PEER REVIEW NOTES
January 2001

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From the CSR Director's Desk

During the past four months, the Center for Scientific Review (CSR) has continued its activities toward restructuring study sections to better meet new and exciting scientific opportunities. Since beginning the reorganization of peer review within CSR, we have laid the groundwork to assess the outcome of this process. These efforts began with the reorganization of neuroscience review committees into three Integrated Review Groups (IRGs) in 1998, after the former Alcohol, Drug Abuse and Mental Health Agency (ADAMHA) institutes were integrated into the National Institutes of Health (NIH). CSR will conduct a survey of approximately 3,000 principal investigators who submitted applications to neuroscience study sections for two rounds of peer review in fiscal year (FY) 2000. In the next few months, questionnaires will be given to researchers who submitted applications to NIH between October 1, 1999 and March 1, 2000 that were reviewed in one of the three CSR Neuroscience IRGs. We hope the results from this survey will provide useful information on the reorganization of CSR neuroscience study sections and help CSR ensure that peer review of neuroscience applications continues to identify the most promising and significant scientific opportunities. Approximately one year after launching this survey, CSR plans to distribute a similar survey to applicants in the area of behavioral and social sciences research.

Additional information on CSR reorganization activities is available through the CSR Web site (http://www.csr.nih.gov/events.htm).

Pluripotent Stem Cell Review Group

An important new scientific opportunity is research involving human pluripotent stem cells. NIH recently established, as a working group of the CSR Advisory Committee, the Human Pluripotent Stem Cell Review Group (HPSCRG). The mission of the HPSCRG is to ensure compliance of all NIH-sponsored research with recently published guidelines on the derivation of human pluripotent stem cell lines (http://

grants.nih.gov/grants/guide/notice-files/NOT-OD-01-003.html). The Chair of the new Review Group is Dr. James Kushner, a CSR Advisory Committee member who is Chief of the Division of Hematology and Director of the General Clinical Research Center at the University of Utah School of Medicine. We anticipate the first meeting of the HPSCRG in Spring 2001.

SRA Internship Program

A key component of CSR's strategy to continue to improve the quality of peer review is recruiting Scientific Review Administrators (SRAs) of the highest caliber. To assist in these efforts, we are establishing an internship program designed to provide scientists with the opportunity to train and try scientific research administration as a career. We will initially pilot this program with intramural researchers from NIH. If the program is as successful as we hope, we will consider broadening it to enroll participants from academic institutions and industry. We hope this program will be mutually beneficial, allowing researchers the opportunity to become more familiar with the peer review process and learn first-hand about the preparation and review of grant applications. Similarly, CSR will gain from this experience by adding to our staff a new pool of researchers with state-of-the-science knowledge and cutting-edge skills. In the meantime, we have continued to hire a number of outstanding permanent SRAs to further strengthen CSR's efforts to fulfill its challenging responsibilities.

Improving IRG Referrals

CSR recently completed its revision of its IRG referral guidelines. These will be accessible shortly on the CSR Web site. In addition, study section and special emphasis panel rosters are available on the CSR Web site 28 days prior to the actual meeting dates. Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) rosters also are available. Hyperlinks from this Web page (http://www.csr.nih.gov/Committees/meetings/ssmeet1.asp) will permit applicants to view the membership of the study sections and special emphasis panels, learn the date of the review meeting, and gain a better understanding of the scientific emphasis for each group. This information is designed to help applicants identify and request the assignment of their application to a specific review group.

Budget Update

The FY 2001 Revised Conference Budget for NIH is $20.3 billion, which is an approximate $2.5 billion (14 percent) increase over the $17.8 billion that was appropriated for NIH in FY 2000. President Bush and the Department of Health and Human Services Secretary Tommy G. Thompson both have expressed their support for continuation of congressional efforts to double the NIH budget over five years. This year's increase represents the third installment toward achieving this goal. Although CSR received its FY 2001 budget allocation quite late, we believe that we

have received adequate funds to support our ongoing and planned initiatives designed to improve NIH peer review.

New Personnel at CSR

The following professional staff members have joined CSR since the September 2000 issue of Peer Review Notes.

Dr. Noni Husain Byrnes is the new SRA of the Bioanalytical Engineering and Chemistry Special Emphasis Panel in the Biophysical and Chemical Sciences IRG. Dr. Byrnes received her Ph.D. in Analytical Chemistry from Emory University. She previously was a research scientist at Procter and Gamble Pharmaceuticals.

Dr. Cathleen Cooper has become the SRA of the Experimental Immunology Study Section and the Bridges to the Future Special Emphasis Panel within the Immunological Sciences IRG. Dr. Cooper holds a Ph.D. in Pathology from the University of Southern California. She previously was an Assistant Professor of Cell Biology at the University of Massachusetts in Worcester.

Dr. Ernestine Johnson has joined the CSR Office of Planning, Analysis, and Evaluation as a Health Scientist Administrator—Special Project Liaison. Before coming to CSR, she was the Program Administrator for the Pediatric AIDS Clinical Trials Groups for the Division of AIDS of the National Institute of Allergy and Infectious Diseases. Dr. Johnson holds a Ph.D. in International Studies from Howard University.

Mr. Don Luckett is the new CSR Information Officer and a Senior Program Analyst in the CSR Office of Planning, Analysis and Evaluation. He comes to us from the Office of AIDS Research, Office of the NIH Director, where he was a Program Analyst in its Therapeutics Section.

Dr. Peter Lyster has just joined CSR as the SRA for the Special Reviews (SSS-E) Study Section that reviews applications for Planning Grants for the National Programs of Excellence in Biomedical Computing. Dr. Lyster earned his Ph.D. in Plasma Physics from Cornell University. He previously was a Research Scientist at the University of Maryland Earth System Science Interdisciplinary Center.

Dr. Eduardo Montalvo has become the new SRA for the AIDS-Related Research (AARR-4) Study Section, and he also will coordinate the review of AIDS-related SBIR applications. Dr. Montalvo's Ph.D. is in Microbiology from the University of Texas Health Science Center in San Antonio. He previously was an Assistant Professor at the University of Texas Health Science Center.

Dr. Janet Nelson is the new SRA of the Special Reviews (SSS-L) Study Section, which reviews SBIR applications in the Biophysical and Chemical Sciences IRG. Dr. Nelson received her Ph.D. in Chemistry from the California Institute of Technology in

Pasadena. She comes to us from the American Chemical Society, where she was a Program Officer at the Petroleum Research Fund.

Ms. Anne Phillips has joined the CSR Planning, Analysis, and Evaluation Office as a Senior Program Analyst to coordinate the redesign of the CSR Web site. She was previously a Program Analyst at the National Institute of Mental Health Office of Science Policy and Program Planning. Ms. Phillips has a J.D. from the Howard University School of Law and a M.L.S. in human-computer interactions from the University of Maryland.

Dr. Clare Schmitt is the new SRA of the Special Reviews (SSS-K) Study Section that reviews SBIR grant applications for the Infectious Diseases and Microbiology IRG. Dr. Schmitt holds a Ph.D. in Microbiology from the University of Texas at Austin. She previously was a Research Assistant Professor at the Uniform Services University of the Health Sciences in Bethesda, Maryland.

Dr. Elaine Sierra-Rivera is now the SRA for the new Pathology C Study Section in the Oncological Sciences IRG. Dr. Sierra- Rivera earned her Ph.D. in Radiation Biology (Cell and Cancer Biology) at the University of Iowa. Before coming to CSR, she was an Assistant Professor in the Department of Radiation Oncology at the Vanderbilt University School of Medicine.

Update on Panel on Scientific Boundaries for Review Efforts

CSR has advanced in the second phase of the Panel on Scientific Boundaries for Review (PSBR) activity. This phase involves the design of study sections within each IRG proposed in the Phase 1 report. The Phase 2 process involves forming Steering Committees for each IRG or group of IRGs. CSR and other NIH Institute and Center program staff will serve on the Steering Committees. A primary responsibility of these committees will be to create the Study Section Boundaries (SSB) Teams. SSB Teams will determine the scientific boundaries for study sections to be established within each of the proposed IRGs.

Phase 2 PSBR activities began with a focus on the proposed Hematology IRG. Currently, there are two Hematology study sections within the Cardiovascular Sciences IRG that each reviews approximately 80 applications per round. Basic applications in this field on clotting, proteases, and vascular biology currently are widely distributed through other IRGs. 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.

The Hematology Steering Committee, chaired by Dr. Michael Martin, comprises CSR review and IC program staff. This Steering Committee met several times over the past year to identify experts outside of the NIH to serve on the Hematology SSB Team and to identify the key scientific areas that will be included in this IRG. The

Hematology SSB team will convene in February. Dr. Mohandas Narla, from the Lawrence Berkeley National Laboratory at the University of California, will serve as the Chair of the SSB Team that will include 12 other non-government experts and 5 NIH staff. Dr. Stuart Orkin serves as the PSBR representative on this SSB Team.

The SSB Team will be charged with designing the study sections in the Hematology IRG, developing referral guidelines for these study sections, and developing the name for the IRG. The SSB Team will use the abstracts from the Spring 2000 Mock Referral to develop its proposals. The tentative schedule is for the recommendations of the SSB Team to be posted in Spring 2001 on the CSR Web site for public comment. The final adjustments and recommendations will be provided to the CSR Advisory Committee, PSBR, and then to the CSR Director in Fall 2001. During Winter/Spring 2002, SRAs will be identified and reviewers recruited for each study section so that they can convene in Summer 2002.

Plans for developing the next three proposed IRGs (Muscle, Bone, Connective Tissue, and Skin; Oncological Sciences; and Biology of Development and Aging) are progressing so that these meetings will be convened in the next few months. As with the Hematology IRG, the first stage of this process will be to convene the Steering Committees.

Additional information on PSBR activities is available from the CSR Web site (http://www.csr.nih.gov/events.htm).

How Are New Investigators Doing?

The R29 First Independent Research and Transition (FIRST) mechanism for new investigators was introduced about 15 years ago as a way to provide new investigators a stepping-stone to stable funding from NIH. The idea was that these applications would be viewed differently from the R01 applications, with less emphasis on preliminary data and an appreciation of the unique situation for one who is just initiating a research program. Further, they were to provide five-year funding to allow sufficient time for new investigators to establish their research programs.

After the R29 program was in place for several years, there were indications that the program was in trouble. NIH established a working group in 1996 to evaluate the R29 mechanism and make recommendations. This group included extramural experts and was co-chaired by Drs. Marvin Cassman (Director, National Institute of General Medical Sciences) and Ellie Ehrenfeld (Director, CSR). The Working Group found that the majority of new investigators chose to apply for funding through an R01 grant rather than the R29 mechanism. While the R29 mechanism appeared to offer a better chance of initial funding (with a success rate in FY 1998 of 25 percent compared to 22 percent for R01 applications from new investigators), it was found that the R29 investigators on average competed less successfully when submitting subsequent R01 applications than investigators who had begun their support with an

R01. Finally, the R29 mechanism provided lower levels of funding than R01s. The Working Group concluded that the level of support provided by the R29 mechanism was in some cases inadequate, and that this could compromise the research, resulting in insufficient progress to merit continued funding.

Based on the Working Group's Report, NIH discontinued the R29 mechanism in June 1998, and it directed all new investigators to apply for research support through the traditional R01 mechanism. (For information on this policy change, see http://grants.nih.gov/grants/policy/r29transition.htm.) The elimination of the R29 mechanism did not mean that NIH had reduced its commitment to supporting new investigators. NIH has and continues to demonstrate a serious commitment to maintain the proportion of new investigators and to increase the level of funding for these researchers. This commitment includes several specific efforts including routinely alerting study section reviewers which applications have been submitted by new investigators. The face page of the application was changed to include a box specifically identifying a new investigator. For a year after the elimination of the R29 mechanism, NIH provided a list of potential new investigators to SRAs and reviewers. This list was prepared by conducting a search of all applicants' prior NIH funding. This additional step was another way to "flag" applications from new investigators for reviewers. NIH also encouraged new applicants to describe their level of experience in the text of their application. Additionally, reviewers are requested to note during the study section meeting whether an applicant is a new investigator.

Since the elimination of the R29 mechanism has budgetary implications, i.e., average costs of an R01 are higher than those for an R29, this means that the overall NIH investment of dollars for new investigators has increased. Thus, the evaluation of the effects of this policy change has included tracking changes in the number of applications submitted by new investigators as well as the overall funding level for these applications.

Several factors complicate an evaluation of the impact that changing the funding mechanisms has for new investigators. First, it has been a relatively short period of time since the R29 mechanism was discontinued in June 1998. Second, the definition of who is a "new investigator" is not straightforward. The R29 mechanism defined a new investigator as one who is independent of a mentor and yet at the beginning stages of his or her research career. Eligible applicants could not have had more than five years of research experience since completing their postdoctoral research training or its equivalent. R29 applicants also could not have served as the principal investigator on most Public Health Service (PHS)-supported research projects with the exception of Ks, R03, R15, and R21 awards. To restrict the search of R01 grants awarded to a similar group after the change in policy, only those applicants who did not have an NIH research project grant (which includes the following mechanisms: R01, R03, R15, R21, R22, R23, R29, R35, R37, P01, P42, U01, and U19) were included. It was not possible to screen the data for the length of time since the individual completed his/her postdoctoral training.

The data generated by NIH's Office of Extramural Research indicates that the number of new investigators and the amount of NIH funds supporting them have increased over time. As seen in the table below, both the number and amount of awards made to new investigators increased between FY 1995 and 1999. The latter FY represents the first year after elimination of the R29 mechanism.

Awards (R01 and R29) Made to New Investigators* FY 1995-1999

FY	Awards	Amount
1995	1,413	$228,523,620
1996	1,371	243,176,293
1997	1,503	259,740,459
1998	1,500	283,779,954
1999	1,623	387,582,340

* A new investigator is one who has never received a prior research project grant.

The success rates for new investigators have remained fairly stable as shown by the table below, which provides success rates for original and amended applications during the transition years immediately before and after the elimination of the R29 mechanism.

Success Rates for R01 Applications from New Investigators FY 1998-1999

FY	Application Status	Success Rates (%)
1998	Original	18
	A1	32
	A2	38
1999	Original	19
	A1	33
	A2	40

A concern often expressed by reviewers as well as applicants is that the process of streamlining during the review meeting has a greater impact on new investigators than on previously funded researchers. It is often stated that new investigators whose grants are "unscored" are very discouraged and are less likely than previously funded investigators to submit an amended application. The available

data do not support this point of view. From FY 1995 to 1998, there is a higher proportion of both new investigators and previously supported investigators with scored (yet unfunded) applications that resubmit than those with unscored applications. For investigators with unscored applications, the rate of resubmissions does not differ between new investigators and previously funded investigators. Thus, the streamlining procedure does not seem to discourage new investigators differentially from previously funded investigators.

NIH places a high priority on supporting new researchers. The number of awards and the level of funding provided to first-time investigators will continue to be monitored closely. NIH believes this is critically important and encourages reviewers to pay careful attention to those applications from new investigators, who are, after all, the next generation of scientists.

Format Reminder For Grant Applications

The majority of grant applications submitted to the NIH follow the established requirements for type size, page limits, margins, and other format specifications. Applicants certainly know it is in their best interests to submit applications that are clear and easy to read, allowing reviewers to concentrate on the evaluation of the scientific merit of the application.

However, there have been complaints from reviewers and SRAs that the number of applications that do not follow the format specifications has been increasing. Therefore, NIH has recently published a reminder about format requirements in the NIH Guide to Grants and Contracts (Format of Grant and Cooperative Agreement Applications Submitted to NIH: (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-012.html). Applications that do not follow the requirements are subject to return and may not be submitted in a correct format until the next receipt cycle. In addition, a study section may defer applications that are not in appropriate format and require the investigator to submit a corrected version for the next review meeting.

The expectation is that this announcement will serve to remind both investigators and Offices of Sponsored Research at institutions of the format requirements and the importance of submitting applications that follow these specifications. To provide assistance in understanding and meeting these requirements, a special Web site has been developed with the announcement and frequently asked questions (http://www.format.nih.gov). In addition, a dedicated e-mail address has been established for questions about format specifications (format@mail.nih.gov); questions are normally answered the day they are sent. The central e-mail address for other grant application questions remains the same: grantsinfo@nih.gov.

The scale of the effort of the peer review process (over 46,000 applications were considered in FY 2000) requires that certain standards be established for application format. The cooperation of investigators and institutions in following these standards will help NIH achieve the goal of identifying and supporting the best possible

biomedical and behavioral research.