NIH PEER REVIEW NOTES
February 1999

FROM THE DIRECTOR'S DESK

Many changes are underway in CSR, as reported in past issues of Peer Review Notes (http://www.csr.nih.gov/review/peerrev.htm). In this issue we provide an update on the integration of review activities related to behavioral and social sciences applications of the former ADAMHA institutes. In another article, we report establishment of two clinical special emphasis panels. To manage the continued rapid pace of work in CSR, we are continuing to recruit new staff members to join the many who came on board in 1998, listed below. Also in this issue, we provide information related to NIH-wide changes: implementation of modular research grants and development of Electronic Research Administration. In addition, we've included an article clarifying the oft-confusing distinction between peer review conducted in CSR and the peer review performed by Institute review units.

Finally, I'd like to update you regarding the substantial progress of two ad hoc subcommittees of CSR Advisory Committee: the Panel on Scientific Boundaries for Review (http://www.csr.nih.gov/events.htm) and the Working Group on Review of Bioengineering and Technology and Instrumentation Development Research (http://www.csr.nih.gov/events.htm). The Boundaries Panel, chaired by Bruce Alberts, President of the National Academy of Sciences, is developing a recommended set of broad, scientifically defensible domains into which study sections should be grouped, i.e., integrated review groups (IRGs) that recognize and accommodate changes in the continually evolving scientific landscape. The recommended structure will likely reflect the principle that provision should be made for as much science as possible to be reviewed in organ/disease-based IRGs, in the context of the biological question that is being investigated. The remainder will be reviewed in trans-system IRGs, designed around biological mechanisms. Mechanisms for obtaining investigator input into the assignment of their applications are being discussed. Having drafted very preliminary recommendations, the Panel will meet with CSR staff in February to gain their important input. The Panel also will recommend principles for constituting study sections within these IRGs as well as principles for operating study sections intended to modify the culture of peer review. The Panel expects to have a report available for broad community comment this summer.

The activities of the Working Group on Review of Bioengineering and Technology and Instrumentation Development Research complement those of the Boundaries Panel. This group, chaired by Lee Huntsman, Provost of the University of Washington, is determining impediments to and outlining principles for achieving fair, high-quality and rigorous review of technology-related applications. The Group expects to release a report for comment at a yet-to-be-scheduled town hall meeting in April, and to issue their final report in late spring.

Many thanks and Happy New Year to all of you who participate in these activities and in the peer review process. May this be a fruitful year for everyone, on both personal and professional fronts.

Ellie

NEWS FROM CSR

Integration of Behavioral and Social Sciences Review

The first phase of integration of review of behavioral and social sciences applications from NIMH, NIDA, and NIAAA into the Center for Scientific Review (CSR) is now complete. Based on recommendations from Institute Directors, from CSR and Institute staff, and from the external community, 19 study sections have been defined and clustered within three recommended integrated review Groups (IRGs): Behavioral and Biobehavioral Processes (BBBP); Risk, Prevention and Health Behavior (RPHB); and Social Science, Nursing, Epidemiology, and Methods (SNEM). Descriptions are available at www.csr.nih.gov/review/bss.htm. Applications received for the February 1, 1999, receipt date will be assigned to the new study sections within these IRGs for review in June, 1999.

As part of the second phase of implementation, reviewers from existing committees in the three Institutes and from study sections within CSR whose terms do not expire before July 1999, have been asked to indicate their preference for the new study sections. In addition, Scientific Review Administrators will recruit additional reviewers with appropriate expertise to complete the staffing of study sections within the new IRGs.

The third and final phase of the merger procedure involves review of the applications followed by an assessment of process by Institute and CSR staff. These "feedback" meetings will provide CSR with information to

evaluate progress, and, as necessary, effect improvements in the review process.

New Special Emphasis Panels to Review Clinical Applications

Two Special Emphasis Panels (SEPs) have recently been formed to review clinically-oriented grant applications, namely, the Clinical Cardiovascular Sciences (CCVS) SEP and the Clinical Oncology (CONC) SEP. These two SEPs were formed following a recommendation by Dr.Michael Simmons, Professor of Pediatrics at the University of North Carolina, who was engaged by CSR to address concerns of the clinical community regarding fairness of review of clinical research. Dr. Simmons noted that within the Oncological Sciences integrated review Group (IRG) and the Cardiovascular sciences IRG, most clinical applications were being reviewed in study sections where less than 30% of the applications were clinical. Because a previous report had indicated that success rates for clinical applications in such low-density study sections were less than the success rates of laboratory-oriented research, Dr. Simmons recommended that clinical applications in these two IRGs be clustered and reviewed in SEPs.

The first meeting of the CCVS SEP, chaired by Gordon H. Williams, M.D., Professor, Harvard Medical School, was held in December 1998. Approximately 10 patient-oriented-research (POR) applications, self-referred by the applicants who were offered the choice of having their applications reviewed by the SEP or a standing study section within the Cardiovascular Sciences IRG, were reviewed at this meeting. The first meeting of the CONC SEP will take place in March 1999 and will be chaired by Margaret Tempero, M.D., Professor and Deputy Director, Eppley Cancer Center, University of Nebraska Medical Center. This SEP has clustered all applications received in the area of clinical cancer therapeutic and chemoprevention research, a total of approximately 50 applications. Clinicians conducting patient-oriented research in scientific areas covered by the Cardiovascular Sciences IRG or the Oncological Sciences IRG are encouraged to direct their research grant applications to either SEP for review.

New Staff at CSR

The past year has been a busy one in bringing on new staff for the Center for Scientific Review. Below is a list of the new Assistant Chiefs and Scientific Review Administrators who joined CSR in 1998.

Assistant Chiefs in the Division of Receipt and Referral:

Dr. Janet Newburgh
Dr. Kalman Salata

Scientific Review Administrators:

Dr. Sally Amero, *Genetic Sciences Initial* Review Group (IRG)GNS
Dr. Daniel Berch, *Biobehavioral and Social Sciences IRG*
*Mr. Jay Cinque, *Brain Disorders and Clinical Neuroscience IRG*
*Dr. Mary Custer, *Molecular, Cellular and Developmental Neurosciences IRG*
*Dr. Jim Debbas, *Integrative, Functional and Cognitive Neuroscience IRG*
Dr. Thomas Dowell, *Pathophysiological Sciences IRG*
*Dr. Bernie Driscoll, *Integrative, Functional and Cognitive Neuroscience IRG*
Dr. Joanne Fujii, *Molecular, Cellular and Developmental Neurosciences IRG*
Dr. Patricia Hand, *Oncological Sciences IRG*
Dr. Rona Hirschberg, Chief, *Infectious Diseases and Microbiology IRG*
*Dr. Syed Husain, *Molecular, Cellular and Developmental Neurosciences IRG*
Dr. Jay Joshi, *Brain Disorders and Clinical Neuroscience IRG*
*Dr. Gloria Levin, *Biobehavioral and Social Sciences IRG*
*Dr. Richard Marcus, *Integrative, Functional and Cognitive Neuroscience IRG*
Dr. David Monsees, *Health Promotion and Disease Prevention IRG*
Dr. Teresa Nesbitt, *Surgery, Radiology, and Bioengineering IRG*
Dr. Alexander Politis, *Immunological Sciences IRG*
Dr. Arnold Revzin, *Biophysical and Chemical Sciences IRG*
Dr. Anne Schaffner, *Molecular, Cellular and Developmental Neurosciences IRG*
Dr. Eugene Vigil, *Cell Development and Function IRG*
Dr. Mary Claire Walker, *Aids and Related Research IRG*
Dr. Cheri Wiggs, *Biobehavioral and Social Sciences IRG*

*Transferred from NIDA or NIMH as part of neuroscience integration

FURTHER NEWS FROM NIH

NIH Implements Modular Research Grants

NIH officially announced implementation of modular research grants in the December 18 issue of the NIH Guide to Grants and Contracts. The main

feature of this concept is that grant applications will request direct costs in $25,000 modules, without budgetary detail for individual categories. A single dollar figure for total direct costs is to be given for each year of the project as well as for the entire project, with no routine escalation for future years. In addition to these budgetary changes, information on Other Support should not be submitted with the application, but only if requested after integrated review and if an award is likely. Biosketches should be expanded to include past and current related research activities of key personnel, and a narrative justification should be provided for personnel, any consortium or subcontract arrangements, and any changes in the number of modules from year to year. Further details about modular research grants, including sample Biosketches and Budgets, can be obtained from the Modular Grants Web site at http://www.nih.gov/grants/funding/modular/modular.htm.

Modular grant application procedures will apply to all unsolicited and solicited competing individual research project grants (R01), small grants (R03), Academic Research Enhancement Awards (R15), exploratory/ developments grants (R21), Small Business Technology Transfer Phase I grants (R41), and Small Business Innovation Research Phase I grants (R43) that request direct costs up to $250,000 per year. Projects requesting more than $250,000 in any one year will be subject to the traditional application procedures, although solicited applications (i.e., RFAs) above $250,000 may be modular at the discretion of the Institute issuing the RFA. The modular procedures will be effective beginning with the April 1999 receipt dates for small business applications, with the May 25, 1999 receipt date for Academic Research Enhancement Awards, and with the June 1, 1999 receipt date for individual research project grant, small grant, and exploratory/ developmental grant applications.

Regarding implications of modular procedures for reviewers, it is anticipated that the absence of budget detail will enable reviewers to focus on the science aspects of the proposal. Narrative justifications will continue to provide information regarding the roles and percent efforts of the key personnel, and regarding any variations in the number of modules per year. Based on their knowledge and experience regarding the estimated cost for the Specific Aims proposed, reviewers should be able to confirm the appropriateness of the number of modules requested, or to recommend a change in the number of modules.

NIH welcomes comments on the experiences and concerns of investigators, reviewers, applicant organizations and staff. Comments on modular grant procedures may be addressed to modulargrants@NIH.gov.

Electronic Research Administration (ERA) and the NIH ERA Commons

The NIH is committed to the design, development, and deployment of an Electronic Research Administration (ERA) system that will greatly facilitate preparation of grant applications by research investigators, processing of applications by NIH staff, and management of awards by both grantee organizations and NIH staff. The ERA system will eventually place the entire life cycle of grants administration processes within a client-server common file database environment. Two client/server database systems will support the ERA. The system supporting extramural users (grantee/ contractor organizations; academic institutions, research institutes, medical research, small business) is called the NIH ERA Commons, building on the metaphor of a place in colonial times where members of the community gathered to conduct business. The Commons provides grantee organizations access to official NIH grant/contract information, and a means for submitting information electronically to NIH. Once information is received into the Commons, it is faithfully replicated into the second ERA NIH database system, called IMPAC II. The extramural community accesses the Commons via secure interactive Internet sites. Software behind these sites provides all necessary functionality, including security, auditing, record submission, updating, modification, and in some instances deletion.

Initial deployment of the NIH Commons occurred in autumn of 1996 with 10 grantee organizations participating in a test of the Commons interfaces. Feedback received from these 10 organizations lead to refinement and expansion of the Commons functionality. The current deployment phase, underway since July 1998, involves participation by the 65 Federal Demonstration Partnership (FDP) grantee organizations. Each organization can establish an unlimited number of user accounts for their faculty and administrative staff. Grantee organization users can access a "Status" interface that monitors the progress of submitted grant applications as they move through the NIH system. Within the next month, individual users will also be able to establish a "Professional Profile" containing curriculum vitae-related information, and registered organizations will be able to establish a similar "Organizational Profile". Storage of these profiles in the NIH ERA systems (Commons and IMPAC II) will allow automatic insertion into submitted grant applications.

During the coming year, the functionality of the Commons will be further expanded to allow electronic submission of both Type 5 SNAP (Streamlined Non-competing Award Process) applications, and competing grant applications (PHS 398). It will also be used to monitor trainee participation in awards (PHS 2271). NIH anticipates that, by the end of 1999, 100 -150

grantee organizations will be using the Commons; full unlimited production deployment is targeted to occur in 2000.

PEER REVIEW AT THE NIH

The Center for Scientific Review (CSR) reviews 70% to 75% of all grant applications submitted to NIH, regardless of the Institute or Center (IC) to which it is assigned. The remaining 25% to 30% are reviewed within 18 of the NIH ICs; there are approximately as many Scientific Review Administrators (SRAs) in all the ICs combined as there are in CSR. CSR concentrates on grant mechanisms with the most standardized requirements across NIH, whereas IC review committees are able to tailor reviews to the special needs of the IC.

The need for IC review stems from the great diversity of programmatic needs in terms of funding mechanisms within each institute. Not only can each mechanism have its own set of review criteria, but ICs may use the same mechanism in very different ways. For example, Small Grants (R03) can range from three-month $25,000 awards to two-year awards at $50,000 per year, depending on the needs of the IC. Moreover, funding mechanisms such as program projects, center grants, and cooperative agreements are large, multi component projects, frequently require highly specialized reviews with site visits or applicant interviews. ICs also support special initiatives through the use of Requests for Applications (RFAs) which require specially convened review committees and a review cycle considerably shorter the standard CSR schedule. This large diversity of grant mechanisms and review considerations challenge a process in which a large number of applications must be evaluated in a relatively short time.

To accommodate these needs, peer review at NIH is carried out both in CSR and in the ICs. CSR provides NIH with the capability to review large numbers of applications with standardized requirements. These include regular research project grants (R01), postdoctoral fellowships (F32), Small Business Innovation Research Grants (R41, R42, R43, R44), and Area Grants (R15). Review committees in ICs deal with grant mechanisms having either review criteria or eligibility requirements unique to an institute. The most common types of grant mechanisms reviewed in ICs include Institutional Training Grants (T32), pre-doctoral fellowships (F31), Career Development Awards (K01, K02, K05, K07, K08, K23, etc.), Program Projects and Centers (P01, P50), Small Grants (R03), Developmental Grants (R21), Cooperative Agreements (U01, U10, etc.), and applications responding to RFAs. But there are exceptions to the current general practice. For example, some ICs review unsolicited R01 applications in specific

programmatic areas, such as clinical trials and health services, whereas CSR has managed reviews of RFAs and specialized mechanisms upon request from an IC.

Beyond these differences, the review process is standardized across NIH. CSR and ICs both use chartered standing committees and special emphasis panels (SEPs), use similar rating criteria for research grants, and use the same policies and procedures in the conduct of review meetings. Overall, the resulting process provides NIH with the flexibility to manage both large numbers of applications and to attend to the more specialized needs of Institute-specific programs.

[Referral & Review]

CSR Home Page