NIH PEER REVIEW NOTES

October 1997

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FROM THE CSR DIRECTOR'S DESK

The introduction of the concept of peer review was a powerful and innovative event for our research enterprise. Having benefited from refinements over its distinguished 50-year history, the NIH peer review system remains the cornerstone of its extramural programs and has generally been looked upon as a model by organizations worldwide. The need to examine the peer review system as performed by the Center for Scientific Review (CSR, formerly the Division of Research Grants-see article below) is particularly important at this time, as the way in which science is practiced continues to change rapidly. Increasingly, researchers are addressing complex problems that require multidisciplinary, multiexperimental approaches to move the field forward.

As I engage in outreach efforts to the extramural community, with diverse groups within and external to NIH, I continue to hear a set of consistent questions that center on issues related to the organization and composition of our study sections: Is the most productive, highest impact work going to too few study sections, causing much of "the best science" to compete with itself? Are some study sections reviewing applications in fields that are no longer active, causing an undeserved "entitlement"? Are newly emerging fields generally at a disadvantage when they are evaluated by preexisting review panels? Is there the optimum balance between the breadth needed to judge the importance and potential impact of a research proposal and the depth required to assess technical expertise in multiple disciplines? Are we

able to recruit the best reviewers, including those with vision and a broad overview, as well as those with knowledge in specific subspecialties? Are segments of the research community, such as clinical researchers, behavioral scientists, developers of technology and instrumentation, and those conducting interdisciplinary studies, not receiving appropriate consideration by the existing system?

To answer these questions and to redress any deficiencies that may be uncovered will require an analysis of the optimal way in which to organize, constitute, and direct review groups. Therefore, I have asked Linda Engel, Associate Director for Planning and Outreach, to assemble a Panel on Scientific Boundaries for Review. This blue-ribbon panel will be composed of approximately a dozen members with scientific stature in diverse fields. They will apply their broad vision to consider the above questions and other issues that cover the full range of research from basic, disease-oriented, translational and patient-oriented research, through research to develop infrastructure and technology. Their focus will extend across cellular and molecular, physiological systems-based, behavioral, and population-based studies.

As the first step in a multi-step process, the Panel will be asked to consider whether reorganization of the study sections is needed, and if so, to recommend a strategy by which the breadth of disciplines supported by the NIH could be reconstituted into newly defined, intellectually defensible scientific domains. These recommendations may serve, in turn, as the basis of a subsequent effort to reorganize scientific review groups (SRGs, the formal designation for study sections) and their subsequent arrangement within integrated review groups (IRGs). We have learned many useful lessons from the recent reorganization of neuroscience review resulting from the integration of the National Institute of Mental Health, the National Institute on Drug Abuse, and the National Institute on Alcohol Abuse and Alcoholism into NIH. We are hoping that the Panel will start its work by late fall, and that this major assessment of the system can be accomplished within 18 months.

Continued dialogue with the outside community and with staff in the NIH Institutes is critical to the success of this activity. Thus, there will be extensive opportunities for all concerned parties to provide input to the process. Together we can improve the CSR peer review system by optimizing our ability to identify the science that promises to have the greatest impact in this time of exceptional opportunity.

Ellie



DRG IS NOW THE CENTER FOR SCIENTIFIC REVIEW

The Division of Research Grants (DRG) has been renamed the Center for Scientific Review (CSR). The name change highlights the fact that the Center is the focal point at NIH for the conduct of peer review

and, thus, more accurately reflects the mission of the organization. The establishment of a Center is designed to signal a broadening of the mission to include a new emphasis on the development and implementation of innovative and flexible ways to conduct referral and review for all aspects of science.

As part of a concurrent restructuring, the referral and review functions of the Center have been reorganized into three review divisions and the Division of Receipt and Referral, the latter under the direction of Dr. Suzanne Fisher. The three review divisions, which encompass broad areas of research, are the Divisions of Molecular and Cellular Mechanisms, Physiological Systems, and Clinical and Population-Based Studies. The three divisions are headed by Drs. Elliot Postow, Donna Dean, and Jean Paddock, respectively. The role of the division directors is to promote and ensure the able functioning of the Integrated Review Groups (IRGs) within their divisions, to oversee consistency in implementation of policy, and to develop and implement new initiatives that will improve the review system and accommodate changing scientific directions and priorities.

Each review division has between five and seven IRGs. The IRGs consist of small clusters (averaging six) of the approximately 100 study sections in CSR. Each IRG is headed by a chief who is responsible for managing and directing the review process within the IRG, while continuing to serve as a Scientific Review Administrator (SRA) of a study section. More information on the IRGs and their component study sections can be found on the CSR/DRG home page at http://www.drg.nih.gov/review/irgdesc.htm.



NIH ADOPTS EXPLICIT STATEMENTS OF REVIEW CRITERIA

Five explicit review criteria will be used to structure scientific peer reviewers' written critiques and discussions of unsolicited research project grant applications beginning with applications submitted on or after October 1, 1997. Scientific Review Administrators will orient chairpersons and reviewers during the fall 1997 to the new review guidelines in preparation for subsequent implementation at the next round of review panel meetings.

For the February/ March 1998 meetings, reviewers will be asked to assess **significance**, **approach**, **innovation**, **investigator**, and **environment** as separate elements in their critiques. In recommending an overall level of merit, reviewers are to weight the above criteria as they deem appropriate for each application. An application need not be strong in all categories to be judged likely to have a major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward. The intent of the new criteria is to refocus the review of grant applications on the quality of the science and the overall impact of the research, rather than solely on the details of the technique and the methodology.

The use of the five criteria will be monitored and reviewed after approximately one year, at which time any necessary modifications will be considered. The opinions of reviewers, applicants, and NIH staff will be solicited, and debate and discussion will be welcomed. Additional information on the review criteria can be found on the World Wide Web under the NIH Office of Extramural Research's Grants/Peer Review home page (http://www.nih.gov/grants/peer/peer.htm) and in the June 1997 issue of *NIH Peer Review Notes* in the article *Peer Review Oversight Group (PROG) May 1997 Meeting*.



AREA (R15) PROGRAM UPDATE

Since 1985, Congress has included funds in the NIH budget to stimulate research in educational institutions that provide baccalaureate training for a significant number of our Nation's research scientists but that have not been major recipients of NIH support. NIH has implemented this initiative through the Academic Research Enhancement Award (AREA) program. AREA grants are intended to support health-related research projects conducted by faculty in institutions that are not research intensive.

In 1997, the NIH made several significant changes in the AREA program, both philosophical and procedural. These changes will be in effect for applications reviewed during the fall 1997 review meetings. An important philosophical change is that the AREA grant is no longer regarded as simply a stepping stone for an investigator to move on to a "traditional" NIH grant mechanism. In recognition of the nonresearch-intensive environment and teaching loads under which investigators at AREA-eligible schools work, AREA grants are now seen as a legitimate end in themselves for the conduct of meritorious research, albeit small-scale. Thus, the three objectives now established for the program are: (1) Strengthening the research environment at institutions that are not research intensive; (2) Exposing students at such institutions to research; and (3) Providing support for meritorious research.

The procedural changes are several. Applications will now be accepted in response to ongoing Program Guidelines with three receipt dates a year (January 25, May 25, and September 25). (Note: AREA applications on AIDS-related research should be submitted on May 1, September 1, and January 2.) Principal investigators can submit competing continuation (type 2, renewal) applications to continue projects beyond the initial award period. For all AREA applications, appendix material may be included, following the instructions in the PHS 398. "On time" procedures will pertain to application information on the budget and Other Support (i.e., certain information is requested only if needed after scientific merit review and before an award).

An important procedural change for applicants and for reviewers is the additional information required

in the application, which must be evaluated by reviewers. This information concerns the institution's appropriateness for an AREA, its student profile, the support it will provide for the project, and the investigator's experience supervising students in research.

AREA applications are typically reviewed by chartered scientific review groups or special emphasis panels that have a "critical mass" of AREA applications. Scientific Review Administrators are encouraged to recruit reviewers from AREA-eligible schools and/or reviewers who are sensitive to the goals of the AREA program. Streamlined review procedures (designation and discussion of only the top half of the applications) are now used for AREA applications, but they are not percentiled. The new review guidelines for AREA applications now include, as part of the CRITIQUE, an assessment of the impact of an AREA on the institution. Because most AREA grants are made from the Congressionally mandated set aside funds, these applications do not compete with other research project grant applications (i. e., R01, R03, R21, R29, P01, etc.) for the "same pot of money," although Institutes can make additional AREA grants from their own non-set-aside funds. A central office at NIH works with the individual Institutes in facilitating the awarding of AREA grants.



MODULAR RESEARCH GRANTS AND "ON TIME" APPLICATIONS PROPOSED

The Modular Research Grant proposal, one of four ongoing NIH reinvention initiatives, has two major objectives: to offer investigators and institutions procedures for requesting project support to facilitate science and simplify administration; and to allow NIH extramural staff to focus their professional expertise on essential scientific and financial management matters in making awards. The two components to this initiative, either one of which or both of which could be implemented, are: (1) Modular Research Grant procedures; and (2) "On Time" procedures.

Broadly sketched, the Modular Research Grant component would allow investigators to request research project grant support in first-year, total-direct-cost amounts of \$50,000, \$75,000, \$100,000, \$125,000, or \$150,000. Although budgetary detail would be eliminated from the application, a narrative justification of personnel and unusual costs would be required. Reviewers would recommend budget modifications in \$25,000 modules, and Institute staff would make any final adjustments either in \$25,000 modules or possibly according to specific Institute needs and requirements. The amount awarded in the first year would be the same for all years of the grant, although after the first year the budget could be increased by increments of \$25,000 to accommodate planned changes in project activities. Applicants requesting amounts between \$150,000 and \$500,000 would provide only the total amount for each budget category, rather than a detailed budget, as is currently done. There would be no change in the procedures for applying for the institutional rates for Facilities and Administrative costs (formerly, indirect costs).

The "On Time" component refers to procedures by which applicants would provide further budget detail and updated information on Other Support, if requested, in time to make the award. This request would be made only from the 25 to 30 percent of applicants for whom an award would be likely as indicated by the results of the initial scientific review. As currently proposed, the "On Time" component could apply to applications requesting either a modular amount or between \$150,000 and \$500,000 in first-year, total-direct costs.

Since the late spring, there has been a series of discussions of the proposal with several national advisory councils; the trans-NIH functional committees concerned with extramural program management, review policy, program issues, and grants management; the DHHS Office of Grant and Contract Policy; the Federal Demonstration Partnership; the Society of Research Administrators; the Association of American Medical Colleges; and the National Council of University Research Administrators. There are plans to present it to Scientific Review Group (SRG) members, at a meeting on October 9, the Council on Government Relations, the Federation of Associations and Societies of Experimental Biology, the Association of Independent Research Institutes, and other professional groups and representatives of the scientific community. The proposal was one of four principal agenda items at the Reinvention Roundtable II meeting held September 30, 1997 at NIH and chaired by the Director of NIH.

A description of the proposal, in a slide-show format, is available through NIH's home page (http://www.nih.gov/grants/reinvention/modular/modular.htm) with an E-mail address for comments (MRGrants@od.nih.gov). The deadline for responses has been extended to the end of October. Following the discussion period, senior NIH staff will determine the feasibility of the concept and its possible implementation.

The 15 or so substantive comments that have been received via the E-mail address are from persons at institutions throughout the U.S., with some of the respondents indicating that they were currently or had been SRG members. The comments make many of the same points heard in the various "live" discussions on the proposal.

The majority of the comments endorsed the idea enthusiastically, questioning the value of time currently spent on the budget, not only in the review process, but also in the application process. A couple of the comments doubted that there would be much in the way of time or labor savings, and argued the need for reviewers to have detailed cost information. One comment suggested extending the cap to \$200,000 because \$150,000 is below the mean and is sure to rise.

As mentioned earlier, comments on the two aspects of the proposal (modular research grants and "on time" procedures) are still being sought through the end of October, so share your thoughts with NIH at: MRGrants@od.nih.gov.



CSR TRAVELERS' RECEIPTS

With the Federal Travel Regulations Amendment No. 50, dated October 28, 1996, for CSR reviewers and consultants:

(1) Receipts are now required for the following regardless of the amount:

Transportation (air, train)

Lodgings

Shipping (this includes reviewers mailing applications to meetings. Reimbursement will not be made without a receipt.)

Telephone (purpose identified)

(2) Receipts are required *only if cost exceeds \$75* for the following:

Excess baggage

Clerical Assistance

Fees relating to travel outside the continental U.S.

Hire of special conveyances (taxicabs, automobiles, aircraft)

Operating expenses of privately owned conveyances (e.g., parking garages, highway tolls)

If you have specific questions, please call the CSR Travel and Consultant Reimbursement Section on (301) 435-1125.



GRANT APPLICATIONS REVIEWED

Presented below are the numbers of competing grant applications reviewed by NIH scientific review groups for the October 1988 – 1997 national advisory councils and board meeting cycles. These statistics, which represent applications reviewed by scientific review groups primarily in June and July, were obtained from the NIH IMPAC database.

From the October 1988 to the October 1997 council cycles, the total number of grant applications increased by 22%, from 10,351 to 12,660. The high point was 13,659 in the October 1994 council cycle. The number of applications assigned to the Center for Scientific Review (CSR, formerly DRG) for

review has fluctuated over the 10-year period with a low of 7,546 in October 1990 and a high of 9,145 in October 1995. CSR typically reviews two-thirds of all applications. The high point for Institute/Center review is almost 4,800 applications during the October 1994 council cycle. This was an increase of more than 2,000 applications from the October 1988 council cycle. Part of this increase was due to the increased number of applications received in response to Requests for Applications (RFAs), which have dropped since October 1994. The percent of amended applications reviewed rose from 20.6 in October 1988 to a high of 29.5 in October 1995. Effective with applications received in October 1996 the number of amended applications permitted by an investigator has been limited to two, resulting in a decline in the percent of amended applications from 29.4 in October 1996 to 23.3 in October 1997.

	October Council Cycles						
	1988	1989	1990	1991	1992		
Applications Reviewed	10351	10909	11012	11487	11997		
CSR	7612	7932	7546	7575	8170		
Percent CSR Reviewed of Total	73.5	72.7	68.5	65.9	68.1		
Institute/Center	2739	2977	3466	3912	3827		
Percent IC Reviewed of Total	26.5	27.3	31.5	34.1	31.9		
Research Grants	8688	9846	10045	10133	10845		
Research Projects	7095	7896	8084	8081	8701		
SBIR/STTR	741	876	826	882	845		
Research Centers	166	166	219	221	224		
Other Research	686	908	916	949	1075		
Training Applications	1628	1050	914	1313	1136		
Fellowships	1441	803	755	1013	926		
Training Grants	187	247	159	300	210		
Other Applications	35	13	53	41	16		
Applications Amended	2135	2519	2682	2871	2803		
Amendments as a Percent of							
Total	20.6	23.1	24.4	25	23.4		
Applications Responding to RFAs	508	607	1213	1455	1250		
Percent RFAs of Total Reviewed	4.9	5.6	11	12.7	10.4		

	October Council Cycles					
	1993	1994	1995	1996	1997	
Applications Reviewed	13011	13659	13288	12089	12660	
CSR	8728	8862	9145	8574	8475	
Percent CSR Reviewed of Total	67.1	64.9	68.8	70.9	66.9	
Institute/Center	4283	4797	4143	3515	4185	
Percent IC Reviewed of Total	32.9	35.1	31.2	29.1	33.1	
Research Grants	11937	12218	11676	10,628	11297	
Research Projects	9073	9543	9226	8496	8853	
SBIR/STTR	1247	1323	1379	1182	1188	
Research Centers	264	226	193	139	116	
Other Research	1353	1126	878	811	1140	
Training Applications	1041	1319	1449	1339	1255	
Fellowships	834	1090	1264	1170	1141	
Training Grants	207	229	185	169	114	
Other Applications	33	122	163	122	108	
Applications Amended	3424	3634	3924	3555	2958	
Amendments as a Percent of						
Total	26.3	26.6	29.5	29.4	23.3	
Applications Responding to RFAs	1800	1798	1322	1163	1246	
Percent RFAs of Total Reviewed	13.8	13.2	9.9	9.6	9.8	



CSR/DRG HOME PAGE

Note: The home page will be updated soon to reflect the reorganization of the Division of Research Grants (DRG) and its name change to the Center for Scientific Review (CSR). However, the home page URL and staff E-mail addresses will continue to include the DRG initials for some time.

Since the last issue of Peer Review Notes, the CSR/DRG home page (http://www.drg.nih.gov/) has undergone some minor changes to help organize the information in a more systematic format. The link to the NIH Extramural Trends publication has been incorporated under the Referral & Review page. The link to the Office of Research Integrity (ORI) sanctions listing has been incorporated under the Resources page. Archives have been created under both Referral & Review and News & Events to store old items that users may wish to access.

As promised, the meeting schedule under <u>Referral and Review</u> has been enhanced to include an alphabetized listing of all NIH <u>Scientific Review Group meetings</u>, complementing the chronological listing. This list includes meeting times and locations for the current, previous, and next council rounds. The meeting information is updated nightly on the web. Also available from the News & Events page are the <u>minutes</u> from the most recent DRG Advisory Committee meeting (April 1997).

The <u>Guidelines</u> for review of specific grant applications under <u>Referral & Review</u>, <u>Policy & Procedure</u>, now include two new additions to the web site: <u>R15</u> (AREA) and <u>R21</u> (Pilot Projects or Feasibility Studies).

All CSR staff members have new E-mail addresses. These new addresses can be found on the <u>CSR/DRG telephone and E-mail directory</u>. For most staff members, the new address is the individual's last name (up to seven letters), followed by the first initial of the first name and "@drg.nih.gov."



PERSONNEL UPDATE

HHS

Appointments:

Dr. J. Jarrett Clinton, Acting Surgeon General, Department of Health and Human Services. He will continue to serve as Acting Deputy Assistant Secretary for Health.

NIH

Appointments:

Dr. Janet Cuca, NIH Review Policy and Special Projects Officer, Office of the Director (OD) and Vice-Chair of the NIH Review Policy Committee

Dr. Teresa Levitin, Director, Office of Extramural Program Review, National Institute on Drug Abuse (NIDA)

Dr. John J. McGowan, Deputy Director, National Institute of Allergy and Infectious Diseases (NIAID)

Dr. W. Sue Shafer, Deputy Director, National Institute of General Medical Sciences (NIGMS). She will continue to serve as Director of the NIGMS Division of Extramural Activities.

Dr. Robert Wittes, Deputy Director for Extramural Sciences, National Cancer Institute (NCI)

Retirements:

Dr. Roger Dahlen, Chief, Biomedical Information Support Branch, National Library of Medicine (NLM) and a member of the NIH Review Policy Committee

Dr. Peter L. Frommer, Deputy Director, National Heart, Lung, and Blood Institute (NHLBI)

Dr. John Kalberer, Jr., NIH Coordinator, Disease Prevention and Health Promotion, OD

Ms. Ruth Monaghan, Deputy Chief, Grants Administration Branch, NIGMS, and supervisor of its National Research Service Award Payback Service Center

Dr. James Snow, Director, National Institute of Deafness and Other Communication Disorders (NIDCD)

CSR/DRG

Appointments:

Dr. Andrea Harabin, Scientific Review Administrator (SRA), Lung Biology and Pathology Study Section

Dr. Jean Paddock, Director, Division of Clinical and Population-Based Studies

Dr. Samuel C. Rawlings, CSR Evaluation Officer. At present, he will continue to serve as a Referral Officer and SRA of the Sensory Disorders and Language Study Section.

Ms. Chris Wisdom, Executive Officer and Director, Division of Management Services

Departure:

Dr. John Beisler, SRA, Biophysical Chemistry Study Section joined the NCI as a program administrator in the Anti-tumor Drug Development Program, Division of Cancer Treatment and Diagnosis.

Peer Review Notes Editorial Board

Departure:

Dr. Claudia Blair, Director, Division of Extramural Outreach and Information Resources, OD, NIH, has served on the editorial board since October 1991. Her knowledge, work ethic, and graceful style have been of tremendous value to the quality and timeliness of Peer Review Notes (PRN). The Center for Scientific Review and the PRN Editorial Board thank Dr. Blair for her dedicated service to Peer Review Notes.

Appointment:

Dr. Janet Cuca, NIH Review Policy and Special Projects Officer, Office of Extramural Research (OER), OD and Vice-Chair of the NIH Review Policy Committee replaces Dr. Blair as the OER representative to the board. Dr. Cuca's former positions at NIH include editor of Peer Review Notes, SRA in CSR and NCI, and Chief of the Scientific Review Branch in the National Eye Institute (NEI). The Center for Scientific Review and the PRN Editorial Board welcome Dr. Cuca to the Board.



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