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

NATIONAL ADVISORY RESEARCH RESOURCES COUNCIL
MINUTES OF MEETING
SEPTEMBER 21, 2006

The National Advisory Research Resources Council convened for its 134th session at 8:00 a.m. on Thursday, September 21, 2006, in Conference Room 6, Building 31. Dr. Barbara M. Alving, Acting Director, National Center for Research Resources (NCRR), National Institutes of Health (NIH), presided as Chair. The meeting was open to the public until 11:45 a.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.

COUNCIL MEMBERS PRESENT

Dr. Robert J. Beall
Dr. Kenneth G. Cornetta
Dr. Machi F. Dilworth
  Liaison Member, NSF
Dr. Catherine C. Fenselau
Dr. Kelly D. Garcia
Dr. Roland F. Hirsch
  Liaison Member, DOE
Dr. Joan S. Hunt
Dr. Kevin B. Johnson
Dr. Cynthia E. Keppel
Dr. Barbara B. Knowles
Dr. Bettie Sue Masters
Dr. Thomas G. McGuire
Col. (Dr.) Debra M. Niemeyer
Dr. Thomas J. Rosol
Dr. Richard Rudick
Dr. Arthur W. Toga
Dr. M. Roy Wilson
Dr. Tilahun D.Yilma
Ms. Sheila C. Zimmet
Dr. Stuart M. Zola

COUNCIL MEMBERS ABSENT

Dr. Wah Chiu

SPECIAL INVITED GUESTS FOR OPEN SESSION

Dr. Ronald Sokol, Professor and Vice Chair of Pediatrics, University of Colorado at Denver and Health Sciences Center; Chair, Steering Committee, Rare Diseases Clinical Research Network

STAFF OF OTHER NIH COMPONENTS

Dr. Nuria E. Assa-Munt, CSR
Dr. John L. Bowers, CSR
Dr. Rashmi Gopal-Srivastava, ODP/ORD
Dr. Rajan S. Munshi, CSR

Dr. Dana J. Plude, CSR
Ms. Shelly M. Pollard, OD/OCPL
Dr. Kim Pelis, OD/OCPL
Dr. Tara C. Polek, CSR
Dr. Jean D. Sipe, CSR
Dr. Margaret D. Snyder, OER/OD/NIH

OTHERS PRESENT

Dr. Donna J. Dean, Lewis-Burke Associates, LLC, Washington, D.C.
Dr. T. J. Dunlap, Texas Methodist Hospital Research Institute, Houston, TX
Mr. Stephen J. Heinig, Senior Staff Associate, Division of Biomedical and Health Sciences Research, Association of American Medical Colleges, Washington, D.C.

OPEN SESSION

I. Call to Order: Dr. Barbara M. Alving, Acting Director, NCRR

Dr. Alving welcomed Council members and guests to the 134th meeting of the National Advisory Research Resources Council. Five new members of the Council were introduced: Dr. Kevin B. Johnson, Dr. Thomas J. Rosol, Dr. Richard Rudick, Dr. M. Roy Wilson, and Dr. Tilahun D. Yilma.

Dr. Kevin B. Johnson is an Associate Professor and Vice Chair of Biomedical Informatics, with a joint appointment in the Department of Pediatrics, at the Vanderbilt University Medical Center. He received his M.D. degree from Johns Hopkins University. As a medical student, he was involved with numerous research projects but was particularly interested in database development and the uses of advanced technologies for capturing clinical data. Dr. Johnson is involved in three main research areas: clinical information systems development; uses of advanced computer technologies; and development of computer-based documentation systems for the point of care.

Dr. Thomas J. Rosol is the Dean of Ohio State University's College of Veterinary Medicine. He joined Ohio State's faculty in 1986 and has taught in the Colleges of Medicine and Public Health, Dentistry, and Veterinary Medicine. Dr. Rosol is a Diplomate of the American College of Veterinary Pathologists. He is known for his research of parathyroid hormone-related protein in multiple animal cancers. He has received several prestigious national awards, including honors from the National Institutes of Health.

Dr. Richard Rudick directs the Division of Clinical Research at the Cleveland Clinic, where he is also Director of the Mellen Center for Multiple Sclerosis Treatment and Research. He obtained his M.D. degree from Case Western Reserve University. In 2002, he became the founding Chairman of the Division of Clinical Research at Cleveland Clinic Foundation. Dr. Rudick has assembled multidisciplinary research teams within the Mellen Center to conduct clinical and translational research in disease pathogenesis, imaging, clinical trials, and health services research. Dr. Rudick's research has been

funded by NIH and the National Multiple Sclerosis Society continuously for 25 years.

Dr. M. Roy Wilson was named the Chancellor of the University of Colorado at Denver and Health Sciences Center in July 2006. He came from the four-campus Texas Tech University Health Sciences Center, where he had served as president since 2003. Dr. Wilson was an initial Advisory Council member of NIH's National Center on Minority Health and Health Disparities and served four years as chair of its Strategic Plan subcommittee. He is an international glaucoma expert who received his M.D. degree from Harvard University Medical School.

Dr. Tilahun D.Yilma is a Distinguished Professor of Virology in the Department of Medical Microbiology and Immunology, School of Medicine at University of California, Davis. He is also the Director of the International Laboratory of Molecular Biology for Tropical Disease Agents. Dr. Yilma received both his D.V.M. and his Ph.D. in microbiology from UC Davis. Dr. Yilma has served on numerous NIH/NCRR Study Sections and Special Emphasis Panels. Currently, he is a member of the Board of Agriculture & Natural Resources of the National Academies Division of Earth & Life Sciences, as well as the European Action on Global Life Sciences.

Dr. Alving described several new information products developed by NCRR's Office of Science Policy and Public Liaison. These products include an NCRR overview brochure; two exhibits for use at scientific conferences and other off-site meetings; a permanent exhibit soon to be displayed in Building 31; a revision of the NCRR Web site (currently underway); and the recent launch of the *e-Reporter*, an electronic version of the *NCRR Reporter* magazine. Together, these products enhance the communications program and offer new opportunities to communicate NCRR's contributions to research.

II. Consideration of Minutes: Dr. Barbara M. Alving, Acting Director, NCRR

The minutes of the Council meeting held on May 18, 2006, were approved as written.

III. Future Meeting Dates: Dr. Barbara M. Alving, Acting Director, NCRR

The next Council meeting will be held on Thursday, January 18, 2007.

IV. Personnel Update: Dr. Barbara M. Alving, Acting Director, NCRR

DHHS Personnel

- President Bush named Rear Admiral W. Craig Vanderwagen, M.D., as his choice to be DHHS Assistant Secretary for Public Health Emergency Preparedness. He was officially sworn in on July 26, 2006, and assumed his new duties immediately. As a U.S. Public Health Service officer, he has served as Acting Chief Medical Officer, Director of the Division of

Clinical and Preventive Services, and Medical Doctor in the Indian Health Service.

NCRR Personnel

Division for Clinical Research Resources

- Dr. Andrea Sawczuk joined NCRR as a Health Scientist Administrator in September 2006. From 2001 through 2006, Dr. Sawczuk served as a Scientific Review Administrator in the Scientific Review Branch of the National Institute of Neurological Disorders and Stroke. She came to NIH from a faculty position at the University of Medicine and Dentistry of New Jersey. Prior to 1995, she had an academic appointment at the University of Washington, where she also completed her training in dentistry, oral medicine, and neuroscience.

- In May of 2006, Ms. Dorothy A. West joined NCRR as a Program Analyst. Prior to joining NCRR, Ms. West served as Senior Program Analyst in the Division of Extramural Activities at NIDDK.

Office of Grants Management

- Ms. Tiffany M. Walker joined NCRR in May 2006 as a Grants Management Specialist. Ms. Walker was previously employed at the Office of Grants Administration of the National Cancer Institute.

- Ms. Carla P. Giddings came to NCRR in July 2006 as a Grants Management Specialist. Ms. Giddings was previously employed by the Center of Scientific Review at NIH.

- Ms. Tracee S. Gilchrist joined NCRR in July 2006 as a Grants Management Specialist. Prior to joining NCRR, Ms. Gilchrist worked for the National Heart, Lung, and Blood Institute.

- Mr. Binh Nguyen joined NCRR in July 2006 as a Grants Management Specialist. In his previous position, he worked for the National Institute of General Medical Sciences, Grants Council Operation section.

Office of the Director

- Ms. Miriam (Fawn) Friedman joined the Financial Management Office in May 2006 as a Budget Analyst. Ms. Friedman comes to NCRR from the National Institute of Child Health and Human Development, where she also served as a Budget Analyst.

- Ms. Sabrina A. Posley joined the Office of Administrative Operations in May 2006 as an Administrative Technician. Ms. Posley was previously employed by the National Institute on Aging.

V. Legislative and Budget Updates: Dr. Barbara M. Alving, Acting Director, NCRR

NIH's Fiscal Year (FY) 2007 budget request is $28.4 billion, which was the same as the FY 2006 level. For NCRR, the FY 2007 budget request is $1.1 billion and includes support for AIDS research and no funds for extramural construction, which is a decrease of $0.9 million below the FY 2006 appropriation. Included in the FY 2007 NCRR request is support for trans-NIH Roadmap initiatives, estimated at $13.3 million and 1.2 percent of NCRR's FY 2007 budget request. The request also includes funds for the new program, the Clinical and Translational Science Awards (CTSAs), led by NCRR on behalf of the NIH Roadmap, as well as NCRR support for two new programs: the Genes, Environment, and Health Initiative and the Pathway to Independence Program.

The FY 2007 House spending bill for the Departments of Labor, Health and Human Services, Education, and Related Agencies includes $28.3 billion for the NIH, which is equal to the FY 2006 request. The Committee recommends $1.123 billion for NCRR, which is $25.0 million above NCRR's FY 2007 budget request and $24.141 million above the FY 2006 appropriation. The $1.123 billion includes $25 million for the construction of extramural facilities.

The FY 2007 Senate spending bill for the Departments of Labor, Health and Human Services, Education, and Related Agencies includes $28.5 billion for the NIH, an increase of $0.220 million over the FY 2006 appropriation. The Committee recommends $1.104 billion for NCRR, which is $6.104 million more than the FY 2007 budget request and $5.245 million above NCRR's FY 2006 appropriation. The $1.104 billion does not include any funds for the construction of extramural facilities.

Neither of these bills has passed the full House or Senate and likely will not do so before the end of the Fiscal Year. Consequently, a continuing resolution will be needed at the start of FY 2007. Continuing resolutions provide for the ongoing operation of the Government in the absence of enacted appropriations, usually at the same spending rate as the prior year.

VI. NIH Director's Update: Dr. Elias A. Zerhouni, Director, NIH

Dr. Zerhouni spoke about the challenges facing the NIH and the scientific community as well as strategies to address them. He described an apparent paradox: the NIH budget has doubled, but funding success rates have dropped by a third. Dr. Zerhouni mentioned four events that might be contributing to this apparent paradox: 1) an increase in building and faculty growth throughout U.S. research institutions; 2) a 100 percent growth in NIH applications and 75 percent growth in yearly applicants by 2007; 3) budget appropriations below inflation since 2003; and 4) a budget-cycling phenomenon. These events have caused a series of side effects. A "boom" in applications after the budget-doubling period has led to a supply vs. demand imbalance. The drop in the funding success rate was due to an increased demand—and cost—for grants and a decreased inflation-adjusted budget. Dr. Zerhouni noted that the budget-cycling effect will slightly improve the current supply vs. demand of grants in 2007 and beyond.

Dr. Zerhouni also addressed some common misperceptions about NIH. One misperception is that NIH is increasingly emphasizing applied research over basic research. But in fact the percentages of basic (56.1) and applied research (40.8) are roughly the same today as they were in 1998 (53.9 and 40.5 percent, respectively). Another common misperception is that NIH is shifting from unsolicited research grants to solicited research grants. This is inaccurate. In 1995, only 9 percent of NIH grants were solicited grants; today, nearly the same amount (8 percent) are solicited grants. A third common misperception is that the NIH Roadmap initiative is shifting funds away from the grant pool. But the reality is that the majority of NIH funding (98.8 percent) is non-Roadmap funding. NCRR has used Roadmap funds to support various innovative initiatives such as National Centers for Biomedical Computing; Clinical and Translational Science Awards; and Clinical Research Networks.

Dr. Zerhouni discussed the future of NIH. He emphasized that NIH must develop adaptive strategies based on five key principles. The first principle is to protect the core values and mission of NIH, which are the discovery and generation of new knowledge. The second principle is to protect future generations of scientists by ensuring that new investigators have reasonable access to funding. The third principle is to manage key drives to balance the supply and demand of grants. The fourth principle is to have a proactive communications strategy that delivers a unified message about the value of NIH's investment and the need for sustainability. Finally, the fifth principle is to promote NIH's vision for the future, developing a new paradigm for medical science that is predictive, personalized, pre-emptive, and participatory.

VII. CTSA Initiative Update by NCRR Staff: Dr. Anthony R. Hayward, Director, Division for Clinical Research Resources; Ms. Lori Mulligan, Director, Office of Science Policy and Public Liaison; Dr. Barbara M. Alving, Acting Director; Dr. Sheryl Brining, Director, Office of Review

Overview of the Clinical and Translational Science Awards (CTSA) Program

Dr. Hayward explained that the CTSA Program was designed to energize the discipline of clinical and translational science at academic health centers around the country. Each CTSA application can be tailored to individual institutions based on their needs and available resources. The program will require cooperative agreements between the institution receiving the award and NIH. Also, a national steering committee will aid in sharing and identifying best practices among all awardees.

The CTSA will provide a "home" for clinical and translational science within the academic health centers. This home is expected to include faculty who conduct original research, develop graduate and postgraduate training curricula, and lead programs that integrate clinical and translational science across multiple departments, schools, hospitals, and clinical and research institutes.

Most of the applications received for the 2006 cycle describe a center, rather than a department or institute, as the "home" for clinical and translational science. Key facilities in the applications include a central administration, informatics, study design, biostatistics, ethics, regulatory, and clinical support. Cores described in the applications include molecular pathways, high-throughput genotyping, and imaging. Applications also show strong biomedical informatics components. Budget requests are primarily in the $6 million per year range.

Evaluation of the CTSA Program

Ms. Mulligan noted that both individual CTSA awards—as well as the program as a whole—will undergo evaluation. Evaluation at the individual level will monitor progress of each CTSA institution through annual progress reports, self-evaluation reports, and periodic site visits. The evaluation effort also will assess the short- and long-term impact of the CTSA program and how the CTSAs function as a collective consortium. The CTSA Evaluation Subcommittee currently includes representatives from five NIH Institutes and Centers, including NCRR. The subcommittee has met three times to date. The first two meetings focused on defining the scope, purpose, and objective of the evaluation; discussing the need for a conceptual framework to guide the evaluation; and addressing the challenges and complexities of evaluating the CTSA program. The third meeting focused on discussing the draft conceptual framework and a set-aside proposal for a feasibility study. Ms. Mulligan presented the draft conceptual framework to the Council.

NCRR is in the process of hiring an evaluation contractor to assist in the evaluation process. In October 2006, NCRR will meet with the CTSA Principal Investigators (PIs) to discuss the development of a National Evaluation Steering Committee. Recommendations from the contractor on how to evaluate the CTSA Program are expected to be submitted in the spring of 2007. A report on the CTSA evaluation status will be submitted to the Congressional Appropriations Committee on July 1, 2007.

CTSA Governance

Dr. Hayward briefed the Council on the proposed structure for governance of the CTSA program. A CTSA PI Steering Committee, composed of 12 CTSA PIs and 6 NIH representatives, will be responsible for the highest level of decision making. To avoid a conflict of interest, a separate arm composed of NCRR program officers will be responsible for financial administration of the CTSA program. Dr. Hayward presented a schematic of the proposed CTSA governance to the Council.

In terms of program monitoring, NCRR program staff will conduct site visits and review annual progress reports and external advisory committee reports. These evaluations and reports, along with input from the CTSA Project Team Evaluation Subcommittee, will be shared with NCRR and CTSA program officials who will, in turn, submit their findings to the NCRR director.

CTSA Budget

Dr. Alving noted that the CTSA program is funded by the NIH Roadmap for Medical Research and NCRR-appropriated funds. Up to $6 million in total yearly costs can be requested by each applicant, in addition to other combined current total costs of certain other NIH awards (e.g., NCRR K12, K30, and M01 awards and Roadmap T32 and K12 awards). The length of each CTSA grant is up to 5 years. When fully implemented in 2012, the initiative is expected to provide a total of $500 million annually to 60 academic health centers.

CTSA Review Process

Dr. Brining briefed the Council on the 2006 peer review process for the CTSAs. A total of 35 applications were received for the 2006 cycle. These were divided randomly into two sets, which were reviewed over two meetings (17 in the first batch and 18 in the second). The Director and Deputy Director of NCRR's Office of Review administered both meetings. Considerable effort was taken to systematically communicate with each group of reviewers in exactly the same way. To ensure consistency, each meeting was led using the same written set of instructions.

Reviewers were recruited in tandem for both meetings to ensure similar expertise. Reviewers were drawn from a wide variety of sources within and outside of NIH. The potential names were vetted for expertise, demographics, and conflicts of interest. Evaluation scores were released after the completion of all meetings. The average priority score of the two meetings only differed by 2 percent, which enhanced confidence that the results of the two meetings were indeed comparable.

VIII. Update on Clinical Research Informatics: Dr. Jody Sachs, NIH Roadmap Project Officer, Division for Clinical Research Resources, NCRR; Dr. Peter Highnam, Senior Advisor to the Director, NCRR

As part of the NIH Roadmap's theme of re-engineering the Clinical Research Enterprise, NCRR has taken a leadership role in the Clinical Research Networks and National Electronics Clinical Trials and Research (NECTAR) Network initiatives. The goal of the Clinical Research Networks project is to promote and expand clinical research networks that can rapidly facilitate high-quality clinical studies that address multiple research questions. To accomplish this goal, two projects are being implemented. First, an Inventory and Evaluation of Clinical Research Networks (IECRN) has assessed and created a Web-searchable database of the existing networks. Second, the Feasibility of Integrating and Expanding the Clinical Research Networks Program explores the feasibility of expanding and integrating clinical research networks at academic centers and community-based health care providers who care for sufficiently large groups of well-characterized patients.

A total of 12 feasibility projects underway address a range of medical disciplines over multiple ages, populations, and settings. The development of common infrastructure elements—such as informatics, governance, and common language—will facilitate cooperation among research groups and networks to address research questions of mutual interest and across disciplines. Implementing these goals will require new ways to acquire and organize clinical research information, new standards for clinical research protocols, and education of the clinical research workforce in modern information technology.

NCRR has engaged MITRE, a non-profit corporation, to track and provide strategic advice on informatics developments relevant to clinical research. Three reports developed by MITRE, as part of the NCRR contract, have been posted on NCRR's Web site.

View the MITRE reports. Additional reports are expected and will be posted on this Web page.

IX. The Rare Diseases Clinical Research Network (A Collaborative Effort Between NCRR and the Office of Rare Diseases): Dr. Ronald Sokol, Professor and Vice Chair of Pediatrics, University of Colorado at Denver and Health Sciences Center; Chair, Steering Committee, Rare Diseases Clinical Research Network

Dr. Sokol informed the Council that approximately 25 million people in the United States are affected by more than 6,000 rare diseases. To address this public health issue, NIH established the Rare Diseases Clinical Research Network (RDCRN) in 2003. By supporting translational research, the RDCRN aims to improve the lives of individuals affected by rare diseases. The network is coordinated by NCRR and the NIH Office of Rare Diseases.

The RDCRN is configured into 10 consortia studying 45 diseases. Each of the consortia studies multiple and related rare diseases through several clinical sites, which are located in 55 medical institutions throughout the United States and supported by 7 NIH Institutes and Centers. The network also has international collaborations with clinical sites in Japan, Australia, Brazil, Germany, United Kingdom, France, and The Netherlands.

The RDCRN includes 34 advocacy groups representing many of the diseases studied by the consortia. A data and technology coordinating center (DTCC) and a steering committee also form part of the network. The DTCC has worked together with physician and advocacy organizations in the network to develop national standards for protocols, data collection forms, databases, terminology, and adverse event reporting.

The DTCC also has developed an interactive Web site for the network. The site provides information about each rare disease for the public as well as caregivers and scientists. It includes links to other sites and advocacy organizations, media digital libraries, and access to contact registries. The contact registries, currently holding 2,588 names and other information, allow patients with rare disease to receive notification of new trials.

The RDCRN also offers fellowships for training of health professionals in the study of rare diseases. Several former trainees have gone on to faculty positions and are continuing their studies of rare diseases. All trainees, former and present, will be invited to participate in a poster session to share their research on rare diseases. Participants in clinical trials will also be invited to the network's steering committee meeting to obtain a better understanding of the organization of the RDCRN.

In 2006, NIH's Office of Rare Diseases obtained $600,000 in funding to support six additional RDCRN pilot projects focusing on diagnostics or treatment. Five awards have been presented to date, and some consortia have also obtained additional funding from foundations, NIH grants, or other sources to support research and other activities focused on rare diseases.

CLOSED SESSION

This portion of the Council meeting was closed to the public in accordance with the determination that it was concerned with matters exempt from mandatory disclosure under Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

Council members discussed procedures and policies regarding voting and confidentiality of application materials, Committee discussions, and recommendations. Members absented themselves from the meeting during discussion of and voting on applications from their own institutions, or other applications in which there was a potential conflict of interest, real or apparent. Members were asked to sign a statement to that effect.

X. Application Review

The Council reviewed 334 applications (with total direct costs of $355,041,115). The Council concurred with the review of all applications.

ADJOURNMENT

The Council adjourned at 3:30 p.m. on September 21, 2006.

CERTIFICATION

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

Barbara Alving MD

Dr. Barbara M. Alving
Chair, National Advisory Research Resources Council
and
Acting Director, National Center for Research Resources, NIH

11/29/06
Date

Louise Ramm

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

12/1/06
Date

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.

Attachment:
Council Roster

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