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Enhancing NIH Peer Review: Update



February 29, 2008, marked the end of the diagnostic phase and release of the final draft report. Thereafter, a comprehensive deliberative effort focused on key recommendations and implementation goals. In June 2008, Dr. Zerhouni established a Peer Review Oversight Committee to solidify a final set of recommendations and begin implementation of those recommendations. The final set of recommendations is organized into the following four priority areas.

Engage the best reviewers: The excellence of peer review is directly correlated with the ability to recruit and retain the most accomplished scientists to serve on NIH study sections. Goals include—

- Develop policies that allow reviewers to adjust their commitment for more flexibility.
- Enhance review performance by providing more standardized training and recruitment of reviewers.
- Develop policies that acknowledge reviewers who have demonstrated their commitment with a history of participation in full study section meetings (or equivalent).
- Define service expectations for principal investigators of certain classes of NIH grant awards.

Quality and transparency of review: The process of review should focus on the potential impact, originality and feasibility of the proposed research. Goals include—

- Realigning the structure of applications, review criteria, summary statements and the rating processes to assess the potential impact, originality and feasibility of the proposed research.
- Shorten applications to 12 pages starting with R01s and reduce page lengths of other activity codes appropriately.

• Provide applicants with more detailed feedback from the review process.

Provide balanced and fair reviews across scientific fields and career stages, and reduce administrative burden on applicants: Peer review should fairly evaluate proposals from all scientists, regardless of their career stage or discipline and avoid bias towards more conservative and proven approaches at the expense of innovation and originality. Goals include—

- Continue to support and develop policies to that support the unique needs of Early Stage Investigators, New (to NIH) Investigators, and Clinical Researchers.
- For more experienced investigators, place equal emphasis on a retrospective assessment of accomplishments.
- Continue to grow the transformative research portfolio.
- Establish policies, carefully and progressively, to rebalance and reduce the need for resubmissions, thereby increasing system efficiency.
- Share relevant review and funding data will all applicants.

Develop a permanent process for continuous review of peer review: The NIH peer review process will commit to a continuous quality control and improvement process based on a rigorous and independent prospective evaluation that favors innovative approaches to review and program management.

We will keep you abreast of developments with updates to the Enhancing Peer Review Web site: <u>http://enhancing-peer-review.nih.gov/</u>.

CSR Reviewer Registry Tops 3,000; More Reviewers Sought



The Center for Scientific Review's (CSR) national registry of volunteer reviewers grew to more than 3,000 recently, after 72 scientific societies responded to CSR's call late last year for recommendations for highly qualified investigators to serve on review groups. "It's a unique database," said Dr. Toni Scarpa, CSR Director. "We're able to recruit great reviewers that we might have otherwise missed."

"I identified a reviewer every time I consulted it," said Scientific Review Officer (SRO) Tera Bounds. "The reviewers I found

there are always willing to participate; and, if they are not available when I need them, they commit for the following meeting. I even found a reviewer who is now a permanent member."

SRO Steven Zullo had this to say: "The registry is a good tool to help SROs identify reviewers. It augments the SRO's efforts to coordinate the best reviews." Zullo and Bounds are among a growing number of SROs now using the database to find society-recommended reviewers for meetings. Not only does the registry help SROs more quickly identify experienced, volunteer reviewers, but it offers an opportunity for societies and institutions to have additional input into the peer review process.

CSR is calling for more recommendations: Societies are invited to e-mail <u>RecruitReviewers@csr.nih.gov</u> to find out how they can help ensure that our registry contains their

recommendations for excellent reviewers. Submitting names is easy—we provide an Excel spreadsheet and all the information needed.

If your society has not participated, encourage it to do its part. We encourage those interested in volunteering to contact their respective scientific societies for inclusion in the lists they send to CSR.

CSR is looking for individuals with the following qualifications:

- Substantial and broad independent research experience
- Recipient of major peer-reviewed grants either from NIH or an equivalent agency
- Understanding of the review process
- Willingness to consider serving in the future for four years.

New Round of Assessments to Improve CSR's Review Groups



CSR just launched a new biannual round of in-depth reviews of our Integrated Review Groups (IRGs) by convening study section Chairs from two IRGs to gather insights on emerging areas of science and on improving study section performance.

These IRG reviews will focus on the science our study sections evaluate and occur approximately every two months, from July 2008 to July 2010, until all 25 IRG reviews are complete.

This effort builds on three previous IRG evaluations: the 2007 Open House Workshops, a set of 2006-7 internal IRG reviews, and our ongoing effort to review the scientific boundaries and performance of each IRG every five years, as recommended by the Panel on Scientific Boundaries of Review in 2005.

"Ensuring our study sections are aligned with science and prepared for the future is a constant challenge," said Toni Scarpa. "It's exciting to see our Chairs, Chiefs and SROs work together to do this. Updated and clearer scientific guidelines will not only enhance our review meetings but they also will give applicants a clearer idea of where their applications might best be reviewed."

The first in this round of reviews, held July 23-24, garnered positive feedback from attendees. It evaluated the Brain Disorders and Clinical Neuroscience and Molecular, Cellular and Developmental Neurosciences review groups.

Three Phases of the Reviews

Broad discussions on CSR: Chairs meet with Toni Scarpa and senior CSR staff to discuss CSR processes and current NIH initiatives to improve the peer review process.

Detailed discussions on the past, present and future of each IRG's study sections: Chairs focus on white papers developed as part of CSR's ongoing IRG reviews that provide a retrospective of the past five years of study section evaluations. These white papers will enable Chairs to provide critical guidance:

• Input about fundamental aspects of review, including the scope and breadth of the science reviewed; whether there is accommodation for new directions and emerging areas; and the

appropriateness, qualifications, stature and diversity of reviewers. We also seek input on meeting management, policies and procedures and emerging peer review issues.

- Advice on the emerging trends in the science that will impact the workload, alignment, and types of reviewers that need to be recruited in each study section, especially as applications become more complex and translational.
- Guidance on revising study section descriptions that are more informative and user friendly for applicants and the scientific community.

Focused discussions on the critical role of the study section Chair: Senior CSR staff share "best practices" for chairing meetings, and Chairs make suggestions and discuss with CSR management successful strategies for running high-quality peer review meetings.

Some Reviewers Find Welcome Relief in 'Anytime' Grant Submission



It's a formidable juggling act—serving on a review panel and writing your own grant application. Many reviewers say they find welcome relief in NIH's policy allowing permanent study section members to submit a grant application whenever they have it ready.

Called "continuous submission" and in effect since February, the policy lifts deadlines for appointed members of all chartered NIH study sections who are submitting R01, R21 and R34 applications that would otherwise have standard due

dates. Since this practice began earlier this year, 42 percent of the 1,574 eligible applications submitted by chartered members were reviewed on a continuous basis.

Freedom and Flexibility: "It's way easier if you don't have strict timelines," said Dr. Andrew Thorburn of the University of Colorado Cancer Center. "It gives you the freedom to participate as a reviewer and be comfortable doing a better job with your application," he added. For other reviewers, the benefit of submitting their grant application on a flexible schedule makes all the difference. "It's nearly impossible to submit an application and serve in a study section," said Dr. Kristen Harris of the University of Texas at Austin. "Depending upon how many applications I get, for two to three weeks, I spend all my time reviewing them. So in the past, I just didn't serve on a review panel when I had an application to submit, because I needed the time."

Some want deadlines, even if they are simultaneous or back-to-back. "The deadlines structure things and provide motivation, so I don't think it's an unreasonable challenge to review grants and submit your own application," said Dr. Brent Roberts of the University of Illinois at Urbana-Champaign. "It is a matter of time management."

Dr. Michael Sofroniew of UCLA's School of Medicine said, "working to a deadline is fine for many of us, as we are used to budgeting our time. But I'm in favor of the flexibility." He will be submitting a grant application in the next six months. "It will be convenient, and it's an incentive for senior scientists to be reviewers or study section Chairs."

NIH is currently evaluating this practice and investigating the possibility of expanding it to other reviewers and applicants, such as those who apply for small business grant applications.

Learn more from CSR's Web site: <u>http://cms.csr.nih.gov/NewsandReports/NewFlexReviewers.htm</u>.

New Data Gives Insight on NIH Peer Reviews of Clinical Research Applications



The American Journal of Medicine has published new data that sheds light on why clinical research applications do not fare as well as basic science applications in peer reviews at the National Institutes of Health. CSR initiated this study to follow-up its earlier studies to address the perception that clinical research grant applications are disadvantaged in the NIH peer review process.

Two factors identified: The study shows that nearly all of the difference in review outcomes between these two types of applications is related to the fact that clinical applicants who have R01 grants are less likely to resubmit R01 grant applications or competitive renewal applications for their R01 grants. A contributing, but secondary, factor is the difficulty some clinical applicants have in addressing human protection requirements.

"We saw it as our duty to get to the bottom of the issue," said CSR Director Dr. Toni Scarpa. "Though we are relieved to know the problem is not with our reviewers or review system, we will not rest," he continued. "We will continue to monitor and evaluate our efforts and work to ensure that all research receives fair and expert reviews."

Human subjects concerns: The recent study examined the review outcome of 62,735 nonclinical and 30,187 clinical grant applications (R01s) reviewed between October 2000 and May 2004. The clinical research applications received less favorable scores. Of all the clinical research applications, 14.8 percent were found to have human subjects concerns by their reviewers.

Staying in the game: While 28.3 percent of the nonclinical researchers who had an R01 grant application submitted competing renewal applications, only 20 percent of the clinical researchers who had a R01 grant did. This difference has a major impact on the overall success rate of clinical grant applications because both revised and renewal applications typically receive more favorable scores than new applications.

The full text of this article is available online: Michael R. Martin, Teresa Lindquist, Theodore A. Kotchen; "Why Are Peer Review Outcomes Less Favorable for Clinical Science than for Basic Science Grant Applications?" *American Journal of Medicine*, Volume 121, Issue 7, Pages 637-641 (July 2008): <u>http://www.amjmed.com/</u>.

CSR Acts to Help Remedy Decrease in Small Business Applications

The NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are part of a complex innovation ecosystem that provide dedicated funding for small businesses to engage in innovative, early-stage biomedical and behavioral research and development (R&D) projects with commercial potential for medical solutions and breakthroughs. These congressionally mandated set-aside programs play an important role in achieving the NIH mission, particularly in translating research findings and advancing medical discoveries into tangible products and services.



Program participation, however, has not sustained the momentum seen across other NIH research programs. The numbers of SBIR/STTR applications and firms participating in the program are declining. For example, the number of SBIR applications has decreased from about 6,100 to 3,600 applications since fiscal year 2004.

NIH takes steps to increase SBIR/STTR grant applications

Scoring more applications: As a stop gap to broaden the pool of potentially fundable applications, CSR will "unscore" 40 percent of the lowest ranked SBIR/STTR grant applications, instead of unscoring 50 percent as we do in reviewing other types of grant applications.

Educating the community. CSR and the Office of Extramural Research have hit the road to educate the small business research community about the application process and solicit ideas on how to stimulate greater numbers of SBIR/STTR applications. As part of our efforts, we have worked to spread the word at SBIR/STTR national and regional conferences.

Exploring the possibility of having more flexible application deadlines: CSR is also considering extending to SBIR/STTR applicants the continuous submission program now available only to permanent, chartered members.

What's behind the problem? There are several factors that may explain the disconcerting trend in decreasing SBIR/STTR applications. Some firms are no longer eligible. Some have gone out of business. Some firms are new start-ups that have not yet fully developed the necessary infrastructure to successfully compete for an award. Some are not taking advantage of the opportunities to resubmit. Others yet believe the time and cost for applying relative to the current award levels and the number of grants awarded is not a sufficient opportunity incentive.

CSR and NIH will continue to look for ways to ensure the vitality of the small business program.

CSR to Hire More Scientific Review Officers, Chiefs and Directors



In the coming weeks and months, we expect to hire 30 new Scientific Review Officers (SROs). Our goal is to recruit senior faculty members at major research institutions with impeccable records of independent research. We also expect to hire about six IRG Chiefs, and we will soon recruit new Directors for three of our review divisions: (1) Healthcare, Population and Behavioral Sciences; (2) Basic and Translational Biomedical Sciences; and (3) Physiology and Pathology.

We encourage experienced investigators in many scientific disciplines to consider the benefits of working for NIH. Our staff works on the forefront of their scientific fields, interacts with the best scientists and has a broad impact on the evolution of science. New job announcements are posted on the USAJobs Web site: <u>http://www.usajobs.gov/</u>.

Get more information from CSR's jobs Web site: <u>http://cms.csr.nih.gov/AboutCSR/Employment/</u>.

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