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

# NATIONAL ADVISORY RESEARCH RESOURCES COUNCIL MEETING MINUTES September 16, 2008

The National Advisory Research Resources Council convened its 140th session at 8:00 a.m. on Tuesday, September 16, 2008, in Conference Room 10, Building 31, on the National Institutes of Health (NIH) main campus. Dr. Barbara M. Alving, Director, National Center for Research Resources (NCRR), NIH, presided as Chair. The meeting was open to the public until 12:38 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.

### **COUNCIL MEMBERS PRESENT**

Dr. William F. Bria II Dr. Henry Lewis III Ms. Wendy Chaite, Esq. Dr. Bettie Sue Masters Dr. Valerie Copié Dr. Thomas J. Rosol Dr. Henry N. Ginsberg Dr. Richard A. Rudick Dr. James E. Heubi Dr. Janet L. Smith Dr. Roland F. Hirsch, Liaison Member, Col. James A. Swaby Department of Energy Dr. Arthur W. Toga Dr. Dallas M. Hyde Dr. M. Roy Wilson Dr. Kevin B. Johnson Dr. Tilahun D. Yilma

#### **COUNCIL MEMBERS ABSENT**

Dr. Nancy J. Brown

Dr. James P. Collins, Liaison Member, National Science Foundation

Dr. Mark V. Pauly

#### SPECIAL INVITED GUESTS FOR OPEN SESSION

Dr. Daniel E. Ford, Johns Hopkins University School of Medicine

Dr. Terry L. Maple, Georgia Institute of Technology

Dr. Richard D. Smith, Pacific Northwest National Laboratory

#### STAFF OF OTHER NIH COMPONENTS

Dr. Jonathan A. Arias, CSR

Dr. John L. Bowers, CSR

Dr. Khalid Masood, CSR

#### **OTHERS PRESENT**

Mr. Dane Christiansen, Association for Clinical Research Training

Dr. Donna J. Dean, Lewis-Burke Associates, LLC

Mr. Stephen J. Heinig, Association of American Medical Colleges

Mr. James B. Heohn, EPSCoR/IDeA Foundation

Ms. Cynthia D. McConnell, Research! America

#### **OPEN SESSION**

## I. Call to Order: Dr. Barbara M. Alving

Dr. Alving officially called the meeting to order and welcomed members and guests to the 140th meeting of the National Advisory Research Resources Council.

#### II. NCRR Videocast: Dr. Barbara M. Alving, Director, NCRR

Dr. Alving opened the proceedings by showing a <u>multimedia presentation</u> first presented at last year's strategic planning forum. It depicts NCRR's wide-ranging mission, diverse research teams, and the power of access to shared biomedical resources. Dr. Alving acknowledged the grantees who provided information and images for the video as well as NCRR staff and all others who contributed to it.

# III. Rollout of the NCRR Strategic Plan 2009–2013: Ms. Lori Mulligan, Director, Office of Science Policy, NCRR

Ms. Mulligan presented the <u>NCRR Strategic Plan 2009–2013</u> and the associated print product, Web site, and implementation plan. The plan is available in HTML and PDF formats and may be downloaded from the Strategic Plan Web page.

In order to provide updates on how action items from the plan are being implemented, NCRR has also developed a separate web section called <u>Plan in Action</u>. This section ties various NCRR initiatives, workshops, meetings, and funding announcements to the themes of the strategic plan. In addition, a slide set and a brochure capture high-level strategies and are available for download from the Web page. Ms. Mulligan acknowledged the contributions of grantees, NCRR staff, and others in the creation of the *Strategic Plan*. Dr. Alving added that NCRR will be developing annual reports focused on the major NCRR programs (e.g., Institutional Development Award [IDeA], Clinical and Translational Science Awards [CTSAs]).

#### IV. Consideration of Minutes: Dr. Barbara M. Alving

The minutes of the Council meeting held on May 14, 2008, were approved as written.

# V. Report of the Director: Dr. Barbara M. Alving

#### A. Introduction of New Council Member

Dr. Alving introduced Col. James A. Swaby, a new member of the Advisory Council. Col. Swaby holds a Ph.D. in entomology and currently serves as the 59th Clinical Research Division Director at Wilford Hall Medical Center at Lackland Air Force Base in Texas. In this role, he directs all aspects of clinical investigation for one of four specified missions of the largest medical center in the Air Force. Col. Swaby has served more than 25 years in the Air Force and is an expert in how vector-borne diseases affect U.S military forces around the world.

### **B.** Personnel Update

#### Division of Research Infrastructure

• **Dr. J. Rafael** ("**Raffy"**) **Gorospe** joined the Division of Research Infrastructure in August 2008 as a Health Scientist Administrator. Dr. Gorospe is involved in the day-to-day management and development of strategies to accomplish the objectives of both the IDeA and Research Centers in Minority Institutions (RCMI) Programs. Prior to joining NCRR, Dr. Gorospe was an Assistant Professor of Pediatrics at George Washington University School of Medicine.

#### Financial Management Office

• Mr. Louis Benjamin Frazier II joined the Financial Management Office in June 2008 as a Budget Analyst. Mr. Frazier provides leadership for all phases of budget services, including budget preparation, formulation, presentation, execution, and financial management policy. Prior to joining NCRR, Mr. Frazier was the Director at United Cerebral Palsy of Central Maryland.

#### Office of Administrative Operations

• Ms. Carol L. Roberts-Mitchell joined the Office of Administrative Operations in June 2008 as an Administrative Officer through the Administrative Fellows Program. She will provide comprehensive administrative services to the Office of Review, Office of Grants Management, and Division of Research Infrastructure. Prior to joining NCRR, Ms. Roberts-Mitchell was an administrative manager at Johns Hopkins University, School of Medicine in conjunction with Johns Hopkins Bayview Medical Center.

#### Office of Information Technologies

Mr. Sean Hagan joined the Office of Information Technologies in July 2008 as an IT Specialist/Information Systems Security Officer. Mr. Hagan will ensure that security is integrated into information systems development and operations. He also will represent the NCRR information security interests to NIH. Prior to joining NCRR, Mr. Hagan served as a security specialist under a contract with the Nuclear Regulatory Commission.

#### Office of Review

• **Dr. Martha F. Matocha** joined the Office of Review in May 2008 as a Scientific Review Officer. Dr. Matocha serves as a scientific review officer for Special Emphasis Panels, including the P51 mechanism for the National Primate Research Center grants, and for various standing committees. Prior to joining NCRR, Dr. Matocha was a program officer and deputy branch chief in the Vaccine Clinical Research Branch of the Division of AIDS, National Institute of Allergy and Infectious Diseases.

#### Office of Science Policy

- **Dr. Tina Thomas Bordonaro** joined NCRR in February 2008 as an NCRR detailee in the Division for Clinical Research Resources (DCRR). Effective September 2, she became a permanent employee in the Office of Science Policy. In this capacity, she will continue to support the SEPA program, as well as contribute to NCRR legislative activities. Prior to joining NCRR, Dr. Bordanaro worked in the NIH Director's Office of Legislative Policy and Analysis.
- Ms. Sylvia Parsons came to NCRR on detail as a Health Policy Analyst in March 2008 and became a permanent employee in August. Ms. Parsons helps to manage the annual appropriations process and special projects for the NCRR Director. Prior to joining NCRR, Ms. Parsons had been the Special Assistant to the Extramural Division Director at NINDS.
- **Dr. Alisa Schaefer**, an American Association for the Advancement of Science Fellow, joined the Office of Science Policy on September 15. Dr. Schaefer will participate in trans-NCRR projects that cut across various policy, legislative, and communication issues related to the NCRR's diverse grant portfolio.

Dr. Alving announced that the Office of Science Policy and Public Liaison has been separated into the Office of Science Policy and the Office of Communications. **Ms. Lori Mulligan** is now the Director of the Office of Science Policy, and Dr. Alving has selected **Ms. Cynthia** (**Cindy**) **McConnell** to be the new Director of the Office of Communications. Ms. McConnell comes from Research! America and has extensive experience in communications and outreach. She will begin working in this new role on October 13, 2008. Dr. Alving acknowledged the contributions of Ms. Joyce McDonald, who has been serving in this capacity.

# C. Program Updates

Dr. Alving updated the Council on several key NCRR programs:

#### Clinical and Translational Science Awards (CTSAs)

Fourteen academic health centers in 11 states became the latest members of the National Institutes of Health's Clinical and Translational Science Award (CTSA) consortium in May 2008. Now comprising 38 academic health centers in 23 states, the consortium ultimately will link about 60 institutions together to energize the discipline of clinical and translational science.

The CTSA Consortium Oversight Committee plans to meet October 6–7, 2008, to finalize its strategic/implementation plan. The group will review the current CTSA committee structure and related evaluation/communication activities.

Dr. Alving emphasized that building and sustaining long-term, mutually beneficial relationships is a critical component of the CTSA consortium. For the translational research process to continue to be successful, clinical and translational researchers need to interact with each other; work with NIH; and strengthen existing relationships with businesses, their communities, and the public. To foster these critical connections, the CTSA consortium has launched a new "Building Connections" feature on its Web site (CTSAweb.org). Among its capabilities, the feature highlights ways that CTSAs are working with their own business schools to develop innovative programs and leverage key resources. In addition, NCRR is providing administrative supplements to support various activities of the consortium, such as those related to informatics, education, and communications. She also described a recent solicitation for a CTSA informatics pilot project, which will support implementation and development of tools for clinical investigators to facilitate small and medium-sized research studies.

#### Institutional Development Awards (IDeA)

Dr. Alving reported that the IDeA program has been very active. The IDeA principal investigators are working to improve their ability to collaborate and share resources. The program has tremendous vitality; 700 researchers participated in the National IDeA Symposium of Biomedical Research Excellence held August 6–8, 2008. The symposium showcased grantees' scientific accomplishments, provided a forum for discussions and exchange of ideas on science and training, and featured a student-oriented poster session. In addition, another established collaboration called the WWAMI (representing Washington, Wyoming, Alaska, Montana, and Idaho) is being led by the University of Washington and is currently demonstrating how CTSA and IDeA infrastructures can be leveraged in interactive ways.

#### Research Centers in Minority Institutions (RCMI)

Dr. Alving reported that the RCMI awardees are making tremendous strides. Some are now linked with CTSA programs or working with IDeA colleagues. The Translational Research Network has submitted its first research protocol to be evaluated by a protocol

review committee. The <u>Eleventh RCMI International Symposium on Health Disparities</u> will be held December 1–4, 2008. Many IDeA researchers also plan to attend the meeting, the theme of which is Research Outcomes Accelerating Discoveries for Medical Applications and Practice (ROADMAP).

#### Comparative Medicine Research Resources

The Division of Comparative Medicine convened NIH representatives and a 15-member panel of opinion leaders from the disease models and computational science communities at the Informatics and Access Knowledge Environment conference August 19–20, 2008. One goal of the meeting was to develop a searchable database for animal models. A report based on the conference will be issued in October 2008. Dr. Alving also announced that Comparative Medicine resource directors will meet in October and will discuss the development of business models to ensure future sustainability, which will free up NCRR resources for funding new projects.

#### Biomedical Technology Research Centers (BTRC)

The Division of Biomedical Technology is planning a meeting entitled <u>Multiscale</u> <u>Technologies for Biomedical Research</u> on November 13–14, 2008. The meeting will allow BTRC investigators to interact with leaders from NCRR and National Institute of Biomedical Imaging and Bioengineering leaders and to highlight scientific progress at their sites via a poster session. (**NOTE:** In October 2008, NCRR changed the name of its Biomedical Technology Research Resources [grant mechanism P41] to Biomedical Technology Research Centers.)

#### D. Budget Update

Dr. Alving reported that in late June 2008, a supplemental appropriations act was signed by President Bush, providing \$150 million for NIH to support additional scientific research. NCRR's share of the supplemental funds is \$6.1 million (4 percent), of which \$1 million is designated to support AIDS research activities at the National Primate Research Centers. The remaining funds will be used to strengthen the IDeA program. NCRR has requested a budget of \$1.16 billion, about an \$11 million (1 percent) increase over the FY 2008 appropriation. Dr. Alving noted, however, that the FY 2009 Labor, Health and Human Services, and Education spending bills have not passed. She added that in all likelihood, the FY 2009 spending bills will not be passed into law until the new administration is in place. Continuing resolution(s) will provide for the ongoing operation of the federal government in the absence of an enacted appropriation.

### **E.** Enhancing the Peer Review Process at NIH

Dr. Alving reviewed and summarized various proposals to enhance NIH peer review and described efforts begun in June 2007 to scrutinize and streamline the peer review process for grant applications, with the goal of funding the best science earlier. Working groups have recommended that the process: 1) engage the best reviewers; 2) improve the quality and transparency of the review process; 3) ensure balanced and fair reviews across

scientific fields and career stages, and 4) conduct continuous reviews of the peer review process. Implementation of the recommendations is under way as of September 2008. Action items include enhanced training for reviewers and scientific review officers; separate percentile rankings for new and resubmitted applications; permitting one amended application to reduce the need for application resubmissions; and shortened and restructured applications. Additionally, NIH will consider modifying review sessions to allow similar applications to be clustered. Pilot studies will be developed to test virtual peer reviews.

# VI. <u>Proteomics Research Resource Center for Integrative Biology</u>: Dr. Richard D. Smith, Principal Investigator, Pacific Northwest National Laboratory

Dr. Smith described technological advances in proteomics at the Pacific Northwest National Laboratory (PNNL) and the potential impact of these unique capabilities on a range of biomedical applications. The field of proteomics is currently dominated by "shotgun" proteomics, which derives information on proteins using tandem mass spectrometry (MS) to measure the mass of fragmented peptides. However, inherent under-sampling is a problem because only a fraction of the peptides can be measured, and multiple measurements are thus required to reveal the proteome. Scientists at the Proteomics Center have addressed this limitation by building libraries of accurate mass and time tags, which can be used in subsequent measurements without the need for tandem MS measurements. This circumvents the under-sampling problem and hastens the overall measurement process. In addition, the resource has built the tools to enable this method to be applied efficiently in a range of applications.

Technology development within the resource has emphasized sensitivity, throughput, and the quality of measurements. Also, resource scientists have leveraged capabilities previously developed at PNNL to push proteomics technologies into the high-throughput and sensitivity realms, and to allow advances to be applied as quickly as possible. For example, the use of gas-phase separations based on ion mobility increases the speed of analysis. Dr. Smith anticipated that this technology will allow processing much larger numbers of samples, which should be particularly effective for dealing with biological variation in the discovery of new biomarkers.

As examples, center investigators are collaborating with the Oregon National Primate Research Center to investigate the proteomics of lung fluid from monkeypox-infected macaques, and PNNL scientists are collaborating with the University of California, Los Angeles, to elucidate changes in protein expression in the brains of mice exposed to methamphetamines or neurotoxins. In conjunction with a large Glue Grant study at Harvard Medical School, Dr. Smith's group is making proteomic measurements in biologic samples from burn patients, with the goal of identifying biomarkers that could inform their treatment. In addition, the Center, with support from the U.S. Department of Energy, has developed proteomics approaches to study microbial communities in the ocean, soil, and other environments, which the investigators are extending to the study of "microbiomes" in humans.

Dr. Smith concluded by saying that high-throughput proteomics holds great promise, and the opportunities for clinical and translational applications are significant. However, significant challenges also exist due to the continually advancing nature of measurement capabilities combined with the large and diverse teams now needed to operate such centers effectively. Thus, large resources and centers represent major investments in research infrastructure. Capabilities at larger centers, such as PNNL, provide the most efficient way to equip researchers with valuable proteomics tools, and collaborations provide the needed focus for technology development.

VII. Response to the Evaluation of the P41 Program— An Integrated Approach to Improving NCRR's Biomedical Technology Research Centers Program: Dr. Douglas M. Sheeley, Health Scientist Administrator, Division of Biomedical Technology, NCRR

Dr. Sheeley began by summarizing the NCRR P41 BTRC program, which enables the development of technologies and tools to overcome problems encountered in biomedical research. In 2007, NCRR convened an expert panel of scientists from outside the Center to assess program strengths and areas for improvement. The evaluators issued a report, **Evaluation of the P41 Program**, which included several recommendations falling into four domains: improving metrics for assessing progress; enhancing community engagement; increasing awareness of the program; and integrating BTRC activities with other NIH programs.

In response to these recommendations, NCRR increased the transparency of the application process to reach out to a broader audience of potential applicants, including the small business community. Two program announcements (PAR-08-259 and PAR-08-260) were issued to present the new guidelines for the program and to implement a preapplication process using the XO2 mechanism. The pre-application process allows the BTRC program to emphasize particular areas of interest each year and identify gaps and opportunities for using new tools to improve understanding of the state of the science. Dr. Sheeley further described activities to identify these opportunities and to increase awareness throughout the research community.

NCRR also aims to enhance the BTRC program Web site so that it serves as a portal for knowledge about technologies and NCRR activities and provides informational resources for investigators. In addition, NCRR will convene meetings to increase awareness of the BTRC program and the technologies it has developed. Dr. Sheeley noted that NCRR encourages linkages between the BTRCs and both basic and clinical biomedical researchers. Projects serve as test-beds for the developing technologies, and contribute to their translation and dissemination. To clarify this relationship, NCRR has renamed the Collaborative component of the BTRC program "Driving Biomedical Projects." This change in nomenclature also recharacterizes BTRCs' service component to include sophisticated projects that might not drive the technology forward but do represent collaborations between BTRC investigators and centers engaged in biological research.

With respect to the recommendation to develop metrics, Dr. Sheeley noted that measuring BTRCs' success is often difficult because many projects take a long time to

bear fruit. Stories may sometimes be the best way to exemplify some important successes, such as widespread adoption of a technology. Dr. Sheeley cited image-guided therapy, magnetic resonance imaging, and the assessment of glycomic markers as examples of the impact of BTRC discoveries on research and the clinic. NCRR is also developing an improved tracking system to monitor BTRC performance and achievements, including both stories and statistical information.

# VIII. <u>Update on CTSA Activities— Getting a Clinical Research Protocol Started: The CTSA Response</u>: Dr. Daniel E. Ford, Professor of Medicine, Vice Dean for Clinical Investigation, and CTSA PI, Johns Hopkins University School of Medicine

Dr. Ford explained that the time needed to initiate new studies is longer in the United States than in most other countries and that the number of steps to start a study is increasing. These barriers must be overcome to make a real difference in the pace of translational research. To this end, the CTSA consortium's Clinical Research Management Taskforce convened a workshop in June 2008 to identify ways to improve management of clinical investigations. Faculty members, institutional review board (IRB) members, research administrators, investigators, and protocol reviewers all were invited to participate. Discussion groups addressed specific questions about clinical research management, and all participants shared best practices and discussed quality improvement programs at a poster session.

Before the workshop, a survey was disseminated to the CTSAs. The response rate so far is about 80 percent. Preliminary results indicate that every academic institution is organized differently and that processes and even vocabularies differ. Many respondents viewed IRBs as the primary factor in initiation delays, but Dr. Ford suggested this result might arise from the IRB being the only component common to all institutions. Incomplete applications, particularity about wording, variation in organizational structures, the ratio of IRB members to protocols reviewed, and high IRB staff turnover were cited as contributors to the length of time needed for IRB review and approval. Many respondents also noted that contracting now takes longer than IRB review and approval. Contracting staff pointed out that study sponsors often do not follow master agreements uniformly. Many institutions involve their general counsels in contracting, but legal review takes time. In addition, negotiations of such components as data transfer and publications of findings can be complex. Dr. Ford discussed implementing standard performance measures of clinical study efficiency as one way to address these barriers. Four survey respondents already post such measures for their IRBs and contracting functions.

Dr. Ford noted that the workshop itself was unique in that it provided a forum for IRB research administrators, sponsors, and investigators to consider together the entire study-initiation process. However, he also noted the need to involve general counsel in this process. He added that the question of standardizing study management across sites or having each site maximize efficiency with its own solutions has not been answered.

The CTSA consortium is now assembling a taskforce to help IRBs and contracts offices develop and agree on metrics. Early in 2009, they plan to ask three sites to volunteer to

gather data and apply agreed-upon performance metrics for prior years. The goal is for the CTSAs to start posting their performance measures in September 2010.

IX. Working Group Report—Opportunities for Life Sciences at the Brookhaven

National Synchrotron Light Source II: An NCRR/NIGMS Joint Study: Dr. Amy L.

Swain, Health Scientist Administrator, Division of Biomedical Technology, NCRR

Dr. Swain announced that the National Synchrotron Light Source (NSLS) at the Brookhaven National Laboratory, one of five major synchrotrons in the nation, will close. Built in 1984, NSLS has supported outstanding life sciences research resulting in 400 publications, 25 percent in premier journals, in 2007 alone. Although NSLS continues to be productive, it is a second-generation synchrotron, and more modern technologies are available. A new state-of-the-art synchrotron, NSLS-II, which will offer world-leading flux and brightness, will be built in its place and fully open to the public in 2015. The U.S. Department of Energy, which serves as a steward for synchrotron infrastructure, will spend \$912 million to build NSLS-II, and the new synchrotron will cost about \$150 million to operate. Life scientists, who make up 40 percent of synchrotron radiation users, have expressed concerns about access to and available techniques at NSLS-II. Workshops were held in July 2007, January 2008, and September 2008 to address these concerns and present opportunities at the new facility.

Dr. Swain reported on a panel convened in April 2008 by NCRR and the National Institute of General Medical Sciences (NIGMS). Panelists included several presenters from Brookhaven as well as two prominent users, and staff from federal agencies were present as observers. The panel considered how existing synchrotron technology is used in the life sciences, the new capabilities enabled by NSLS-II, the feasibility and advisability of life scientists sharing beam lines, and the best management model for a life sciences resource at NSLS-II.

This panel issued <u>a report</u> on life sciences opportunities and needs at NSLS-II as well as several recommendations. Among these is the need to emphasize NSLS-II as a national resource. Panelists also noted the importance of access to state-of-the-art beam lines for crystallography at NSLS-II, the need for automated sample handling to enable time-resolved X-ray scattering, and the need for access to X-ray absorption spectroscopy to complement crystallography and other techniques. Because circular dichromism resources are available at other facilities, the panel felt that access to them at NSLS-II is not critical, although they represent a complementary technique. Imaging studies using synchrotron radiation were also emphasized, and NSLS-II will offer unique characteristics that facilitate imaging techniques. Dr. Swain mentioned, but did not discuss in detail, a separate meeting on imaging studies and reported that a report describing recommendations from this meeting is forthcoming.

NIH, along with NIGMS and National Institute of Biomedical Imaging and BioEngineering, is engaged in a careful planning process to ensure continued access to synchrotron radiation by life scientists. In addition, NIH is engaging other agencies to ease the transition to NSLS-II and to maximize research opportunities afforded by its unique features.

# X. <u>Program Eligibility Assessment—Institutional Development Award (IDeA)</u>: Dr. Barbara M. Alving

Established under the NIH Revitalization Act of 1993, the IDeA program has the dual objectives of enhancing the geographical distribution of research funds and increasing research capacity. States or territories are eligible for IDeA funds if they have a success rate of less than 20 percent in competing for NIH grants (based on awards made 2001–2005) or if they have received less than an average of \$120 million in NIH funding from 2001 through 2005 (excluding IDeA awards and research and development contracts).

IDeA supports two specific programs. The IDeA Networks of Biomedical Research Excellence (INBRE) program supports networks of research at undergraduate institutions, enhancing biomedical research capacity and strengthening faculty research capabilities. INBRE funding also provides promising undergraduate students with access to research resources. Twenty-two states and Puerto Rico have INBREs. Another component of IDeA is the Centers of Biomedical Research Excellence (COBRE) program, which aims to strengthen institutional biomedical research capacity by expanding faculty research capability and enhancing research infrastructure. Eighty-four COBREs have been established throughout the IDeA states. The overall IDeA program is similar to the National Science Foundation's Experimental Program to Stimulate Competitiveness in Research (EPSCoR), although EPSCoR does not consider success rates for its eligibility criteria.

Dr. Alving noted that NCRR has been examining the system used to determine eligibility of the states and territories to receive IDeA funding. Data are now available for the 2003–2007 period, and success rates have been trending downward across all NIH grantees. Grant success rates are no longer valid indicators of states' needs, but because eligibility criteria are governed by IDeA legislation, changing the criteria would require a change in the law. In addition, IDeA states were distinct from non-IDeA states when the program was established, but this distinction is less clear now because IDeA states have been winning more research dollars. Dr. Alving also noted the need for some flexibility for states on the cusp of eligibility. She and other NCRR leaders have called for new criteria that include options more in keeping with the intent of the IDeA program.

Dr. Alving suggested maintaining the eligibility criteria for now while thoughtfully exploring other options. Dr. Alving also proposed a Working Group that includes Council members, IDeA state representatives, legal advisors, and NCRR staff to discuss options for proposing legislation that reflects the realities of 2008 and beyond. She also suggested gathering additional input from the community and discussing this topic at the May 2009 Council meeting. She asked for ideas about other eligibility factors or means of introducing new flexibility into the program. Revisiting how funds are allocated (i.e., on a state basis) and developing a set of metrics for success were suggested.

# XI. Working Group Report—The Chimpanzee Sanctuary: Dr. Terry Maple, Georgia Institute of Technology

The Chimpanzee Health Improvement, Maintenance, and Protection Act provided funds to build and maintain a sanctuary, Chimp Haven, for chimpanzees that have "retired" from biomedical research. Chimp Haven houses 130 animals and has funding through 2012. A new fundraising executive was hired recently. As part of its efforts to ensure that the sanctuary can continue operations beyond 2012, NCRR convened a Working Group to examine business management practices and strategies to expand the facility's support base.

Dr. Maple, Chair of the Working Group, reported that the group found Chimp Haven to be a well-run and maintained facility with access to the required expertise. However, more effort is needed to increase stakeholder breadth, and key management positions must be filled. Although expert veterinary care is always available, a veterinarian with leadership skills is needed to provide high-level support for fundraising, marketing, and public relations. Chimp Haven also must aggressively pursue public and private funding, and it should reach out to the humane community to develop partnerships. A good model would be the public-private partnership model already employed by some zoos. Chimp Haven also must work to improve communication of its identity and its achievements to the public, which would, in turn, increase awareness that these chimpanzees are treated well by people who understand and care for them, that the government is helping with support, and that private sources will be sought to ensure the highest level of management.

Dr. Maple reported that, overall, the Working Group thought the facility was moving in the right direction, although some adjustment of the management model is needed, and the leadership should adopt a more businesslike mindset. A proper mix of science and business could project the facility forward into a position of respect in the animal welfare world. Dr. Maple also pointed out that, although raising money could be difficult at this time, Chimp Haven has an opportunity to be a leader among animal sanctuaries, and the nobility of its cause will open the door to humane philanthropy.

Dr. Alving acknowledged the Working Group's efforts. Dr. Franziska Grieder added that two reports based on the Working Group's <u>face-to-face meeting</u> as well as <u>a site visit</u> are available on the NCRR Web site.

# XII. Notification of Planned Workshop—Detection, Impact, and Control of Specific Pathogens in Animal Resource Facilities: Dr. Franziska B. Grieder, Director, Division of Comparative Medicine, NCRR

Pathogens infecting laboratory animals used to study human diseases can alter research outcomes and interpretations, and they could be transmitted to humans. Detection of such contaminants has increased significantly, and scientists recognize that research using pathogen-free animals is important to minimize the confounding of results and to interpret data correctly. However, there is a lack of peer-reviewed publications describing standards for nutrition, water and air quality, stocking density, and veterinary care for

most laboratory animal species, and more information on control and detection of emerging pathogens in several laboratory animal species (e.g., nonhuman primates, fish, mice) is needed.

Dr. Grieder informed the Council of a workshop to explore the topic of detecting pathogens in animal facilities. The goal of the workshop is to assess current status and future challenges in this area. Whereas other meetings are specific to a particular type of animal, this workshop will focus on several species, including nonhuman primates, rodents, and zebrafish. The workshop also will focus on new technologies for detection and surveillance and on the potential impacts of extraneous pathogens on research. NCRR will work with other NIH Institutes and Centers, the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, and the U.S. Department of Agriculture to develop workshop goals.

The workshop will be held April 23–24, 2009, on the NIH campus. Dr. Manuel Moro, of NCRR's Division of Comparative Medicine, will take the lead. Dr. Grieder estimated that 70-80 participants will attend.

#### **CLOSED SESSION**

This portion of the Council meeting was closed to the public in accordance with the determination that it concerned 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.

### **XIII.** Application Review

The Council reviewed 239 applications (with total direct costs of \$111,170,314). The Council concurred with the review of all applications.

#### **ADJOURNMENT**

The Council adjourned at 2:45 p.m. on September 16, 2008.

#### **CERTIFICATION**

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

Dr. Barbara M. Alving

Chair, National Advisory Research Resources Council

and

Director, National Center for Research Resources, NIH

Dr. Louise E. Ramm

Executive Secretary, National Advisory Research Resources Council and

Deputy Director, National Center for Research Resources, NIH