Review Criteria SOP

This standard operating procedure (SOP) includes the following sections: Purpose, Procedure, Contacts, and Links.

Some links will work for NIAID staff only.

Purpose

To provide peer reviewers standard review criteria, and possibly, initiative-specific review criteria, for judging an application's scientific and technical merit.

Procedure

Reviewers give applications an overall impact score after considering the following review criteria. An overall impact score reflects their assessment of the project's likelihood to exert a sustained, powerful influence on its field. Investigator-initiated R01 funding opportunities typically use the standard NIH review criteria only.

Other types of investigator-initiated applications (e.g., P01, R24, and U01) and initiatives (e.g., requests for applications (RFA) and program announcement with special receipt, referral, and/or review considerations (PARI)) may include additional review criteria in the notice of funding opportunity. These additional criteria should be incorporated into the five core criteria so they can be captured in the Commons.

Investigator-Initiated Review Criteria

- **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?
- **Investigators.** Are the principal investigators (PIs), collaborators, and other researchers well suited to the project? If early-stage investigators, new investigators, or in the early stages of independent careers, 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-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, members of both genders, and participants of all ages 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?

For most research grant and mentored career development award applications, NIH instructs reviewers to assess the project's rigor and transparency. Is the prior research that serves as the key support for the proposed project rigorous? Have the investigators presented strategies to ensure a robust and unbiased approach? Have the investigators presented adequate plans to address relevant biological variables? For institutional training grants, institutional and individual career development awards, and individual fellowships, applicants are required to include a plan for formal instruction in rigorous experimental design and transparency to enhance reproducibility. See Enhancing Reproducibility Through Rigor and Transparency (for additional guidance.

Reviewers will also assess the following items in determining an overall impact score:

- **Protections for human subjects.** For research that involves human subjects but does not involve one of the eight 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 eight 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 more information, see the SF 424 Application Guides and Supplemental Instructions.
- **Inclusion of women, minorities, and individuals across the lifespan.** Reviewers assess the adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and participants of all ages, as appropriate, for the scientific goals of the research. Reviewers will also evaluate plans for recruiting and retaining subjects.
  - **Note:** NIH changed the definition of a child from under 21 to under 18 years of age. For more information, see the SF 424 Application Guides and Supplemental Instructions.
- **Vertebrate animals.** The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following three 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 proposed; and 3) 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, tranquilizing drugs, or comfortably restraining devices.

  In addition, if you will euthanize animals and your method will not be consistent with American Veterinary Medical Association Guidelines for the Euthanasia of Animals guidelines, you will need to describe and scientifically justify your methods on the Cover Page Supplement form.

  For more information, see the SF 424 Application Guides and Supplemental Instructions.
- **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, 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, the committee will consider the progress made in the last funding period.
- **Revision applications.** When reviewing a revision application, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the revision application relates to investigation in the original application that was not recommended for approval, the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Investigators and Applicants

- Learn more about review in Application Assigned to a Review Group and Understand the Review Process.
- If you're applying for a grant other than an R01, read NIH Guide notices referenced in the funding opportunity to see if there are additional review criteria.
- For Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) applications, also read the SBIR/STTR SF 424 Application Guide for additional review criteria for Fast Track and Phase II Applications.

Program Officers

- When writing an RFA or PAR, use the investigator-initiated review criteria as defined in the current notice of funding opportunity template provided by the Office of Initiative Development as the basis for writing. If necessary, add wording to expand these criteria.
- On the rare occasion that more criteria are necessary to evaluate applications, work with the scientific review officer to develop additional review criteria. Keep in mind that additional criteria cannot be recorded separately in the Commons, so they would have to be incorporated into the five core criteria.
- For standard program announcements, you cannot include additional review criteria or expand standard review criteria.

Scientific Review Officers

- If additional criteria are required, develop them with the program officer.
- Prepare reviewers to evaluate any initiative-specific review criteria.

Contacts

Applicants with review questions should contact the scientific review officer. For NIAID, see the Scientific Review Program contacts.

For initiative development, Contact for NIAID Staff

Use the contacts listed above for questions about your specific situation. If you have a general question or a suggestion to improve this page, email the Office of Knowledge and Educational Resources at deaweb@niaid.nih.gov.

Links

Animals in Research for Grants SOP

AVMA Guidelines for the Euthanasia of Animals

CSR Study Sections

Grant Application SOP

Human Subjects Research Requirements in Grants SOP

Apply for a Grant

NIH Policy Manual -4204-2048 - Peer Review Process

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