

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

**NATIONAL ADVISORY RESEARCH RESOURCES COUNCIL
MINUTES OF MEETING
SEPTEMBER 7, 2000**

The National Advisory Research Resources Council (NARRC) convened for its 116th session at 8:00 a.m. on Thursday, September 7, 2000, with a meeting of the Executive Subcommittee held in Conference Room 3B13, Building 31. The full NARRC 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 3:00 p.m., the meeting reopened to the public until adjournment at 3:30 p.m.

COUNCIL MEMBERS PRESENT

Dr. Kenneth I. Berns
Dr. Delwood C. Collins
Dr. Muriel T. Davisson
Dr. Robert J. Desnick
Dr. Chien Ho
Dr. Michael M.E. Johns
Dr. Peter G. Katona
Dr. Peter O. Kohler
Dr. Peter A. Kollman
Dr. Evangelia G. Kranias
Dr. William R. Morton

Dr. Judith L. Swain
Dr. Burton A. Weisbrod
Dr. Donald E. Wilson
Dr. James H. Wyche
Lt Col Alfred S. Graziano Jr., USAF
Ex-Officio, DOD
Dr. William W. King
Ex-Officio, VA
Dr. Roland F. Hirsch
Liaison Member, DOE

COUNCIL MEMBERS ABSENT

Dr. Joseph D. Andrade
Ms. Catherine D. Bertram

Dr. Diana S. Natalicio
Dr. Machi F. Dilworth
Liaison Member, NSF

¹For 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. Sally S. Atherton, Professor and Chair, Department of Cellular Biology and Anatomy,
College of Georgia, Augusta, Georgia

Dr. Shiri N. Giri, Professor, Department of Molecular Biosciences, School of Veterinary Medicine,
University of California, Davis, California

Dr. James E. Heubi, Professor of Pediatrics, Clinical Research Center, Children's Hospital Medical
Center, University of Cincinnati School of Medicine, Cincinnati, Ohio

Dr. Edward Greg Koski, Director, Office for Human Research Protections, DHHS

Dr. Tilahun D. Yilma, Director and Professor of Virology, International Laboratory of Molecular
Virology for Tropical Disease Agents, School of Veterinary Medicine, University of California,
Davis, California

STAFF OF OTHER NIH COMPONENTS:

Dr. Sally Amero, CSR/NIH

Dr. John Bowers, CSR/NIH

Dr. Eileen Bradley, CSR/NIH

Dr. Bonnie Mathieson, OAR/OD/NIH

OTHERS PRESENT:

Ms. Adwoa Boahene, *The Blue Sheet*, Chevy Chase, Maryland

Ms. Pamela Moore, *Capital Publications*, Alexandria, Virginia

Dr. Georgia Persinos, *Washington Insight*, Rockville, Maryland

Dr. Tom Quarles, National Science Foundation, Arlington, Virginia

Dr. Douglas Sheeley, Glaxo Welcome, Inc., Research Triangle Park, North Carolina

Dr. Carol Tacket, Professor, University of Maryland, School of Medicine, Baltimore, Maryland

I. Call to Order

Dr. Judith Vaitukaitis, Director, NCRR

Dr. Vaitukaitis welcomed NARRC members and guests to the 116th meeting of the Council. She announced that the following Council members would be unable to attend: Dr. Joseph Andrade, Ms. Catherine Bertram, Dr. Machi Dilworth, and Dr. Diana Natalicio. She introduced a new Department of Defense Ex-Officio member to the Council, Lt Col Alfred S. Graziano Jr., United States Air Force, Chief of the Clinical and Biomedical Research and Development Division, Office of the

Surgeon General, Air Force Medical Operations Agency. She noted that Lt Col Alfred S. Graziano, Jr. replaces Dr. Kenneth Hyams and then introduced invited guests.

II. Consideration of Minutes

The minutes of the May 18, 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, January 18 and 19, 2001. A one-day meeting is under consideration, and Council members will be notified as soon as a decision is made.

IV. Personnel Update

Dr. Vaitukaitis announced personnel changes at the Department of Health and Human Services (DHHS) and NIH. Dr. Edward Greg Koski was named director of the Office for Human Research Protections, DHHS, on June 6, 2000. Dr. Lawrence A. Tabak has been named director of the National Institute of Dental and Craniofacial Research (NIDCR), NIH. Dr. Tabak replaces Dr. Harold Slavkin, who left NIDCR to become dean of the University of Southern California School of Dentistry.

Dr. Vaitukaitis also announced several NCRR personnel changes. Dr. Franziska Grieder has joined the Comparative Medicine area as a health scientist administrator. Dr. Gregory Farber has joined the Biomedical Technology area as a health scientist administrator. In August 2000, Dr. Jill Carrington left NCRR's Comparative Medicine area to take a position with the National Institute on Aging.

V. Legislative Update

Dr. Vaitukaitis directed the Council's attention to a summary of recent Federal legislative activities that affect NIH, and in some cases, NCRR.

VI. Budget Update

Dr. Vaitukaitis reported that the final NIH appropriation for FY 2000 was included in an omnibus bill that was passed in late November, and covered several agencies. The NIH level for FY 2000 is \$17.9 billion, a 14.7 percent increase. NCRR's appropriation is \$680.2 million, a 22.6 percent increase. An across-the-board recision was included in the appropriations bill; the NCRR share of the recision is \$3.6 million, reducing the FY 2000 level for NCRR to \$676.6 million.

Within this substantial funding increase for NCRP, a number of special interest areas were identified by the conferees: \$72.5 million for extramural construction, with half the amount targeted to “smaller and developing” institutions; \$39.5 million for the Institutional Development Awards (IDeA) Program; and \$14.5 million for the Science Education Partnership Awards (SEPA) Program, with an emphasis on funding education programs at science centers and museums. The remainder of the increase has been distributed among other NCRP programs.

The FY 2001 President’s Budget Request was released on February 7. The request includes \$18.8 billion for NIH, an increase of \$1 billion or 5.6 percent over the FY 2000 appropriation. The level requested for NCRP is \$714.2 million, an increase of \$37.6 million, or 5.6 percent over the FY 2000 appropriation. Within this amount, \$72.5 million is included for extramural construction, \$44.7 million for the SIG Program, \$40 million for the IDeA Program, and \$14.5 million for science education. A number of initiatives are to be undertaken through other NCRP programs, including technologies for human and animal imaging research, developing centers of excellence in bioinformatics, synchrotron beamline construction and upgrade, comprehensive centers on health disparities, and new and expanded research career-development opportunities for physicians and dentists and comparative medicine investigators.

The House and Senate Appropriations Subcommittees for Labor, Health and Human Services, Education and Related Agencies held hearings on the President’s budget report for NIH on February 16 and March 30, respectively. House questions covered a variety of topics, including extramural research facilities, diabetes research, institutional development, non-human primate centers, clinical research training, synchrotrons, and science education. The Senate asked no specific questions of NCRP. Both the House and Senate Subcommittees marked up the bill on May 10 with the full Senate committee markup on May 11, and the full House committee markup on May 24.

The Senate Report includes a 15 percent increase for NIH. The Senate mark for NCRP is \$775.2 million, an increase of 14.8 percent. The Senate Report identifies \$75 million for extramural construction and \$60 million for the IDeA Program. The House Report also includes a 15 percent increase for NIH. NCRP will receive \$832 million, including \$75 million for extramural construction and \$100 million for the IDeA Program. The House Report also includes a special provision, which is expected to be deleted in conference, holding NIH to the FY 2001 President’s Budget. No distribution of the House and Senate levels have been made at this time. Both the House and Senate passed their measures; conferees are meeting this week. Because of substantial differences between Congress and the White House, bills may not be sent individually to the President, but may be included in an omnibus appropriations bill covering all appropriations yet to be passed. We are expecting to begin Fiscal Year 2001 on a Continuing Resolution.

VII. Dr. Edward Greg Koski, Director, Office of Human Research Protections, DHHS

Dr. Koski described the mission and goals of the newly established DHHS Office for Human Research Protections (OHRP), which replaces the NIH Office of Protection from Research Risks. Although not permitted to provide specifics before his official confirmation as director, Dr. Koski said OHRP will develop and implement initiatives to revamp the institutional review system and to toughen conflict-of-interest rules. He described the need for a new paradigm that would place human subjects in the center of the review process, instead of Institutional Review Boards (IRBs). To implement such changes, he suggested the following: personal/individual responsibility, particularly at the investigator level; universal IRB standards; institutional accountability; and standardized Data Safety Monitoring Boards. To restore America's confidence in clinical research, public education about the research process and informed consent is critical. He wants OHRP to work with investigators and institutions in a good faith effort to improve human subjects protection. OHRP will develop new guidance on conflicts-of-interest and provide leadership for DHHS and other federal agencies that sponsor research under the Common Rule (45 CFR 46).

VIII. Annual Report of the Scientific and Technical Review Board (STRB) Dr. Shiri N. Giri

Dr. Shiri N. Giri presented the annual report of the STRB on Biomedical and Behavioral Research Facilities. He said the Board is continuing its annual review of proposals for the Extramural Research Facilities Construction Program, supported through the C06 funding mechanism, and the twice yearly review of grants for repair, renovation, and modernization of existing research facilities, supported through the G20 funding mechanism. In FY 1999, since the last STRB report to the NARRC, 72 of 77 C06 applications have been reviewed, scored, and recommended for a funding level of \$67,361,807. Thirty were funded at a level of \$28,959,332, including two from Regional Primate Research Centers (RPRCs) and five from Centers of Excellence. In May 2000, the Board reviewed 94 C06 applications (submitted in response to a 1999 request); 90 were scored at a recommended level of \$147,200,791 and 4 were not recommended for further consideration. NCRR anticipates funding 44 C06 grants in FY 2000.

At its FY 2000 meetings held in October, February, and June, the Board reviewed and scored a total of 69 G20 applications, including 7 from RPRCs, for a combined total recommendation of \$23,996,657.50. NCRR anticipates awarding 17 G20 grants in FY 2000.

IX. Working Group I - NCRR Program Presentations for Comparative Medicine and Biomedical Technology

Comparative Medicine (CM): Dr. John Strandberg, CM Director; and Drs. Franziska Grieder, Ray O'Neill, and Jerry Robinson

Dr. John Strandberg gave an overview of the CM area's activities and programs. He described the Biological Models and Materials Program and cited specific examples of NCRR-supported projects. Dr. Franziska Grieder discussed the goals and objectives of the Laboratory Animal Sciences Program and specifically focused on the accomplishments of the four Mutant Mouse Regional Resource Centers established last year. The Jackson Laboratory provides informatics support to those centers, which are supported through cooperative agreements with NCRR. Dr. Ray O'Neill talked about the NIH Chimpanzee Management Plan (CHiMP) and NCRR's efforts to consolidate existing chimpanzee centers. To date, NCRR has made awards to ISIS to support an expanded database; the University of Texas M.D. Anderson Cancer Center, Bastrop, Texas; and the University of Louisiana at Lafayette. He said that on May 1, 2000, NIH took title to 288 chimpanzees transferred by the Coulston Foundation to NIH. Dr. Jerry Robinson described activities of the Regional Primate Research Centers (RPRCs) Program. The RPRCs have more than 20,000 nonhuman primates representing 30 species. He gave the program objectives and a brief funding history.

Biomedical Technology (BT): Dr. Michael Marron, BT Director; and Dr. Marjorie Tingle, Shared Instrumentation Grant (SIG) Program

Dr. Michael Marron highlighted NCRR-supported BT research, including activities to discover, create, develop and disseminate innovative technologies for a broad spectrum of research projects. He emphasized the BT resource centers collaborative activities on research projects with the biomedical research community. He outlined the four BT area funding components: Biomedical Technology Resource Centers, the SIG Program, and grants for research projects and Small Business Innovative Research/Small Business Technology Transfer. High priority activities and program initiatives for FY 2001 were discussed along with the BT budget for FY 2000. Dr. Marjorie Tingle gave a funding history of the SIG Program and summarized instrumentation applications received this fiscal year and the estimated cost to fund them.

X. Working Group II - NCCR Program Presentations for the Research Infrastructure and Clinical Research

Research Infrastructure (RI): Dr. Sidney McNairy, RI Director; and Drs. W. Fred Taylor and Krishan Arora

Drs. McNairy, Taylor and Arora presented information on the Specialized Neuroscience Research Program (SNRP), the IDeA Program, the Research Centers in Minority Institutions Stroke Initiative, and the SEPA Program. The SNRP was initiated in FY 1999 and five awards were made with the intent to augment and strengthen the capabilities of minority institutions by developing their research infrastructure and developing or expanding the faculty's basic and clinical neuroscience research. During FY 1993, the IDeA Program was initiated to enhance geographical distribution of research funds in 23-eligible states and Puerto Rico. The IDeA Program provides capacity-building assistance for biomedical research efforts in states that have not previously participated fully in the NIH-funded research. The House FY 2001 Appropriations Subcommittee Report includes about \$100 million for the IDeA Program. Institutions within each IDeA-eligible state and Puerto Rico are expected to establish networks that will strengthen and enhance biomedical research collaborations. The FY 2001 RCMI Stroke Initiative is a collaborative effort among NCCR, the National Institute on Neurological Disorders and Stroke, and the National Heart, Lung, and Blood Institute intended to develop innovative and effective strategies to reduce the burden of stroke and cardiovascular diseases in populations that have historically been at a higher risk. This initiative will involve minority medical schools, stroke centers, cardiovascular disease centers, and community health centers. The FY 2000 appropriations bill commends the SEPA Program for supporting science education programs that enhance the interest of the public and K-12 students in biomedical science. The FY 2000 SEPA Program budget was increased from \$4 million to \$15 million, and NCCR anticipates making 30 to 35 awards as a result of this budget increase.

Clinical Research (CR): Dr. Bernard Talbot, General Clinical Research Centers (GCRC) Program

On behalf of the NCCR CR area, Dr. Bernard Talbot presented proposed changes in the General Clinical Research Centers (GCRC) Program Guidelines. Several recommended changes are the result of a revised NIH policy on the timing of IRBs review of grant applications for human subjects protocols and a new NIH requirement that, beginning with the October 2000 grant application receipt date, investigators must submit a data and safety monitoring plan for phase I and II clinical trials. In addition, CR staff proposes that serious adverse events on a GCRC also be reported to NCCR along with other already required organizations, and that a new GCRC position called "medical director" be required to facilitate safe conduct of clinical protocols. The "Provisions for Medical Care" section of the Guidelines would be amended to require that for every protocol a physician with appropriate expertise and admitting privileges be designated as either the principal investigator or a co-investigator. Other suggested changes related to eligibility for NCCR's K23

awards; issues related to space costs funded by NCRP when GCRC facility space has been expanded; information to be provided on type 2 applications to make them consistent with the format of type 5 applications; funding for pilot studies; and changes regarding types of GCRC rebudgeting that do not require NCRP pre-approval. The Working Group concurred with the intent of the proposed changes but provided suggestions to clarify several points, such as defining a serious adverse event.

XI. Closed Session

Council met in closed session from 1:30 p.m. to 3:00 p.m. on Thursday, May 18, 2000, to review grant applications. At 3:00 p.m. the Council resumed in open session to hear reports from the Chairs of the Executive Subcommittee and Working Groups I and II.

XII. Report of Executive Subcommittee Chair Dr. Peter Kohler

Dr. Peter Kohler reported on several items related to NCRP policies and practices, the progress of the ChiMP, and a CR area proposal to expand the research of the GCRCs to satellite sites. On behalf of the Subcommittee, he recommended that NCRP develop a list of the NIH funding mechanisms used by each NCRP program. He said such a guide would expedite NARRC's grant review process when using the electronic council book. He closed his report by proposing agenda items and discussions for future NARRC meetings.

XIII. Adjournment

The Council adjourned at 3:30 p.m.

XIV. Application Review

Council considered 263 applications and concurred with the recommendations of 261. Council also considered and concurred with the recommendations of 149 dual applications.

Two expedited en bloc reviews were conducted prior to the September Council meeting: on July 10, 2000, Council considered and concurred with the recommendations of 46 CO6 applications; and on August 15, 2000, Council considered and concurred with the recommendations of 112 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, NCCR.

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

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

Date

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

Date

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.