DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CENTER FOR RESEARCH RESOURCES

NATIONAL ADVISORY RESEARCH RESOURCES COUNCIL
MINUTES OF MEETING
MAY 18, 2000

The National Advisory Research Resources Council (NARRC) convened for its 115th session at 8:00 a.m. on Thursday, May 18, 2000, with a meeting of the Executive Subcommittee held in Conference Room 3B13, Building 31. The full NARRC was convened at 9:15 a.m. in Conference Room 6, Building 31. Dr. Judith L. Vaitukaitis, Director, National Center for Research Resources (NCRR), National Institutes of Health (NIH), presided as Chair. The meeting was open to the public until 1:30 p.m, at which time it was closed to the public for the review, discussion, and evaluation of grant applications as provided in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code, and Section 10(d) of Public Law 92-463.[1] At 3:30 p.m., the meeting reopened to the public until adjournment at 4:15 p.m.

COUNCIL MEMBERS PRESENT

Dr. Joseph D. Andrade
Dr. Kenneth I. Berns
Ms. Catherine D. Bertram
Dr. Delwood C. Collins
Dr. Muriel T. Davisson
Dr. Robert J. Desnick
Dr. Chien Ho
Dr. Peter G. Katona
Dr. Peter O. Kohler
Dr. Peter A. Kollman
Dr. William R. Morton
Dr. Burton A. Weisbrod
Dr. Donald E. Wilson
Dr. James H. Wyche
Capt. Kenneth C. Hyams
Ex-Officio, DOD
Dr. William W. King
Ex-Officio, VA
Dr. Machi F. Dilworth
Liaison Member, NSF
Dr. Roland F. Hirsch
Liaison Member, DOE

COUNCIL MEMBERS ABSENT

Dr. Michael M.E. Johns
Dr. Evangelia G. Kranias
Dr. Diana S. Natalicio
Dr. Judith L. Swain

[1]For the record, it is noted that to avoid a conflict of interest, Council members absent themselves from the room when the Council discusses grant applications from their respective institutions or when a conflict of interest (COI) may occur. Members are asked to sign COI statements. This does not apply to "en bloc" actions.

SPECIAL INVITED GUESTS FOR OPEN SESSION:

Dr. Robert J. Beall, President and Chief Executive Officer, Cystic Fibrosis Foundation, Bethesda, Maryland
Dr. Thomas A. Buchanan, Professor of Medicine, Obstetrics and Gynecology, University of Southern California School of Medicine, Los Angeles
Dr. Jerry K. Davis, Director, Department of Pathobiology, Division of Comparative Medicine, University of Florida, Gainesville
Dr. Wilfred J. Fujimoto, Professor of Medicine, University of Washington, Seattle, Washington
Dr. Terry Gaasterland, Assistant Professor and Head, Laboratory of Computational Genomics, The Rockefeller University, New York City
Dr. Peter Karp, Director, Bioinformatics Research Group, SRI International, Menlo Park, California
Dr. Ruth Kirschstein, Acting Director, National Institutes of Health, Bethesda, Maryland
Dr. Earl D. Mitchell, Associate Vice President for Multicultural Affairs, Oklahoma State University, Stillwater
Dr. Pamela H. Mitchell, Elizabeth S. Soule Professor, Department of Biobehavioral Nursing and Health Systems, University of Washington, Seattle

STAFF OF OTHER NIH COMPONENTS:

Dr. Sally Amero, CSR/NIH
Dr. Houston Baker, CSR/NIH
Dr. Marjam Behar, CSR/NIH
Dr. Eugene Vigil, CSR/NIH

OTHERS PRESENT:

Dr. Rey Elizondo, University of Texas, El Paso
Mr. Steve Heinig, Association of American Medical Colleges,Washington, DC
Mr. Tom Hogan, *The Blue Sheet*, Chevy Chase, Maryland
Dr. Nancy Moi, SRI International, Menlo Park, California
Ms. Pamela Moore, *Capital Publications,* Alexandria, Virginia

I. Call to Order
Dr. Judith Vaitukaitis, Director, NCRR

Dr. Vaitukaitis welcomed NARRC members and guests to the 115th meeting of the Council. She announced that the following Council members would be unable to attend: Drs. Michael Johns, Evangelia Kranias, Diana Natalicio, and Judith Swain. She introduced four new Council members: Ms. Catherine D. Bertram, Esquire of Whiteford, Taylor, and Preston, Washington, DC; Dr. Robert J. Desnick, Professor and Chairman, Department of Human Genetics, Mount Sinai School of Medicine, New York City; Dr. Peter A. Kollman, Professor and Associate Dean for Academic Affairs, Department of Pharmaceutical Chemistry, School of Pharmacy, University of California, San Francisco; and Dr. William R. Morton, Director of the Regional Primate Research Center and Professor in the Department of Comparative Medicine, University of Washington, Seattle. She also introduced the invited guests.

II. Consideration of Minutes

The minutes of the January 27, 2000 NARRC meeting were approved as written.

III. Future Meeting Dates

Dr. Vaitukaitis announced that the next NARRC meeting will be held on Thursday and Friday, September 7 and 8, 2000. A one-day meeting will be considered, and Council members will be notified when a decision is made.

IV. Personnel Update

Dr. Vaitukaitis announced that Dr. Harold Slavkin resigned his position as Director of the National Institute of Dental and Craniofacial Research to accept the position of Dean at the University of Southern California, Los Angeles. Dr. Neal Nathanson will leave his position as Director of the NIH Office of AIDS Research.

Dr. Vaitukaitis also announced recent NCRR personnel actions as follows: Dr. Richard DuBois, a health scientist administrator in the Biomedical Technology area, retired following a distinguished 32-year Federal career. Mr. John Seachrist is the new Director of the Office of Grants Management. Dr. John Ryan returned to NCRR from the National Cancer Institute. Ms. Antonette Neal joined the Committee Management Office as a committee management assistant to replace Sheryl Lane, who moved to the NCRR Office of Grants Management.

Dr. Vaitukaitis announced that several major personnel appointments are pending and that NCRR will receive ten additional full-time positions.

V. Legislative Update

Dr. Vaitukaitis directed the Council's attention to a summary of recent Federal legislative activities.

VI. Budget Update

Dr. Vaitukaitis reported that the final NIH appropriation for the Fiscal Year (FY) 2000 was included in an omnibus bill that was passed in late November 1999. She reported that the final FY 2000 NIH appropriation is $17.9 billion. NCRR's FY 2000 appropriation is $680.2 million, a 22.6 percent increase. But, an NIH-wide rescission reduces the NCRR level to $676.6 million. The President's FY 2001 budget request was released February 7, 2000 requesting $18.8 billion for NIH, an increase of $1 billion, or a 5.6 percent increase over the FY 2000 appropriation. The request for NCRR is $714.2 million, an increase of $37.6 million, or 5.6 percent over this fiscal year. Within this amount, $72.5 million is approved for extramural construction, $44.7 million approved for shared instrumentation, $40 million approved for Institutional Development Awards, and $14.5 million approved for Science Education Partnership Awards. A number of initiatives in these programs and others will be undertaken, including advancing technologies for human and animal imaging, establishing bioinformatics centers of excellence and a comprehensive center on health disparities, and supporting clinical research training and career development.

VII. Funding for Clinical Research Pilot Projects
Dr. Thomas Buchanan, Professor of Medicine and Obstetrics and Gynecology, School of Medicine, University of Southern California

Dr. Thomas Buchanan explained that at the annual meeting of the directors of the General Clinical Research Center (GCRC), small working groups explore new ideas to enhance the efficiency and effectiveness of the GCRCs in a number of areas. Some of these ideas can be implemented by working with NCRR staff but others need Council approval to be implemented. Last year, for example, the Council approved informatics and related training initiatives recommended by GCRC leadership.

Dr. Buchanan reviewed eight clinical research ideas generated this year by the working groups, and then presented one new initiative for Council's approval. This initiative would allow NCRR to fund pilot clinical research projects of junior faculty–ranks equal to or less than assistant professor–and of senior faculty only if they have a change in research career path. An example of such a career change would be a person who has conducted basic research and then wants to apply that research in a clinical setting. He cited a number of NIH funding mechanisms that already support medical students and associate and full professors, and said this new initiative would help fill a void for junior faculty support. He suggested that pilot project grants would fund scientifically valid, new, and novel hypotheses but would not supplement ongoing research.

Funded projects should generate critical preliminary data and have a clear plan for how the data will be collected and applied. Applications will undergo scientific review by both a local GCRC scientific advisory committee and NCRR. Award recipients would be required to prepare a final report. Awards would be $20,000 for one-year renewable grants, and each GCRC would be limited to receiving a total of $100,000 annually. Dr. Buchanan provided examples of successful pilot project programs underway at the University of Vermont and the University of California, San Francisco. Following discussion and clarification on several points, Council approved the GCRC directors' recommendation for NCRR to support pilot projects through the GCRC program to help junior faculty begin independent clinical research careers at GCRCs where they can benefit from the presence of mentors.

VIII. Clinical Trials Network: Expediting the Drug Development Process
Dr. Robert Beall, President, Cystic Fibrosis Foundation

Dr. Robert Beall explained the Cystic Fibrosis Foundation's (CFF) strategy to reduce time and cost for discovery and evaluation of drugs to treat cystic fibrosis (CF). He said an important element of this strategy is a CFF partnership with NCRR-supported General Clinical Research Centers to facilitate CF clinical trails. There are currently five therapeutic approaches to treating cystic fibrosis, an orphan disease which affects only about 30,000 individuals. He said it typically takes 15 to17 years for a drug to reach development and the cost per drug is about $400 million.

Dr. Beall said the CFF has accredited 114 care centers, which follow about 22,000 of the diagnosed CF patients nationwide. Epidemiological and clinical data on all CF patients of the care-center network is entered in a national data registry, established over 30 years ago. The NCRR-supported GCRC at the University of Washington, Seattle, is the coordinating center for the CF clinical trials network. CFF supports this GCRC's administrative and clinical trail units and NCRR supports the data management and statistical units. The data management unit has reduced paperwork by 92 percent. It is an internet-based system that can rapidly accrue data. In addition, CFF provides about $200,000 in infrastructure support, such as for nurse coordinators, to eight other NCRR-supported GCRCs that are also part of the cystic fibrosis clinical trials. He said a majority of the patients in the cystic fibrosis clinical trials use GCRC facilities. To date, three clinical trials have been completed, six are underway, two are pending, and three concept proposals are pending.

Dr. Beall praised the GCRC participation in the CFF network and said that these clinical trials would not take place without the GCRC program. He said as other GCRCs are added to this network, access, staff support, Institutional Review Board and Scientific Advisory Committee reviews, and budgets for ancillary services, which vary from site to site, should be standardized. Nevertheless, he said, this creative use of resources provides the infrastructure that is critical to making a network such as this move forward.

IX. Research Infrastructure Concept Clearances
Dr. Sidney McNairy, Associate Director, Research Infrastructure, NCRR

Dr. McNairy presented three concepts to Council for approval: (1) NCRR proposes to continue to limit the total budget request for the Animal Facilities Improvement Program support to $700,000 (direct cost), but allow the entire amount to be used for alterations and renovations. The maximum amount that may be used for equipment will be $200,000; (2) NCRR proposes to increase the maximum allowable request from the Regional Primate Research Centers to $1million for the purchase of expensive equipment used for research on HIV/AIDS and other infectious diseases; and (3) NCRR proposes to waive the matching funds requirement for minority graduate and health profession schools competing for funds to upgrade animal research facilities. This support would likely allow them to meet the standards required to receive accreditation by the Association for the Assessment and Accreditation of Laboratory Animal Care. Council unanimously agreed with these concepts. Council also agreed that NCRR's Program Announcement should state that competing institutions have the option to request a waiver of matching funds.

X. Recommendations of Working Group on Bioinformatics
Dr. Peter Karp, Director, Bioinformatics Research Group, SRI International

Drs. Peter Karp and Terry Gaasterland presented the *Bioinformatics Working Group Report* which was developed in response to *The Biomedical Information Science and Technology Initiative* (BISTI) Report. The purpose of the working group's report was to relate the BISTI recommendations to the NCRR mission and to recommend specific actions and priorities for implementation.

The BISTI report recommended establishing five to twenty National Programs of Excellence (NPEs) in biomedical computing; establishing a program directed towards the principles and practices of information storage, curation, analysis, and retrieval (ISCAR); providing resources for basic research to adequately support biomedical computing; and fostering a scalable national computer infrastructure to provide biomedical researchers the computing resources they need.

The Bioinformatics Working Group enthusiastically supported the recommendations of the BISTI report and agreed that NCRR is well positioned to implement many aspects of BISTI. The group thought that the NPEs correspond very closely to NCRR resource centers, that there should be strong support for the focus on education, and that it is important to balance funding for NPEs and research project grants.

The Working Group also thought that the NPEs could be organized either around a computational problem area or a biological research focus. The Working Group recommended that there should be assurances that the equipment needs of the NPEs can be met, that the NPEs should be of variable sizes, and that each NPE should balance five components (research, education and training, service, dissemination, and support of bench scientists). The NPEs should be created as a loosely organized network, and they should be encouraged, but not required, to follow an open software model where source code is freely available and the community can contribute modifications and enhancements.

Regarding ISCAR, the Working Group felt that there were two subareas: development of new biological databases and development of new database software tools. ISCAR is the area of biomedical computing where the most dramatic gains are possible, but there is an extreme shortage of qualified personnel. Of concern was that database content projects need special consideration in the review process since they are resources, not hypothesis-driven research, that may be rejected by review committees.

The Working Group also addressed several other areas of the BISTI report, noting that the lack of individuals educated in biomedical computing is a key problem. The Working Group provided recommendations aimed at building the bioinformatics community, supporting large hardware resources, and converting from academic to production grade software. The group finished by listing several research areas in which BISTI can have an impact.

The Council unanimously agreed to accept the *Bioinformatics Working Group Report* as a report of Council.

XI. Biomedical Technology Update
Dr. Michael Marron, Associate Director, Biomedical Technology

Dr. Michael Marron said the NCRR-supported BT resource centers will be making many changes in the coming year and that he will report new directions at each Council session. In particular, a number of these technology centers are well positioned to partner with the NCRR-supported General Clinical Research Centers to become more involved in translational research activities. Such centers would include those focused on magnetic resonance imaging, electron paramagnetic resonance, mass spectrometry, and computation modeling, for example.
Dr. Marron described recent meetings with several NIH institutes about co-funding scientific opportunities that will bridge technology and clinical research. He said these types of interactions will increase once he hires additional staff, hopefully three new people by September. He outlined a number of other ideas that would clarify and expand the BT centers' roles in funding research projects that focused on both technology development and technology application.

XII. Report of Comparative Medicine Resource Directors' Meeting
Dr. Jill Carrington, Comparative Medicine

Dr. Carrington summarized the Comparative Medicine (CM) resource directors' meeting held at the American Type Culture Collection, Manassas, Virginia, on April 27 and 28, 2000. The meeting objectives were to provide grantees with an opportunity to interact with each other and with NCRR program staff, define issues in resource development, and identify future NCRR program directions.

Dr. Carrington described a number of presentations and also outlined the key points of four working groups. The genetic management group discussed techniques now used effectively at several resource centers and recommended that a special workshop be held to identify available software for genetic data management and to determine the best management strategies. The second working group discussed how resource center directors can better inform the biomedical research community about the resources they provide. This group also recommended that another working group be convened at the next annual directors' meeting to discuss Web site design. The third working group discussed how intellectual property rights affect resource collections and distribution and agreed that resource centers should not be involved in negotiating agreements for items in the collections. This group recommended that another working group be created to work with NCRR and the NIH Office of Technology Transfer to develop common guidelines for the role of resource centers in exchanging restricted materials. The fourth working group discussed how resource center directors can better track user data and publications. The group requested that a new supplemental form, which would be added to the annual progress report, be quickly developed and distributed to resource directors so they can properly gather resource user data.

According to the meeting evaluation forms, a majority of the attendees said the meeting was helpful and many suggested a variety of topics for future meetings. Topics included animal rights issues, animal record keeping standards, and genetic management informatics.

XIII. Outreach: American Association for Laboratory Animal Science
Dr. Judith Vaitukaitis, NCRR

On behalf of Dr. John Strandberg, Associate Director for Comparative Medicine, who could not be present, Dr. Vaitukaitis reported on a meeting of the Association for Minority Health Profession Schools (AMHPS) and the American Association for Laboratory Animal Science. The meting addressed outreach methods to AMHPS organizational members that want to upgrade their animal facilities. She highlighted several presentations to institution officials, including her own on NCRR funding sources for laboratory upgrades.

XIV. Change in Council Operating Procedures
Dr. Louise Ramm, NCRR

Dr. Ramm proposed that the NCRR Director have sole authority to approve administrative supplemental increases to existing grants and awards. She also proposed that NCRR no longer provide a written report to Council members when an administrative action, such as change in program director, principal investigator, or institution is made. Council accepted both proposals.

XV. Closed Session

Council met in closed session from 1:30 p.m. to 3:30 p.m. on Thursday, May 18, 2000, to review grant applications. At 3:30 p.m. the Council resumed in open session to hear remarks by Dr. Kirschstein, Acting Director of NIH, and a report of the Council's Executive Subcommittee.

XVI. Dr. Ruth Kirschstein, NIH Acting Director

Dr. Kirschstein reported that since January 2000 she has been visiting the meetings of the NIH Institute and Center (IC) advisory councils. She reported recent NIH-related activity on Capitol Hill and addressed other issues of concern to her office. She said NIH is prepared to elevate its Office of Research on Minority Health to center status with grant-making authority if directed by Congress to do so. Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases, and NIH Acting Deputy Director, Dr. Yvonne Maddox, co-chair a trans-NIH working group on health disparities. In addition to the activities of this working group, each IC has developed a strategic plan to address health disparities and will begin implementation as soon as possible. She said NIH will likely get addition funding for minority health activities and for NCRR's Institutional Development Awards Program. She said NIH and NCRR are planning new ways to enable IDeA states to improve their research programs. Dr. Kirschstein concluded her remarks with comments on recent events in clinical research involving the extremely heavy workloads of institutional Internal Review Boards (IRBs) and on ways that NIH and DHHS can help improve this situation and data safety and monitoring for phase I and II clinical trials.

XVII. Report of Executive Subcommittee Chair
Dr. Peter Kohler, President, Oregon Health Sciences University

Dr. Kohler said the Executive Subcommittee discussed some of the issues just addressed by Dr. Kirschstein, including the clinical research working group and the responsibilities of the IRBs. The Subcommittee also discussed veterinary research and the need for more interdisciplinary research, including more interface between NCRR's BT and CR areas.

XVIII. Adjournment

The Council adjourned at 4:15 p.m.

XIX. Application Review

Council considered 156 applications and concurred with the recommendations of 155. Council also considered and concurred with the recommendations of 175 dual applications.

An expedited en bloc review was completed May 5, 2000; Council considered and concurred with the recommendations of 132 applications.

Attachments:
A. Council Roster
B. Competing Grants: Summary of Council Recommendations

NOTE: Open Session materials are available from the Executive Secretary or the Committee Management Office, NCRR.

We hereby certify that, to the best of our knowledge, the foregoing minutes and supplements are accurate and complete.

Judith L. Vaitukaitis, M.D. Date
Chair, National Advisory Research Resources Council
and Director, National Center for Research Resources

Louise E. Ramm, Ph.D. Date
Executive Secretary, National Advisory Research Resources Council
and
Deputy Director, National Center for Research Resources

Mrs. Cheryl A. Fee
Committee Management Officer
and
Ms. Antonette D. Neal
Committee Management Assistant

These minutes will be formally considered by the Council at its next meeting; corrections or notations will be incorporated into the minutes of that meeting.