NIH PEER REVIEW NOTES
June 1998

FROM THE CSR DIRECTOR'S DESK

These are extremely busy times in CSR, as we are moving ahead on several fronts simultaneously; and I am pleased and excited with all we have accomplished thus far. Much remains to be completed, but much has been done. I would like to take this opportunity to comment on two initiatives.

Initial Meeting of the Panel on Scientific Boundaries for Review

The Panel on Scientific Boundaries for Review held its first meeting on April 29th, at which they were charged with: (1) defining the broad domains of science that reflect both the current and future research landscape; and (2) developing guiding principles for creating new study sections. The Panel plans initially to carry out its work via Web-based chat groups, and will assess its progress around July 1. I am pleased to announce that Dr. Francisco Ayala, Donald Bren Professor in the Department of Ecology and Evolutionary Biology at the University of California at Irvine, has agreed to chair the group.

Results from First Round of Implementing the New Review Criteria

During the February-March 1998 review meetings, reviewers used the new review criteria for the first time. The new criteria (significance, approach, innovation, investigator, environment) were developed to help rebalance the evaluation for each proposed project from what is perceived as a current emphasis on technical feasibility and methodology to one that includes innovation and the potential impact of the research on the scientific field. The goal would be to have reviews stress the value of innovative concepts and approaches rather than safe science.

Although it is premature to develop any formal or final evaluation, a preliminary assessment might be worthwhile. Not surprisingly, we found that old habits die slowly. Most reviewers seemed to adapt to the change in format, which required them to address each criterion individually, but relatively few reviewers shifted their focus from feasibility to innovation and

the potential impact on the field. Many were not clear on how to evaluate innovation or how to weigh the criteria. CSR staff will continue to work with reviewers on these and other issues as identified.

I wish all of you a healthy and productive summer.

Ellie Ehrenfeld

CHANGE IN NIH POLICY OF SUPPORTING NEW INVESTIGATORS

NIH has announced a policy to provide new investigators, who are so important to the future of biomedical research, with the maximum freedom in identifying the level and period of support needed for their proposed projects. Under this policy, new investigators are encouraged to submit traditional research project grant (R01) applications, which will be identified as being from new investigators. At the same time, effective June 1998, First Independent Research and Transition (FIRST; R29) Award applications will no longer be accepted.

To ensure fair reviews for new investigators, who often lack experience in preparing applications, NIH staff used the winter 1997-1998 round of study section and Advisory Council meetings to explain the change in policy. New investigators, well before the June date, were also encouraged by NIH staff to submit R01 applications.

For the June meetings, reviewers will be reminded of the definition of new investigators, and provided with a list of new investigators who have submitted applications for review at their meeting. The NIH is also revising application forms to allow new investigators to indicate this status.

During the transition period when this change in policy is being implemented, NIH will make every effort to ensure that new investigators are not disadvantaged and to accommodate their needs. NIH has committed to support at least the current number of new investigators and possibly to direct more resources to their support.

NEW NIH CAREER AWARDS IN CLINICAL RESEARCH

On April 6th the NIH announced three new career development awards designed to attract talented clinicians to the challenges of clinical research and to improve the quality of clinical research training. Each award addresses recommendations in a Report of the NIH Director's Panel on Clinical Research, which was chaired by Dr. David Nathan, President of the Dana-Farber Cancer Institute in Boston (see the Report at http://www.nih.gov/news/crp/97report/index.htm). The Panel felt strongly that the NIH should enhance the Nation's capacity for clinical research by establishing new support mechanisms for young clinical investigators, by improving the availability of formal training in clinical research, and by increasing access to experienced research mentors.

K23 The Mentored Patient-Oriented Research Career Development Award will support clinicians who have finished their clinical training and need 3 to 5 years of supervised research and study to develop into an independent investigator in patient-oriented research. The program of training will consist of a mixture of didactic and supervised research experiences tailored to the developmental needs of the candidate. The receipt dates are February 1, June 1, and October 1, and applications will be reviewed by Institute Scientific Review Groups. The NIH anticipates making at least 80 awards in Fiscal Year (FY 1999). For more information about the K23 award, use the following Web site address: http://www.nih.gov/grants/guide/pa-files/PA-98-052.html .

K24 The Mid-Career Investigator Award in Patient-Oriented Research supports clinical scientists who are within 15 years of their specialty training and can devote between 25 percent and 50 percent of their professional effort to serve as a mentors to the next generation of clinical scientists. Project periods are between 3 and 5 years. The NIH expects to make between 60 and 80 awards in FY 1999. Additional information is available at http://www.nih.gov/grants/guide/pa-files/PA-98-053.html .

K30 The Clinical Research Curriculum Award supports institutions as they develop formal curricula designed to impart to new clinical investigators the fundamental skills, methodology, theories and conceptualizations necessary to establish an independent career in clinical research. Institutions with a strong clinical research faculty who are also committed to establishing a clinical research core curriculum are invited to apply for these 5 year renewable grants.. The National Heart, Lung, and Blood Institute will administer this program for the NIH. The receipt date is October 21st, and it is expected that approximately 20 awards will be made

in FY 1999. Additional information is available at http://www.nih.gov/grants/guide/rfa-files/RFA-OD-98-007.html .

NIH POLICY ON INCLUDING CHILDREN IN NIH SUPPORTED RESEARCH INVOLVING HUMAN SUBJECTS

In the March 6, 1998, issue of the NIH Guide for Grants and Contracts, NIH published guidelines for including children in research involving human subjects. Applications submitted to NIH for and after October 1, 1998, are governed by these guidelines, and must describe plans for including or excluding children in the study population of a proposed project. (For this policy, a child is defined as "an individual under the age of 21 years.")

This policy was developed because medical treatments applied to children were sometimes based upon testing done only on adults; and therefore, adequate data were often not available to support treatment modalities for diseases and disorders affecting adults and children. These concerns were specifically brought out in the FY 1996 House and Senate Appropriations Committee reports. The Committees "encouraged" NIH to establish guidelines to include children in human subject research supported by the NIH.

In essence, the NIH guidelines for the inclusion of children parallel earlier efforts with respect to adequate representation of both genders and minorities in study populations. As with the earlier guidelines, there is a list of justifications (7 in these guidelines) for excluding the specific group of people. Also the responsibilities extend to both sides of the review process. Thus, Institutional Review Boards are now required to address the appropriateness of representation of children in human subject research in terms of the aims of the research and ethical standards. Scientific Review Groups will also evaluate the scientific rationale for the inclusion or exclusion of children in the research protocols. Finally, as with the earlier guidelines, there will be special codes to be entered into the IMPAC computer system.

Program, review and other NIH staff will be trained in this new policy in June and July 1998, and reviewers will be trained by staff of the Center For Scientific Review at the fall review meetings. Background materials will also be available on the WEB by accessing: http://www.nih.gov/grants/guide/

notice-files/not98-024.html

GRANT APPLICATIONS REVIEWED

Presented below are the numbers of competing grant applications reviewed by NIH scientific review groups for the May 1994 - 1998 national advisory councils and board meeting cycles. These statistics, which represent applications reviewed by scientific review groups primarily in June and July, were extracted from the NIH IMPAC database.

	May Council Cycles				
	1994	1995	1996	1997	1998
Applications Reviewed	14608	14518	12500	12531	13099
CSR	9955	10497	9196	9066	9147
Percent of Total	68.1	72.3	73.6	72.3	69.8
Institute/Center	4653	4021	3304	3465	3952
Percent of Total	31.9	27.7	26.4	27.7	30.2
Research Grants*	13123	12824	11011	11051	11693
Research Projects	10111	9915	8884	8565	8840
SBIR/STTR	1731	1695	986	1297	1352
Research Centers	170	204	270	302	283
Other Research	1111	1014	871	887	1218
Training Applications	1399	1610	1459	1439	1346
Fellowship	1226	1378	1256	1295	1218
Training Grants	173	232	203	144	128
Other Applications	86	84	30	41	60
Applications Amended	3917	4254	3959	3312	3428

Amendments as a Percent of Total	26.8	29.3	31.7	26.4	26.2
Applications Responding to RFA's	1815	1200	646	448	866
RFA's as a Percent of Total	12.4	8.3	5.2	3.6	6.6

* Research Grants includes Research Projects, SBIR/STTR, Research Centers, and OtherResearch.

[Referral & Review]

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