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

# NATIONAL ADVISORY RESEARCH RESOURCES COUNCIL
# MEETING MINUTES
# JANUARY 30, 2008

The National Advisory Research Resources Council convened for its 138th session at 8:00 a.m. on Wednesday, January 30, 2008, in Conference Room 6, Building 31, on the NIH main campus. Dr. Barbara M. Alving, Director, National Center for Research Resources (NCRR), National Institutes of Health (NIH), presided as Chair. The meeting was open to the public until 2:00 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. Nancy J. Brown
Dr. James P. Collins, Liaison Member, NSF
Dr. Valerie Copié
Dr. James E. Heubi
Dr. Roland F. Hirsch, Liaison Member, DOE
Dr. Kevin B. Johnson
Dr. Barbara B. Knowles
Dr. Bettie Sue Masters
Colonel (Dr.) Debra M. Niemeyer, (ex officio)
Dr. Thomas J. Rosol
Dr. Richard A. Rudick
Dr. Janet L. Smith
Dr. Arthur W. Toga
Dr. Tilahun D. Yilma
Ms. Sheila C. Zimmet
Dr. Stuart M. Zola

## COUNCIL MEMBERS ABSENT

Dr. Kenneth G. Cornetta
Dr. Kelly D. Garcia (ex-officio)
Dr. Cynthia E. Keppel
Dr. Henry Lewis, III
Dr. Mark V. Pauly
Dr. M. Roy Wilson

## SPECIAL INVITED GUESTS FOR OPEN SESSION

***National Primate Research Center (NPRC) Directors***
Dr. David M. Anderson, Washington National Primate Research Center
Dr. Ronald C. Desrosiers, New England National Primate Research Center
Dr. Nancy L. Haigwood, Oregon National Primate Research Center
Dr. Dallas M. Hyde, California National Primate Research Center
Dr. Joseph W. Kemnitz, Wisconsin National Primate Research Center
Dr. Andrew A. Lackner, Tulane National Primate Research Center
Dr. Stuart M. Zola, Yerkes National Primate Research Center

***Clinical and Translational Science Awards (CTSA) – Consortium Principal Investigators***
Dr. Lars F. Berglund, UC Davis Clinical and Translational Science Center
Dr. Gordon R. Bernard, Vanderbilt Institute for Clinical and Translational Research
Dr. Daniel E. Ford, Johns Hopkins Institute for Clinical and Translational Research
Dr. Henry N. Ginsberg, Irving Institute for Clinical and Translational Research
Dr. David S. Guzick, University of Rochester Clinical and Translational Sciences Institute
Dr. Gary W. Hunninghake, University of Iowa's Institute for Clinical and Translational Science
Dr. Robert A. Rizza, Mayo Center for Translational Science Activities
Dr. David S. Stephens, Atlanta Clinical and Translational Science Institute

**STAFF OF OTHER NIH COMPONENTS**

Mr. Ronald Barnett, OSP/OBA/OD
Mr. John T. Burklow, OCPL/OD
Dr. Noni H. Byrnes, CSR
Ms. Diane D. Christensen, OFC/OD
Dr. Timothy C. Hays, OPASI/OD
Dr. Wendy L. Johnson-Taylor, DNRC/NIDDK
Dr. Alan M. Krensky, OPASI/OD
Dr. Bonnie J. Mathieson, OAR/OD
Dr. Marc L. Rigas, CSR
Dr. Susan B. Shurin, NHLBI
Dr. Margaret D. Snyder, OER/OD
Ms. M. Virginia Wills, NIAID

**OTHERS PRESENT**

Ms. Wendy Chaite, Esq., Lymphatic Research Foundation, East Hills, NY
Dr. Donna J. Dean, Lewis-Burke Associates, LLC, Washington, DC
Mr. Claudio A. Noetzli, Lewis-Burke Associates, LLC, Washington, DC
Mr. Jon G. Retzlaff, Lewis-Burke Associates, LLC, Washington, DC
Dr. Harry P. Selker, Tufts-New England Medical Center, Boston, MA
Dr. Irena Tartakovsky, Association of American Medical Colleges, Washington, DC

**OPEN SESSION**

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

Dr. Alving welcomed Council members and guests to the 138th meeting of the National Advisory Research Resources Council.

**II. Consideration of Minutes: Dr. Barbara M. Alving**

The minutes of the Council meeting held on September 11, 2007, were approved as written.

**III. Report of the Director: Dr. Barbara M. Alving**

***NCRR Division Highlights***

Division for Clinical Research Resources: Under the Clinical and Translational Science Award (CTSA) program, there are now 24 academic health centers working together as a national consortium to advance the complete spectrum of research from basic biology to clinical medicine. Dr. Alving informed the Council that they would be hearing more

about the CTSAs when representatives of the Consortium Oversight Committee presented later in the morning. In addition, she informed the Council that the consortium was sponsoring a two-day workshop that began that evening (January 30) in conjunction with the CTSA Education and Career Development Steering Committee. The goal of the workshop is to create a national set of core competencies in degree-granting programs for clinician-scientists that will define the discipline of Clinical and Translational Science.

Dr. Alving also reported that review of the applications submitted in November 2007 for the 2008 awards would begin in February 2008 and that awards would be announced in July 2008. A request for applications for the 2009 awards was published in December 2007, and a pre-submission webcast will be held in March 2008. Awards will be announced in July and October 2009.

Dr. Alving also recognized the CTSA Principal Investigators in attendance.

Division of Comparative Medicine: On November 1, Dr. Jay Hove, of the University of Cincinnati, was one of 12 NIH-supported scientists to receive a Presidential Early Career Award for Scientists and Engineers. The Division of Comparative Medicine nominated Dr. Hove for his innovative research, which combines optics, engineering, and biomedicine to describe dynamic flow interactions that occur in sick and healthy animal models. He has received NCRR funding to create a technology for imaging flow, using zebrafish as a model system. Dr. Hove will address the Council at its May 2008 meeting.

Dr. Alving also recognized the NPRC Directors in attendance.

Division of Biomedical Technology: The Division supports a broad spectrum of technologies, techniques, and methods through 50 Biomedical Technology Research Resources (BTRRs) at academic and other research institutions nationwide. These resources also support entrepreneurial activities and are willing to interact with the CTSA program to integrate their translational expertise.

In addition, Dr. Alving noted that an independent panel of experts evaluated the BTTR program last year; earlier, the Council was given a copy of their assessment. Dr. Alving indicated that the BTTR evaluation was a valuable critique of this important program, and that NCRR appreciated the panel's thorough review. The division is currently reviewing the recommendations and will brief the Council on next steps at the May Council meeting.

Division of Research Infrastructure: Dr. Alving reported that there was tremendous activity underway in the division. For instance, leaders of the Institutional Development Award (IDeA) program are exploring opportunities to enhance their programs and increase sharing of established network systems. She said she had recently met with them about finding ways to work in a more cohesive approach and to further promote translational science.

## III-A. Budget Update

In 2007, NCRR funded 986 grants; 80 research and development contracts, including loan repayment contracts; and 125 full-time training positions. Dr. Alving reported that President Bush signed the FY 2008 Omnibus Appropriations bill into law on December 26, 2007, finalizing FY 2008 funding levels for agencies that had been operating under FY 2007 levels through continuing resolutions. The FY 2008 NIH budget includes $29.2 billion, an overall increase of 1.1 percent from FY 2007. Funding for NCRR is $1.15 billion, a 1.4 percent increase from FY 2007.

Dr. Alving reviewed NCRR's funding history for some programs.

- Funding for CTSAs and General Clinical Research Centers (GCRCs) started with a base of $286 million in FY 2005 and has increased to $462 million in FY 2008. Approximately 20 percent of funding for GCRCs and CTSAs comes from NIH Roadmap funding, and other funds come from the transition of GCRCs to CTSAs and from the folding in of K12, K30, and T32 programs.

- NCRR has redirected funding from some of its programs to the CTSAs. One result is that the Gene Vector Laboratory program is now funded by other Institutes and Centers (ICs) with specific categorical interests.

- Funding for the Institutional Development Awards program, which has been built up substantially since its inception, has remained stable.

- Funding for the Research Centers in Minority Institutions (RCMI) program has also remained stable. Dr. Alving expressed an interest in promoting dynamic opportunities among RCMI institutions and between RCMI institutions and CTSAs.

- Funding for NPRCs has remained stable.

- Funding for the Shared Instrumentation Grant and High-End Instrumentation programs also has remained stable. Dr. Alving pointed out that NCRR plans for these 1-year awards at the beginning of the year. In addition, funding that NCRR does not want to commit to out-year activities may be redirected into these programs at the end of the year. In 2007, NCRR received extra funding for these awards, which was then planned to be redirected to the CTSA in 2008.

## III-B. Meetings and Events

### *Strategic Planning*

NCRR held a forum in December 2007 to receive input on its strategic plan. Early this year, a draft of the strategic plan will be disseminated to the Council, forum participants, and the public for comment. Feedback will be reviewed and consolidated in March, and the final strategic plan and specific action plans will be presented at the May Council meeting. NCRR intends to review the plan on an annual basis.

***Women in Biomedical Careers***

Dr. Alving reported that Dr. Elias Zerhouni, NIH Director, and Dr. Vivian Pinn, Director of the NIH Office of Research on Women's Health (ORWH), have formed a trans-NIH working body to review opportunities for women in biomedical research careers and to ensure that these opportunities are maximized and sustained. In line with these efforts, NCRR and ORWH will hold a conference on March 4, 2008, to explore best practices for promoting career development of women in biomedical research. Colonel Debra Niemeyer, ex officio Council member who is involved in workforce planning, will share how the military approaches these issues. Conference participants also will hear from representatives of Ernst & Young; Deloitte & Touche; and academic health centers. The conference will be webcast. Dr. Alving encouraged Council members to register and participate.

**III-C. Personnel Update**

***NIH***

- **Dr. Josephine P. Briggs** has been named—by Dr. Elias Zerhouni, NIH Director—as Director of the National Center for Complementary and Alternative Medicine. Dr. Briggs was Director of the Division of Kidney, Urologic, and Hematologic Diseases at the National Institute of Diabetes and Digestive and Kidney Diseases from 1997 to 2006, and she served as a senior scientific officer at the Howard Hughes Medical Institute for a year and a half. Dr. Briggs also participated in the December strategic planning forum.

***NCRR***

- **Dr. Eugene C. Rich** has joined NCRR in a one-year program as Dr. Alving's Senior Advisor for Program Outreach and Coordination. Dr. Rich was Chair of the Department of Medicine at Creighton University from 1996 to 2006 and has spent the past year on Capitol Hill as a Robert Wood Johnson Health Policy Fellow. He has been active in research, academic administration, and public policy concerning medical education and health care.

- **Ms. Lili M. Portilla** has joined NCRR as a permanent staff member, serving as Senior Advisor for Technology Transfer. Ms. Portilla comes to NCRR from the National Heart, Lung, and Blood Institute (NHLBI), where she worked in the Director's Office of Technology Transfer and Development. She will provide advice to all Divisions in the areas of intellectual property and technology transfer.

- **Ms. Jennifer A. Czajkowski** has agreed to serve as Acting Director of the NCRR Office of Information Technologies (OIT). Ms. Czajkowski, Deputy Director of the Division of Customer Support at the NIH Center for Information Technology, is filling in for Ms. Delores Lee who has recently retired, after leading OIT since 1997.

### III-D. Future Meeting Date

The next Council meeting will be held on Wednesday, May 14, 2008.

## IV. Research at the National Primate Research Centers (NPRCs): Dr. John (Jack) D. Harding, Health Science Administrator, Division of Comparative Medicine, NCRR; Dr. Nancy L. Haigwood, Oregon NPRC; Dr. Ronald C. Desrosiers, New England NPRC; Dr. Stuart M. Zola, Yerkes NPRC; Dr. Dallas M. Hyde, California NPRC

Dr. Harding provided the Council with an overview of the NPRC program, which aims to provide infrastructure and expertise for researchers who study non-human primates. Although preference is given to NIH grantees, other researchers also have access to the NPRCs. There are eight NPRCs nationwide, each serving as a national resource. They house about 28,000 animals. The majority of these animals, about 60 percent, are rhesus macaques, but NPRCs also house other species of macaques, baboons, new-world monkeys, and a small number of chimpanzees. NPRCs support a wide array of scientific disciplines, including models for most major human diseases.

The NPRC base grants are funded through the P51 mechanism. These base grants support each Center's administration and infrastructure, including animal facilities, cores such as immunology or genetics, resource improvement projects, and studies to improve animal welfare. The NPRC base grants do not fund research projects directly; many related R01 grants are funded by other NIH ICs. NCRR-supported activities do include a pilot research program, and many pilot projects go on to become R01-funded projects outside the Centers. The FY 2007 NPRC budget was about $79 million. During this fiscal year, NPRCs interacted with about 2,000 NIH grantees, called affiliate scientists; trained non-human primate veterinarians, graduate students, postdocs, and foreign primatologists; and supported about 1,000 individual projects.

The principal investigator for each NPRC is an individual of high rank in the grantee institution, such as a dean, provost, or vice president. NPRCs are thus linked to their home institutions at the highest levels, ensuring access to institutional resources. NPRC directors, who manage the day-to-day activities of their Centers, are highly experienced senior scientists and primatologists. In addition, each director has his or her own laboratory and extramurally funded research projects. Other personnel critical to the NPRCs' mission and infrastructure include veterinarians, administrators, technicians, and animal care staff. Also critical to the NPRCs' mission are the doctoral-level core scientists who not only provide scientific expertise at the Centers, but also serve as resources for the larger research community. There are 300 core scientists across all eight NPRCs.

Dr. Harding concluded his presentation by outlining challenges from a programmatic perspective:

- Maintaining and expanding the program in the context of stable budgets.

- Responding to changes in demand. Although the demand for rhesus macaques has remained constant over the years, the demand for other non-human primates fluctuates.

- Enhancing integration of activities among NPRCs and with other NCRR and NIH grantees. NPRCs are 46-49 years old and have collaborated extensively. To build on those collaborations, working groups have been established to enhance integration by focusing on specific cross-cutting topics, such as colony management, informatics, genetics and genome banking, and training.

- Integrating NPRCs with CTSAs. Five NPRCs are located in institutions that also have CTSAs, and of these, many have integrated their programs into CTSA initiatives. The three remaining NPRCs are associated with CTSA applications under review.

- Enhancing and enlarging colonies of specific pathogen-free rhesus macaques and other non-human primates by reducing or eliminating viruses that interfere with some experiments.

- Enhancing informatics capabilities. Dr. Harding reported on a productive meeting about the usefulness of the Biomedical Informatics Research Network infrastructure for complex problems. Development of a single database as a point of entry for outside researchers is planned.

Dr. Harding then introduced the NPRC directors, four of whom provided brief summaries of ongoing research supported by NPRCs.

***Heart Disease, Diabetes, and Obesity*: Dr. Nancy L. Haigwood, Director, Oregon National Primate Research Center**

Heart disease, diabetes, and obesity are complex metabolic conditions arising from many factors. Although a large amount of progress has occurred in research on these conditions, they still constitute a large portion of public health burden. The use of non-human primates provides a great opportunity to accelerate progress, and results from research on non-human primates can be translated into applications toward human health. The major NPRC goals in research on heart disease, diabetes, and obesity are:

- to develop naturally occurring and experimentally induced models in non-human primates;

- to use them to determine the biological mechanisms that lead to these diseases;

- to understand the genetic and environmental factors that influence disease onset and progression; and

- to translate results into new strategies for prevention and treatment.

Dr. Haigwood presented several examples of models—developed in NPRCs—that led to exciting opportunities in this field of research. In a model for atherosclerosis, the arteries of some baboons fed a North American diet exhibit diseased vessels, fatty streaks, and fibrous plaque lesions. Yet as with humans, some baboons fed this diet do not exhibit diseased arteries. High-pedigreed baboon colonies will aid researchers in teasing out the genetic aspects of baboons that develop diseased arteries on this diet compared with those that do not. Dr. Haigwood also discussed unpublished work focused on therapies to treat cardiovascular disease.

NPRCs also have developed models for obesity and diabetes research. Baboons receiving a normal, low-fat, monkey chow diet display a range of weights, from lean to obese, and some exhibit laboratory and clinical indications of type 2 diabetes or its precursors. Similar results occur in rhesus macaques fed a typical American diet: 60 percent of these animals become obese, but 40 percent do not. These models will help researchers explore host factors that lead to or prevent obesity. In addition, monkey models can be used to build on research in other animal models. For example, the architecture of pancreatic islet cells is more similar between monkeys and humans than between mice and humans. Mouse models have yielded knowledge about this architecture, and now monkey models can be used to build on that knowledge by enabling researchers to study natural disease.

Seventy-three active NIH-supported research projects employ non-human primates to study cardiovascular disease, hypertension, diabetes, metabolic syndrome, and obesity. Dr. Haigwood provided a representative sample of projects.

<u>Baboons</u>

- Diet and genotype in primate atherosclerosis.
- Angiotensin, sodium, and genes in primate hypertension.
- Novel therapy for diabetes.

<u>Rhesus Monkeys or Marmosets</u>

- Pathobiology and gene transfer in cardiovascular disease.
- Effect of fish oil and alpha lipoic acid on the progression of insulin resistance.
- The common marmoset as a primate model of maternal obesity.

Dr. Haigwood concluded by emphasizing that primate models can provide in-depth knowledge of the molecular and genetic bases of adipose formation and the renal and metabolic complications that can ensue. Successful understanding of the causes and consequences of these conditions will require both basic and translational research using these models.

***Infectious Diseases and HIV/AIDS*: Dr. Ronald C. Desrosiers, Director, New England National Primate Research Center**

In the arena of infectious disease, the goals of the NPRCs are to better understand the pathogenesis of infectious diseases relevant to human health, using non-human primate models, and to develop and use non-human primate models of infectious diseases, with an ultimate goal toward translational development. In some cases, activities in the area of infectious diseases have led to improvements in the health and well-being of the animals themselves. NPRCs have linked to several major programs, including the Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases, the Centers for AIDS Research, the Center for HIV-AIDS Vaccine Immunology, and CTSAs.

Dr. Desrosiers presented a list of contributions made by the NPRCs from 1983 to the present. In the field of AIDS research, NPRCs played a role in the discovery of the simian form of HIV, a direct demonstration that AIDS is caused by a virus, a demonstration that a vaccine is feasible, generation of the first pathogenic molecular clone, and a demonstration that the gut is the principal site of early virus replications. NPRCs also have served as a testing ground for vaccine and microbicide concepts and products prior to testing in humans. Several contributions also have been made toward the study of non-AIDS infectious diseases. NPRCs have contributed to the development of a hepatitis B vaccine, the definition of hepatitis C virus, and work on herpesvirus saimiri and Lyme disease. NPRCs also were involved in the identification and characterization of type D virus, which had decimated primate colonies in the 1980s.

NPRCs house more than 1,500 monkeys under BSL-2 and BSL-2+ containment and more than 600 monkeys under BSL-3 containment. Personnel include 32 on-site faculty in AIDS research and 21 on-site faculty in research on non-AIDS infectious diseases. More than 50 infectious agents, including Ebola virus, yellow fever, Marburg virus, *Plasmodium*, *H. pylori*, and multidrug-resistant tuberculosis, are under investigation at NPRCs. The NPRCs take seriously their charge to serve as a resource. More than 50 percent of monkey assignments in infectious diseases are allotted to external investigators, and NPRCs provide samples, reagents, and techniques to hundreds of investigators at several institutions around the world. They also provide investigators with specific pathogen-free and superclean specific pathogen-free monkeys. In addition, NPRCs offer specialized training in veterinary medicine, veterinary biology, diagnostic testing, antibody testing, and other procedures specific to primate studies.

Dr. Desrosiers reported that NPRCs will serve a new role as gatekeepers in HIV vaccine development efforts. He pointed out that three large, extensive human trials of HIV vaccine candidates found no effect in preventing HIV infection or lowering viral load. In the most recent failed trial, the frequency of infection might even have been enhanced. The National Institute of Allergy and Infectious Diseases' (NIAID) Division of AIDS and the HIV Vaccine Trials Network held a workshop in conjunction with experts in primate research. This workshop explored ways to use non-human primates more efficiently in HIV vaccine development, and recommendations from the workshop, which will be published soon, call for a greater reliance on the SIV model for testing, with the most promising approaches moving forward. Representatives from NPRCs participated in this

workshop, and NPRCs will play a key role in the enactment of these recommendations. In addition, the paradigm of vaccine development is shifting from product development and clinical testing toward an emphasis on discovery.

***Neuroscience, Neuroimaging, and Neurodegenerative Diseases*: Dr. Stuart M. Zola, Director, Yerkes National Primate Research Center**

Dr. Zola discussed the important role of NPRCs in research focused on development of the nervous system; normal and abnormal brain function; and ways to prevent, treat, and cure neurodegenerative and psychiatric diseases. NPRCs are involved at all levels of research in neuroscience, including molecular genetics, nerve cell interactions and networks, brain systems, and behavior. Also, the NPRCs are collaborating with the CTSAs to conduct research, education, and training.

According to a 2003 World Health Organization report, brain disorders cause the greatest burden of disease worldwide. The cognitive and neuropathologic trajectories involved are perplexing—not because scientists do not know what they are, but because they do not know how to manage them. A relatively new diagnosis in these trajectories is mild cognitive impairment (MCI), where a person functions fairly well in life but experiences impaired memory compared with his or her age- and education-matched peers. Individuals with MCI are at higher risk than the normal population for later diagnoses of dementias, particularly Alzheimer's disease (AD). This is an important research area in which the use of non-human primates can aid in predictive work. A great deal of research is under way for the entire trajectory, with a focus on early diagnosis. Such work will allow researchers to address the nervous system before it becomes too compromised, and the work will thus facilitate more effective interventions. Work on treatment and prevention is also under way.

Historically, research in neuroscience and neurodegenerative diseases has been translational in nature, a "dance" between research in non-human primates and that in humans. Research using non-human primates helps in the development of frameworks on which to base human research, and human research provides additional questions to explore in non-human primates. One technology that has arisen from work in non-human primates is infrared eye tracking, which allows researchers to determine, with much precision, how and where an animal looks at a stimulus. This technology has been translated to the clinic, and trials are under way to test its ability to predict who will develop MCI and, of those with MCI, who will develop AD. Other studies focus on the use of eye tracking to rehabilitate patients with brain injury or cognitive impairment.

Dr. Zola noted that work in non-human primates has made substantial contributions to memory research. Moreover, the NPRCs hold the promise of developing the first animal model of AD as well as of other neurodegenerative diseases. The NPRCs conduct work that brings the pieces together for predictive health.

***Regenerative Medicine, Stem Cells, and Gene Therapy*: Dr. Dallas M. Hyde, Director, California National Primate Research Center**

NPRC research in regenerative medicine, stem cells, and gene therapy is focused on translational applications and includes non-human primate models to understand human health and disease and assess new therapies. The reproductive and developmental features of old-world monkeys are similar to those of humans, and a long and productive history of reproductive research at NPRCs has laid the foundation for stem cell research, particularly through the use of assisted reproductive technologies that led to the development of nuclear transfer techniques.

All major stem and progenitor cell populations are under study at NPRCs. Dr. Hyde highlighted several examples of important discoveries:

- The first transplants of CD34+ hematopoietic stem cells, giving rise to new techniques to enhance engraftment.
- Age-related differences with mesenchymal stem cells.
- The importance of endothelial progenitor cells in regenerative therapies to treat vascular insults and ischemic diseases.
- New techniques for derivation and directed differentiation of embryonic stem cells.
- New techniques for induced pluripotent stem cells and comparing these cells to embryonic stem cells.
- Identification and characterization of organ-specific progenitor cells, such as those from the kidney.

The Wisconsin NPRC provided the groundwork for the implementation of the National Stem Cell Bank, and the California NPRC developed novel applications and techniques that led to the Center of Excellence in Translational Human Stem Cell Research. The Center of Excellence brings basic, translational, and clinical scientists together to form multidisciplinary teams with studies focused on pediatric models and childhood illnesses. Although these teams focus on pediatric models, their research will be applicable to all age groups and increase understanding of age-related differences in stem cells. Activities at the California NPRC/Center of Excellence explore the use of stem cells for transplantation and *in vivo* imaging to track engrafted human cells in non-human primates, and they also include a pilot and feasibility program that extends to outside investigators, providing resources and research opportunities. Collaborative partners include Indiana University School of Medicine, Childrens Hospital Los Angeles, and the BC Children's Hospital in Vancouver, British Columbia.

The Washington NPRC is a part of the Northwest Genome Engineering Consortium, which is supported by the NIH Roadmap to explore methods to reduce risks associated with insertional mutagenesis that can occur with gene transfer. The California NPRC also

houses a Center for Fetal Monkey Gene Transfer for Heart, Lung, and Blood Diseases, which is supported by NHLBI and explores questions such as the routes and timing of gene therapy delivery, pediatric models of non-myeloablative conditioning, pre-clinical data for investigational new drug applications, safety, and methods to monitor long-term gene expression. The Center has pilot funding for NHLBI-supported investigators through a competitive process, and gene therapy projects with non-human primates are conducted each year.

Dr. Hyde emphasized that non-human primates continue to be essential in stem cell and regenerative medicine research. It is critical to obtain substantial amounts of data and to determine safety before moving into clinical trials. Investigators need a fundamental understanding of stem cells, how different stem cell populations compare, and how they interact with the host over time. Autologous, allogeneic, and xenogeneic models are all necessary, as are techniques for transplant tolerance and approaches addressing all age groups. Work in non-human primates can address questions that cannot be assessed ethically in humans or answered in other species. This work also can demonstrate safety and efficacy, and it can accelerate the clinical development of new therapies. As do other NPRCs, the California NPRC serves the research community through collaborations, cores, cell banks, reagents, outreach programs, and pilot funds; staff scientists teach and train the next generation of scientists through a variety of training programs and collaborative opportunities.

**V.** **Clinical and Translational Science Award (CTSA) Program - Challenges and Opportunities: Dr. Lars F. Berglund, UC Davis Clinical and Translational Science Center; Dr. David S. Guzick, University of Rochester Clinical and Translational Sciences Institute; Dr. Robert A. Rizza, Mayo Center for Translational Science Activities; Dr. Henry N. Ginsberg, Irving Institute for Clinical and Translational Research; Dr. Gordon R. Bernard, Vanderbilt Institute for Clinical and Translational Research; Dr. Daniel E. Ford, Johns Hopkins Institute for Clinical and Translational Research; Dr. David S. Stephens, Atlanta Clinical and Translational Science Institute; Dr. Gary W. Hunninghake, University of Iowa's Institute for Clinical and Translational Science**

CTSA directors made presentations to the Council about their activities and the challenges they face. As Dr. Alving had reported at the beginning of the meeting, there are now 24 CTSAs funded in 2006 or 2007. The 2006 CTSA grantees are 16 months into funding. All CTSAs have faced significant challenges, but the 2007 class also has had to adapt to changed financial circumstances during the first few months.

Dr. Lars Berglund, Co-Chair of the CTSA Consortium Oversight Committee, provided the Council with an overview of the consortium. In addition to the comprehensive task of starting CTSAs at each institution, all CTSA grantees are committed to working together, and this commitment is facilitated by the program framework envisioned by NCRR. This framework comprises two layers: an oversight level consisting of the Consortium Oversight Committee, Pediatrics Oversight Committee, and Clinical Integration Committee, and a steering committee level consisting of committees, task forces, and working groups focused on such themes as informatics, community engagement,

education and career development, translational science, public-private partnerships, and evaluation. All CTSA institutions are represented in these groups, and the two organizational levels of the consortium interact through liaisons between the oversight level and other committees.

In their short time of existence, CTSAs have identified several opportunities. Similar to the NPRCs, the consortium members now have an in-depth knowledge of specific site strengths, including unique faculty and core resources. They have found flexibility in the ability to leverage resources within and across institutions, and they have created a forum to share best practices and resources and a mechanism for promoting translational research education and projects. However, working together as a consortium has its challenges. CTSA directors must balance their time between their individual institutions and the consortium, and all 24 institutions must integrate their activities and cultures. The CTSA Consortium also faces a lack of designated resources; it is supported by resources drawn from each site. The consortium also must balance between top-down and bottom-up communication, which it has accomplished through experiential development of consortium governance and actions.

Dr. Berglund reported that the CTSA Consortium has developed efficient inter-CTSA collaborations through the committee framework and is helping to provide a national identity and unified voice for translational science. The consortium also is identifying mechanisms to make clinical trial and research environments more efficient with a task force that addresses issues such as education, contracts, and institutional review boards (IRBs). The consortium has energized faculty and created opportunities, facilitated NIH research programs, and contributed to changes in institutional cultures. It also has developed a recipe for success:

- Invest in people through training and pilot grants, serving as a magnet for new recruits, connecting people, and engaging the community.

- Streamline processes for contracts, IRBs, use of clinical research centers, resource partnerships, and engagement with the private sector.

- Promote translational science through partnerships among the consortium, institutional centers, and granting agencies.

Dr. Berglund concluded his presentation by highlighting ways in which the CTSA at the University of California, Davis (UC-Davis), interacts with other NCRR programs. A scientist at the UC-Davis NPRC serves in the CTSA as Director for Translational and Pilot Grant Programs, and there is reciprocal representation on the CTSA Oversight and NPRC Advisory committees. In addition, the NPRC and CTSA at UC-Davis collaborate on pilot programs, workshops, and training opportunities.

***Implementing the CTSA vision - accomplishments and challenges*: Dr. David S. Guzick, PI, University of Rochester Clinical and Translational Sciences Institute**

Dr. Guzick noted that before the CTSA, the University of Rochester had shared a vision with the NIH Roadmap and had implemented some building blocks for clinical and translational science. These building blocks included appointment of a Senior Associate Dean for Clinical Research, expansion of biostatistics and bioinformatics, creation of cross-departmental programs, identification of faculty leaders, and establishment of a research process improvement team. The University has a GCRC, one of eight initial centers first funded in 1960. Since the start of the University of Rochester's CTSA, however, the GCRC has seen a 14 percent increase in the number of active protocols and a 15 percent increase in the number of first-time principal investigators. The University of Rochester also has a K30 that was first funded in 1998 and renewed in 2005, with 153 trainees accepted through December 2007. As a result of this K30, 75 investigators have completed training and 49 are still in training, and the University has conferred 72 M.P.H. degrees. The K30 also has resulted in $22 million in new grant funding, almost 350 first-author publications, and 15 individual K awards. The research portfolio at the University of Rochester is fairly balanced and includes basic research, patient-oriented translational research, patient-oriented experimental therapeutics, population-based studies, research on health services and outcomes, and research on ethics and health policy.

With the CTSA, the University of Rochester has created a structure bringing together intellectual leadership and experiences across the entire institution, which has enhanced clinical and translational science elements already present, simplified government structures, given scientists a sense of ownership, and allowed scientists to work together in new ways. Dr. Guzick noted that elements of education and training, community engagement, and regulatory support were already in place at the University of Rochester. However, bringing those elements together under the CTSA umbrella has made a difference. The CTSA has promoted enthusiasm and collegiality: 45 faculty put forth effort on the CTSA grant, and more than 80 reviewers volunteered to review pilot study projects. The University has 18 T32 grantees and 7 K12 scholars, 3 of whom have received other career development awards, and it offers a Mentor Development Program, Stem Cell Symposium, and Nanotech Symposium. The CTSA has eight pilot awardees, three novel methods projects, eight technology access awards, and three upstate consortium pilot awards (see below). Dr. Guzick noted that these accomplishments create buzz around the University.

In addition, investigators have convinced university leadership, as well as the governor of New York, of the importance of a new clinical science building. This became a top priority for the university in 2007, and the governor announced an appropriation of $50 million to support construction. The new building will be located adjacent to the existing medical and nursing school campuses, and it is designed to include a large amount of open space that encourages faculty and staff to interact. Dr. Guzick reported that, according to the Center for Governmental Research, the University of Rochester Clinical and Translational Sciences Institute has a total economic impact of $30 million per year

and about 600 jobs. Construction of the new building will result in labor income of about $43 million and 830 person-years of full-time labor.

The University of Rochester Clinical and Translational Sciences Institute also has created an Upstate New York Translational Research Network, which has constructed a Web site and conducted an inventory of translational research and resources throughout upstate New York. Within this network, the Human Subjects Working Group has developed a memorandum of understanding to simplify multi-institutional IRB submission, and a Pilot Studies Working Group has reviewed 10 pilot study proposals and funded 3 with $20,000 from the CTSA and $150,000 from the Albany-based Foundation for Healthy Living.

Dr. Guzick concluded by emphasizing the importance of the CTSA in creating a physical home for clinical and translational research, creating excitement for bringing key functions together, and making progress toward the vision of transforming clinical and translational science. He expressed interest in maintaining this momentum even within budgetary constraints.

***Mayo Clinic Research Vision*: Dr. Robert A. Rizza, PI, Mayo Center for Translational Science Activities**

Dr. Rizza began his presentation by noting that, although the Mayo Clinic has had a long-standing commitment to clinical and translational research, it still has been transformed by the CTSA.

The Mayo Clinic aims to understand, optimally treat, and ultimately predict, prevent, and cure disease. The Clinic has a research budget of about $500 million a year: $200 million from NIH, $200 million from Mayo, and the remainder from other government sources. Its workforce includes clinician-scholars, clinical scientists, and basic scientists, grouped into specifically focused centers and cores, all working together toward the Mayo Clinic's overall mission. The Clinic's vision for research involves a cycle—or wheel—beginning with discovery, which occurs in all areas of Mayo and yields clues about pathways or mechanisms in health or disease. These mechanisms are explored further in the Mayo GCRC, and promising concepts move forward to the Center for Patient-Oriented Research and clinical trials, which evaluate the safety and efficacy of novel therapeutics. Results from these studies move into research focused on quality, outcomes, and health policy, which evaluate and optimize health and systems of care in populations. Ideas from these studies are explored further in the Rochester Epidemiology Project, which conducts population-based assessments. This cycle is bidirectional, and research can begin at any point in it. For example, results from population-based assessments could be explored further in basic science laboratories, or results from outcomes research could inform clinical trials.

The CTSA has galvanized the entire organization. As Dr. Rizza reported, the CTSA has focused an organization that already thought it was focused. For example, the CTSA has facilitated the development of a vision for individual medicine, bringing genomics, proteomics, bioinformatics, metabolomics, and biotechnology under a single entity. The

CTSA also has pushed Mayo to set career development as an overall organizational priority, and it has brought together practice, education, and research. All of Mayo's researchers, centers, and cores focus on the patient, but the CTSA has served as a unifying force.

Dr. Rizza also discussed the Mayo Health System, which includes 800 physicians and provides primary care to 2.5 million people in Minnesota. Although this system has won several awards for its clinical practice, it has not conducted research. With the CTSA, Mayo is now organizing practice- and community-based networks and adding electronic and bioinformatic resources, all toward outcomes- and community-based research. These networks will contribute to the overall cycle—or wheel—that forms the vision for research at the Mayo Clinic. Dr. Rizza also emphasized that sustaining these networks will be a challenge in light of budgetary constraints.

***Irving Institute for Clinical and Translational Research*: Dr. Henry N. Ginsberg, PI, Columbia University, CTSA**

Before receiving its CTSA, Columbia had a K30 and a K12. It also housed an eclectic GCRC, which conducted many psychiatric, epidemiological, and long- and short-term inpatient studies. The GCRC supported 75 investigators who conducted 80-100 research protocols, and GCRC-supported investigators published 600 peer-reviewed papers from 2000 through 2005. However, the GCRC was surrounded by walls, and investigators worked in "silos." Core support systems could not be extended; training funds were limited; and aside from epidemiologic studies conducted in the community, no community engagement occurred. Dr. Ginsberg described the role of the GCRC at Columbia University as a "hotel/motel system," with investigators and their participants moving in and out. It was efficient, effective, and productive; however, there was no proactive mandate to change how research was conducted.

With the CTSA, Columbia University has created the Irving Institute for Clinical and Translational Research. It aims to train and mentor a new generation of multidisciplinary clinical and translational researchers, expand and optimize the use of outstanding new and existing resources at Columbia, and support pre-clinical and clinical departments in the recruitment and retention of outstanding clinical and translational researchers. Most importantly, however, the CTSA is changing the way people think about and conduct research at Columbia. Columbia's CTSA has taken a dual approach to its mandate from NIH/NCRR. On the one hand, it has taken an evidence-based approach that includes expanding and enhancing its GCRC and its training and mentoring efforts, increasing biostatistical support and increasing and diversifying core support for investigators across the campus. However, Columbia also has undertaken new and innovative initiatives with the goal to integrate biomedical informatics into clinical and translational research, enhance regulatory knowledge and ethics, engage in and integrate community-based research, and develop new methods for clinical and translational research. Most importantly, Columbia hopes to change the culture of research at its campus.

The Biomedical Informatics Resource, which aims to use informatics to change the way research is conducted, is one example of activities facilitated by the CTSA. A central

project in this Resource is the development of a Work Web, where someone with an idea can type in keywords and identify other Columbia researchers who can help him or her initiate a project. Work Web pulls in data from human resources, PubMed, CRISP, and Columbia files on grants and contracts. Work Web is wiki-based to facilitate communication between potential collaborators.

Another activity facilitated by the CTSA is a project focused on multidisciplinary approaches to obesity research at Columbia. A group of CTSA investigators conducted a Google search on the Columbia University Medical Center Web site to identify centers, research areas, and researchers working on aspects of obesity research. The project has identified 60 investigators across 16 academic departments and 21 divisions, and it has determined how many of these investigators are affiliated with collaborative centers, how many are affiliated with more than one center, and how many have no collaborations. Columbia is contacting these investigators to ask for their help in expanding the network, and it is developing a survey to determine why many investigators are not collaborating with others. The CTSA will then have an open house for all interested investigators, with the goal of forming new interest groups and collaborations.

Yet another activity facilitated by the CTSA is the Community Engagement Resource (CER), which will enhance the quality and quantity of population- and community-based research, facilitate the integration of a community-based provider network into the research agenda of the Irving Institute and Columbia, and more effectively communicate with the community to foster research of mutual benefit. So far, a CER Research Committee has been established to enhance collaboration among Columbia and community-based researchers. In addition, Columbia has received an NCRR National Clinical Research Associates grant to develop models for the conduct of clinical trials in community medical practices. Columbia also has collaborated with emergency medicine staff to engage them in community research.

Dr. Ginsberg also discussed Columbia's Pilot and Collaborative Clinical and Translational Studies Resource, which continued the University's Pilot Studies Program in conjunction with the Clinical Trials Office. This Resource awarded eight pilot awards each in the 2006–2007 and 2007–2008 academic years. The Resource also created a two-phase Multidisciplinary Award Program. The first phase encouraged investigators to form new teams and submit 6-month planning grants with someone they had not worked with before. Four of these grants were funded. The second phase of this grant will award $125,000 for 1 year apiece to two of the four teams. Awardees will be selected based on the use of creative, novel, multidisciplinary approaches; use of CTSA resources; meaningful involvement of junior scientists; and well-documented planning activities demonstrating the interdisciplinary process.

As did other CTSA directors, Dr. Ginsberg pointed to budgetary constraints as a major challenge. Columbia may lose significant funding at the time of their renewal, but how to accommodate this loss (i.e., sacrifice programs or make cuts across the board) has not been determined.

***Vanderbilt Institute for Clinical and Translational Research*: Dr. Gordon R. Bernard, PI, Vanderbilt University CTSA**

Dr. Bernard discussed an informatics tool that is already in place at Vanderbilt and can facilitate the activities of its CTSA. StarBRITE is a Web site designed to support research the same way Vanderbilt's clinical system supports clinical care. The site boasts a shared data infrastructure; a central repository with up-to-date study documents, authorizations, and protocols; workflow tracking with checklist support; and a unified system for tracking research education, mentoring, conduct, collaboration, resource utilization, and productivity.

To help investigators begin new research, StarBRITE includes an online voucher system in which an investigator can complete a form that undergoes administrative review within 1 day. Approval is granted for a maximum of $2,000 in pilot funds, which is enough to start investigators on their "eureka" moments. The system also assists investigators who are starting new projects with a component, similar to TurboTax, that asks the investigator a series of questions and provides him or her with a customized action plan in terms of protocol review and regulatory requirements. Because the system sets expectations at the beginning, investigators have a better chance of meeting all requirements in a more efficient way. Instead of trying to get everything done in series, investigators have a more systematic plan and can get work done in parallel.

Another component of StarBRITE is REDCap, a research support tool that facilitates data collection. The system teaches investigators to build databases organized along certain organizational structures. This component, which has been built for investigators at both Vanderbilt and Meharry Medical College, allows investigators to create project-specific databases stored on HIPAA-compliant servers and helps them avoid storing sensitive data on flash drives and other unsecured media. REDCap can be accessed from the Internet anywhere in the world, and it supports more than 200 studies with 300 users from Vanderbilt and collaborating institutions.

StarBRITE also facilitates transparency. In the past, investigators interested in collaboration could only track IRB approvals, but with StarBRITE they can find out about data collection and other project activities. The system also includes a recruitment support tool that lists almost 5,000 individuals willing to participate in research studies, as well as a studio system that pairs principal investigators with experts as they navigate the process of idea, hypothesis, design, implementation, analysis, and translation. For individuals who do not need full studios, regularly scheduled clinics are open for investigators to discuss problems that arise in their projects.

Another resource, which is not part of the Vanderbilt CTSA but linked to it, is the DNA Databank, a large resource for genome-phenome correlation. This resource is designed to extract DNA from leftover, de-identified blood samples; create de-identified "synthetic derivatives" of electronic medical records; enable DNA sample retrieval based on clinical queries; and support genome-wide association studies and genotyping panels. The DNA Databank is capable of generating 250,000 samples within 4-5 years. Dr. Bernard showed

the Council an example of a synthetic derivative, which reads like a medical record and is searchable by various characteristics.

Dr. Bernard noted that CTSA funds have been used to compensate people for activities, such as mentoring, that used to be considered volunteer time. These funds also have helped Vanderbilt to establish core resources in clinical epidemiology, behavioral research, implementation science research (supporting studies that improve safety, timeliness, equity, efficiency, and cost-effectiveness of care), and surveillance epidemiology. Vanderbilt has also established a clinical investigation career track for M.D./Ph.D. students interested in clinical and translational research. In this new track, M.D. students take 1 year to get fundamental training in clinical and translational research before commencing their fellowships and completing their Ph.D. degrees.

Vanderbilt is involved in several community partnerships within Nashville and throughout the state of Tennessee, with Meharry and Metro General Hospital as its main partners. Investigators at partner institutions have full access to the Vanderbilt Clinical Research Center, vouchers, pilot funds, studios, and other aspects of the StarBRITE system.

Dr. Bernard closed his presentation by discussing budgetary constraints, including a reduction of about 24 percent for year 1 and a reduction of about 20 percent, not counting inflation, from year 1 to year 2. These constraints threaten such critical items as biostatistics, informatics, pilot funds, T2 support, clinical research inpatient stays, and novel methodologies such as further development and support of StarBRITE.

***Johns Hopkins – Pre CTSA*: Dr. Daniel E. Ford, PI, Johns Hopkins Institute for Clinical and Translational Research**

Johns Hopkins University is a comprehensive, large research institution with two GCRCs—Johns Hopkins Hospital and Bayview—and a mixed-use inpatient unit at Johns Hopkins, a small inpatient unit at Bayview, and pediatrics and neurobehavioral units. Before receiving its CTSA, the University had more than 50 postdocs pursuing degrees in clinical investigation, supported by funds from a K12 and the Graduate Training Program in Clinical Investigation. It also had a T32 predoctoral clinical research program. Coordination across research units was less than optimal, and the ratio of sponsored research funding to the number of patents filed was very low. Despite objective evidence of promotions, clinical investigators did not feel valued by their departments. In addition, investigators expressed frustration with the complexity of starting and conducting research studies using human subjects.

Dr. Ford reported that the CTSA application process started many changes, including the creation of the Institute for Clinical and Translational Research. This Institute now serves as the voice for clinical investigators and a center for training in translational research. It will create databases to measure the process and efficiency of translational research, thus allowing Johns Hopkins to evaluate the effect CTSA funding has had. The Institute also will include a center for clinical research informatics, which will maintain a database of all participants in clinical research studies. Dr. Ford, who is Vice Dean for Clinical

Investigation, directs the Institute, but deputy directors come from the Institute for Basic Biomedical Sciences; the Cancer Center; and the Departments of Pediatrics, Medicine, and Surgical Oncology. In addition, one deputy director oversees the development of a community research network with other area hospitals.

CTSA funding has led to the creation of new support offices in research participant recruitment and retention and clinical research informatics. Another support office, called Research Navigators, is somewhat similar to Vanderbilt's system. In this office, people work with research teams to focus on the big picture, develop timelines, and identify which steps to take first. The support office focused on clinical research networks works with other area hospitals. The CTSA also has led to the creation of translational cores in proteomics, genetics, drug and vaccine development, and imaging. These cores include investigators from several departments, thus bringing together investigators who had not worked together before the CTSA.

Dr. Ford also discussed the effects of the CTSA on the Hopkins GCRCs, which have served more than 500 faculty across 68 departments and divisions. The University is consolidating administrative processes and systems between the two units to create a single service center. It also has transformed the inpatient beds at Bayview to higher-intensity outpatient beds, and the mixed-use inpatient unit at Johns Hopkins Hospital continues to serve multiple investigators. The University also has a pilot program to move services into a wider range of settings.

Dr. Ford noted the importance of a clear evaluation and measurement scheme in monitoring the CTSA's progress. Other challenges for the CTSA include the coordination of a wide range of translational research at the University, priority-setting for users of services, the creation of pathways for public-private partnerships, and the balance between local demands and the demands of the national CTSA Consortium.

***Atlanta CTSA: Opportunities and Challenges*: Dr. David S. Stephens, PI, Atlanta Clinical and Translational Science Institute**

Dr. Stephens informed the Council that Emory University has traditionally formed partnerships with the Georgia Institute of Technology (Georgia Tech) and Morehouse College to address issues in health care and that Emory has worked with Morehouse to serve a largely indigent population. He described the Atlanta CTSA as an opportunity to develop these partnerships further with a focus on discovery, training, and community. He also discussed the transformative power of the CTSA on other partnerships. Emory works with the Centers for Disease Control and Prevention to address public health and public health research, with two NCRR-supported Glycobiology Centers at the University of Georgia, and with the Yerkes National Primate Research Center. Emory also participates in the Georgia Research Alliance, a state organization that promotes technology development and transfer. Emory also has formed a partnership with Kaiser, and new projects are under way.

The Atlanta CTSA has transformed the Emory GCRC. It has expanded into pediatrics, an area that was underserved by Emory's GCRC. Children's Healthcare of Atlanta, a clinical

interaction developed through the CTSA, unifies pediatric clinical intervention sites around the area. The interdisciplinary programs and strategic themes of the Atlanta CTSA address cross-cutting issues such as health disparities, informatics, vaccines, animal models, and imaging. Other programs, such as those addressing ethics and translational methodologies, have been expanded, and Emory is now bringing those programs under a single entity.

Emory also has taken an inventory of pilot projects and made that inventory available to investigators. Money to support these projects is available at Emory University and supplemented by the CTSA. So far, seven pilot projects at Morehouse and Emory have been funded. Other CTSA efforts include a translational technology program, which addresses an area in which obtaining funding has been difficult; a Web-based portal to a variety of biomedical informatics services; and a research ethics consultation service, which uses a case-based approach to advise investigators on ethical issues. New education programs include an expanded interdisciplinary curriculum; a plan to develop training opportunities with the NIH Clinical Center; and a new dual-degree program to combine an M.D. or Ph.D. in the sciences with an M.S. in clinical research.

Dr. Stephens added that promoting the vision of the Atlanta CTSA in the face of budget cuts is the area of most concern. Funding for the education program, particularly the mentored scholars program, and maintenance of the clinical interaction network in pediatrics are other challenges. Dr. Stephens also noted the challenges of: 1) learning how best to engage the community; 2) becoming an incubator for community projects; and 3) serving as a translator between the health sciences center and the community.

***University of Iowa's Institute for Clinical and Translational Science*: Dr. Gary W. Hunninghake, PI, University of Iowa**

Dr. Hunninghake emphasized that the CTSA galvanized the attention of the University. The University of Iowa created an Institute for Clinical and Translational Science approved by the Iowa State Board of Regents. The Institute involves all 11 colleges within the University and has the support of deans, the vice president for research, and the hospital. The University provides additional funds to support the CTSA; the hospital has contributed $34 million toward new research space; and the University provides all the CTSA's funds for informatics. The governance structure for the new Institute is supported by 39 major centers and institutes and includes an internal advisory committee, on which members serve on a rotating basis, and a community roundtable involving community health centers, whose patients are primarily African American and Latino. Four Native American centers will be joining this roundtable.

In terms of education, the University of Iowa has formally established master's and Ph.D. programs in translational biomedicine. These programs are housed in the Graduate College and administered by the Institute. The Institute has developed ties with the M.D./Ph.D. training program and linked the University's 1-year certification program to the Doris Duke program. The Institute aims to develop short-term experiences for students; short-term training programs for health care workers participating in clinical and translational research; and training programs for study coordinators.

With respect to community engagement, the new Institute has obtained support from all major medical groups and hospitals, the largest insurance provider, and the community health centers. The Institute would like to develop local research and education programs throughout the state of Iowa and formally obtain community input in its existing research programs. It also plans to work with health care entities throughout the state to develop sets of best practice guidelines.

In terms of research, the Institute has developed information technology programs to help investigators store, manage, and analyze their data. It has collaborated with the University's centers on grant applications, and like the Vanderbilt and Johns Hopkins CTSAs, it has developed new core resources to help investigators navigate regulatory and scientific requirements. The Institute also has begun efforts to bring together investigators who have not previously considered multidisciplinary research. For example, the Institute will hold a multidisciplinary conference on obesity, where participants will be encouraged to develop innovative ideas for new research and interactions.

Dr. Hunninghake expressed a vision in which the University of Iowa's Institute for Clinical and Translational Science is the preferred support structure for all faculty engaged in clinical and translational research, bringing people out of their silos to develop new multidisciplinary research interactions. To that end, the Institute is working to develop communication between existing university centers and major research programs. Dr. Hunninghake also noted that the University aims to participate in the overall CTSA Consortium's development of national research and education programs and to have a major impact on the recruitment of minority faculty and the development of diversity programs.

## VI. Recognition of Retiring Council Members: Dr. Barbara M. Alving

Dr. Alving recognized Dr. Kenneth G. Cornetta, Dr. Cynthia E. Keppel, Ms. Sheila C. Zimmet, and Dr. Stuart M. Zola for their service to the Council.

## VII. Research, Condition, and Disease Categorization (RCDC): Dr. Timothy C. Hays, RCDC Project Director, Office of Portfolio Analysis and Strategic Initiatives, Office of the Director, NIH

Dr. Hays described a new process under way to categorize grants and contracts supported by NIH. At present, NIH reports to Congress and the public how much it spent and estimates of future spending in approximately 250 research and disease categories (www.nih.gov/news/fundingresearchareas.htm). Each IC provides the central NIH budget office with data on what it has spent on a particular category. How the category is defined depends on the IC. There are no central definitions for most categories on which NIH reports.

In 1998, the National Academies issued a report recommending that NIH improve how it categorizes research. The Academies reiterated this recommendation in a 2003 report. In addition, Congress expressed that it was difficult to understand how NIH generated the numbers it reported and requested improvements. In 2004, NIH tried a pilot in which

bioinformatics tools and text mining were used to categorize research, and at the same time, NIH began to rely more heavily on electronic submission vehicles such as grants.gov. In the 2006 NIH Reform Act, Congress mandated that NIH "shall establish an electronic system to uniformly code research."

Research, Condition, and Disease Categorization (RCDC) is an electronic system that codes and reports NIH spending on grants, research and development contracts, and intramural research across the 27 ICs each fiscal year in approximately 360 research and disease areas. Dr. Hays explained that RCDC's aim is to create one central definition capturing the various category components needed by all ICs. This single definition will provide a greater degree of consistency, and RCDC also will be efficient and transparent, because RCDC will list all projects in a category. In addition, the system will provide opportunities for further analysis of the NIH portfolio.

Dr. Hays reported that NIH will introduce RCDC project listings to the public in February 2009, showing FY 2008 data. NIH will begin explaining the new process to the public in the summer of 2008. Dr. Hays added that when the system goes live, NIH will also provide a side-by-side summary for FY 2007 data, showing how much NIH spent as defined by the current categorization method next to the amount NIH would have reported if the RCDC system had been in place.

## 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.

### Application Review

The Council reviewed 204 applications (with total direct costs of $116,378,886). The Council concurred with the review of all applications.

## ADJOURNMENT

The Council adjourned at 3:30 p.m. on January 30, 2008.

**CERTIFICATION**

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

Barbara Alving

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

7/07/08
Date

Louise Ramm

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

4/8/08
Date