

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

FY 2008 Budget for the National Institutes of Health:
A New vision for Medical Research (Part II)

Witness appearing before the
Senate Subcommittee on Labor-HHS-Education Appropriations

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Mr. Chairman and Members of the Committee:

It is a privilege to present to you the President's budget request for the National Center for Research Resources (NCRR) for Fiscal Year 2008. The Fiscal Year 2008 budget includes \$1,112,498,000. I appreciate this opportunity to discuss with you our vision of the future of health and medicine and to share ways NCRR programs are transforming clinical and translational research.

The NCRR, which is one of the 27 Institutes and Centers at the National Institutes of Health (NIH), provides NIH-supported laboratory and clinical researchers with the infrastructure, tools, and training they need to understand, detect, treat, and prevent a wide range of diseases. With this support, scientists engage in basic laboratory research, translate these findings to animal-based studies, and then apply them to patient-oriented research. Through innovative programs and resources that transcend geographical boundaries, NCRR connects researchers with one another, and with patients and communities across the nation. These connections bring together innovative research teams and the power of shared resources, multiplying the opportunities to improve human health.

TRANSFORMING CLINICAL RESEARCH

Given its mission and support to more than 30,000 basic and clinical researchers, NCRR has become the leader of the NIH Roadmap for Medical Research effort to energize the discipline of clinical and translational research. To remove the barriers identified by the research community, NCRR launched the Clinical and Translational Science Award (CTSA) program, which is a national consortium designed to more rapidly and efficiently facilitate the transfer of discoveries made in the laboratory into new treatments for patients. Through the CTSA, academic health centers are developing centers, departments, or institutions for interdisciplinary teams that cover the complete spectrum of research from basic biology to clinical medicine. These academic homes also will train the next generation of researchers in translational and clinical research.

On September 30, 2006, we made the first CTSA awards to 12 academic health centers throughout the country. We will award the second group of CTSA's this fall. By 2012, the CTSA Consortium is expected to include approximately 60 CTSA's.

The impact of the CTSA Consortium will be far greater than the number of awards made. The Consortium will develop better designs for clinical trials, forge new partnerships with health care organizations, and expand outreach to minority and medically underserved communities. The CTSA's will focus on both types of

translational research— ensuring first that basic discoveries are applied to the clinic and second that they are further translated into community practice. Improving clinical research informatics will be a prominent focus of the Consortium. Institutions are taking steps to prioritize their efforts to ensure that standards are developed, interoperability is enhanced, and communication resources are accessible to researchers and their patients.

To improve communication with the public and our stakeholders about our progress, as well as to foster collaborations within and beyond the Consortium, we recently launched the CTSAWeb.org site. I encourage you to visit the site and learn more about the CTSA Consortium. We also have started plans to evaluate the Consortium to ensure that the program spurs innovation, integration, inclusion, and dissemination.

Already, we are starting to see significant changes within and across the CTSA institutions. As a result of this effort, academic health centers are developing new curriculums, revamping their organizational structures, creating unprecedented partnerships with other medical and research disciplines, and generating medical advances. For example, the Institute for Translational Medicine and Therapeutics (ITMAT) at the University of Pennsylvania— a trans-institutional endeavor with the Children’s Hospital of Philadelphia, the Wistar Institute, and the University of Sciences in Philadelphia— is leading clinical and translational research and fostering interdisciplinary science. Now with the CTSA award, ITMAT will also become the home to new centers in bioinformatics, personalized medicine, imaging, and chemical biology. At the same time, the University of Texas Health Science Center at Houston CTSA is encouraging participatory research by connecting with Hispanic communities on the border. By linking with NCRR’s Science Education Partnership Award program in Houston, this CTSA is improving the public’s understanding of the importance of clinical trial participation. As the CTSA’s begin to work together, the benefits of the program will extend to the greater research community and ultimately be incorporated into clinical care.

I am pleased to report that this transformation is creating new energy and opportunities within NCRR and across the NIH. The CTSA initiative is further enhancing NCRR’s long-standing investments in advancing translational research and providing new opportunities for community engagement. The addition of the CTSA Consortium to the matrix of NCRR programs is providing opportunities for increased cohesion and interaction throughout our entire research portfolio. Similarly, the truly trans-NIH nature of the CTSA program is facilitating interactions among the NIH Institutes and Centers and helping to ensure that the benefits of the Consortium are realized across the full spectrum of medical research.

ADVANCING TRANSLATIONAL RESEARCH

Helping to propel the CTSA discovery engines are NCRR's translational research programs. Our readily available animal models and biomedical technology resources are fueling advancements in clinical care. We are exploring opportunities to enhance interactions among our translational programs and the CTSA Consortium to further capitalize on our research investments.

Animal models are the bridge between basic science and human medicine. The NCRR provides such models through specialized laboratory animals, research facilities, and training. Linking NCRR's animal resources with CTSA's will allow for more seamless translation from pre-clinical findings to clinical trials. This is already underway at two CTSA's, the University of California at Davis and the Oregon Health and Science University, which are connecting with the NCRR-supported National Primate Research Centers at their institutions. To provide researchers with easier access to animal models, and thus further accelerate translational research, we sponsored a workshop in 2006 to explore approaches to develop a resource that would enable researchers to find and use animal and other biological resources more efficiently. Based on stakeholder recommendations, we are planning to fund a comprehensive electronic catalog of animal model resources in FY 2008.

Technologies are critical throughout all stages of biomedical research— from basic discovery to clinical application. The NCRR support for biomedical technology (BT) resource centers provides researchers with a broad spectrum of technologies, techniques, and methods. Across the nation, researchers depend on these centers for a wide variety of clinical and translational studies. For example, researchers at the University of Illinois are developing software to help analyze the motions of viruses, so that they can better predict the virulence of these organisms. At the University of Wisconsin-Madison, another BT resource center, researchers are using advanced nuclear magnetic resonance technologies to develop faster and more cost-effective methods for studying how biological systems work and respond to drugs. In the future, technologies developed at the BT resource centers may lead to discoveries that the CTSA's can translate into improved patient care.

ENHANCING COMMUNITY ENGAGEMENT

The launch of the CTSA initiative has further enhanced our appreciation of the need to actively engage not only the researchers but also the American public. Our programs are providing opportunities for people in underserved communities to participate and shape medical research. Our innovative science education programs are inspiring children to pursue careers in biomedical research and are increasing the public's understanding of medicine. By reaching out to new collaborators and strengthening our partnerships, NCRR is facilitating connections that are sparking new discoveries and maximizing the effectiveness of the matrix of NCRR programs.

NCCR has two successful programs that are creating new research opportunities for underserved communities. First, the Research Centers in Minority Institutions (RCMI) program increases the number of minority scientists engaged in biomedical research and enhances the research capacity and infrastructure at minority colleges and universities that offer doctorate degrees in health sciences. This program increases the number of minority scientists engaged in biomedical research and facilitates studies on minority health. Second, the Institutional Development Award (IDeA) program fosters health-related research and increases the competitiveness of investigators at institutions in 23 states and Puerto Rico, which have historically low aggregate success rates for grant awards from the NIH. The IDeA program provides workforce development, research opportunities, science education, and extends high-speed connectivity to IDeA institutions to facilitate research collaborations. For example, NCCR funded the Lariat Project to provide six states (Alaska, Hawaii, Idaho, Montana, Nevada, and Wyoming) with high-speed, fiber-optic network connections. This project has improved not only research capacity in these states, but also enhanced their economic development, higher education, and healthcare opportunities. To ensure these underserved communities have access to innovative research opportunities, we are exploring ways to facilitate partnerships with these communities and the CTSAs.

One of the many ways that community engagement is improving research is through a component of the IDeA program called IDeA Networks of Biomedical Research Excellence (INBRE) program. This program enables critical connections among different research institutions and facilities, as well as between mentors and students. For example, the Montana INBRE brought together the seven tribal colleges within the state to conduct collaborative research projects. Today, these tribal colleges, which prior to the INBRE program had not interacted on research projects, are working together to identify research areas and collaborate with other undergraduate institutions within Montana.

Community engagement is synonymous with the NCCR Science Education Partnership Award (SEPA) program. By bringing together active biomedical and clinical researchers with educators, community leaders, and other interested organizational leaders, SEPA is stimulating public interest in health issues and encouraging young people to pursue careers in medical research. SEPA grantees currently collaborate with several RCMI and IDeA institutions and are beginning to make similar connections through CTSA community engagement activities. At Jackson State University, RCMI- and IDeA-funded researchers have partnered with the Jackson Public Schools through a SEPA grant to provide mentoring and research internships for students and professional development for teachers. Another SEPA project at the University of Utah, offers over 100 online activities, podcasts, and virtual labs on topics ranging from cloning to stem cells.

Innovative partnerships are providing the cohesion needed to ensure that the matrix of NCCR programs results in a maximum return on investment for all

Americans. We are expanding our outreach efforts with the pharmaceutical industry, healthcare organizations and providers, and other Federal agencies, such as the Food and Drug Administration and the National Science Foundation. These collaborative partnerships will not only enable us to make research discoveries faster, but will ensure that these discoveries are quickly translated into improved patient care.

CONCLUSION

Through our matrix of programs and partnerships, NCRRE expects to fulfill its charge to transform the practice of clinical and translational research and in turn, improve the future of health and medicine. The launch of the CTSA Consortium marks an exciting time in the history of NIH and for our nation. It further enhances NCRRE's long-standing investment in basic, translational, and clinical research. Our innovative programs and partnerships are maximizing our research investment to ensure that medical advances are reaching the people who need them.

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Dr. Barbara M. Alving is the Director of the National Center for Research Resources (NCRR) at the National Institutes of Health. NCRR provides laboratory scientists and clinical researchers with environments and tools that they can use to prevent, detect, and treat a wide range of diseases. NCRR connects researchers with one another and with patients and communities across the nation to bring the power of shared resources and research to improve human health.

Dr. Alving earned her medical degree *cum laude* from Georgetown University School of Medicine, where she also completed an internship in internal medicine. She received her residency training in internal medicine at the Johns Hopkins University Hospital, followed by a fellowship in hematology. Dr. Alving then became a research investigator in the Division of Blood and Blood Products at the Food and Drug Administration. In 1980, she joined the Department of Hematology at the Walter Reed Army Institute of Research and became Chief of the Department in 1992. She left the Army at the rank of Colonel in 1996 to become the Director of the Medical Oncology/Hematology section at Washington Hospital Center in Washington, D.C. In 1999, she joined the National Heart, Lung, and Blood Institute (NHLBI), serving as the Director of the extramural Division of Blood Diseases and Resources until becoming the Deputy Director of the Institute in September 2001. She served as the Director of the Women's Health Initiative from 2004 until 2006. From September 2003 until February 1, 2005, she served as the Acting Director of NHLBI. After serving as Acting Director of NCRR, Dr. Alving was appointed Director in April 2007.

Dr. Alving is a Professor of Medicine at the Uniformed Services University of the Health Sciences in Bethesda, a Master in the American College of Physicians, a former member of the subcommittee on Hematology of the American Board of Internal Medicine, and a previous member of the FDA Blood Products Advisory Committee. She is a co-inventor on two patents, has edited three books, and has published more than 100 papers in the areas of thrombosis and hemostasis.

