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PEER REVIEW NOTES September 1999 (Revised 10/1/99)

FROM THE CSR DIRECTOR'S DESK

Fiscal Year 1999 was a banner year for NIH. The generous increase in the budget allowed the Institutes and Centers to announce new initiatives, and the biomedical research community responded enthusiastically, with substantial impact on the peer review system. It was a particularly challenging year for the Center for Scientific Review (CSR), whose less-than-full complement of staff was already burdened by high workloads and the implementation of changes in the peer review process (e.g., new review criteria and modular grants). Against this background, the number of applications normally assigned to CSR increased; review of applications previously evaluated in the former Alcohol, Drug Abuse, and Mental Health Administration Institutes was transferred to CSR; and the Center was called upon to review applications submitted in response to a number of trans-NIH initiatives that otherwise would have been reviewed in the Institutes. Not only were there many more applications to review, but the effort required to manage the process was greater, since many applications were multi- disciplinary and -institutional. The response of CSR staff was outstanding!

That Dr. Varmus' recent Leadership Forum focused on issues related to the increasingly complex way we do science only portends a greater challenge for NIH and CSR. There will likely be more trans-NIH initiatives that involve extensive collaborations within and across disciplines and institutions. The CSR peer review system, designed many years ago with a focus on individual, investigator-initiated research, may no longer provide the one size that fits all. More flexible ways of operation are likely required to facilitate the advance of much of today's science.

In anticipation of this trend, a number of activities are already underway to ensure that CSR's review process will serve the science. First, we are staffing up. We hired 24 Scientific Review Administrators (SRAs) since October 1998 and are in the process of recruiting 10 more. Our aim, pending provision of the necessary funds, is to reach a total of 140 SRAs, approximately one for each standing study section, plus its associated special emphasis panels. This will allow our staff the time and flexibility to accommodate special requests for review of new initiatives by the Institutes and by central NIH offices (e.g., Women's Health, Minority Health), to provide summary statements more rapidly after the meetings, and to maintain their professional contacts and development. In addition, the CSR Advisory Committee has undertaken a number of initiatives, many of which I have reported on previously. One working group, the Panel on Scientific Boundaries for Review, is conducting a comprehensive examination of the organization and function of the CSR review process in two parts. The Phase 1 Draft Report is posted (http://www.csr.nih.gov/bioopp/select. htm) for comment through October 15. In the draft report, the Panel proposes 21 new Integrated Review Groups (IRGs), recommends some cultural norms to govern the operation of the CSR review process, and outlines principles and procedures for Phase 2, in which groups of expert extramural scientists and NIH staff will create the scientifically based study sections that will populate each IRG. I encourage you to read the report and submit your comments via the form provided on the web so the Panel may consider them before finalizing its report later this year.

To complement the across-IRG assessment of the Scientific Boundaries Panel, Working Groups for each IRG are being established to assess, at five-year intervals, the organizing principles and operating procedures for the study sections within each IRG. These external advisory groups will evaluate the appropriateness of research topics and scope of applications reviewed; the evolution of topics and scope of research; how well newly- emerging research areas are being incorporated; and the performance of SRA, Chair and members. To date, such groups have been or are in the process of being instituted for 8 of the 19 current IRGs: Cell Development and Function; Oncological Sciences; Biophysical and Chemical Sciences; Musculoskeletal and Dental, Cardiovascular Sciences; Brain Disorders and Clinical Neuroscience; Molecular, Cellular, and Developmental Neuroscience; and Integrative, Functional, and Cognitive Neurosciences. Their recommendations will be useful in Phase 2 of the Scientific Boundaries Panel activity.

But, no matter how good our organization is, the system is no better than the consultants who render their judgments, and more flexibility is also required to expand the reviewer pool. Thus, in conjunction with the Advisory Committee, we are continuing to explore alternatives to the standard term of service for clinicians and senior leaders in other fields, who cannot meet the demands of managed care and/or serve three-times-per year for four years. We are also exploring ways to enable veterans of the system, who have since gained valuable broad, long-term perspective, to contribute once again.

All participants in the system need information and guidance regarding their roles and responsibilities. To this end, "Guidelines for Study Section Chairs" is now being disseminated; a similar document for reviewers will be produced; and the role of the SRA is being summarized. Plans are also underway to produce a video to convey best practices to first-time reviewers.

Our progress in all these activities depends heavily on the involvement of the

extramural research community. To facilitate your participation, we are working to make the system as transparent as possible and are in the process of redesigning the CSR web site.

More to come in the next year and Millennium!

E.

CSR WEB SITE TO UNDERGO REVISION

A major effort has been initiated to overhaul the CSR web site (<u>http://www.csr.</u><u>nih.gov</u>). User surveys are now underway to determine what information our customers need and how they would like it presented. Your input regarding the content or navigation of our site is welcome. Please send your suggestions or comments to Dr. Patricia Straat at <u>straatp@csr.nih.gov</u>.

CSR WELCOMES NEW STAFF

CSR has been actively recruiting. Following is a list of the new scientific staff members who have joined CSR since February 1999.

Director, Division of Physiological Sciences

Dr. Michael Martin, who holds a Ph.D. in physiology (neurosciences) and has extensive research and administrative experience, has recently been named Director, Division of Physiological Sciences, CSR. As Division Director, Dr. Martin will coordinate and monitor peer review activities of more than 40 standing study sections clustered in six Integrated Review Groups (IRGs).

Assistant Chief in the Division of Receipt and Referral

Dr. Narayani Ramakrishnan

Scientific Review Administrators

Dr. Julian Azorlosa, Biobehavioral and Social Sciences Integrated Review Group (IRG)
Dr. George Barnas, Pathophysiological Sciences IRG
Dr. John Bishop, Integrative, Functional and Cognitive Sciences IRG Dr. Gillian Einstein, Molecular, Cellular and Developmental Neurosciences IRG Dr. Nancy Hicks, Social Science, Nursing, Epidemiology, and Methods IRG Dr. Daniel Kenshalo, Integrative, Functional and Cognitive Sciences IRG Dr. Michael Kozak, Biobehavioral and Social Sciences IRG *Ms. Mary Sue Krause, Social Sciences, Nursing, Epidemiology, and Methods IRG *Ms. Victoria Levin, Risk, Prevention and Health Behaviors IRG Dr. Lee Mann, Risk, Prevention and Health Behaviors IRG Dr. Michael Nunn, Molecular, Cellular and Developmental Neurosciences IRG Dr. Angela Pattatucci, AIDS and Related Research IRG Dr. Michael Sayre, Cell Development and Function IRG Dr. Ranga Srinivas, AIDS and Related Research IRG Dr. Marcia Steinberg, IRG Chief, Cell Development and Function IRG Dr. Tom Tatham, Biobehavioral and Social Sciences IRG Dr. Lawrence Yager, Infectious Diseases and Microbiology IRG

* Transferred from NIMH as part of the behavioral sciences integration.

APPLICATION SUBMISSION: POLICY REMINDERS

This article summarizes several policies that have been in effect for several years regarding the submission of grant applications. The purpose is to save applicants any inconvenience that may result from failure to adhere to these requirements.

Submission of Duplicate Applications

It has been a long-standing Public Health Service (PHS) policy that the same application will not be reviewed within the PHS more than once. Reasons for this policy are to avoid added burdens on the review system, as well as avoid added burdens on principal investigators and their institutions. Therefore, the submission of identical or very similar applications to the agencies of the PHS or to different Institutes/Centers within an agency is not allowed, even if the duplicate submissions occur for different review rounds or in response to different initiatives (e.g., Program Announcements or Requests for Applications). The two exceptions to this policy are: 1) an application for an Independent Scientist Award (K02) may propose essentially identical research as proposed for an individual research project, and 2) an individual research project or center grant application.

In accordance with this policy, the Division of Receipt and Referral, CSR, cannot accept any application that is essentially the same as one currently pending initial review, unless the applicant first withdraws the pending

application. Nor will CSR accept any application that is essentially the same as one already reviewed.

Applicants may submit substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique and indicating how the amended application differs from the previous version.

Limitation on Submission of Amended/Revised Applications

In June 1996, NIH announced a policy (http://grants.nih.gov/grants/policy/ amended apps.htm) limiting the number of amended versions of an application that will be accepted to two. The amended versions must be submitted within two years of the original application. If an applicant is not successful after three attempts at funding (the initial submission and two revisions), she/he is expected to make a significant change in the direction and approach for subsequent research applications. It is not appropriate to submit an essentially identical or only slightly changed application as a new application. Such applications identified by the Division of Receipt and Referral, CSR, will be withdrawn from the review process.

Type Size and Page Limitations

The application kits (PHS 398, PHS 416, SBIR, and STTR) for submitting grant applications to the NIH include instructions limiting the type size and number of pages to be used in preparing applications. In all cases, the type size should be no smaller than 10 point, the type density no more than 15 characters per inch, and there should be no more than 6 lines of type within a vertical inch. Applications with type size exceeding these specifications are difficult for reviewers to read.

Page limitations are specified in each application kit, although they are sometimes modified in specific instructions for Program Announcements or Requests for Applications. Peer reviewers (who are themselves applicants) expect that all applications they review will conform to these requirements. Applications that do not conform to these instructions may be returned to the applicant organization before assignment, or may be withdrawn from the review process after assignment. Therefore, applicants are urged to be sure that their applications conform to these requirements.

Submission of AIDS and AIDS-related Applications

NIH has established an expedited schedule for receipt, review and award of AIDS and AIDS-related applications. These applications have receipt dates several months later than non-AIDS applications (May 1 submission for peer

review in July and for October Council consideration, September 1 submission for peer review in October and for January Council consideration, and January 2 submission for peer review in March and for May Council consideration). The purpose of the later receipt dates is to enable NIH to comply with the requirement that the interval between submission and the funding decision not be longer than six months. If AIDS and AIDS-related applications are submitted in advance of these special receipt dates, they will not be assigned earlier nor will they be reviewed earlier. Rather, applicants will be contacted and asked if they wish the applications held for the next receipt date or returned to take full advantage of the additional time to work on their applications.

Questions on any of these policies may be directed to the Division of Receipt and Referral, Center for Scientific Review at 301-435-0715.

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