PEER REVIEW NOTES
September 2001

From the CSR Director's Desk

Reorganization Update

The Center for Scientific Review (CSR) continues to advance in its Phase 2 reorganization activities to redesign the study sections within the Integrated Review Groups (IRGs). During Phase 2, CSR is recruiting experts from various scientific communities to participate on Study Section Boundaries (SSB) Teams. These teams meet to design a set of study sections and develop guidelines for each IRG proposed by the Panel on Scientific Boundaries for Review (PSBR).

To date, CSR has convened three SSB Team meetings and posted the results of their deliberations on our Web site for public comment. The Hematology SSB Team met in February 2001, and the study section guidelines it proposed were available for comment through July 2001. The SSB Teams for the Biology of Development and Aging and the Musculoskeletal, Oral and Skin Sciences IRGs met in July 2001. Their recommendations are available on our Web site for public comment until November 12 and October 19, 2001, respectively. We welcome your input and invite you to submit your comments at http://www.csr.nih.gov/PSBR/ IRGComments.htm.

Another round of meetings will begin this fall. The Cardiovascular Sciences SSB Team will meet October 31 through November 2. SSB Teams for the two bioengineering IRGs—Fundamental Bio-logy and Technology Development; and Surgery, Applied Imaging and Applied Bio-engineering—will both meet November 7-9, so that members can discuss

and address overlapping issues or concerns that may arise. A meeting of the Oncological Sciences SSB Team scheduled for September 11-13 was canceled due to the national tragedy that occurred then. This meeting will be rescheduled soon.

Approximately three months after these meetings are concluded, three more SSB Teams will meet to define the Digestive Sciences, Immunological Sciences, and Renal and Urological Sciences IRGs. Please check our Web site for future updates on these and other PSBR activities: http://www.csr.nih.gov/EVENTS/ updatephase2.htm.

NIH staff will consider comments received from the research communities and consult with external experts as necessary in making modifications to the proposed study sections. Final approvals will follow presentations and discussions by the CSR Advisory Committee.

New study sections established as a result of this reorganization initiative will begin meeting no sooner than one year after approval. When significant overlap in scientific topics occurs between IRGs, we may seek further guidance from the affected communities and postpone implementation. The reorganization of study sections is a cautious and iterative process that is deliberately progressing slowly in order to achieve the best possible review committees. Your input and assistance is vital to the success of this effort, and we thank you for your support.

SRA Internship Program

CSR initiated a pilot program to train individuals interested in research administration on August 1. Four NIH intramural researchers were selected from 29 highly qualified applicants. These interns will have an opportunity to learn more about the peer-review process and scientific administration at NIH during this 1-2 year program. CSR hopes that these interns will offer CSR flexible workload assistance and serve as a potential pool of trained applicants for future Scientific Review Administrator (SRA) positions. If this pilot is successful, CSR will hire additional interns from the NIH intramural community next year. CSR plans to open the program so that scientists in academia and industry may participate in future years.

New Fellowship Study Sections

As you may recall from the last issue of *Peer Review Notes*, CSR plans to review applications for individual National Research Service Awards (NRSA) in dedicated fellowship sections beginning with those submitted for the August 5, 2001 submission date. A summary of this initiative and our progress is now available on our Web site: http://www.csr.nih.gov/events/ fellowship_ss/ fellow_ss.htm

Redesign of CSR's Web Site

We are beginning to redesign the CSR Web site. We have given it a fresh look and added many new pages. Additional changes are planned to improve access to critical information on our ongoing activities. You are encouraged to visit our site for the latest CSR information and news: http://www.csr.nih.gov.

Ellie Ehrenfeld, Director, CSR

New Personnel at CSR

Since the last issue of *Peer Review Notes*, restrictions on hiring new Federal employees were modified. We are pleased to report that CSR has been able to hire many new employees to fill new and vacant positions.

Dr. George Chacko is the new SRA of the Special Reviews (SSS-H) Study Section that reviews applications in the area of computational biology. He received an M.V.Sc. in veterinary pathology from the College of Veterinary Medicine in Bangalore, India, and a Ph.D. in biochemistry from Ohio State University in Columbus. Dr. Chacko comes to CSR from the Laboratory of Immune Cell Biology at the National Cancer Institute, where he was a Cancer Research Training Award Fellow.

Dr. Alicia Dombroski just became the SRA of the Microbial Physiology & Genetics 1 Study Section. She holds a Ph.D. in biochemistry from the University of Rochester. Dr. Dombroski recently was an associate professor of microbiology and molecular genetics at the University of Texas Health Science Center in Houston.

Dr. Samuel Edwards has become the SRA of the Allergy and Immunology Study Section. He holds a Ph.D. in zoology from the University of Maryland in College Park. Dr. Edwards comes to CSR from the University of South Florida in Tampa, where he was a research assistant professor in its Department of Pharmacology and Therapeutics.

Dr. Jeffrey Elias recently became the new SRA of the Behavioral and Biobehavioral Processes 5 Study Section. He holds an M.S. in developmental psychobiology from the University of Northern Illinois in Dekalb and a Ph.D. in life span psychology from the University of West Virginia. He previously was Director of Research for its Sanford Center for Aging.

Dr. Robert Freund has become the SRA of the Experimental Virology Study Section. He received his Ph.D. in molecular biology from Harvard University. He previously was an assistant professor in the Department of Microbiology and Immunology at the University of Maryland at Baltimore.

Dr. Patricia Greenwel is the new SRA for the Alcohol and Toxicology Subcommittee 1 Study Section. She received an M.S. and a Ph.D. in experimental pathology from the Albert Einstein College of Medicine. Dr. Greenwel comes to CSR from the Mt. Sinai School of Medicine, where she was an assistant professor in its Department of Biochemistry and Molecular Biology and its Department of Medicine.

Dr. Ann Hardy is now the SRA of the Social Sciences, Nursing, Epidemiology and Methods 5 Study Section. She received a master's degree in microbiology and a doctorate in public health from the University of Pittsburgh Graduate School of Public Health. Dr. Hardy recently served as the Associate Director for Science in the Division of Health Interview Statistics at the Centers for Disease Control and Prevention.

Dr. Mary McCormick is the new SRA for the Special Review (SSS-G) Study Section that reviews applications for shared instrumentation grants. In the next review round, she will coordinate the review of applications for genetics and infectious diseases fellowships. Dr. McCormick earned her Ph.D. in molecular biology from the State University of New York at Stony Brook. Prior to coming to CSR, she was a senior program analyst at the Howard Hughes Medical Institute in Bethesda.

Dr. Daniel McPherson is now the SRA for the Diagnostic Radiology Study Section. He holds a Ph.D. in organic chemistry from Auburn University. Dr. McPherson comes to CSR

from the Oak Ridge National Laboratory in Tennessee, where he was a staff scientist.

Dr. Weijia Ni has become the SRA for the Behavioral and Biobehavioral Processes 3 and 5 Study Sections. He holds a Ph.D. in psycholinguistics from the University of Connecticut in Storrs. Before coming to CSR, Dr. Ni was an associate research scientist at the Yale University School of Medicine.

Dr. Michael Schaefer recently joined CSR to be the SRA of the new F08 Fellowship Study Section: Prokaryotic and Eukaryotic Molecular Biology and Genetics. He earned his Ph.D. in biochemistry and biophysics from Texas A&M in College Station, Texas. Dr. Schaefer had been an associate professor in the Division of Molecular Biology and Biochemistry at the University of Missouri in Kansas City.

Dr. Paul Wagner has become the SRA of the new Skeletal and Muscle Biology Special Emphasis Panel. He received his Ph.D. in biochemistry from Washington State University in Pullman, Washington. Dr. Wagner comes to CSR from the Laboratory of Biochemistry at the National Cancer Institute.

Role of the Program Officials at Study Section Meetings

Reviewers may notice Institute and Center (IC) representatives attending portions of their study section meeting, usually sitting at the periphery of the room. IC program staff bear important responsibilities in the initial review process, and it may be useful to review these.

Prior to review meetings, the SRAs handle applicant questions concerning study section assignment, submission of extra data, concerns about reviewer expertise, and other related issues. During review meetings, program staff serve as resources for the SRA if any IC-specific policy questions arise. After the meetings, however, program staff are responsible for working with applicants in all matters related to the review and funding process. Though the resumes produced by the SRAs capture the review discussions, program staff gain a richer understanding by being present during these discussions. They are thus better able to assist applicants and perform related duties. Program staff are also responsible for presenting program positions on study section recommendations at IC council meetings.

CSR study sections usually review applications with a range of primary IC assignments, and program staff members usually attend only a portion of the study section meetings when applications assigned to their IC are discussed. An SRA therefore will often arrange the order of review by IC assignments so that program representatives can attend only the portion of the review that is of the greatest interest and relevance.

Program staff often assists the SRAs in identifying prospective study section members. The SRA may also consult with program staff to identify ad hoc reviewers for applications with unusual scientific content. A good working relationship between SRA and program staff therefore assures the highest quality scientific review and the most helpful service to the applicants.

Scanning Applications

CSR has now completed an extensive pilot of using CD-ROMs containing optically scanned grant applications in the eight study sections reviewing AIDS applications. These CDs take

the place of the books of paper duplicates that reviewers have in the past been provided for their unassigned applications. The electronic images on the CDs are equivalent to black and white photocopies. Reviewers still receive paper copies of assigned applications.

About half of all members in the pilot brought a laptop computer to the meeting to refer to the electronic applications. Members without laptops were supplied paper copies at the meeting. Reviewers have overwhelmingly reported a preference for CDs because of their light weight and the increased mobility they afford. Ease of use and the addition of bookmarks for enhanced navigation through the applications also contributed to reviewer enthusiasm for the CDs. Less than 2 percent of reviewers indicated a preference for paper.

Due to the success of this pilot, CSR will expand the use of CDs to a second IRG in the February/March 2002 review cycle. We are also developing a plan to optically scan all applications received by CSR by the spring of 2002. To achieve this goal, CSR will take advantage of NIH's upgraded bulk photocopiers that currently generate paper duplicates. These digital copiers can store electronic images that can be used to create CDs or paper sets of applications on demand. CSR hopes to introduce CDs (with paper available by request) to all study sections by the latter half of 2002. Along the way, we will carefully monitor the effect this change may have on the peer review process.

Application Format Update

In response to concerns from reviewers and SRAs, NIH recently increased its efforts to ensure compliance with format requirements for grant and cooperative agreement applications. The increased use of scanning (see previous article) also requires that applications follow the NIH requirements for format. In the first few months of the year, approximately 200 applications were returned, and investigators had to wait until the next cycle to submit their applications. Since May 2001, when problem applications are identified in CSR's Division of Receipt and Referral, investigators have been contacted and asked to correct the problems in a few days. Corrections have been obtained for more than 300 research and small business grant and fellowship applications. In a few cases, the "corrected" version was still not compliant with the NIH requirements and the application was returned for submission in the next cycle. In a few other cases, the corrected version was submitted too late and the applications had to be held for the next cycle. Not all of the applications with problems are identified in the initial spot-checking, and noncompliant applications may be returned or deferred later in the review process.

Checking and obtaining corrected versions of grant applications is a very labor-intensive process for CSR staff. Principal investigators and offices of sponsored research are asked to pay more careful attention to the requirements for type size, page limits, margins, etc. These requirements are highlighted in many places in the latest version (rev. 5/01) of the PHS 398 application kit: http://grants.nih.gov/grants/forms.htm. The *NIH Guide for Grants and Contracts* announcement of May 4, 2001 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-037.html) provides additional information, including a link to Frequently Asked Questions and a special e-mail address for asking questions about application format (format@mail.nih.gov). Failure to follow these requirements may significantly delay the review of an application.

New Version of PHS 398

In July 2001, the newest revision of the PHS 398 grant application kit ("Application for a DHHS Public Health Service Grant" PHS 398, rev. 5/01) was made available for use. All applications received on or after January 10, 2002 MUST use this version of the application kit. While applicants are permitted to use the prior (rev. 4/98) version until then, they are encouraged to use the new version now.

There are a number of changes in the revised application kit that investigators should note and take advantage of:

- This version is available primarily in an electronic format: http://grants.nih.gov/grants/forms.htm. It will be updated on an ongoing basis to incorporate suggestions for making it more user-friendly and to reflect changes in procedures and policies. You should thus be sure you are using the most up-to-date instructions and forms when you submit an application. Updates will be announced in the *NIH Guide* and listed at the following Web site: http://grants.nih.gov/grants/funding/phs398/phs398.html#updates.

- The form pages may be filled in using Adobe Acrobat Reader software, although the full-featured version of this software package is needed to save pages. Some of the form pages (Continuation Page, Biographical Sketch Format Page, and Other Support Format Page) are also available in Microsoft Word format. NIH has established a Frequently Asked Questions site that includes many helpful hints for downloading and using the new application kit: http://grants.nih.gov/grants/forms_faq.pdf

- The electronic version has numerous links to instructions and information on grant policies and information in the *NIH Guide*.

- The PHS 398 is now to be used in applying for Small Business Innovation Research (SBIR) grants and Small Business Technology Transfer (STTR) grants in addition to R01, R03, R15, R21, and other research grants, Career Awards (K series), and Institutional Training Awards (T32, T35). The application kit thus includes three additional sets of instructions and forms.

- Page 1 has a yes/no checkbox to identify phase III clinical trials.

- Page 1 also has a yes/no checkbox for exempted human subjects research.

- There is now a standard Biographical Sketch format for modular and nonmodular applications and a four-page limit.

- There also is a new format page for modular budget justification.

- Information on the inclusion of women and minorities is now included in the Human Subjects Section, not the Research Plan. All information on the use and protection of human subjects is thus consolidated in one section.

- Information categories in the race/ ethnicity tables have been updated to reflect the current Office of Management and Budget criteria.

- Appendix materials may no longer include manuscripts submitted for publication; only publications and manuscripts accepted for publication are allowed.

Questions regarding the PHS 398 should be directed to GrantsInfo (GrantsInfo@nih.gov or 301-435-0714).

Questions regarding the use of the new forms and the Adobe Acrobat Software may be directed to 301-435-0940.

Note: There is also a new version of the PHS 2590 ("Non-competing Grant Progress Report"). See this site for more information: http://grants.nih.gov/grants/funding/2590/2590.htm.

New Special Emphasis Panels

CSR reviewers, professional societies, and patient advocate groups often ask about the process of forming new special emphasis panels (SEPs) that meet on an ongoing basis. The impetus for forming these new study sections is varied, such as increased workload, emerging area of science, congressional mandate, or scientific community or NIH Institute/Center (IC) interest. In addition to the 44 new neuroscience, AIDS, and behavioral science study sections, 7 additional study sections have been formed over the last four years: Clinical Oncological Sciences, Clinical Cardiovascular Science, Urological Sciences, Vaccines, Bioinstrumentation, Epidemiology and Disease Control 3, and Pathology C. An eighth study section, the Skeletal Muscle Biology SEP, will hold its first meeting this fall. Some of these eight review groups may be temporary, pending future evaluation and analysis.

CSR has developed a process that we hope will allow for maximum community input once a need to discuss a new or modified study section is identified. One of the three CSR review divisions will assume the lead responsibility for overseeing the discussions. With the assistance of CSR and NIH program staff, the given Division Director will identify the subject areas that need to be represented and individuals from the extramural scientific community who represent these fields. The various community representatives are then invited to participate in a working group to develop a recommendation for the CSR Advisory Committee. In this way, CSR hopes to insure that all stakeholders (members of the research community, relevant IC program staff, and CSR staff) will be involved in the process of creating the new study section. The majority of individuals involved in the working group will be from the extramural research community.

Once the working group is formed, CSR staff will provide it with information on the applications in the areas under consideration. This information may include a collection of abstracts of applications reviewed during one or more review cycles, a title list of applications reviewed during the past year, or some other compilation of information describing the applications under consideration. Using this information, the working group will develop its recommendations. If a new study section is justified, the working group will prepare proposed guidelines for it. The report of the working group then will be submitted to the CSR Advisory Committee for further public discussion before implementation.

Skeletal Muscle Biology SEP

In recent years, the community has shown a growing interest in having CSR consolidate the review of skeletal muscle biology applications into one study section. Over the past summer, members of Congress urged CSR to consider establishing a muscle biology study section. CSR thus worked with NIH program staff to develop a working group of outside experts from the relevant research communities, e.g.,

the muscle disorders including dystrophies, geriatrics, rehabilitation, exercise, muscle metabolism, muscle physiology, etc. Twenty-four members were recruited, including a chair, Dr. Leslie Leinwand, from the University of Colorado at Boulder: http://www.csr.nih.gov/EVENTS/muscleBioRoster.htm. At a March 2001 meeting, the working group considered the various options and subsequently developed a report with a set of guidelines for a new Skeletal Muscle Biology SEP. This report was accepted by the CSR Advisory Committee, and it is posted on the CSR Web site: http://www.csr.nih.gov/News/MBWGnews.htm. The SRA for this new SEP, Dr. Paul Wagner, has recruited members for the October 2001 review round.

The Skeletal Muscle Biology SEP is temporary, and it may be modified as a part of the larger PSBR reorganization process. The Study Section Boundaries (SSB) Team established to define the boundaries of the Bone, Muscle, Connective Tissue and Skin IRG proposed by the PSBR met in July 2001. This SSB Team has recommended a Skeletal Muscle, Exercise and Rehabilitation Study Section which has many of the elements of the Skeletal Muscle Biology SEP that starts this fall (http://www.csr.nih.gov/PSBR/MOSS/MOSSIntro1.htm). If the recommendations of this SSB Team are accepted, the Skeletal Muscle Biology SEP would emerge as the Skeletal Muscle, Exercise and Rehabilitation Study Section in the next two years.

Fundability of Unscored Applications

Scientific Review Groups are responsible for making recommendations on applications. According to NIH policy, applications may be scored, unscored, or not recommended for further consideration (NRFC). "Unscored" applications that fall in the lower half of all the applications considered may have scientific merit, but they are almost never funded. In theory, however, an unscored application could be funded if a compelling reason was presented to the relevant NIH advisory council. On the other hand, an application given an NRFC designation because it has no significant and substantial merit cannot be funded. A NRFC designation is also given to applications with unacceptable human subjects risks, vertebrate animal risks, or biohazards. Such applications would similarly not be candidates for funding. The complete policy statement on this issue is available at the following Internet address: http://odoerdb2.od.nih.gov/oer/policies/oer_announce_1996_04.htm.