NIH Peer Review:

Grants and Cooperative Agreements

Welcome

The mission of the National Institutes of Health (NIH) is to seek fundamental knowledge about the nature and behavior of living systems and to apply that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability. NIH has a longstanding and time tested system of peer review to identify the most promising biomedical research. This document provides an overview of the NIH peer review system, including descriptions of its core values and safeguards on fairness.

The NIH Peer Review Process

The NIH peer review process forms the cornerstone of the NIH extramural research mission and ensures that applications submitted to the NIH are evaluated by scientific experts in a manner free from inappropriate influences. Currently the NIH handles approximately 80,000 applications and engages approximately 20,000 reviewers per year.

The NIH Center for Scientific Review (CSR) is the central receiving point for all applications submitted to the NIH, and to some other federal agencies. CSR's Division of Receipt and Referral assigns each application a unique number; checks the application for compliance with format and policy requirements; assigns the application to a Scientific Review Group (SRG) for initial peer review; and assigns the application to an NIH Institute, Center, or Office for eventual funding consideration.

Most applications are submitted to the NIH electronically and are received through the Grants.gov site, the central portal of the United States government for receipt of electronic applications. While NIH still receives a few types of applications in paper format, the agency is working to convert all submissions to electronic format in the near future.

The NIH is composed of 24 different research components with grant making authority called Institutes and Centers (ICs), each with its own specific research agenda. In addition to receiving and referring all applications, CSR manages the initial peer review (see below) of most research and fellowship applications. The NIH ICs manage the initial peer review of some applications, primarily those with IC-specific features such as those submitted in response to Requests for Applications (RFAs), institutional training grant applications, and career development award applications.

Two Levels of Peer Review

In order for the NIH to award research funds, an application must be approved by two levels of NIH peer review. The two levels of NIH peer review help ensure that the assessment of scientific and technical merit is separate from the funding decision.

The first level of review (initial peer review) is an assessment of scientific and technical merit, and is conducted by a Scientific Review Group (SRG) composed primarily of non-federal scientists who have expertise in relevant scientific disciplines and current research areas. Appointed members may serve up to a six-year term and require approval by the NIH Deputy Director [or in the case of the National Cancer Institute (NCI), the NCI Director]. The outcome of the initial review is provided to the funding component (NIH IC), and to the Project Director/Principal Investigator (PD/PI), in a written document called the NIH Summary Statement.

The second level of review (Council review) is performed by IC National Advisory Councils or Boards. Councils make recommendations on priority areas of research, pending policy, and funding of particular applications. They are composed of both scientific members and public representatives chosen for their expertise, interest, or activity in matters related to health and disease. Appointed members usually serve a four-year term (or usually six-year terms in NCI), and require approval by the Secretary, DHHS or in some cases the President of the United States.

In addition, both levels of NIH peer review are conducted in accordance with the Federal Advisory Committee Act (FACA). FACA requires that each advisory committee (SRG and Council) meeting be conducted in the presence of a Designated Federal Official (DFO), who ensures that the meeting is conducted in compliance with applicable laws, regulations, and policy. For SRG meetings, the DFO is commonly referred to as the Scientific Review Officer (SRO); for Council meetings, the DFO is commonly referred to as the Executive Secretary.

Only the Director of an NIH IC with funding authority stipulated in law or regulation is authorized to make final funding decisions.

Core Values of NIH Peer Review

The core values of NIH peer review are (1) expert assessment, (2) transparency, (3) impartiality, (4) fairness, (5) confidentiality, (6) integrity, and (7) efficiency. These values drive NIH to seek the highest level of ethical standards, and form the foundation for the laws, regulations, and policies that govern the NIH peer review process.

Expert Assessment: NIH policy requires that the scientific expertise in the initial review panel be suitable for evaluating the potential impact of the proposed work. As appropriate for the applications under consideration, NIH recruits reviewers to encompass broad and diverse scientific views, as well as to assess specific aims and methodology. Evidence of a reviewer's qualifications may be found in his or her publication record, research funding history, other scientific achievements, and/or recommendations from colleagues in the field. Also, in certain cases, public representatives may be recruited to provide perspective from the patient or advocacy point of view, or individuals with knowledge of technology transfer or accounting practices may serve as reviewers. Therefore, both CSR and the ICs recruit reviewers on the basis of their expertise

and stature in the field, mature judgment, impartiality, and ability to work in a group. Close attention is given to equitable geographic distribution and to ethnic and gender representation. Appointments are made without discrimination on the basis of age, ethnicity, gender, sexual orientation, disability, cultural, religious, or socioeconomic status.

Transparency: Applications submitted to the NIH are evaluated for scientific and technical merit using established, published review criteria. Only the review criteria published in a Funding Opportunity Announcement (FOA) may be used as the basis for the evaluation of applications submitted for that FOA.

Reviewers of research applications provide an Overall Impact score to reflect their assessment of the "the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved." Overall Impact is defined in specific ways for different types of NIH funding mechanisms. For fellowships, Overall Impact is defined as "the likelihood that the fellowship will enhance the candidate's potential for, and commitment to, a productive independent scientific research career in a health-related field."

The review criteria for NIH funding mechanisms are stipulated broadly in regulation and further defined in NIH policy. For example, the standard review criteria used for all NIH research applications are Significance; Investigators; Innovation; Approach; and Environment. For fellowship applications the standard review criteria are Fellowship Applicant; Sponsor, Collaborators, and Consultants; Research Training Plan; Training Potential; and Institutional Environment & Commitment to Training. Additional criteria may be added for special initiatives but must be specified in the FOA.

Reviewers are asked to assess additional review criteria, as appropriate for the work proposed. These additional criteria include Protections for Human Subjects; Inclusion of Women, Minorities, and Children; Vertebrate Animals; and Biohazards.

Finally, reviewers are asked to comment on several additional considerations that do not factor into the final Overall Impact score. These considerations include justification for an application from a foreign institution, special considerations for select agent research, plans for sharing research resources, the budget request and proposed project period. The comments from the reviewers are transmitted to the PD/PI and appropriate NIH staff.

The NIH also strives for transparency by publicizing descriptions of our standing review panels, the rosters of individuals who participate on review panels, and information on each funded grant. Finally, the guidelines

sent to reviewers and descriptions of the NIH peer review process are posted on the NIH websites.

Impartiality: Any circumstance that might introduce conflict of interest, the appearance of conflict of interest, bias, or predisposition into the review process by any participant in the process, must be managed to avoid inappropriate influence in the review process. Bases for conflict of interest in NIH peer review include financial interests, professional relationships, employment, study section membership, personal relationships, and other interests.

Reviewers must sign a pre-meeting and a post-meeting Conflict of Interest certification; Federal employees serving as SRG members and Council members must adhere also to the Standards of Ethics for Federal Employees. Also, each reviewer participating in initial peer review must certify that he or she is not a federally-registered lobbyist. If a reviewer indicates his or her status as a federally-registered lobbyist, he or she may not participate in NIH peer review.

The NIH operates with a clear separation of function for review staff and program staff. Thus, no member of the NIH extramural staff may serve as a reviewer on an NIH review panel, and no member of the NIH review staff may participate in review functions and portfolio management in the same scientific area. Additionally, an individual may not participate in both an application's initial peer review and Council review to avoid any one individual from having undue influence on the evaluation of an application.

Finally, the NIH has policies for managing appeals of initial peer review based on documentable flaws in the review process. In certain circumstances, the appeals process results in re-review of the application. The four

acceptable bases for an appeal of initial peer review are:

- Evidence of bias on the part of one or more peer reviewers.
- Conflict of interest on the part of one or more peer reviewers.
- Lack of appropriate expertise within the SRG
- Factual error(s) made by one or more reviewers that could have altered the outcome of review substantially.

Fairness: All applications received for NIH review are evaluated using equivalent review processes. For example, the NIH uses a nine-point scoring scale (1 = highest impact, 9 = lowest impact) in reviewing all types of applications (with the exception of a few special initiatives.) The final impact score is calculated as the average of individual reviewers' scores, multiplied by 10 (range of 10 through 90). Numerical scores on the same nine-point scale are assigned also to each of (at least) five "scored" review criteria. For certain funding mechanisms, the final impact scores are percentiled across different review panels to balance variable scoring behaviors among SRGs. A percentile is the approximate percentage of applications that received better impact scores than that particular application from the SRG during the past year.

Similarly, standard review criteria are used for the evaluation of all applications of a particular funding mechanism, except for a few special initiatives. Because applications evaluated in different study sections often are considered in the same Council meeting, the use of standard criteria for each funding mechanism helps to ensure equitable evaluation.

A written outcome of review – the NIH Summary Statement - is provided to the Advisory Council, the PD/PI, appropriate NIH staff, and reviewers of subsequent resubmission applications. The Summary Statement contains, at a minimum, written

critiques and criterion scores from at least three reviewers, the final score or non-numerical outcome designation, and the meeting roster. It may also contain a summary of the discussion at the SRG meeting.

Confidentiality: In order to protect confidential information, portions of NIH review meetings (initial peer review and Council) are closed or partially closed to the public if grant applications (and contract proposals) are being reviewed or discussed. Federal employees with a need to know, reviewers, and support contractors are allowed to attend NIH review meetings.

In addition, all discussions, application materials (except those in the public domain such as publications), and information about conflicts of interest and assignments of individual reviewers to particular applications are strictly confidential. In fact, reviewers must sign a confidentiality certification indicating that they have read and understand the confidentiality rules for NIH peer review, and do so under penalty of perjury. The NIH Summary Statement is shared by NIH only with the PD/PI, Council members, appropriate NIH staff, and reviewers of subsequent resubmission applications.

Review communications and grant applications are handled so as to protect sensitive data and confidential information. Nearly all initial peer review meetings use the Internet Assisted Review (IAR) system for communicating application and meeting materials to reviewers. The IAR system operates with a secure internet connection that requires both password protection for reviewer access and authorization by the SRO.

Communications and materials required for Council meetings are managed in the Electronic Council Book (ECB), another secure, online information system. The ECB is used by Advisory Council members to create queries, view basic application data and Summary Statements and, when appropriate, vote on applications as part of an Early Concurrence process. The ECB also is used by NIH staff for managing council business processes including special assignments, conflicts of interest, Early Concurrence, IC-specific web pages and documents.

Integrity and Ethical Considerations: The NIH is fully committed to maintaining public trust in the NIH research enterprise by supporting our grantees in adhering to the highest standards of research integrity. All NIH extramural staff, including review staff, participate in annual training in the proper handling of allegations of research misconduct. Also, reviewers and Council members are instructed to report any suspicion or allegation of research misconduct directly to the DFO in charge of the meeting, and to do so in strictest confidence.

Each NIH IC designates a senior official, a Research Integrity Officer (RIO), to handle incoming allegations of research misconduct, and each DFO is instructed to contact the appropriate RIO right away should an allegation of research misconduct be received. The DFO may decide to defer the application from review until the proper authorities can deliberate on the situation.

The Public Health Services Policies on Research Misconduct delegate authority for managing investigations of research misconduct to the Office of Research Integrity (ORI) in DHHS. Allegations that involve NIH funding and have sufficient detail to allow consideration are forwarded by the NIH to ORI for consideration and appropriate action.

Efficiency: With the steadily increasing pace of biomedical research, the NIH peer review system continuously strives to reduce the time between submission of applications to awards for the most meritorious projects. (In some cases, an accelerated schedule from application

submission to award is mandated in statute.) As a funding agency in the United States government, the NIH has converted a large portion of its operations for receiving applications to use of the Grants.gov portal. Grants.gov is a central receiving point for applications submitted electronically to the U.S. federal government. This system is environmentally-friendly as it avoids receipt of paper applications and facilitates movement of applications to appropriate NIH staff and reviewers. For instance, previously paper applications were mailed or shipped to reviewers via U.S. mail or courier, but now reviewers are given access to electronic copies of applications via the secure IAR site. Other web-based capabilities allow potential reviewers to identify conflicts of interest with particular applications early in the process, so that another eligible reviewer can be assigned to the application as soon as possible. This system also allows reviewers to submit their written critiques directly to the NIH for electronic production of Summary Statements, an often time-consuming step in the grants process. The NIH also utilizes an online system – the eRA Commons – to communicate with applicant organizations and PDs/PIs. This system allows investigators to see their Overall Impact scores within three days after conclusion of the initial peer review meeting, and to access their Summary Statements when they are released.

Finally, NIH has expedited production of Summary Statements. Reviewers are provided templates for their written critiques, and are instructed to provide their written critiques in brief, bulleted format rather than lengthy prose. This simple format change significantly reduces burden on reviewers and review staff.

Continuing Competition

Most NIH grants are issued for 3, 4, or 5-year periods, with progress reports and staff approval required each year before the next year's funds can be awarded. However, at the end of that award period, an investigator who wishes to continue their research must submit an application for additional funds (termed renewals) and re-compete through the NIH peer review system. At this stage, the evaluation of scientific and technical merit also includes an assessment of progress made during the previous award period. In this way, the NIH peer review system ensures accountability and support of the most meritorious research.

The Culture of NIH Peer Review

While laws, regulations, and policy are essential to the success of the NIH peer review system, the culture of NIH peer review is almost as important. Reviewers and scientists in the community know that their success and the advancement of their scientific field depend on the rigor and fairness of NIH reviews. The core values of NIH peer review thus have been internalized, and a culture of fairness and honesty exists within the peer review community. Reviewers thus devote weeks of their time to serve NIH and view it as their professional obligation to participate in the appropriate and fair review of applications.

Participation of Global Scientists

Scientists from around the globe are recruited as peer reviewers. Foreign scientists are recruited for their scientific and technical expertise and are not recruited on the basis of their official position or duties. To accommodate the participation of global scientists in peer review, the NIH has adopted emerging technologies, reducing the need for international travel. These technologies include the use of Internet Assisted Meetings for online discussions, video conferencing, and telepresence meetings, which use life-size video screens.

Conclusion

By promoting a fair and equitable competitive process and by enlisting active researchers to make the assessments of scientific and technical merit, NIH peer review well serves the advancement of scientific knowledge and the health of the people of the United States and around the world. Nonetheless, we always strive to do better and continually look for ways to evolve the NIH peer review process and identify the highest quality research as new opportunities in biomedical science arise. Suggestions may be sent to ReviewPolicyOfficer@mail.nih.gov.

You can download a copy of this document at:
http://grants.nih.gov/grants/PeerReview22713webv2.pdf

NIH Institutes/Centers (ICs)

FIC	Fogarty International Center
NCATS	National Center for Advancing Translational Sciences
NCCAM	National Center for Complementary and Alternative Medicine
NCI	National Cancer Institute
NEI	National Eye Institute
NHLBI	NIH Heart, Lung, and Blood Institute
NHGRI	National Human Genome Research Institute
NIA	National Institute on Aging
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIAID	National Institute of Allergy and Infectious Diseases
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NIBIB	National Institute of Biomedical Imaging and Bioengineering
NICHD	Eunice Kennedy Shriver National Institute of Child Health and Human Development
NIDCD	National Institute on Deafness and Other Communication Disorders
NIDCR	National Institute of Deafness and Craniofacial Research
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIDA	National Institute on Drug Abuse
NIEHS	National Institute of Environmental Health Sciences
NIGMS	National Institute of General Medical Sciences
NIMH	National Institute of Mental Health
NIMHD	National Institute on Minority Health and Health Disparities
NINDS	National Institute of Neurological Disorders and Stroke
NINR	National Institute of Nursing Research
NLM	National Library of Medicine

Top 5 NIH Web Sites to Get You Started

NIH Home Page
www.nih.gov

Office of Extramural Research Home Page
www.grants.nih.gov

Center for Scientific Review
www.csr.nih.gov

Research Portfolio Online Reporting Tools (RePORT)
www.RePORT.nih.gov

Peer Review Process
grants.nih.gov/grants/peer_review_process.htm

NIH Peer Review Revealed
www.csr.nih.gov/video/video.asp

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