DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Fiscal Year 2003 Budget Request

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Statement by

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on
Fiscal Year 2003 President's Budget Request
for the National Center for Research Resources

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Center for Research Resources (NCRR) for Fiscal Year 2003, a sum of $1,091,374,000, which reflects an increase of $78,836,000 over the comparable Fiscal Year 2002 appropriation.

We cannot do today's science with yesterday's tools. As director of the National Center for Research Resources, I hear regularly from the scientific community that to do quality work, scientists must have access to state-of-the-art research tools and technologies. NCRR provides the biomedical research community with the research tools, specially designed research facilities, biologic models of human disease, and other resources necessary for studies that define the causes of human disease. I am pleased to have this opportunity to share with you recent research contributions made possible by NCRR-funded programs, and to outline our future plans for facilitating biomedical discovery through development of novel technologies and strategic provision of research resources.

NCRR's cross-cutting research resources transcend the entire spectrum of scientific inquiry funded by the institutes and centers within the National Institutes of Health (NIH). Each year, more than 28,000 investigators, supported by more than $4 billion in competitive grants from other NIH components, as well as from other Federal agencies and the private sector, use NCRR-supported research resources to conduct their studies. To get the most out of dollars

committed to research resources, NCRR encourages investigators and institutions to share scarce or expensive research resources. In addition, NCRR supports research resource facilities for both basic and clinical research that are shared institutionally, regionally, or nationally. Those include networks for General Clinical Research Centers (GCRCs), Regional Primate Research Centers, Biomedical Technology Resource Centers, Research Centers in Minority Institutions, and many other resources, including bio-repositories–all essential to NIH-supported research. The clinical research settings of the GCRCs allow countless investigations of human diseases, both rare and common. The biologic models validated and supported by NCRR have exposed many of the basic mechanisms that underlie human disorders. NCRR-funded technology resources have broad applications, ranging from molecular structures to views of the brain affected by degenerative processes, including Alzheimer's and Parkinson's diseases. Other resources include those for generating vectors for human gene transfer, and centers for isolation of human pancreatic islet cells for transplantation into patients with Type 1 diabetes mellitus. Resource sharing is a cost-effective approach to funding biomedical research.

The challenge for NCRR is to keep pace with the biomedical community's changing needs for research tools and to ensure that tomorrow's research queries have tomorrow's critical instrumentation and technologies in hand. The research resources and tools needed for scientific investigations change dramatically over time as more complex research queries are posed and require new technologies and biomaterials with greater sensitivities and much higher through-puts. Many research tools now considered critical to understanding the cause of disease and protecting the health of Americans were unheard of just a few years ago. For instance, the Magnetic Resonance Imagers, or MRIs, now found in hospitals and medical centers across the country were rare and experimental less than 20 years ago. Today, MRI is an essential clinical tool, saving countless invasive surgical procedures each year. NCRR supported the development of MRI from its earliest iterations–as an obscure technology used only in chemistry labs–to the clinical tool that physicians have come to depend on. NCRR continues to support the evolution of MRI and other technologies, including mass spectrometry and synchrotron beam lines for crystallographic studies of macromolecules encoded by the tens of thousands of genes within the human and other genomes. These advanced technologies evolved from the basic research efforts

of physicists and engineers who needed these sophisticated instruments for studies of particle physics. The NIH biomedical research community, frequently in collaboration with investigators from other Federal agencies, adapted the physicists' tools to study the molecular causes of disease and to develop specific therapies to prevent, cure, or ameliorate the disease.

ADVANCED TECHNOLOGIES

The shared resources supported by NCRR provide a fertile environment to stimulate collaborations among investigators. Interdisciplinary research teams are indispensable, as scientists begin to address more complex research problems. One example is the exploration of the human genome and the macromolecules encoded by the more than 30,000 genes identified to date within the human genome. Working at the scale of the proteome (proteins expressed by the genome), investigators may need to characterize thousands of proteins to address fundamental questions that cannot be answered by examining just one protein at a time. To assist examination of such complex problems, NCRR will initiate a program to support a system or an integrative approach for biomedical research resource centers equipped thematically with the most advanced technologies, including structural and protein purification techniques, mass spectrometry, and DNA microarrays to address the biocomplexity of research. Research teams at these centers will include investigators with wide-ranging but complementary expertise, including physicists, physical chemists, engineers, bioinformaticists, computer programmers, and both physicians and basic scientists trained in sophisticated biomedical research.

In order to respond rapidly to scientists' changing needs, NCRR works in trusted partnership with the biomedical research community and with other NIH institutes and centers. An overwhelming number of scientists we hear from have identified an urgent need for bioinformatics tools to collect, manage, analyze, and share the enormous data sets that arise from genomics, proteomics, and imaging efforts. Last year, NCRR launched an ambitious pilot project known as the Biomedical Informatics Research Network (BIRN). BIRN is a collaborative effort with the San Diego Supercomputer Center, the National Science Foundation, and several universities. An essential feature of the BIRN testbed is the creation of infrastructure that can be

deployed rapidly to other research sites throughout the country and promises to have applications beyond neuroimaging, the project's initial focus.

Another successful pilot venture is the Internet-based network, CFnet, which NCRR established a few years ago in partnership with the Cystic Fibrosis Foundation. The initial goal of CFnet was to determine if phase 1 and 2 clinical trials could be facilitated across several GCRC sites with Web-based data management. The effort proved so successful that we anticipate extending CFnet to an additional 12 GCRC sites and will include phase 3 clinical trials. NCRR, in collaboration with Internet2, plans to establish a comparable network at the eight minority-serving medical schools to facilitate their participation in clinical trials and in studies designed to examine the factors contributing to health disparities and ways to eliminate them. This network will be extended to the entire cohort of institutions currently supported through NCRR's Research Centers in Minority Institutions program. NCRR also plans to initiate networking with a subset of academic institutions within the Institutional Development Award (IDeA) program.

GENOMICS AND GENETIC MEDICINE

NCRR supports national repositories for biologic models, which play an indispensable role in uncovering the basis of human health and disease. The genomes of animal species are remarkably similar to ours; consequently, animal models offer a wealth of information about human gene function. NCRR plans to support national resources to systematically validate, classify, and characterize genetically altered animal models. National genotyping laboratories will be established to serve both the clinical research and animal model communities.

Research with embryonic stem cells may hold the key to treatment of disorders for which no effective therapies exist. These cells have the potential to develop into any type of cell in the body. To explore the full potential of these cells, NCRR will fund studies of several animal models, including nonhuman primates and rodents, to identify the factors within their microenvironments that induce embryonic stem cells to transform into insulin-producing islet cells, blood-forming cells, dopamine-producing neurons, and more–ultimately for therapeutic

purposes.

Despite the fact that half of all NIH-funded research grant applications include animal-based research, relatively few veterinarians are research trained, and veterinary schools have too few faculty who can serve as mentors or role models for students. To address this need, NCRR proposes to establish academic Centers of Veterinary Research Excellence (COVRE) in colleges of veterinary medicine. The goal of COVRE is to develop a pool of research-trained veterinarians who will fill a rapidly growing need in biomedical science. COVRE will provide competitive support to further develop the research infrastructure–the research facilities, instrumentation and investigator development–of Veterinary Schools of Medicine.

RESEARCH TRAINING AND CAREER DEVELOPMENT

To address the need for research-trained physicians and dentists in patient-oriented research, NCRR will expand its support for several NIH-wide career-development programs. The NCRR proposes to enhance support for the Mentored Patient Oriented Research Career Development Awards (K23), and Mid-Career Investigator Awards (K24). NCRR will continue to be a major supporter of the institutional Clinical Research Curriculum Awards (K30). In FY 2001, NCRR demonstrated its commitment to the development of a cadre of clinical researchers by supporting more K23 awards than any other NIH component, except one. NCRR will expand support of the loan repayment program for NCRR-supported junior investigators (dentists and physicians) who are pursuing patient-oriented clinical research career development.

NCRR proposes to expand support for clinical research pilot studies in GCRCs so that promising junior investigators and established investigators with novel ideas may collect important preliminary data to support the feasibility of research questions proposed in their research grant applications. NCRR also intends to begin funding of a new institution-based career development program for physicians and dentists. The Mentored Clinical Research Scholar Program was created as an institutional patient-oriented career development program. The program flexibly integrates educational instruction through seminars, workshops, and formal courses that may

lead to advanced degrees and the acquisition of biomedical research expertise in a mentored setting. Candidates must participate for a minimum of two years, but not longer than five years, and may be eligible for the loan repayment program. Candidates may earn an M.S., M.P.H., or Ph.D. degree in areas relevant to clinical research. The goal is to prepare physicians and dentists for independent careers in patient-oriented research.

Another NCRR effort is to enhance medical students' interest in clinical research careers through support for the Mentored Medical Student Clinical Research Program. This program provides medical and dental students with support for one year of didactic clinical investigation and mentored research at institutions with a GCRC or an RCMI Clinical Research Center. The goal is to provide support for up to five students per GCRC site per year. A similar program for veterinary students will be expanded.

RESEARCH CAPACITY BUILDING

NIH proposes to continue support for construction or renovation of extramural research facilities through the Research Facilities Improvement Program in FY 2003. The research community has expressed a need for Biosafety Level (BSL) 2/3/4 facilities for handling dangerous bacteria, viruses, and other agents; good manufacturing procedures (GMP) facilities for manipulation of cell therapies and production of vectors for human gene transfer. Applications from smaller institutions will be given special consideration for funding. Separately, at least $5 million of funds appropriated for construction for FY 2003 will be required to finish building a chimpanzee sanctuary system.

The NIH Institutional Development Award (IDeA) Program provides support to enhance the biomedical research capacities of institutions in states that have not fully participated in NIH research funding in the past. To develop and enhance their research infrastructure, NIH launched two program initiatives: the Centers of Biomedical Research Excellence (COBRE) and Biomedical Research Infrastructure Networks (BRIN). In response to recommendations of institutional officials and investigators in the IDeA states and Puerto Rico, NCRR proposes to

create an Internet-based network with distributed databases, using Internet2 to link the BRINs and COBREs, to foster collaborations among the participating institutions. IDeAnet will provide access to bioinformatics tools for data analysis and visualization, as well as access to scalable computing up to the teraflop level.

HEALTH DISPARITIES

Finally, in order to address health disparities, NCRR proposes to establish Comprehensive Centers for Health Disparities Research. These Centers will develop the capacity of RCMI medical schools to conduct basic and clinical research in type 2 diabetes and cardiovascular disease, both of which disproportionately affect minority populations. The Centers will provide support to further develop the requisite research infrastructure, recruit magnet clinical investigators, recruit and develop promising junior faculty, and facilitate substantial collaboration between the RCMI grantee institutions and more research-intensive universities. Partnerships between investigators at GCRC sites will be developed.

Mr. Chairman, the NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's second annual performance report, which compares our FY 2001 results to the goals in our FY 2001performance plan.

I will be happy to respond to any questions you may have. Thank you.