and disability. As part of this mission, applications submitted to the NIH for grants or cooperative agreements to support biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact. Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria, and additional review criteria (as applicable for the project proposed).

Core 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. An application does not need to be strong in

all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

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?

Investigator(s). Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

New Investigator: An NIH research grant Program Director/Principal Investigator (PD/PI) who has not yet competed successfully for a substantial, competing NIH research grant is considered a New Investigator. For example, a PD/PI who has previously received a competing NIH R01 research grant is no longer considered a New Investigator. However, a PD/PI who has received a Small Grant (R03) or an Exploratory/Developmental Research Grant Award (R21) retains his or her status as a New Investigator. A complete definition of a New Investigator along with a list of NIH grants that do not disqualify a PD/PI from being considered a New Investigator can be found at http://grants.nih.gov/grants/new_investigators/resources.htm.

Early Stage Investigator (ESI): An individual who is classified as a New Investigator and is within 10 years of completing his/her terminal research degree or is within 10 years of completing medical residency (or the equivalent) is considered an Early Stage Investigator (ESI). The 10 year period after completion of the terminal degree or residency may be extended to accommodate special circumstances including various medical concerns, disability, pressing family care responsibilities, or active duty military service. If an extension of ESI status has been approved, the SRO will bring this to the reviewers' attention.

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?

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?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, 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?

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.**

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.

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.

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.

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), 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.

Renewal Applications. When reviewing a Renewal application (formerly called a competing continuation application), the committee will consider the progress made in the last funding period.

Revision Applications. When reviewing a Revision application (formerly called a competing supplement application), 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

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/priority score.

Applications from Foreign Organizations. As applicable for the FOA or submitted application, reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Select Agents 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 (http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm); 2) Sharing Model Organisms (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>); and 3) Genome Wide Association Studies (GWAS) (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>).

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

NIH Small Research Grant Program (Parent R03)

Program Announcement (PA) Number: PA-10-064

<http://grants.nih.gov/grants/guide/pa-files/PA-10-064.html>

Executive Summary

- **Purpose.** The National Institutes of Health (NIH) Investigator-Initiated Small Grant (R03) funding opportunity supports small research projects that can be carried out in a short period of time with limited resources. Investigator-initiated research, also known as unsolicited research, is research funded as a result of an investigator submitting a research grant application to NIH in an investigator's area of interest and competency. All investigator-initiated small grant applications described in this announcement will be assigned to NIH Institutes and Centers (ICs) according to standard Public Health Service (PHS) referral guidelines and specific program interests. Investigators are strongly encouraged to consult the list of participating ICs and special research interests. The R03 grant mechanism supports different types of projects including pilot and feasibility studies; secondary analysis of existing data; small, self-contained research projects; development of research methodology; and development of new research technology. The R03 is intended to support small research projects that can be carried out in a short period of time with limited resources.
- **Mechanism of Support.** This FOA will utilize the NIH Small Research Grant (R03) award mechanism
- **Funds Available and Anticipated Number of Awards.** Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. The total amount awarded and the number of awards will depend upon the mechanism numbers, quality, duration, and costs of the applications received.
- **Budget and Project Period.** The total project period for an application submitted in response to this funding opportunity may not exceed two years. Direct costs are limited to \$100,000 direct costs over the R03 2 year period, with no more than \$50,000 in direct costs allowed in a single year.
- **Application Research Strategy Length:** The R03 application Research Strategy section of the PHS398 may not exceed 6 pages, including tables, graphs, figures, diagrams, and charts. See [Table of Page Limits](#).
- **Eligible Institutions/Organizations.** Institutions/organizations listed in [Section III, 1.A.](#) are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.
- **Number of PDs/PIs.** More than one PD/PI (i.e., multiple PDs/PIs) may be designated on the application.
- **Number of Applications.** Applicants may submit more than one application, provided that each application is scientifically distinct.

- **Resubmissions.** Applicants may submit a resubmission application, but such application must include an Introduction addressing the previous peer review critique (Summary Statement). See new NIH policy on resubmission (amended) applications ([NOT-OD-09-003](#), [NOT-OD-09-016](#)).
- **Renewals.** The R03 is not renewable.
- **Application Materials.** See [Section IV.1](#) for application materials.
- **General Information.** For general information on SF424 (R&R) Application and Electronic Submission, see these Web sites:
 - SF424 (R&R) Application and Electronic Submission Information:
<http://grants.nih.gov/grants/funding/424/index.htm>
 - General information on Electronic Submission of Grant Applications:
<http://era.nih.gov/ElectronicReceipt/>
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (301) 451-5936

Section V. Application Review Information

Review Process

Applications submitted for this funding opportunity will be assigned on the basis of established PHS referral guidelines to the ICs for funding consideration.

Applications that are complete will be evaluated for scientific and technical merit by (an) appropriate scientific review group(s) in accordance with NIH peer review procedures (<http://grants.nih.gov/grants/peer/>) using the review criteria stated below.

As part of the scientific peer review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific and technical merit, generally the top half of applications under review, will be discussed and assigned an impact/priority score;
- Receive a written critique; and
- Receive a second level of review by appropriate national advisory council or board .

The R03 small grant supports discrete, well-defined projects that realistically can be completed in two years and that require limited levels of funding. Because the research project usually is limited, an R03 grant application may not contain extensive detail or discussion. Accordingly, reviewers should evaluate the conceptual framework and general approach to the problem. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or from investigator-generated data. Preliminary data are not required, particularly in applications proposing pilot or feasibility studies.

The mission of the NIH is to support science in pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend healthy life and reduce the burdens of illness and disability. As part of this mission, applications submitted to the NIH for grants or cooperative agreements to support biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact. Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria, and additional review criteria (as applicable for the project proposed).

Core 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. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

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?

Investigator(s). Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

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?

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? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, 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?

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.**

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.

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.

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.

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), 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.

Revision Applications. When reviewing a Revision application (formerly called a competing supplement application), 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

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/priority score.

Applications from Foreign Organizations. As applicable for the FOA or submitted application, reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Select Agents 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 (http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm); 2) Sharing Model Organisms (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>); and 3) Genome Wide Association Studies (GWAS) (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>).

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

Mentored Patient-Oriented Research Career Development Award (Parent K23)

Funding Opportunity Announcement (FOA) Number PA-11-194

<http://grants.nih.gov/grants/guide/pa-files/PA-11-194.html>

Part 1. Overview Information

The overall goal of the NIH Research Career Development program is to help ensure that a diverse pool of highly trained scientists are available in appropriate scientific disciplines to address the Nation's biomedical, behavioral, and clinical research needs. More information about Career programs may be found at the NIH Extramural Training Mechanisms website.

The objective of the NIH Mentored Patient-Oriented Research Career Development Award (K23) program is to provide salary and research support for a sustained period of "protected time" (3-5 years) to ensure a future cadre of well-trained scientists working in Patient-Oriented Research (POR) who will become competitive for NIH research project (R01) grant support.

FOA Purpose. The purpose of the NIH Mentored Patient-Oriented Research Career Development Award (K23) is to support the career development of investigators who have made a commitment to focus their research endeavors on patient-oriented research. Individuals with a clinical degree who are interested in further career development in biomedical research that is not patient-oriented should refer to the Mentored Clinical Scientist Career Development (Parent K08) Award. Prospective candidates are encouraged to contact the relevant NIH staff for IC-specific programmatic and budgetary information: [Table of IC-Specific Information, Requirements and Staff Contacts](#)

Required Application Instructions

It is critical that applicants follow the instructions in the [SF 424 \(R&R\) Application Guide](#), especially [Supplemental Instructions to the SF424 \(R&R\) for Preparing an Individual Research Career Development Award \(CDA\) Application \("K" Series\)](#) except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts*). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in [Section IV](#). When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not be accepted for review.**

Section II. Award Information

- **Funding Instrument.** Grant
- **Application Types Allowed.** New, Resubmission, Revision. The [OER Glossary](#) and the SF 424 (R&R) Application Guide provide details on these application types.

- **Funds Available and Anticipated Number of Awards.** The number of awards is contingent upon NIH appropriations, and the submission of a sufficient number of meritorious applications.
- **Award Budget.** Award budgets are composed of salary and other program-related expenses, as described in Section II.
- **Award Project Period.** The total project period may not exceed 5 years.

Section III. Eligibility Information

- **Eligible Organizations.** Institutions/Organizations listed in Section III are eligible to apply.
- **Eligible Individuals (Program Director/Principal Investigator).** Individuals listed in Section III are eligible to apply.
- **Number of Applications.** Number of applications by the applicant organization and candidate are listed in Section III

Section V. Application Review Information

Review Process

1. Criteria Review Process

Only the review criteria described below will be considered in the review process. As part of the [NIH mission](#), all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

Reviewers should provide 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.

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.

Candidate

- Does the candidate have the potential to develop as an independent and productive researcher focusing on patient-oriented research?
- Is the candidate's academic, clinical, and (if relevant) research record of high quality?

- Is there evidence of the candidate's commitment to meeting the program objectives to become an independent investigator focusing on patient-oriented research?
- Do the letters of reference from at least three well-established scientists address the above review criteria, and do they demonstrate evidence that the candidate has a high potential for becoming an independent investigator?

Career Development Plan/Career Goals & Objectives

- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate leading to scientific independence?
- Is the candidate's prior training and research experience appropriate for this award?
- Are the goals and scope of the plan when considered in the context of prior training/research experience and the stated training and research objectives, appropriate?
- Are the content and duration of the proposed didactic research activities during the proposed award period clearly stated and appropriate?
- Are there adequate plans for evaluating the candidate's research and career development progress?

Research Plan

- Are the proposed research question, design, and methodology of significant scientific and technical merit?
- Is the research plan relevant to the candidate's research career objectives focusing on patient-oriented research?
- Is the plan for developing/enhancing the candidate's research skills appropriate and adequate?
- If applicable, are there adequate plans for data and safety monitoring of clinical trials?

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)

- Are the qualifications of the mentor(s) in the area of the proposed patient-oriented research appropriate?
- Do the mentor(s) adequately address the above review criteria including 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 focusing on patient-oriented research?
- 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?

Environment & Institutional Commitment to the Candidate

- Is there clear commitment of the sponsoring institution to ensure that a minimum of 75% of the candidate's 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?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, 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 the [Human Subjects Protection and Inclusion Guidelines](#).

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. For additional information on review of the Inclusion section, please refer to the [Human Subjects Protection and Inclusion Guidelines](#).

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 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

Not Applicable.

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

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

Training in the Responsible Conduct of Research

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.

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 \(GWAS\)](#).

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.

Review Criteria

Reviewers should become familiar with the detailed Review Criteria:

(1) Guidelines for Reviewers

<http://cms.csr.nih.gov/PeerReviewMeetings/ReviewerGuidelines/>

(2) Inside the NIH Review Process Video

<http://cms.csr.nih.gov/ResourcesforApplicants/PolicyProcedureReview+Guidelines/OverviewofPeerReviewProcess/InsidetheNIHGrantReviewProcessVideo.htm>

Scoring System and Procedure

This scoring system was designed to encourage more reliable scoring of applications. Highly rating all applications greatly diminishes the ability of a reviewer or study section to communicate the scientific impact of an application. Therefore, reviewers who carefully consider the rating guidance provided in determining their scores improve not only the reliability of their scores, but also improve their ability to communicate the scientific impact of the applications reviewed.

SCORING

Summary

- The NIH grant application scoring system uses a 9-point scale
- A score of 1 indicates an exceptionally strong application with essentially no weaknesses. A score of 9 indicates an application with serious and substantive weaknesses with very few strengths; 5 is considered an average score
- Ratings are in whole numbers only (no decimal ratings)
- This scale is used by all eligible (without conflict of interest) SRG (Scientific Review Group) members to provide an overall impact/priority score and for assigned reviewers to score five individual criteria (e.g., Significance, Investigator(s), Innovation, Approach, Environment)
- For the impact/priority score rating, strengths and weaknesses across all of the review criteria should be considered
 - For each criterion rating, the strengths and weaknesses within that review criterion should be considered
- Reviewers should consider not only the relative number of strengths and weaknesses noted, but also the importance of these strengths and weaknesses to the criteria or to the overall impact when determining a score
 - For example, a major strength may outweigh many minor and correctable weaknesses
- For information about using the critique template, see [Critique Template Instructions](#)
- NIH expects that scores of 1 or 9 would be used less frequently than the other scores

Preliminary Scores

- Before the review meeting, assigned reviewers will determine preliminary scores for each of the five scored review criteria and a preliminary score for the overall impact/priority
- The impact/priority score should reflect the reviewer's overall evaluation, not a numerical average of individual criterion scores
- Reviewers should consider the full range of the rating scale and the scoring descriptors in assigning preliminary and final scores
 - However, a reviewer should not assume that the applications assigned to him/her necessarily cover that entire range of scores, and should assign scores as appropriate for the work or science proposed
- An application does not need to be strong in all categories to be judged likely to have major impact
 - For example, a project that by its nature is not innovative may be essential to advance a field
- Reviewers must enter the criterion scores into the Internet Assisted Review (IAR) site in the NIH Commons for them to appear in the summary statement
 - If entered in IAR, the scores will be transferred to a table at the beginning of the reviewer's critique
- Assigned reviewers may submit criterion scores only after their critiques have been uploaded
 - At the SRO's discretion, discussants who are assigned to the application and SRG members who are not assigned to the application may submit criterion scores without critiques
- In the READ phase of the meeting reviewers may submit their scores and critiques, but may not edit them
- These preliminary scores are not retained, but will be replaced by final scores that are given by private scoring and are based on the outcome of the deliberations at the peer review meeting

Criterion Scoring

- In most cases, up to five, individual criteria are scored, but certain funding opportunity announcements may include more than five scored criteria
- Criterion scores are provided for both discussed and not discussed applications
- Criterion scores are intended to provide additional information on how each assigned reviewer weighed that particular section so that the reader has a better idea of strengths and weaknesses that need improvement
- Providing scores without providing comments in the review critique is discouraged
- The impact/priority score for the application is not intended to be an average of criterion scores
- Criterion scores are entered into the Internet Assisted Review site for the meeting; the same screen also allows uploading of the written critique at the same time
- If the reviewer's opinion changed as a result of discussion at the meeting, the reviewer should change his/her criterion scores to match his/her critiques and overall impact/priority score
- The criterion scores appear in a table at the beginning of each critique in the summary statement

Impact/Priority Score

- Discussed applications will receive numerical impact/priority scores from all eligible reviewers (e.g., without conflicts of interest)

- The impact/priority score for an application is based on each individual reviewer's assessment based on the five scored criteria plus additional criteria regarding the protection and inclusion of human subjects; vertebrate animal care and welfare; biohazards, and criteria specific to the application
- Reviewers are guided to use the full range of the rating scale and spread their scores to better discriminate among applications
- Reviewers whose evaluations or opinions of an application fall outside the range of those presented by the assigned reviewers and discussant(s) should ensure that their opinions are brought to the attention of the entire committee
- In addition, the SRO and Chairperson should ensure that all opinions are voiced before final scoring is conducted
- Reviewers should feel free to assign the score that they believe best represents the impact of the application, and not feel constrained to limit their scores to the upper half of the score range if they do not feel such a score is warranted
- After the meeting, individual reviewer scores will be averaged and the result multiplied by 10 to determine the final impact/priority score
- The range of the final application scores is from 10 to 90

Non-Numeric Scores

- Not Discussed (ND)
 - Applications unanimously judged by the peer review committee to be less competitive are not discussed at the peer review meeting
 - These applications do not receive a numerical impact/priority score
 - These applications do receive individual criterion scores
 - No set number of applications are discussed; in some meetings, the "Not Discussed" option may not be used
- Not Recommended for Further Consideration (NRFC)
 - NRFC for an application occurs by majority vote of the peer reviewers
 - NRFC occurs in the following scenarios:
 - Application lacks significant and substantial merit
 - Application presents serious ethical problems in the protection of human subjects from research risks
 - Application presents serious ethical problems in the use of vertebrate animals, biohazards, and/or select agents
 - NRFC-scored applications do not proceed to the second level of peer review (National Advisory Council/Board) because they cannot be funded
 - The NRFC is a serious committee recommendation that is substantially different from Not Discussed (ND)
- Other Non-numeric Scores
 - Deferred (usually due to lack of sufficient information, quorum, allegations of research misconduct)
 - Abstention (used rarely)
 - Conflict (score put in by a reviewer who is in conflict with the application)
 - Not Present

Reviewer Guidance and Chart

- For the impact/priority score and for the individual criterion scores, the far right column (in the table below) provides a descriptive guide of how strengths and weaknesses are considered in assigning a rating
 - **Minor weakness:** easily addressable weakness, does not substantially lessen impact
 - **Moderate weakness:** lessens impact
 - **Major weakness:** Severely limits impact
- Impact (far left column) is the project's likelihood to have a sustained, powerful influence on the research field(s) involved
 - High Impact = 1 to 3
 - Moderate Impact = 4 to 6
 - Low Impact = 7 to 9
- Each review criterion should be assessed based on how important each review criterion is to the work being proposed
 - As a result, a reviewer may give only moderate scores to some of the review criteria but still give a high overall impact/priority score because the one review criterion critically important to the research is rated highly; or a reviewer could give mostly high criterion ratings but rate the overall impact/priority score lower because the one criterion critically important to the research being proposed is not highly rated.
- An application does not need to be strong in all categories to be judged likely to have major impact, e.g., a project that by its nature is not innovative may be essential to advance a field.

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
Low	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses

Additional Information for Scoring Guidance Table

Non-numeric score options: NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND = Not Discussed

Minor Weakness: An easily addressable weakness that does not substantially lessen impact

Moderate Weakness: A weakness that lessens impact

Major Weakness: A weakness that severely limits impact

PERCENTILING

PERCENTILING

- For the appropriate applications (certain activity codes or RFAs), scores will be percentiled to the appropriate base (e.g. study section base if the number of R01 applications > 25; CSR-all or IC-all base if <25)
- All percentiles are rounded to a whole number
- Until a base has been established from three rounds of review (i.e., May 2010 Council), percentiles are based on less than three application rounds