NIH PEER REVIEW NOTES

June 1997

Contents

FROM THE DRG DIRECTOR

This issue of Peer Review Notes marks the end of my first five months at DRG. Like a new graduate student embarking on a Ph.D. program, I am relieved to find that I love the work and can pass all my courses. Nonetheless, I am well aware that the qualifying exams are yet to come.

In preparation for this future, the DRG management team and I have initiated a number of projects, including: analyzing and reorganizing the study sections to more accurately reflect contemporary science; evaluating and improving reviewer participation in the peer review process; increasing the interactions of DRG with the NIH Institutes and Centers to improve communication and cooperation within the NIH community; establishing dialogues with specific segments of the research community to address their concerns; helping to develop and implement exciting advances in information technology;

and promoting general outreach to the entire community. Although our peer review system at the NIH is the best in the world, it can still be improved, and we can do it.

As we embark on this process, I am grateful for the past support, and I am hopeful for the future assistance of my many advisors and colleagues, both within and outside DRG.

- Ellie Ehrenfeld


Return to Top

DRG ADVISORY COMMITTEE APRIL 1997 MEETING

The 16th meeting of the DRG Advisory Committee (DRGAC) took place on April 28 and 29, 1997. The major topics of discussion were the review of individual postdoctoral fellowship applications; changes in the review of applications for Academic Research Enhancement Awards (AREAs); reevaluation and reorganization of DRG study sections and initial review groups to respond to the changes in science; integration activities involving DRG and Institute initial review activities in the area of the neurosciences; and changes designed to expedite the application receipt, referral, and initial review processes.

During the meeting, the DRGAC decided to increase the number of annual meetings from two to three, with the third meeting to take place in February. These meetings will be coordinated with the three annual meetings of the Peer Review Oversight Group (PROG). Dr. Yamamoto, the Chairperson of DRGAC, also mentioned specific topics for future discussion: including, the review of clinical research applications; the implementation of changes in review criteria and review mechanisms; systematic inclusion of senior scientists on study sections and initial review groups; ways to expedite the receipt, referral, and initial review processes; guidelines for the review of applications in the neurosciences; and the review of fellowship applications.

The minutes of the April meeting will be available on the DRG Web Site in the near future. The minutes of the November 1996 and two previous advisory committee meetings are available now on the web site. To get the minutes, type: http://www.drg.nih.gov/, and then click on *News & Events*. If you have any questions or wish to receive a hard copy of the minutes, contact Sam Joseloff at (301) 435-0691(phone), (301) 480-3963 (fax), or sj29@nih.gov(E-mail).


Return to Top

PEER REVIEW OVERSIGHT GROUP (PROG) MAY 1997 MEETING

Rating of Grant Applications: Review Criteria. The Peer Review Oversight Group (PROG) met on May 5, 1997. At that meeting, NIH Director Harold Varmus announced his decision regarding the number and format of the explicit criteria to be used in NIH grant application review. In a brief historical review, Dr. Varmus indicated that the Rating of Grant Applications (RGA) was originally raised to focus the review of grant applications on the quality of the science and the impact it might have on the field, rather than on details of technique and methodology. He emphasized the need to focus on projects that will lead to changes in how we think about science, and to encourage investigators to take more risks. Dr. Varmus pointed out that the original RGA report was interesting but tried to mechanize what had previously been a largely intuitive process, thereby generating anxiety within the scientific community that reviewers would lose their autonomy in making scientific judgements to a mathematical formula. It is now clear that NIH will retain the single, global score assigned by each reviewer for each scored application. In the midst of the anxiety generated by this scoring issue, the PROG took up the issue of creativity, and whether it should be explicitly stated as a separate criterion. Meanwhile, Dr. Wendy Baldwin, Deputy Director for Extramural Research and Chair of the PROG, has been working on the six-point plan to address creativity, presented at the last (February 1997) PROG meeting.

Dr. Varmus then announced the new explicit statements of the five scientific review criteria to be used across the NIH: **Significance, Approach, Innovation, Investigator, and Environment**. He indicated that consideration of each criterion should contribute to the overall score assigned by a reviewer, and should reflect the overall impact a project will have on the scientific field. The emphasis on each criterion may vary depending on the nature of the application and its relative strengths. Use of the criteria will take effect with the October 1997 application receipt dates. PROG members discussed possible ways of assessing the success of these criteria in providing information to NIH program staff and to research investigators. The use of these criteria will be monitored and reviewed in approximately one year (June 1998) for possible modification. At that time, opinions of reviewers, applicants, and NIH staff will be solicited, and debate and discussion will be welcomed.

PROG members felt the criteria would clarify and respond to many concerns voiced by members of the scientific community, and would serve the important function of refocusing reviewers away from details of technique and methodology. Dr. Varmus emphasized the importance of having reviewers understand and support the NIH's mission of identifying and funding the best science, since these reviewers are the scientific peers of investigators, the scientists who best know the science. Dr. Ellie Ehrenfeld, Director of the Division of Research Grants (DRG), volunteered to personally orient as many study sections as possible, to convey Dr. Varmus's message. Dr. Alan Leshner, Director of the National Institute on Drug Abuse, enthusiastically supported the idea of uniform criteria for all peer review, not only for the DRG but across the entire NIH.

The criteria have been shared with NIH staff at all levels, and have been posted on the NIH OER Grants home page so that all applicants can be familiar with them in advance of implementation. They will be

announced in *The NIH Guide for Grants and Contracts*. Dr. Baldwin encouraged PROG members to consider writing brief notes for their own professional association newsletters about the criteria, as a means of information dissemination. Notices will also be sent to offices of sponsored research at grantee institutions.

Rating of Grant Applications: Scoring Metric. One part of the RGA that has not changed is the assignment of a global score. An additional recommendation within the area of scoring was to change the scale used in assigning scores. Dr. Baldwin outlined the shortcomings of the current scale, as noted in the RGA report: lower numbers represent better scores and the number of points of discrimination (41, given the 1-5 scale with increments of tenths of a point) is overly large. She presented three possible options for dealing with the scoring method: (1) no change, given that the scale has already been effectively halved by current review streamlining procedures; (2) evolutionary change, i.e., keep the 1-5 scale but set limits within that range, such as using only halves or quarters of a point; or (3) revolutionary change, i.e., create a whole new system. She pointed out that currently the scoring is not a major problem; weak projects do not get wonderful scores or the reverse. But we periodically ask ourselves whether we are getting useful discriminations among applications which can help the Institutes in making funding decisions. Members agreed that this was a topic PROG should address, but Dr. Ehrenfeld suggested that, in light of other changes being implemented currently, this issue be deferred for a year. This suggestion was adopted but with some examination of extant data in the interim.

The NIH Review Rebuttal and Appeal Processes. The PROG also considered the issue of whether the NIH-created appeal process should be retained. An applicant contesting the review process currently has several options, including first discussing issues with the program official and scientific review administrator, then formally rebutting the review in writing. The rebuttal either is then resolved by the program and review staff or is taken to the Institute's national advisory council or board for adjudication. It was noted that rebuttals deal only with errors in the review process, not with differences of scientific opinion. For the past several years, NIH also has offered an appeal process for those dissatisfied with the outcome of the rebuttal. This process has been used only infrequently, and in practical terms does not appear to be advantageous to applicants who use it. Frequently even when the appeal process results in a re-review, the program official and applicant agree that it would be better to revise the application. Dr. Baldwin and Dr. Ehrenfeld jointly proposed elimination of the appeal process and a move toward greater use and uniformity of the rebuttal process across the NIH. PROG members agreed with both suggestions, adding that greater clarity of explanation of the rebuttal process is also needed. The PROG will have oversight responsibility but will not be involved in arbitration of individual cases. They also advised general dissemination of best practices' guidelines, which should be shared with the applicant community. Eliminating the appeal process was viewed as a way of actually strengthening the rebuttal process.

Integration of Review: Neuroscience Research Applications. The draft referral guidelines for new DRG neuroscience scientific review groups, the product of NIH staff and extramural scientists' working groups on the integration of the review of neuroscience research applications, were presented. These were enthusiastically accepted by the PROG. Additional NIH Institutes have joined in this effort, and

final referral guidelines for actual implementation will be presented at the next PROG meeting (fall, 1997). (For more information on this topic, see Reorganization of DRG Neuroscience Review in this newsletter.)

Integration of Review: Behavioral and Social Science and AIDS-Related Research Applications. Additional integration of review activities within DRG is now beginning for the behavioral and social sciences and for AIDS related research. Dr. Virginia Cain of NIH's Office of Behavioral and Social Sciences Research, Office of the Director, NIH, and Dr. Ellen Stover of the Office of AIDS Research, National Institute of Mental Health, announced these new integration efforts to the PROG. It is anticipated that, based on lessons learned in the integration of the review of neuroscience research applications, activities in these two areas may proceed fairly rapidly.

Locus of Review: DRG or the Institutes and Centers. In parallel to the review integration activities, PROG will be considering how it is decided whether applications are to be reviewed in DRG or an Institute or Center's review section. At their next meeting, members will hear the results of a poll of Institute and Center Directors on how these decisions are currently and might best be made. Dr. Ehrenfeld indicated that this question should be considered in the context of how fields of science may develop in the future, the increasing flexibility being built into DRG, consideration of related fields and multidisciplinary projects, and who might produce the best possible review for the science. PROG member Dr. Mary Jeanne Kreek advocated that any decisions should incorporate flexibility. Dr. Baldwin commented that such decisions should not be driven by whether applications are responsive to Requests for Applications (RFAs) and Program Announcements (PAs), or are investigator initiated.

Working Group on Review of Clinical Applications. In an interim report of the Working Group on the Review of Clinical Research, group chair Dr. David Kupfer listed issues to be considered in the creation of guidelines for profiling the composition of scientific peer review groups. These issues include reviewer information, such as areas of expertise, academic and clinical degrees, institutional position and affiliation, research funding, and review/scoring behavior, as well as success rates within panels in relation to panel composition, whether there is a critical mass necessary for appropriate review of clinical applications, and how best to characterize that critical mass. The group hopes to develop strategies for strengthening the review of clinical research applications.

PROG's Next Meeting. The PROG will meet next in the fall, 1997. In addition to updates on review integration activities, other items to be discussed at that meeting include the scoring metric and strengthening of the rebuttal process. Members will hear the report of the NIH committee on opportunities for new investigators, the results of Dr. Baldwin's query to Institute and Center Directors on locus of review, and the report of the working group on clinical research. Full minutes of the May 1997 meeting are forthcoming on the World Wide Web at http://www.nih.gov/grants/oer.htm under Peer Review.


Return to Top

NEW INSTRUCTIONS FOR SCORING FELLOWSHIP APPLICATIONS

In order to provide the most useful advice to Institute staff, beginning with the October 1997 Council round, DRG will implement certain modifications to the way fellowship applications are reviewed. The goals are: (1) to spread priority scores so that clear and meaningful distinctions can be made among applications; and (2) to develop scoring consistency across review groups to provide better comparative information from which Institutes can make more informed funding decisions.

Rather than associating scoring ranges with adjectival descriptors of degrees of merit, reviewers are now being asked to follow procedures similar to those in use for review of research grant applications. That is, reviewers are asked to anchor the score for an "average" fellowship application to a rating of 3.0. Scores for applications better than the average application are then to be spread across the range from 1.0 to 3.0, and scores for applications worse than the average application are to be spread across the range from 3.0 to 5.0. To further assist reviewers during review and discussion, the assigned reviewers may refer to whether applications are in the top quarter (1.0 to 2.0), 2nd quarter (2.0 to 3.0), 3rd quarter (3.0 to 4.0) or bottom quarter (4.0 to 5.0). The "Reviewers' Postdoctoral Fellowship Checklist," which reviewers use as a guide when preparing reviews, has been revised to reflect these quartiles.

Drafts of the revised postdoctoral checklist and the scoring policy were presented for comment to fellowship reviewers during the May 1997 Council round. The documents were also shared with the NIH Training Advisory Committee. Because of the positive reaction, the above changes were implemented. These changes were part of a total package on improving the review of fellowship applications. Other possible improvements still being discussed are revising the Guide for Reviewers' Preliminary Comments and providing percentile ranks for fellowships.

Return to Top

REORGANIZATION OF DRG NEUROSCIENCE REVIEW

The review responsibilities of the DRG neuroscience study sections are being reorganized. There are two reasons for this change: to include in DRG study sections applications currently reviewed by the National Institute of Mental Health (NIMH) and the National Institute on Drug Abuse (NIDA); and to take a fresh look at the way the review responsibilities of these study sections are determined. The Directors of the National Institute on Aging (NIA), the National Institute of Child Health and Human Development (NICHD), NIDA, NIMH, the National Institute of Neurological Disorders and Stroke (NINDS), and DRG are overseeing the process and have established the following principles to be used

in developing the review guidelines:

- The array of applications being considered by a study section should be determined by the scientific focus of the research rather than by the professional affiliation of the principal investigator, the grant mechanism (i.e., kind of award) applied for, or the research technique to be utilized.
- The range of science to be considered by a study section should allow a breath of perspective, yet this should be balanced by an appropriate depth of scientific expertise.
- To allow flexibility in review, the range of scientific expertise of study sections should overlap.
- When both clinical and basic research are reviewed by a single study section, representation of expertise in both areas should be adequate.
- The structure of the initial review process should be flexible enough to accommodate emerging scientific areas.

An NIH committee, comprised of staff from the above five Institutes and DRG, was established to develop and oversee the process of creating the new study sections. They concluded that neuroscience was too broad for a single group to design the necessary study sections and divided the field into five areas: molecular and cellular neuroscience; developmental neuroscience; integrative, regulatory, and behavioral neuroscience; cognitive neuroscience; and brain disorders and clinical neuroscience. Working groups, each comprised of six members of the extramural research community and six NIH staff members, were given the responsibility of defining study sections appropriate for the review of applications in each area. The working groups were given abstracts of applications reviewed during one review cycle and asked to define the review responsibilities of an appropriate group of study sections and to provide a list of areas of scientific expertise that should be represented among the members of the study sections. The working groups met on March 24-25 to develop their recommendations. The groups interacted with each other to address areas of overlap. Membership of the working groups and their recommendations are available on the DRG home page. Comments on the recommendations may be sent to neuro@drgpo.nih.gov.

Since the March meeting, four more Institutes - the National Institute on Deafness and Other Communication Disorders (NIDCD), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institute of Dental Research (NIDR), and the National Heart, Lung, and Blood Institute (NHLBI) - have joined the process, and the array of newly designed study sections has been expanded to include the capability to review the neuroscience grant portfolios of these Institutes. The working groups' recommendations will be considered through the summer by the broader research community. Then, study section guidelines will be finalized and presented to the NIH Peer Review Oversight Group (PROG) at its November 1997 meeting. The final version will be posted on the web before the end of the year, and these newly constituted study sections will review applications received for February 1998 (and later) receipt dates.


Return to Top

THE ROLES OF SCIENTIFIC REVIEW ADMINISTRATORS DURING THE REVIEW PROCESS

This is the second article in a series on the roles of NIH staff during the grant application review process. As stated in the February 1997 issue of Peer Review Notes: "NIH requires separation of extramural staff functions to ensure fairness and objectivity in the review process. NIH staff consisting of the Scientific Review Administrator (SRA), the Grants Technical Assistant (GTA), the Program Administrator, and the Grants Management Specialist have important and complementary roles and responsibilities in managing the grants process and in ensuring the proper stewardship of Federal funds. Each member of the NIH team is responsible for work that is essential to NIH making well-reasoned funding decisions." This article covers the roles of the SRA.

To meet requirements of the Federal Advisory Committee Act, the SRA is the Designated Federal Official (DFO) with legal responsibility for managing the scientific review group (SRG) meeting. The SRA is responsible for all meeting arrangements and for making every effort to see that the SRG arrives at scientifically valid recommendations, without attempting to influence those recommendations. The specific roles of the SRA are organized around four phases of the review cycle:

1. Pre-Application Receipt

The SRA may be consulted by program staff early in the development of special solicitations for applications (e.g., Program Announcements and Requests for Applications) to contribute to such aspects as scheduling of the review and developing review criteria. Also, for particularly complex or new grant mechanisms, the SRA and /or other review staff may be asked to participate, with the program and grants management staff, in direct pre-application consultations with prospective applicants to provide objective information about such areas as the application format, review procedures and schedule, and special instructions for submission.

2. Preparation for Review Panel Meeting

After an application is assigned to an SRG, it becomes the primary responsibility of the SRA. The SRA manages and coordinates all aspects of the pre-review process. This includes reviewing applications for completeness and conformity to administrative requirements; identifying the need for and securing additional information; ensuring that appropriate expertise is available for the review and securing appropriate additional reviewers if needed; assigning applications to appropriate reviewers for detailed written reviews; distributing all necessary documents to the reviewers; determining the deadline for receipt of additional material; and determining if site visits or applicant interviews are needed.

The SRA is the contact for all communication with the applicant until the conclusion of the initial

review meeting. If during the pre-review phase an applicant contacts other NIH staff or reviewers concerning the review, the applicant should be redirected to the SRA. The SRA is charged also with coordinating the exchange of information with the program and grants management staff throughout the pre-review process.

The SRA may solicit and receive from program staff suggestions concerning reviewers, pertinent background information, and information regarding any administrative issues that may be relevant to the review. Even though review dates are selected to accommodate the schedule of reviewers, to the extent practical, SRAs also consider review dates that are compatible with the schedules of other NIH staff. Also, SRAs provide program and grants management staff timely information about review meetings and project site visits. Examples of such materials are proposed meeting dates, the meeting agenda, and the order of application review.

3. Review Panel Meeting

The SRA, as the DFO, has legal responsibility for managing the SRG meeting and receiving its members' recommendations on behalf of the NIH. The SRA must ensure the fairness and consistency of the review process and that the review is conducted according to relevant laws, policies, regulations, and established NIH procedures. For example, the SRA is responsible for ensuring adherence to regulations regarding conflict of interest. Also, the SRA is responsible for controlling the environment and the context within which a review occurs. This includes ensuring that only information relevant and essential to a determination of scientific merit is utilized by the reviewers. In general, the SRA is responsible for the management of all aspects of the SRG meeting.

4. Post-Review Panel Meeting

Following the review meeting, the SRA and GTA enter data into the NIH computer system and the application priority scores and percentile ranks are generated. These scores are mailed to the applicants by the Division of Research Grants as soon as possible. The SRA also prepares and releases a summary statement, in a timely manner, for each application reviewed. If there is a rebuttal, the SRA contributes comments to the program director who prepares the response.

The SRA attends appropriate National Advisory Council meetings, and promptly provides any additional information requested by the institute staff for presentation of rebuttals and staff actions to the Council. In addition, the SRA must be prepared to clarify the information or recommendations in summary statements.

As the fourth phase of the review cycle ends, the SRA is well into phase 2 (Preparation for Review Panel Meeting) for the applications received for the next council round. Thus, the dynamic role of the SRA, which presents both challenges and rewards throughout the review cycle, continues.

Return to Top

NEW STUDY SECTIONS CHARTERED AND STUDY SECTION MEMBERSHIPS INCREASED IN DRG

Recently, eight new study sections have been chartered in the Division of Research Grants (DRG), NIH, and the number of members of several existing study sections has been increased. These actions will provide DRG with more flexibility in the review of research applications including applications in new and emerging areas of scientific research. The new study sections, their Initial Review Groups (IRG)s, and their areas of scientific interest are listed below.

Community Prevention and Control (CPC) Study Section, Biobehavioral and Social Sciences IRG: This study section was formed to review applications in the general area of community-based health and health related behavior. It will review applications that focus on the primary and secondary prevention and control of disease (e.g., cancer, hypertension) and injury from licit agents (e.g., alcohol, tobacco). More specifically, the CPC will review applications for the support of research that assesses the effect of broadly-based or community approaches directed to behavioral change on the health status of human subjects across all the developmental stages (infant, child, adolescent, and adult).

Geriatrics and Rehabilitation Medicine (GRM) Study Section, Musculoskeletal and Dental Sciences IRG: This study section was formed to review applications in the fields of geriatrics, clinical gerontology, and rehabilitative medicine. It will review applications in the general areas of physiology and therapeutics of impaired physical functioning; exercise and physical manipulation as prevention and rehabilitation strategies; failure to thrive and patient oriented research and interventions in this area; and clinically oriented applied studies related to cardiovascular, endocrine, and nutritional pathophysiologic aging changes and disorders.

Neurological Sciences-3 (NLS-3) Study Section, Neurological Sciences IRG: This study section was formed because of the large and increasing number of applications assigned to Neurological Sciences 1 & 2 (NLS 1&2) study sections. It will review applications involving gene and enzyme therapy for central nervous system disorders, blood-brain-barrier, cerebral blood flow, neuronal-glial cell neuropathology, and neuroimmunopathology.

Diagnostic Imaging (DMG) Study Section, Surgery, Radiology, and Bioengineering IRG: This study section was formed because of the consistently heavy workload in the Diagnostic Radiology (RNM) study section. It will review applications for support of research that emphasizes medical physics, magnetic resonance engineering, magnetic resonance physics, positron emission tomography engineering/physics, single photon emission tomography image analysis; ultrasound engineering/image analysis; laser/photon imaging spectroscopy engineering/physics; x-ray detector engineering/physics;

image analysis; and medical radiology (research oriented).

Also, within the *Health Promotion and Disease Prevention IRG*, four new study sections have been created and chartered. This change reflects the integration of the review activities of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) within the NIH. The review activities of two NIAAA review committees, Alcohol Biomedical Research Review Committees 1&2 (ALCB 1&2), and two DRG study sections, Toxicology 1&2 (TOX 1&2) have been merged into the four new committees listed below.

Alcohol and Toxicology -1(ALTX-1) Study Section: This study section will review applications concerning the biotransformation and pharmacokinetics of toxicants and alcohol. This includes the enzymology and molecular biology of biotransformation enzymes, tissue-specific metabolism, alterations of membranes, transport processes, lipid peroxidation, and oxidative stress.

Alcohol and Toxicology -2 (ALTX-2) Study Section: This study section will review applications on the effects of toxicants and alcohol at the cellular and genetic level related to the pathological endpoints of carcinogenesis, teratogenesis, maternal systems-dependent developmental abnormalities, and immunotoxicology.

Alcohol and Toxicology -3 (ALTX-3) Study Section: This study section will address the effects of toxicants and alcohol on the central nervous system.

Alcohol and Toxicology -4 (ALTX-4) Study Section: This study section will deal with basic research on the molecular, cellular, physiologic, and pharmacologic mechanisms of toxicant and alcohol action on distinct organ systems other than the central nervous system.

Membership Increased

In order to accommodate increases in workload and to add expertise for emerging areas of scientific research, the number of authorized members of the following nine existing study sections has been increased.

Cardiovascular (CVA)
Chemical Pathology (CPA)
Diagnostic Radiology (RNM)
Human Development and Aging-3 (HUD-3)
Medical Biochemistry (MEDB)
Metabolic Pathology (MEP)
Neurological Sciences -2 (NLS-2)
Neurology C (NEUC)
Sensory Disorders and Language (CMS)


Return to Top

SBIR AND STTR INFORMATION

This article calls attention to a recent Small Business Innovation Research (SBIR) conference and summarizes several recent policy changes that affect applicants for SBIR and Small Business Technology Transfer (STTR) awards. NIH is one of 10 Federal agencies participating in the SBIR program and one of 5 Federal agencies participating in the STTR program. Both programs are guided statutorily by policies set by the Small Business Administration.

On January 22, 1997, NIH held a conference to discuss strategies to strengthen and enhance the NIH SBIR program. The meeting was called by Dr. Wendy Baldwin, the NIH Deputy Director for Extramural Research. A summary of the meeting and other program information are available on the NIH's "Small Business Funding Opportunities" web site at http://www.nih.gov/grants/funding/sbir.htm. Suggestions to enhance the SBIR and STTR programs can be sent by E-mail to dder@nih.gov.

The recent policy changes that affect SBIR and STTR applicants involve streamlined review, "just-in-time" applications, revised applications, receipt dates for applications, and protection of principal investigators' Social Security Numbers. The streamlined peer review process has been extended to SBIR and STTR applications. This new process, which is already in use for research project grant (R01) applications, allows greater discussion of the more competitive applications. All applications are reviewed and critiqued, but only those applications judged to be highly meritorious will be discussed and scored by the scientific review group at its meeting. Approximately half of the applications should be discussed. Reviewers score these applications, generally between 100 (best) and 250-300. All applicants will receive a summary statement, but for applications not scored, the summary statements will be limited, usually, to the written comments of the reviewers.

"Just-in-time" (JIT) procedures for SBIR and STTR Phase I grants have been adopted to reduce the administrative burden at time of application, without compromising the information needed by the scientific peer review group. Consequently, the instructions to applicants for some budget categories have been modified and other items should not be completed at the time of submission of the application. This information will be requested by the awarding component if the application is likely to be funded. The application instructions that have been modified include the following: (a) completion of the budget page; (b) documents regarding the performance site(s); (c) "Other Support" of the principal investigator and other key personnel, excluding consultants; and (d) documentation to establish the "primary employment" of the principal investigator with the applicant small business organization. (Item (d) applies only to SBIR applications.) The JIT procedures do not apply to applications submitted for Phase II awards.

The SBIR and STTR application process is also affected by recent general changes in NIH policy. Grant applications for Phase I and Phase II awards will continue to be received by the published receipt dates: 1st and 15th of April, August, and December for STTR and SBIR, respectively. However, an application

received after the published receipt date may be acceptable if it has a legible proof of mailing date by the carrier not later than one week prior to the deadline date. The receipt date will be waived only in extenuating circumstances.

The policy regarding revised applications for the SBIR and STTR programs is the same as that for all other NIH research grant applications. An applicant may submit no more than two revisions of an application within two years after the date that the application was first submitted.

Finally, as part of the design and implementation of Electronic Research Administration, the NIH is assessing measures for protecting private information, including the Social Security Number (SSN). However, although the provision of the principal investigator's SSN is voluntary, it is critically important to the NIH for the accurate identification, referral, and review of applications, and for efficient management of grant programs. Consequently, the SSN of the principal investigator is requested now only on the Personal Data form page. It should not be listed on the face page or elsewhere in the application. Upon receipt, the Personal Data page is separated from the application, and the data, including the SSN, are encrypted in the NIH database.

 Return to Top

---

ACADEMIC RESEARCH ENHANCEMENT AWARD CHANGES

The National Institutes of Health (NIH) is continuing to make a special effort to stimulate research in educational institutions that have provided baccalaureate training for a significant number of the Nation's research scientists, but that have not been major recipients of NIH support. Since Fiscal Year (FY) 1985, Congressional appropriations for the NIH have included funds for this initiative, which NIH has implemented through the Academic Research Enhancement Award (AREA) program (R15).

AREA funds are intended to support new or ongoing health-related research projects proposed by faculty members of eligible institutions. The AREA award enables qualified scientists to receive support for small-scale research projects. These grants create a research opportunity for scientists and institutions otherwise unlikely to participate extensively in NIH programs that support the Nation's biomedical and behavioral research effort. It is anticipated that investigators supported by the AREA program will benefit from the opportunity to conduct independent research; that the grantee institution will benefit from a research environment strengthened by AREA grants and participation in the diverse extramural programs of the NIH; and that students will benefit from exposure to, and participation in, research, and be encouraged to pursue graduate studies in the health sciences.

In response to comments and suggestions from the extramural community and NIH staff, an NIH committee recently examined the AREA program and recommended several changes to it. The changes

were announced by Dr. Ruth Kirschstein, Deputy Director, NIH, at the Council of Undergraduate Research's April Dialogue on April 11, and were published with the program guidelines in the NIH Guide to Grants and Contracts, Vol. 26, No. 12, April 11, 1997. The changes are as follows:

- Applications will be accepted in response to ongoing Program Guidelines (Program Announcement PA-97-052), and will not be solicited through a request issued annually.

- Applications for these awards will be accepted and reviewed three times per year, instead of once per year. The receipt dates will be January 25, May 25, and September 25. However, this year, 1997, the May 25 receipt date will be extended to June 25.

- Applications for competing continuations (renewals, Type 2s) of AREA grants will be accepted. Thus, recipients of AREA awards may apply for an AREA grant to continue their research project.

- Applications for AREA grants may now include appendices, and must follow the instructions in the Application for a Public Health Service Grant PHS 398 for submitting these.

- As part of the initial merit review, a streamlined review process, which is employed for the review of most NIH research grant applications, will be used.

- Applications must provide specific information regarding the investigator's experience in supervising students in research, the institution's student population, its success in training students who pursue careers in the biomedical and behavioral sciences, and its suitability for an AREA award. *In the initial scientific review, applications will be evaluated on these factors in addition to the usual scientific merit considerations.* New review guidelines will be prepared for AREA applications

- AREA grantees will be required to submit both annual Progress Reports and a Final Progress Report.

The AREA Program Guidelines (PA-97-052) give detailed information about AREA grants, including eligibility criteria, "just-in-time" application procedures, and the names of NIH officials to contact regarding scientific issues. The Guidelines are available on the NIH Grants web site at (http://www.nih.gov/grants/funding/funding_program.htm), with a Notice summarizing the changes to the program and the list of schools/academic components that are *not* eligible for FY 1997 awards.

Return to Top

DRG TO REVIEW APPLICATIONS SOLICITED BY NIGMS FOR HIGH RISK/ HIGH IMPACT RESEARCH

The National Institute for General Medical Sciences (NIGMS) issued a Program Announcement in the NIH Guide for Grants and Contracts (PA-97-049, 3/28/97) describing a new program to provide pilot-scale support for potentially ground-breaking ideas/methods/systems that meet the following criteria:

1) The proposed research lacks sufficient preliminary data for feasibility to be established, and therein lies the "risk";
2) The successful demonstration of feasibility would have a major, precedent-setting impact on biomedical research; and
3) The research falls within areas supported by NIGMS.

The awards will be coded R21s (Exploratory/Development Grants), and may not exceed $70,000 per annum, direct costs, for a maximum of two years. The receipt dates for applications will be February 1, June 1, and October 1. The applications will be reviewed in DRG study sections, but will not receive percentile scores and will not be included in the base from which percentiles of other applications are calculated. Applications must demonstrate the potential for ground-breaking, precedent-setting significance of the proposed research, with particular emphasis on novel and innovative approaches that clearly require additional preliminary data for their value to be established. The program is *not* intended to provide preliminary data that would establish an investigator's technical qualifications, to provide data in response to a previous critique of an R01 or R29 application, or to augment current funding for similar goals. An additional factor to be considered in making award decisions is the overall level of support available to an investigator.

There is no dollar "set-aside" for the program, but the NIGMS expects to fund all highly meritorious projects meeting the program objectives. Staff will recommend for funding only those proposals clearly meeting the stated requirements. Complete details on this program can be found in the NIH Guide, referenced above, and both the Program Announcement and additional Information for Applicants can be found on the NIGMS Web Site.

 Return to Top

---

GRANTS INVOLVING FOREIGN INSTITUTIONS AND INTERNATIONAL ORGANIZATIONS

The NIH recognizes that special research opportunities exist because of unusual talents, resources, populations, and environmental conditions in other countries that are not readily available in the United

States or that augment existing United States resources. Therefore, NIH makes research grants to foreign institutions, for up to five years of support. Generally, program projects, centers, resources, FIRST Awards (R29), or Institutional National Research Service Awards (T32) are not made to foreign institutions.

During the initial review process, applications from foreign institutions are evaluated and scored with standard review criteria. Reviewers are also asked to comment on: special resources or characteristics of the research project, such as access to special subject populations, animal resources, equipment or techniques; whether similar research is being done in the United States; and whether there is a need for additional research in this area. These issues are not review criteria and are not used in arriving at a priority score. These comments are placed in a special section of the summary statement, and they are used by Institute or Center (IC) staff in making award decisions.

IC staff must document in the official grant file why an application from a foreign institution has been selected for an award. One criterion is the special nature of the foreign site as commented on by the initial review group in the summary statement. Three additional criteria are: that the project has specific relevance to the mission and objectives of the IC and has the potential for significantly advancing the health sciences in the United States; that the application was approved by the IC's Advisory Council or Board; and that assurance was received that the foreign institution is in compliance with human subject, animal welfare, and gender and minority requirements.

Finally, research awards to foreign institutions and international organizations, except conference grants (R13s), require concurrence from the Department of State to ensure conformance with the international policies of the U.S. Government.

 Return to Top

---

PERSONNEL UPDATE

NIH

Appointments: Mr. William Dommel, Director of Education, Office for Protection from Research Risks, Office of the Director (OD)

Dr. Mary Nekola, Chief, Scientific Review Office, National Institute of Aging (NIA)

Dr. Olivia Preble, Chief, Grants Review Branch, National Cancer Institute (NCI)

Dr. John Ryan, Scientific Review Administrator (SRA), National Center for Research Resources

Ms. Laverne Stringfield, NIH Committee Management Officer, OD

Dr. Donald Summers, Associate Director, Frederick Cancer Research and Development Center, NCI

Departure:

Ms. Sue Ohata, Chief, Division of Extramural Inventions and Technology Resources, OD, joined the Howard Hughes Medical Institute as the Manager of Intellectual Property.

Retirements:
Dr. Niles Bernick, Extramural Programs Review Policy Officer, OD

Dr. Robert Browning, Chief, Grants Review Branch, NCI

Dr. Michael Oxman, Chief, Scientific Review Office, NIA

Deaths:
Dr. Harold J. Fournelle joined the NIH Clinical Center in 1961 in the Environmental Services Branch's bacteriology lab. He then moved to DRG to be the executive secretary of the microbiology fellowship review committee. At the time of his retirement in 1973, he was executive secretary of the research training committee in the National Institute of Neurological Disorders and Stroke.

Dr. David L. Joftes joined the NCI in 1974 as chief of the National Organ Site Program. He later moved to the Division of Extramural Activities where he was chief of the Contracts Review and Referral Branch, and later chief of the Contracts Review Branch until his retirement in 1989.

DRG

Appointments:
Dr. Michael Simmons, Professor of Pediatrics, University of North Carolina School of Medicine at Chapel Hill has been appointed as a consultant to address issues related to review of clinical research applications.

Dr. Laurence Stanford, SRA, Neurology B-1 Study Section

Ms. Christine Wisdom, Acting Executive Officer, DRG. Mr. John Jones, who served as Acting Executive Officer from March 1996 to April 1997, returned to the National Institute of Neurological Disorders and Stroke.

Departure:
Dr. Anne Clark, SRA, Lung Biology and Pathology Study Section, joined the National Heart, Lung, and Blood Institute as an SRA in the Review Branch.

Retirements:
Dr. Asher Hyatt, Coordinator and SRA Special Reviews, Biophysical and Chemical Sciences Initial Review Group

Dr. Nicholas Mazarella, Referral Officer, and SRA, Physiological Sciences Study Section

Deaths:
Dr. Betty June Myers, a former SRA of the Tropical Medicine & Parasitology and Specials Study Sections, died unexpectedly at her residence on March 19, 1997. She retired in October 1990.

Dr. Marcel Pons, Referral Officer, and SRA of the AIDS and Related Research C and the Chronic Fatigue Syndrome Study Sections died on February 21, 1997. (See Eulogy to Marcel Pons.)

Mr. Richard W. "Dick" Turlington, a former information officer for the DRG, died on January 11, 1997, in Hendersonville, North Carolina. He retired in 1979.

 Return to Top

---

EULOGY TO MARCEL PONS

Be not burdened with times of sorrow;
I wish you the sunshine of tomorrow.
My life's been full, I savored much:
Good friends, good times, a loved one's touch.

On February 26, 1997, coworkers, family, and past associates participated in a memorial service at the NIH Clinical Center chapel to celebrate the life of Marcel Pons. Marcel was born October 9, 1932 in New York City and was educated in the New York City Public School system. He received a bachelor of arts degree in biology and chemistry in 1954 from the New York University (NYU). Thereafter, Marcel ventured west to study at the University of Michigan, from which he earned both a master of science (1956) and a doctoral degree in bacteriology (1959). (In 1956, Marcel was a member of the U.S. Olympic Fencing Squad.) After completing his doctoral studies, Marcel received a two-year PHS Postdoctoral Fellowship to work at the Children's Hospital and Harvard Medical School, in the laboratory of Nobel Laureate John F. Enders.

Upon completing his education, Marcel returned to New York to accept a position with G. K. Hirst in the department of virology at the Public Health Research Institute of the City of New York. He later held adjunct appointments with NYU Medical School and Hunter College. He left New York again, to become Director of the Laboratory of Molecular Virology at the James N. Gamble Institute of Medical Research in Cincinnati, Ohio, with adjunct appointments at the University of Cincinnati College of Medicine. During this period (1960 to 1988), Marcel was an active, productive, and recognized researcher and mentor, with an emphasis on virology, in particular influenza.

Since 1988, Marcel was a Scientific Review Administrator (SRA) and a Referral Officer in the Division of Research Grants (DRG). He was instrumental in establishing the virology and AIDS study section (ARRC), where he worked until his death. In recent years, he also administered the review of chronic fatigue syndrome applications. Marcel was widely recognized by his associates, especially in the AIDS group, as informed, thorough, and efficient. In addition, he had a wonderful talent for storytelling, too-often hidden behind a quiet, no-nonsense, work-oriented demeanor. He was also known as a voracious reader and an accomplished chef. He is survived by his wife, Joyce, and two daughters, Lisa and Missy.

Return to Top

DRG HOME PAGE

The DRG home page (http://www.drg.nih.gov/) has a new look. A new DRG logo has replaced the 50th anniversary logo. Also new are:

Under *News and Events*

1. A *chronological* list of Scientific Review Group (SRG) meetings for DRG and the Institutes and Centers. The list includes meeting times and locations for the current, previous, and next national advisory council rounds. The meeting information is updated nightly. Plans are in place to enhance the *alphabetized* list of the SRG meetings to provide the same comprehensive information provided by the chronological list.

2. The November 1996 DRG Advisory Committee minutes.

Under *Referral and Review*

1. The scientific area descriptions for the DRG Initial Review Groups and Study Sections.

2. The document "Review Procedures for Initial Review Group Meetings." The guidelines for review of applications for specific types and mechanisms of award (e.g., R01, F32, and SBIR) are included at the end of this document.

3. Links to the NIH Office of Extramural Research's (OER) Grants home page.

4. The latest issue of Peer Review Notes.

Return to Top

GRANT APPLICATIONS REVIEWED

Presented below are the numbers of competing grant applications reviewed by NIH initial review groups for the May 1997 and May 1993 national advisory councils and boards meeting cycles. These statistics, which represent applications reviewed by initial review groups primarily in February and March, were obtained from the NIH IMPAC database.

From the May 1993 to the May 1997 council cycles, the total number of grant applications reviewed by NIH decreased 5 percent, from 12,938 to 12,263. The decrease in the total number of applications reviewed occurred in the Institute and Centers (IC). The total number of applications reviewed in the Division of Research Grants (DRG) increased slightly. The grant mechanism with the largest change (decrease) in number of applications was the Research Project Grant (RPG), dropping 1,085 applications, from 9,444 to 8,359. The number of RPG applications reviewed in DRG dropped 4 percent, from 6,696 to 6,406. The number of RPG applications reviewed in the ICs dropped 29 percent, from 2,748 to 1,953. The drop in IC-reviewed applications for RPGs correlates closely to the reduction in the number of Request for Applications (RFAs), most of which are reviewed in the ICs. Provisional Trend Data on RPG Applications during this decade is available under Awards Data on the NIH/OER grants home page (http://www.nih.gov/grants/oer.htm).

	May 1997	May 1993
Applications reviewed	12,236	12,938
DRG	8,807	8,754
Institutes/Centers	3,429	4,184
Research grant applications	10,763	11,569
Research projects	8,359	9,444

Small business/Technology transfer	1,284	1,022
Research centers	249	203
Other research	871	900
Training applications	1,433	1,309
Fellowships	1,290	1,117
Training grants	143	192
Other applications	40	60
Applications amended	3,254	3,411
Percent of total number reviewed	27	26
Applications responding to RFAs	499	1,417

Return to Top

DRG OFFICE OF THE DIRECTOR AND PEER REVIEW NOTES EDITORIAL BOARD

Division of Research Grants
Office of the Director

Dr. Ellie Ehrenfeld
Director

Dr. Anthony Demsey
Associate Director for Policy and Analysis

Ms. Linda Engel
Associate Director for Planning and Outreach

Ms. Christine Wisdom
Acting Executive Office

Peer Review Notes Editorial Board

Chairperson
Dr. Samuel Rawlings
Scientific Review Administrator,
Sensory Disorders and Language Study Section
Division of Research Grants

Dr. Claudia Blair
Director, Division of Extramural Outreach and Information Resources
Office of Reports and Analysis
Office of Extramural Research
Office of the Director, NIH

Dr. Mark Green
Chief, Extramural Project Review Branch
National Institute on Alcohol Abuse and Alcoholism

Mr. Robert Moore
Director, Statistics and Analysis
Office of Reports and Analysis
Office of Extramural Research
Office of the Director, NIH

Ms. Jo Pelham
Scientific Review Administrator,
Geriatrics and Rehabilitation Medicine Study Section Division of Research Grants

Dr. Michael Rogers
Director, Pharmacology, Physiology, and Biological Chemistry Division
National Institute of General Medical Sciences

Editor

Mr. Nicholas Moriarty
Program Analyst, Office of Planning and Outreach
Division of Research Grants

 Return to Top

Last Revised: June 9, 1997