PEER REVIEW NOTES
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From the CSR Director's Desk

Training of Reviewers and Chairs

A scientist recently wrote to me about accountability in the peer review process. One of his concerns focused on the review of amended applications. "Reviewers should not be permitted to find additional fault with a revised application," he argued, "except for new sections that may have been provided in response to previous comments."

In my response, I explained that the purpose of a review is to provide an overall evaluation of an application's scientific and technical merit, not to decide whether previously identified "flaws" have been corrected. Applications with no identified "flaws" may still not be rated highly if the scientific problem is not inherently important or interesting. I did not, however, totally dismiss his concerns. I noted that some reviewers focus on relatively minor flaws but fail to identify the fundamental problems in the application. The best way to prevent this from happening is to improve the training of reviewers so that the real considerations leading to the priority scores given are clearly articulated.

Peer review at National Institutes of Health (NIH) is a complex enterprise. New reviewers must digest a substantial amount of material about peer review guidelines and the peer review process before they can be productive and effective. Likewise, new Chairs who have not received proper training or mentoring may need several review rounds to find their way in managing a review meeting. This situation can be problematic since the quality of the peer review process can be influenced significantly by how meetings are managed.

To enhance the effectiveness of peer review meetings overseen by the Center for Scientific Review (CSR), I recently charged a committee of CSR staff to develop new guidelines and materials for training both reviewers and Chairs. This committee

currently is defining recommended practices for training reviewers. It then will focus on practices for training study section Chairs. The committee will report its progress at the September meeting of the CSR Advisory Committee.

In conjunction with these activities, CSR is also producing a video of a "mock" study section to train new study section members. This video should be finished in September of 2002 and be available for distribution soon thereafter.

I should emphasize that all of us at NIH appreciate how busy—and sometimes overwhelmed—our reviewers are. Any training practice adopted will certainly need to take this into account, and we will be sensitive to placing any additional burdens on our reviewers.

Internet-Assisted Review Update

A few years ago, the National Institute of Allergy and Infectious Diseases (NIAID) developed a web-based system to manage electronic submission of reviewer critiques. The system facilitates efficient and informed discussion at review meetings by making critiques and preliminary scores available to reviewers prior to the study section meeting. When CSR tested the system in a pilot program, we quickly appreciated its benefits. We have now instituted the system in nearly all of our standing study sections.

Because the NIAID system proved to be so useful, NIH is using it as a model to develop an enhanced, next-generation Internet-Assisted Review (I-RA) system. Some new or enhanced features for reviewers include the ability to send critiques in Microsoft Word or WordPerfect formatted files and the ability to submit streamlining votes. The new system will also help expedite the production of summary statements. We expect the launch of a pilot version of the new I-RA system in fall 2002.

Congressional Testimony

In March of this year, I participated on NIH panels that testified at budget hearings for the U.S. Senate and House of Representatives. Besides explaining the basics of peer review at NIH, I stressed the importance of having the right scientific expertise to evaluate applications and the proper organization of study sections. I also explained that the number and complexity of grant applications NIH receives have increased tremendously over the last few years. To manage these increases, NIH has invested in new technology to make the review process more efficient. I discussed our efforts to handle applications electronically, provide reviewers with CD-ROMs instead of boxes of paper review materials (see article below), and use Internet-assisted review tools.

Fellowship Committee Update

CSR recently revised its approach to reviewing postdoctoral fellowship (F32) applications. These applications previously were reviewed in different venues. Some F32s were reviewed in special emphasis panels dedicated to reviewing them while other F32s were reviewed along with R01 applications in chartered study sections. Though these applications were carefully assigned according to scientific topic, this practice resulted in inconsistencies in review procedures and scoring. In 1999, I appointed Dr. Maxine L. Linial, Fred Hutchinson Cancer Research Center, to rigorously examine CSR's fellowship application review practice and to make recommendations. Her recommendations led CSR to create dedicated fellowship study sections. Twelve new fellowship study sections have since been established

(http://www.csr.nih.gov/events/fellowship_ss/fellow_ss.htm).

The fellowship study sections met for the first time in October/November 2001 for the January 2002 Council round. In this initial round, they reviewed 568 applications or 81 percent of the 698 fellowship applications submitted to NIH. In the May 2002 Council round, NIH received 936 fellowship applications, and CSR fellowship study sections reviewed 780 or 83 percent of them.

It is worth noting that National Research Service Award (NRSA) stipends were recently raised substantially (see http://grants.nih.gov/training/nas_report/NIHResponse.htm). As a result, CSR expects that the number of fellowship applications submitted to NIH will increase. However, this increase has not yet materialized. The number of fellowship applications NIH received for the October 2002 Council round (approximately 950) is consistent with the number of received for the October round over the past several years.

Ellie Ehrenfeld, Director, CSR

New Personnel at CSR

CSR continues to recruit Scientific Review Administrators (SRAs) and other professionals to fill new and vacant positions.

Dr. Abraham Bautista has become the SRA for the AIDS and Related Research 2 and 5 Study Sections. He previously was a professor of physiology at the Louisiana State University Medical Center in New Orleans. Dr. Bautista received his Ph.D. in medicine and immunology from the University of Aberdeen in Scotland.

Dr. Joanna Pyper has been recruited from CSR's Internship Program to be the SRA of the Virology Study Section. Prior to being a CSR intern, she was a research fellow in the Picornavirus Virus Replication Section of the Laboratory of Infectious Diseases at the National Institute of Allergy and Infectious Diseases. Dr. Pyper holds a Ph.D. in virology from The Johns Hopkins University.

Dr. Mariela Shirley has joined CSR to be the SRA of the SSS-N Study Section, which reviews grant applications for the Risk, Prevention and Health Behavior Integrated Review Group (IRG). She earned her Ph.D. in clinical psychology from Vanderbilt University. Dr. Shirley recently was an assistant professor of psychology at the University of North Carolina at Wilmington.

Dr. Shen Yang is now the SRA for the SSS-1 Study Section, which reviews business grant applications for the Oncological Sciences IRG. He holds a Ph.D. in biophysical chemistry from Yale University. Dr. Yang comes to CSR from DuPont Pharmaceuticals in Newark, Delaware. He was a senior investigator in its Department of Drug Metabolism and Pharmacokinetics.

Dr. Deborah Young-Hyman is the new SRA for the Risk, Prevention and Health Behavior 2 Study Section. She recently was an associate professor in pediatrics and medicine at the University of Maryland School of Medicine. Dr. Young-Hyman received her Ph.D. in clinical psychology from the Institute for Advanced Psychological Studies at Adelphi University in Garden City, New York.

Dr. Ronald Suddendorf has become an Assistant Chief in CSR's Division of Receipt and Referral. He received his Ph.D. in analytical chemistry from the University of Arizona in Tucson. Dr. Suddendorf

previously was an SRA at the National Institute on Alcohol Abuse and Alcoholism. He coordinated its review of grant applications related to biochemistry, physiology, and medicine of alcohol abuse.

Employment Opportunities at CSR

CSR is seeking scientists with experience in a number of disciplines to serve as SRAs managing the NIH peer review process. Some of the areas where CSR has immediate openings include AIDS, biochemistry, bioengineering, biophysics, chemistry, cognitive neuroscience, digestive sciences, imaging science, infectious diseases, microbiology, nursing, oncology and visual neuroscience. SRAs are usually required to have both postdoctoral and grant application experiences and must be familiar with the scientists within their discipline. If you know any outstanding scientists who might be interested in a challenging and rewarding SRA position, please encourage them to visit the CSR Web site (http://www.csr.nih.gov) or call CSR's Human Resources Department at (301) 435-1122 for more information. NIH is an Equal Opportunity Employer.

Study Section Reorganization Update

Designing New Study Sections

CSR is in the second phase of its reorganization activities in accord with recommendations of its Panel on Scientific Boundaries for Review (PSBR). During this phase, CSR organizes Steering Committees composed of CSR staff and staff from the appropriate Institutes to solicit nominations of scientists from relevant communities to participate on Study Section Boundaries (SSB) Teams. Each SSB Team recommends guidelines for designing study sections within an Integrated Review Group (IRG) proposed by PSBR. (More information is available at http://www.csr.nih.gov/review/reorgact.htm.)

Public Comment Opportunity

Between February 2001 and April 2002, CSR convened 11 of the planned 17 SSB Team meetings. The guidelines proposed by each SSB Team will be posted on CSR's Web site (http://www.csr.nih.gov/PSBR/IRGComments.htm) for a period of 90 days to allow comment by the scientific community. We strongly encourage you to comment and to share this information with your peers.

Guidelines Currently Posted

Guidelines for four IRGs are now available for comment: (1) Oncological Sciences, (2) Digestive Sciences, (3) Immunology, and (4) Endocrinology, Metabolism, Nutrition and Reproductive Sciences. Guidelines for the Renal and Urological Sciences IRG will be available for comment soon. Beginning in July 2002, four more SSB Teams will meet to define four additional IRGs: (1) Infectious Diseases and Microbiology, (2) Pulmonary Sciences, (3) Molecular Approaches to Gene Function, and (4) Fundamental Genetics and Population Biology.

Resolution of Shared Interests

NIH staff will consider the proposed study section guidelines and the comments received from the research communities. CSR will consult with experts as necessary to clarify shared interests and make other modifications to the proposed guidelines. The Director of CSR, following presentations and discussions by the CSR Advisory Committee, will approve the final

form and substance of each study section's guidelines. The process developed by CSR to implement these recommendations is deliberately cautious and iterative in order to achieve substantial community involvement and the best possible review committees.

Additional Year of Advance Notice

New study sections will begin meeting no sooner than one year after the CSR Director approves them to ensure that applicants are fully aware of the nature of the study sections before they submit their applications, and to complete logistical arrangements.

Application Details That Matter

Principal investigators understandably focus their time and energy on writing the Research Plan for their grant applications. However, there are a number of other areas that also need attention. Failure to follow the instructions in the application kit can lead to a significant delay in the review of an application—something everyone wants to avoid. CSR's Division of Receipt and Referral has identified the following top ten areas of potential problems.

Please pay attention to the following issues in submitting your applications:

- **Version of the application kit**. Only the May 2001 (5/01) revision of the PHS 398 application kit may be used; previous versions are not acceptable for any part of the application. For fellowships, the December 1998 version of PHS 416 is still being used, but a new version is expected soon.

- **Format of the application**. The type size requirements (10 point or larger, no more than 15 characters and spaces per inch, no more than 6 lines of type per vertical inch) must be followed for all sections of the application. It is not acceptable to use smaller fonts for the Biographical Sketch, Literature Cited section, etc. Smaller fonts, however, may be used for text within a chart or table so long as it is still legible.

- **Modular Budget**. Applications for R01, R03, R15, and R21 grants that request $250,000 or less must use the modular budget format.

- **$500K Acceptance**. Unsolicited applications requesting $500,000 or more in any year must have acceptance from an Institute/Center. Staff at the appropriate Institute/Center should be contacted at least 6 weeks prior to the submission date.

- **Animal Approval**. Institutional animal care and use committee (IACUC) approval for studies involving vertebrate animals must be received prior to the review of the application.

- **Vertebrate Animals**. Applications that involve vertebrate animals need to address the five points required: detailed description of proposed use; justification of use and numbers; veterinary care; limitation of discomfort, distress, pain, injury; and method of euthanasia.

- **Human Subjects**. Applications that involve human subjects research must address the risks to the subjects, the adequacy of protection against risks, the

  potential benefits of the proposed research to the subjects and others and the importance of the knowledge to be gained, or provide a justification for an exemption with sufficient information

about the involvement of the human subjects to allow a determination by peer reviewers and NIH staff that a claimed exemption is appropriate. Applicants must also address the inclusion of appropriate representation of women, minorities, and children; data safety and monitoring plans; and plans for valid analyses of data on women and minorities in NIH defined phase III clinical trials. Additional information on these policies is available through the following Web page: http://grants.nih.gov/grants/peer/peer.htm.

- **Reference Letters**. For fellowships and many career award (K series) applications, three sealed reference letters must be included. If a revised fellowship or career award application is submitted, reference letters must be included again.

- **Career Awards**. Not all Institutes/Centers utilize every type of career award. It is important to make sure that the subject matter of an application fits an Institute/Center's portfolio for K awards.

- **Predoctoral Fellowships**. Only a few Institutes/Centers accept individual predoctoral (F31) applications. It is important to make sure that the subject of a predoctoral application fits within the mission of an Institute/Center that utilizes this type of fellowship.

The consequences of not paying attention to these requirements may be that you are asked to make a correction in a very short period of time or that your application is returned and you have to wait until the next cycle to submit. It therefore is important to read, clarify, and follow the instructions before you submit an application.

These instructions and other critical information are available on the Office of Extramural Research (OER) Web site (http://grants.nih.gov/grants/oer.htm) and CSR's Web site (http://www.csr.nih.gov). Questions may be directed to OER's Division of Extramural Outreach and Information Resources (GrantsInfo@nih.gov or 301-435-0714) and CSR's Division of Receipt and Referral (301-435-0715).

Supplying Reviewers Unassigned Applications on CDs

CSR has successfully completed a number of pilot studies where reviewers were provided CD-ROMs that contain scanned grant application images. These CDs replaced the bulky paper copies of unassigned applications usually mailed to study section members. Reviewers still received paper copies of applications/appendices that they were specifically assigned to review.

Both reviewers and NIH found significant benefits in using these CDs. CSR therefore will make them available to increasing numbers of study sections. Two IRGs with about 20 study sections used CDs for their February/March 2002 meetings. Another three IRGs will use CDs for their June/July meetings. As a result, more than 40 study sections will be using this new medium. Additional IRGs will follow as the infrastructure to produce additional CDs is put in place.

Benefits for Reviewers

More than 99 percent of the reviewers providing feedback expressed very high enthusiasm for the CDs. A major reason cited is their light weight and mobility. These reviewers reported that CDs increased

their flexibility in reading and reviewing applications because they were no longer tied to a large box of applications. About half of the reviewers indicated that they would not change the number of applications they read. Twenty percent said they might read more. A similar number, however, said that they might read fewer applications. Since these individuals only used CDs once, their views could change as they become more familiar with the medium.

Many study section members also commented on the ease of navigation between and within applications. The CDs have menus that allow reviewers to access applications by the name of the principal investigator or the number of the application. Bookmarks inserted in each application file allow users to quickly jump to the beginning of any major section. In addition, a search engine also allows users to search for keywords within one or all applications on the CD.

CDs also provide reviewers convenient access to critical documents, such as prior summary statements, reviewer guidelines, program announcements, and other important review documents.

Preparing for the Future

As part of this initiative, NIH has been scanning all applications received since January 2002. New copiers now being used capture and store images while retaining a high-speed paper copying capability. Scanning operations have thus been integrated into existing receipt operations in a very cost-efficient manner without disrupting workflow. Having electronic images of all new applications has improved internal administration and storage capabilities at NIH.

Scanning applications is an interim measure that is helping CSR prepare for handling applications received electronically. Pilot e-Grant projects are expected to begin in 2003. The experience in manipulating large electronic files has already taught valuable lessons.

Technical Challenges

The enhancement most frequently requested by those using CDs is improved graphics. The resolution of the CD images is equivalent to the black and white photocopies that have been used to distribute copies of unassigned applications. Many applications, however, now contain high quality grayscale or color images that are poorly rendered at this resolution.

Current limitations in technology prohibit CSR from offering improved graphics. Scanning applications at a high resolution would severely limit the number of applications on each CD, reduce the electronic speed of access, and slow down the scanning and CD production process. These challenges are all the more significant given the 16,000 applications CSR receives each round.

Some study section members seeking to print applications from their CDs have found that the bit-mapped files print slowly through their printer setup. All individuals who would like hardcopies mailed to them are encouraged to call their SRA's office.

New compression algorithms in the pipeline and other technological improvements will likely help NIH address these limitations in the future.

CSR Review Internship Program

CSR intends to continue its Review Internship Program in 2003. This program provides training to biomedical and behavioral scientists interested in pursuing careers in science administration or learning more about NIH. It also offers CSR flexible workload assistance and a source of trained candidates for future SRA positions.

CSR initiated a pilot test of the program with NIH intramural scientists in August 2001. A total of six individuals have been recruited into the program since. Most of the participants and CSR staff have been pleased with their experiences. One intern has already been hired as a full-time SRA, and we hope to hire more in the future.

The Review Internship Program may be expanded to include researchers from outside NIH. If this occurs, we will post a notice on our Web site and place recruitment ads in appropriate scientific journals. In any event, we expect to begin soliciting applications soon, with a submission deadline of December 1, 2002. We hope to recruit at least six qualified scientists in May 2003, with a start date of September 2003.

Program Benefits

Interns are mentored by an experienced SRA and receive hands-on experience (1) man-aging a small study section or Special Emphasis Panel, (2) recruiting scientists to serve on peer reviewer groups, (3) editing summary statements, and (4) assisting in the referral of applications to review groups. All interns participate in the 3-month SRA training program as well as in weekly question and answer sessions and other activities to learn about CSR and NIH. Interns receive 1- to 2-year appointments, full-time benefits, and salaries commensurate with experience. They are also offered opportunities to attend two scientific meetings a year. Interns appointed for a second year work more independently, and they may be offered opportunities to work at an NIH Institute or Center helping to coordinate an NIH research program.

Eligibility Requirements

Applicants must be researchers with a Ph.D. or other professional degree and have at least 4 years of postdoctoral scientific experience. Selection criteria will include the following: (1) a strong scientific background in one or more areas reviewed by CSR, (2) outstanding written and verbal communication skills, (3) strong organizational skills and the ability to work independently, (4) capability to analyze information and solve problems, and (5) ability to interact with the scientific community in identifying and recruiting reviewers.

A Model for Future Programs

The Review Internship Program currently is the only NIH program designed to assist bench scientists seeking to move into research administration. We thus hope that it may become a model for future NIH programs to increase the career options for biomedical and behavioral researchers.