PEER REVIEW NOTES
May 2001

From the CSR Director's Desk

PSBR Update

The Center for Scientific Review (CSR) is continuing Phase 2 of its reorganization activities in response to the Panel on Scientific Boundaries for Review (PSBR) Report. (http://www.csr.nih.gov/events/summary012000.htm). This phase involves the design of study sections within each of the proposed Integrated Review Groups (IRGs). A tentative schedule for the implementation of this phase can be viewed at http://www.csr.nih.gov/events/tentativesched.htm. The Phase 2 effort began with a focus on the proposed Hematology IRG. The PSBR report recommended that a Hematology IRG be established to consider applications ranging from basic through clinical studies focusing on blood cells and their diseases as well as studies on the coagulation system and its pathology. Currently, there are two hematology study sections within the Cardiovascular Sciences IRG that are more narrowly focused on both basic and applied aspects of the blood system. Basic applications in this field on clotting, proteases, and vascular biology currently are widely distributed among several other IRGs.

A Hematology Steering Committee was established, comprising CSR review and Institute program staff. This committee met several times over the past year to identify experts outside of the National Institutes of Health (NIH) to serve on the Hematology Study Section Boundaries (SSB) Team and to identify the key scientific areas that might be included in this IRG. Professional societies and organizations involved in hematological research were asked to nominate experts to serve on this SSB Team as well. The Hematology SSB team convened in February 2001. Dr. Mohandas Narla, from the Lawrence Berkeley National Laboratory at the University of California, served as Chair of the SSB Team, which included 12 other non-government experts and 5 NIH staff. Dr. Stuart Orkin, from Harvard Medical School, served as the PSBR representative on this SSB Team.

The SSB Team was charged with designing the study sections in the Hematology IRG, developing referral guidelines for its study

sections, and developing the name for the IRG.

The SSB Team's report and recommendations have now been posted on the CSR Internet site and are accessible at http://www.csr.nih.gov/psbr/irgcomments.htm. Individuals and professional organizations are encouraged to review and comment on the recommendations. After 90 days, the Hematology Steering Committee will review the comments and summarize them for the CSR Advisory Committee, which will review the final draft guidelines and make recommendations to the CSR Director in the fall (2001). Over the next year or so, CSR will implement the recommendations and establish the new Hematology IRG and its study sections.

Plans are progressing for developing the next three proposed IRGs: Muscle, Bone, Connective Tissue, and Skin; Oncological Sciences; and Biology of Development and Aging. Steering Committees have been formed and SSB Team meetings will be convened in the next few months. We encourage all investigators to periodically check the CSR homepage at http://www.csr.nih.gov/ to review the progress of this process, since developments will be posted there as we address specific scientific interests of the different IRGs that have been proposed.

Study Section Members Satisfaction Survey

The majority of the CSR reviewers participated in a voluntary survey conducted in 117 CSR study sections during the May/August 2000 round. The goal of the survey was to gain insight into the overall level of satisfaction our reviewers had during their service on study sections and special emphasis panels. In addition, the survey was designed to determine the number of applications assigned to reviewers, the length of time it took reviewers to prepare their written reviews, the usefulness of orientation materials provided reviewers, and other aspects of how well the study sections are functioning and are being provided support by CSR staff. The Executive Summary of the Report is accessible on the CSR Web site at http://www.csr.nih.gov/events.htm. A draft was provided along with a copy of the survey instrument as background information to all reviewers in the last review round.

In summary, a total of 2,808 reviewers participated in the study out of the potential pool of 2,864 reviewers. Over 90 percent of the respondents were at least "satisfied" with their service, and a majority of respondents were "very satisfied." Reviewers indicated that it takes an average of 30 hours to prepare an average of six written critiques. Reviewers spent about 8 hours serving as a reader for an average of 2.5 applications. Most respondents were willing to tolerate a wide range of demands on their time and responded that their actual workload was about what they had expected. Individuals who had previously underestimated the time they would need to spend, however, tended to be less satisfied. Respondents rated nearly all aspects of their service very highly, particularly the quality of CSR staff leadership. While there was some heterogeneity of opinions within the responses, reviewers were generally satisfied with their study section service, the orientation materials, and the performance of their study section chair and CSR staff.

Ellie Ehrenfeld, Director, CSR

New Personnel at CSR

Soon after President Bush came into office, restrictions were placed on hiring new

Federal employees. As a result, CSR has been limited in its ability to hire professional staff since January 2001, when the last issue of *Peer Review Notes* was published. We are please to report that the Administration recently lifted restrictions on hiring scientific staff, and we expect to be hiring new Scientific Review Administrators and other professionals soon. In the meantime, CSR was able to hire one individual to help us implement PSBR recommendations.

Ms. Terra Vinson has joined the CSR Office of the Director as a program analyst to help coordinate efforts to reorganize the CSR study sections. She comes to us from the U.S. Department of Education's Office of Student Financial Assistance, where she was an institutional review specialist. She holds an M.P.A. in health policy and management from the Robert F. Wagner Graduate School of Public Service at New York University.

Using Optical Scanning and CD-ROMs in Grant Review

CSR already has conducted a pilot using CD-ROMs that contain optically scanned grant applications. Special emphasis panels that review Bioengineering Partnership applications in the areas of imaging and tissue engineering were provided CDs for their last three meetings, and we are continuing this practice for their current round of meetings. Members of these study sections are highly enthusiastic and particularly pleased to do without the large box of applications they used to receive. Following this positive response, the CSR Advisory Committee expressed strong endorsement for pilot-testing similar CDs in regular study sections.

Since CSR already photocopies all applications and NIH has acquired new digital copiers, an opportunity has emerged to efficiently retain the images and create CDs with electronic application images while still allowing the option to generate paper copies. CSR therefore has joined with the electronic Review Administration (eRA) at NIH to further assess the optical scanning of grant applications. All AIDS grant applications submitted for the May 1, 2001, receipt date have been scanned using this technology. Study sections within the AIDS and Related Research (AARR) IRG will be receiving a CD containing scanned versions of all applications to be considered at their respective meetings. Certain applications will be deleted from the disks provided to individuals when a conflict is identified. As was the case with the bioengineering pilot, the CDs will replace the large books of photocopied applications that are typically mailed to reviewers. The scanned versions will have the graphic quality of a black and white paper photocopy. Assigned reviewers and discussants, however, will still receive the higher quality original paper copies submitted by the applicant. (The feasibility of generating grayscale images to better depict graphics is being investigated but the substantial increase in file size is a limiting factor). The CDs will be compatible with both PCs and Macintoshes and will not only contain the scanned applications but also the review guidelines and relevant program announcements.

The CDs autostart the Adobe Acrobat Reader that is supplied on the disk and presents a menu of options which contains a hyperlinked list of applications, guidelines, and help. The scanned images displayed will be in the "smart" Adobe portable document format (PDF), which includes both photographic images and digital text. Since optical character recognition is only 95-99 percent accurate, the digital text is hidden but cleverly linked to the image that

is viewed by the users, allowing them to search and copy sections. A set of bookmarks also allows quick navigation to the main sections of an application. Since a faithful copy of the application image is maintained in the file, it can be reliably copied, printed, or read on the screen.

CSR will continue to carefully assess the use of scanned application images in the peer review process. While there are clear benefits in paper savings, increased portability and reduced need for storage space, CSR will closely monitor the impact procedural changes have on the quality of peer review. The experience gained from this effort will be put to good use in preparing for the transition to electronically submitted applications (e-grants). While e-grants are still some time away, the scanning of applications presents an opportunity to learn how to utilize electronic applications to best benefit the peer review process. As we learn to effectively utilize scanned images of applications, expansion to further study sections will be considered.

New Fellowship Study Sections

CSR plans to review applications for individual National Research Service Awards (NRSA) in dedicated fellowship study sections beginning with the August 5, 2001, submission date. These new study sections will review the majority of fellowship applications sent to the NIH, such as applications for predoctoral (F30 and F31) awards, postdoctoral (F32) awards, and senior (F33) fellowships. This change, however, will not affect fellowship applications reviewed by a specific Institute or Center.

CSR has piloted several approaches to reviewing F32 fellowship applications. In 1994, we discontinued the required review of fellowships in dedicated fellowship study sections and began assigning many of these applications on the basis of scientific topic to study sections that also reviewed regular research grants. This practice resulted in fellowships being reviewed in several different formats, including R01 study sections, ad hoc groups, and a few remaining fellowship study sections. In 1999, the inconsistencies in review and scoring of these applications prompted Dr. Ellie Ehrenfeld, Director of CSR, to appoint Dr. Maxine L. Linial of the Fred Hutchinson Cancer Research Center to study the situation in detail and to recommend the best practice for fellowship review. After careful consideration and discussion of her analysis, the CSR Advisory Committee approved a plan to resume the practice of using dedicated study sections to review fellowship applications, except those in the areas of behavioral and social sciences and AIDS-related research. This plan is scheduled to be implemented in August 2001. We will consider applying this practice to all study sections in the future.

No Other Changes Planned

It is important to note that the review criteria for fellowship applications will not be altered, and beyond creating new fellowship study sections, no other aspect of the application and review process will be changed. As in the past, applicants should refer to the appropriate NRSA program announcement (http://grants.nih.gov/training/ nrsa.htm) and the PHS 416-1 application instructions (http://grants.nih.gov/grants/funding/ 416/phs416.htm) for eligibility and application requirements and other special features of the individual fellowship programs. Applicants can gain further guidance by examining the current review criteria for the specific fellowships they are

seeking (http://www.csr.nih.gov/guidelines/guidelines.htm). CSR will continue to review fellowship applications in three review cycles, with submission dates of April 5, August 5, and December 5 of each year. After receiving an application, CSR will assign it to one of the new fellowship study sections and inform the applicant by mail of the assignment. There is only one exception. The NRSA Individual Predoctoral (F31) Fellowships for Minority Students and Students with Disabilities will continue to have submission dates of May 1 and November 15. These applications will be reviewed in special emphasis panels and not in the new fellowship study sections. Any questions regarding assignments should be directed to the Division of Receipt and Referral at (301) 435-0715. These and all other questions pertaining to the review process may also be directed to the Scientific Review Administrator (SRA) responsible for the appropriate study section. A list of the SRAs and the meeting dates for the fellowship study sections will be available in the near future at http://www.csr.nih.gov/committees/rosterindex.asp.

The New Fellowship Study Sections

Number	*Name*
ZRG1 F01	Brain Disorders and Clinical Neuroscience
ZRG1 F02A	Integrative, Functional and Cognitive Neuroscience A
ZRG1 F02B	Integrative, Functional and Cognitive Neuroscience B
ZRG1 F03A	Molecular, Cellular and Developmental Neuroscience A
ZRG1 F03B	Molecular, Cellular and Developmental Neuroscience B
ZRG1 F04	Biochemistry, Biophysics and Chemistry
ZRG1 F05	Cell and Developmental Biology
ZRG1 F06	Endocrinology, Embryology and Reproductive Sciences
ZRG1 F07	Immunology
ZRG1 F08	Prokaryotic and Eukaryotic Molecular Biology and Genetics
ZRG1 F09	Oncological Sciences
ZRG1 F10	Basic and Clinical Aspects of Respiratory, Cardiovascular, Digestive and Renal Systems

Update on Review Policy and Procedures

Reviewer Use of Applicant Web Sites

Applications submitted to NIH often include the applicant's Web site address with the suggestion that readers may view additional information at that site. Applicants, however, are told that they must include all key information into the body of the application and not rely on appendices or Internet URLs to convey additional information.

The following statement on "URLs in NIH Applications" was released on 11/30/1999 for publication in the *NIH Guide*:

"All applications and proposals for NIH funding must be self contained within specified page limitations. Unless otherwise specified in the NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site." (http://grants.nih.gov/grants/guide/notice-files/not-od-00-004.html)

Assignment of the Applications of Study Section Members

Applications sent to NIH by an investigator (or the investigator's spouse, parent, or child) who is a member of a Scientific Review Group (SRG) cannot be reviewed by that SRG. The application must be assigned to another SRG or reviewed in a Special Emphasis Panel.

The Code of Federal Regulations 42 CFR Ch. 1, 52h.5 Conflict of Interest (10-1-97 Edition) states that "(1) No member of a peer review group may participate in or be present during any review by said group of a grant application, contract project, or contract proposal in which, to the member's knowledge, any of the following has a financial interest: (i) The member or his or her spouse, parent, child, or partner, (ii) any organization in which the member or his or her spouse, parent, child, or partner is serving as an officer, director, trustee, partner, or employee, or is otherwise similarly associated, or (iii) any organization with which the member or his or her spouse, parent, child, or partner is negotiating or has any arrangement concerning prospective employment or other similar association. (2) In the event any member of a peer review group or his or her spouse, parent, child, or partner is currently or expected to be the principal investigator or member of the staff responsible for carrying out any research or development activities contemplated as part of a grant application, contract project, or contract proposal, that group is disqualified and the review will be conducted by another group with the expertise to do so. If there is no other group with the requisite expertise, the review will be conducted by an ad hoc group no more than 50 percent of whose members may be from the disqualified group...."

Listing of Mail Reviewers on SRG Rosters

Sometimes an SRA will need to request specific expertise to review a portion of an application because that expertise is not on the SRG. The SRA may ask an expert who is not a committee member to write a "mail review." Persons who write such reviews must be listed on the roster, which is the legal documentation of the experts who have contributed to the evaluation of the applications under discussion at the meeting and who have had access to confidential material.

Application Format — Update

In January 2001, NIH published a reminder regarding the format of grant and cooperative agreement applications. Of the approximately 14,000 applications processed in the following 3 months, 200 were found to be out of compliance with the format requirements and had to be returned for submission in the next review cycle. NIH will continue to screen applications for obvious problems with the required format. Beginning in May 2001, however, a greater effort will be made to help applicants quickly address format problems. When noncompliant applications are identified, the investigators will be contacted and given 4 business days to fix the problem. If the application cannot be fixed in that time period, there may be delays in review. This spot-checking will not necessarily identify all applications with format compliance problems. If reviewers or other NIH staff identify noncompliant applications later in the process, they may still be returned or deferred at that time.

Further information, including the format requirements for applications, is found in the *NIH Guide* announcement of May 4, 2001: http://grants.nih.gov/grants/guide/notice-files/not-od-01-037.html. This

announcement includes a link to Frequently Asked Questions about format compliance (http://www.format.nih.gov/FAQ/FAQ.htm). A special e-mail box has been set up for questions about application format: format@mail.nih.gov.

Handling of Human and Animal Subjects in Grant Applications

When grant applications call for the use of human subjects, reviewers are responsible for providing an independent evaluation of the research and must address in their reviews whether the use of human subjects is appropriate and comment on the plan to include men, women, minorities, and children. Applications that include clinical trials must have a data and safety-monitoring plan, which the reviewers should also evaluate. When animal subjects are involved, reviewers are likewise responsible for providing an independent evaluation of the research and assessing the appropriateness of the research and any risk involved. In both cases, when an exemption is cited by the applicant, the reviewers should determine if the exemption is justified.

Additional information on preparing applications involving human subjects can be found in the "NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects in Grant and Cooperative Agreement Applications." (http://grants.nih.gov/grants/peer/hs_review_inst.pdf)To view or print this document, you will need to use the Adobe Acrobat Reader software, which can be downloaded free of charge from http://www.adobe.com/.

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Employment Opportunities

Center for Scientific Review
National Institutes of Health

NIH Health Scientist Administrators

The Center for Scientific Review (CSR) at the National Institutes of Health (NIH) seeks to identify highly qualified research scientists who are interested in serving as Scientific Review Administrators for NIH study sections. They should have broad scientific knowledge of, and a history of proven independent research experience in, one of the following areas: AIDS research, behavioral science, bioanalytical chemistry, biochemistry, bioengineering, bioinfomatics, biophysics, biostatistics and/or research design, cancer research, cell biology, epidemiology of aging, immunology, instrumentation, microbiology, neuroscience (visual perception), neurodegeneration, proteomics, psychopathology, social sciences, or structural genomics.

Applicants should be highly motivated individuals with excellent judgment and highly developed communication, analytic, interpersonal, organizational and writing skills. These individuals will shape the future of scientific review.

Scientific Review Administrators are responsible for understanding the current state and identifying future directions of a specific area of biomedical and behavioral science; selecting members of review panels; managing study section meetings; facilitating interactions with study section members and communicating the results of their deliberations and recommendations to applicants and the staff of the NIH institutes that fund the research.

Applicants must have a Ph.D. or equivalent degree (or have equivalent training and experience), postdoctoral research training, a significant record of independent research accomplishment, and administrative experience. Salary will depend on experience and accomplishments. A recruitment or relocation bonus may be available.

Please send your curriculum vitae to:

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or

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