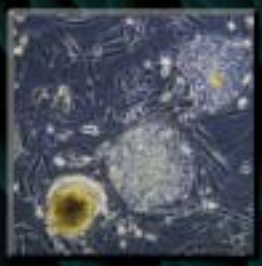
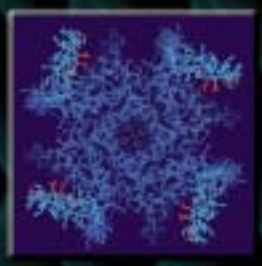
NCRR

A CATALYST FOR DISCOVERY





2004-2008 Strategic Plan
Challenges and Critical Choices

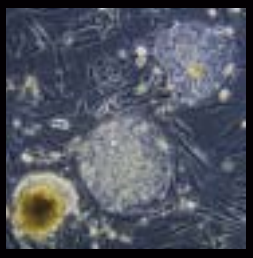
U.S. Department of Health and Human Services
National Institutes of Health
National Center for Research Resources

On the Cover:

Dr. Noel Bairey Merz at Cedars-Sinai Medical Center in Los Angeles is scientific chair of the Women's Ischemia Syndrome Evaluation (WISE) study, a multisite investigation that is identifying aspects of heart disease unique to women. The WISE study depends on the resources and expert staff at the NCRR-supported General Clinical Research Centers. (Photo by Alan Braus, Cedars-Sinai Medical Center)

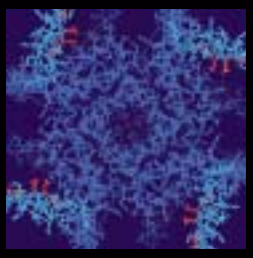
The laboratory mouse has become the primary mammalian model for studying genomics. To study the function of a particular gene, scientists often create mice lacking that gene (knockout mice) or transfer the gene into mice that did not have it previously (transgenic mice). NCRR created a network of Mutant Mouse Regional Resource Centers to preserve these and other types of genetically modified mice and distribute them to biomedical researchers. (Photo courtesy of Johns Hopkins University)

Dr. Donnell Bowen (top), a pharmacologist associated with the Research Centers in Minority Institutions (RCMI) Program, works with student Jillian Davis at Howard University in Washington, DC. The university's RCMI focuses on biomedical imaging and molecular structure. Dr. Bowen's research aims to reduce the toxicity of anticancer drugs. (Photo by Ron Caesar, Howard Magazine)



Because stem cells have the capacity to generate many cell types in the body, scientists are investigating the potential of these cells for replacing damaged or missing cells in diseases such as Parkinson's disease and diabetes. Pictured are human embryonic stem cells (the rounded, dense cell clusters) growing on a blanket of connective tissue cells (the flat, elongated cells). (Courtesy of Dr. James Thomson, University of Wisconsin-Madison)

Dr. Branimir Sikic (right), program director of the NCRR-supported General Clinical Research Center (GCRC) at Stanford University, conducts clinical trials of cancer drugs at the GCRC. (Photo by Arturo Beckles, Stanford University)



Potassium channels are multiprotein complexes embedded in the cell membrane that play important roles in nerve conduction, muscle contraction, and other bodily processes. This computer-generated model shows the channel's central passageway that selectively allows potassium ions to exit the cell. The channel's three-dimensional structure was deciphered using NCRR-supported instrumentation and resources. (Courtesy of The Rockefeller University)

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Acknowledgment

The National Center for Research Resources (NCRR) acknowledges the support and thoughtful input from the members of its National Advisory Research Resources Council and hundreds of investigators and administrators across the biomedical research community. Their contributions and insights are essential for setting NCRR's future priorities to facilitate discovery. NCRR's *2004-2008 Strategic Plan: Challenges and Critical Choices*, will serve as the framework for NCRR's programmatic activities over the next five years. The Strategic Plan will guide NCRR's priorities for investments, including local and national networks, research resources, technology development, instrumentation, biological models, and biomedical informatics tools to facilitate research intended to prevent, alleviate, or treat human disease.

CONTENTS

INTRODUCTION

NCRR's programs serve as a "catalyst for discovery" for NIH-supported investigations that are intended to ultimately improve human health.

The National Center for Research Resources, a component of the National Institutes of Health, is Congressionally mandated "to strengthen and enhance the research environments of entities engaged in health-related research by developing and supporting essential research resources." (PHS Act, Title III, Part E, Section 479)

Through development and support of a broad range of state-of-the-art research resources, technologies, and biological models of human disease, the National Center for Research Resources (NCRR) strengthens all lines of health-related scientific inquiry and contributes to major scientific discoveries by National Institutes of Health (NIH)-supported investigators and others. To address new and evolving research needs, NCRR supports research to create and develop critical resources and technologies as well as promotes resource sharing and interdisciplinary collaborations. In addition, NCRR programs enhance research through competitive funding for building or modifying research laboratories that host progressively more complex research. These facilities are often equipped with state-of-the-art technologies and instrumentation that can only be used to the fullest potential by properly trained investigators. NCRR provides support for mentoring promising investigators to develop their research skills and become the independent researchers of tomorrow.

To ensure that research resources meet current and evolving needs, NCRR staff must continually interact with investigators and administrators across the biomedical research community. Scientific trends and research needs change at an astonishing pace, yet effective research resources for addressing investigator needs cannot be generated overnight and must be established before lack of essential research tools becomes an obstacle to research progress. NCRR's interactive strategic planning process generated many suggestions for future program activities, and the Strategic Plan will serve as a solid foundation for these efforts.

In 1994, NCRR was among the first NIH components to publish a strategic plan based on extensive input from the scientific community. That initial five-year plan and its successor, published in 1998, have informed and guided NCRR's priorities for developing the requisite technologies, models, algorithms, and research resources to facilitate research. These resources include mutant mouse regional resource centers, several repositories for a wide range of other genetic mutants, access to almost three dozen beam lines at sophisticated synchrotron resources for state-of-the-art crystallographic studies, imaging technologies, and resources for isolating human pancreatic islet cells—a potential therapy for some patients with type 1 diabetes.

In 2003, NCRR published a notice in the *Federal Register* requesting input on four broad, basic resource questions from biomedical scientists, high-level administrators in research institutions, scholarly organizations, and NIH senior program staff. Responses provided through NCRR's web site, as well as other

correspondence, represented a broad cross-section of the research community. This initial input served as a framework for NCRR's Fall Strategic Planning Forum, held in Arlington, Virginia, in September 2003. At least half of the participants at the forum had no prior history as former NCRR grantees or resource users. This approach was intended to get fresh ideas and address new areas. At this two-day forum, distinguished members of the biomedical research community identified scientific trends and needs and also shared their recommendations for addressing critical problems.

SCIENTIFIC TRENDS

Many of the trends identified by participants at the Strategic Planning Forum were extensions of the trends noted in NCRR's previous strategic planning process. Respondents noted the following dominant trends in biomedical science:

- Addressing today's more complex research problems requires an interdisciplinary team, which in turn depends on a wide range of advanced technologies.
- With increased use of "cyberspace-based" communications, investigators need access to more sophisticated computational resources for modeling, simulation, and data management.
- The public has a growing concern about the safety of human subjects participating in clinical research studies.
- As genomes of more species are fully sequenced, a greater number of genes are studied in mutant organisms, creating a rapidly expanding need for biological repositories and more efficient technologies to generate genetically altered models of human disease.
- As research becomes more multidisciplinary and team based, the research infrastructure must change. A different approach or paradigm must be used to train young investigators, and all members of the research team must receive credit for their respective contributions, especially junior investigators.

NCRR will address these and other emerging trends, as described in the goals and objectives set forth in this 2004-2008 Strategic Plan.

ABOUT NCRR

NCRR consists of four divisions—biomedical technology research and research resources, clinical research resources, comparative medicine, and research infrastructure. Together, these four divisions are well positioned to address scientific trends and provide support for developing and sustaining critical research tools for health-related research. NCRR has no NIH intramural programs. Increasingly, NCRR's divisions work interactively to provide integrated, interdisciplinary resources and expertise to the biomedical community. NCRR develops and provides access to advanced technologies and other resources for investigators supported by other NIH components. In addition, NCRR research resources and technologies are available to investigators supported by other Federal agencies and private sector programs.

The Division for Biomedical Technology Research and Research Resources supports research, investigator training, and access to new and existing

instrumentation, software and algorithm development, and cutting-edge technologies. Current emphases include integrated technologies, molecular and cellular structural biology technologies, noninvasive imaging and spectroscopy, mathematical modeling, simulation, and advanced computing.

The Division for Clinical Research Resources develops and supports resources to facilitate clinical research and assure the safety of participants in research. National clinical research resources accelerate the translation of research findings developed in the laboratory to patients. As clinical research becomes more complex, a collaborative research approach is essential and must include several critical partners with complementary expertise. To enhance translation of research findings from the laboratory, a national network of about 80 General Clinical Research Centers (GCRCs) provides a range of resources for direct patient research. More than 10,500 investigators conduct nearly 8,000 research projects at these centers annually, predominantly through more than 400,000 outpatient research visits annually. Other resources provide key service functions, such as the Islet Cell Resource Centers, which are critical to ascertaining the therapeutic potential of islet cell therapy in patients with type 1 diabetes. In addition, several career development programs have been designed to attract talented medical students, physicians, and dentists to the challenge of clinical research careers.

The Division of Comparative Medicine supports a wide range of research, including the identification and development of new and improved biologic models for the study of human diseases, such as AIDS, seizure disorders, and Parkinson's and Alzheimer's diseases. In addition, special programs support research resources and repositories, such as those for genetically altered adult and embryonic stem cells and zebrafish mutants. To address the growing need for research-trained veterinarians, several career development programs are in place. The division also supports a network of eight National Primate Research Centers (NPRCs). The NPRCs have contributed to the development of a variety of vaccines for infectious diseases. Other NPRC studies examine premature birth and the prevention of the vertical transmission of SIV (analogous to HIV) to infants. The NPRCs also work closely with investigators from India, Indonesia, China, and Nepal to help them acquire the research skills to address health problems that are of greatest risk to their populations. The NPRCs provide a unique setting to develop their research skills.

The Division of Research Infrastructure provides competitive funding to modernize and construct research laboratories capable of supporting sophisticated research. Other programs are designed to strengthen the research capacity of minority-serving institutions, as well as to enhance the number of research-trained faculty at research institutions in states that traditionally have not received significant levels of competitive NIH research funding. These programs are designed to support competitive multidisciplinary centers designed to increase the institutions' capacity to conduct cutting-edge biomedical research.

NCRR GUIDING PRINCIPLES

As in the past, NCRR will continue to give priority to those resources and projects that are critical to the research enterprise and without which the national biomedical community could not achieve its full potential. To help set priorities across the various programs, participants in the NCRR Strategic Planning Forum recommended that NCRR give highest consideration to the following:

- Cutting-edge and innovative technologies and research tools;
- High-risk research that may require long-term support to have significant societal payoff;
- Flexible and diverse resources that can readily respond to unanticipated research opportunities;
- Shared and accessible resources that effectively leverage Federal dollars; and
- Biomedically important resources that are unlikely to be supported by other Federal agencies or private sector organizations.

CLINICAL RESEARCH RESOURCES AND NETWORKS

Goal

Ensure that the clinical research community has ready access to specialized resources and inpatient or outpatient clinical research facilities with highly trained staff and state-of-the-art research instrumentation and technologies. These resources are essential for rapidly translating research findings from the laboratory to the patient.

Clinical investigators study behavioral, biochemical, physiological, and other characteristics (such as genotypes and phenotypes) of patients, seeking clues to identify the causes or consequences of disease and improve the quality of life. Clinical investigators also develop and evaluate promising new therapies in clinical research trials, which depend on patient volunteers. NCRR supports clinical research studies through its national network of General Clinical Research Centers (GCRCs) and through clinical research centers at primarily minority institutions. Additional NCRR resources develop and provide investigators with clinical-grade vectors for gene transfer and human pancreatic islets for transplantation into patients with type 1 diabetes. Other resources provide human tissues and organs for laboratory studies.

Objectives

- When feasible, incorporate **standard vocabularies into clinical research data definitions**, thus enhancing collaboration and optimizing sharing and mining of data collected from study participants. Effective data sharing demands incorporation of standard vocabularies, ontologies, and meta-data.
- Integrate **informatics and scalable computing across GCRCs, Minority-Serving Institution–Clinical Research Centers (MSI–CRCs), and other sites**. Support distributed databases and integration of software tools to assist clinical researchers in collecting, managing, analyzing, and mining their data. Include partnerships with GCRC informatics managers, collaborative research networks, and institutions as well as medical standards communities to assure cross communication.
- Promote **sharing of various types of data by providing incentives and tools for sharing**. Increase knowledge of and access to data that is available for sharing, including the tools for combining several sources and types of data.

Increasing Responsibilities for Human Subject Protection

Medical advances depend on an untold number of volunteers who agree to participate in clinical studies. Although potential new therapies are thoroughly tested in the laboratory or on animal models before administration to humans, every clinical study carries some degree of risk for participants. Clinical research has become much more complex and frequently requires closer observation of patient participants. Clinical researchers must adhere to a seemingly complex set of Federal, state, and institutional policies and regulations designed to protect the safety and privacy of human research subjects. To help researchers meet these responsibilities, NCRR established a new staff position, the Research Subject Advocate (RSA), at the GCRCs nationwide.

Most current RSAs are physicians, but some are nurses, pharmacists, or biomedical ethicists. Although the role of the RSA is still evolving, RSAs assist principal investigators in developing the data and safety monitoring plans required for all NIH-funded clinical studies. These plans stipulate the individuals responsible for adverse event tracking, the procedures for safety monitoring performance, and agency reporting requirements. In small studies or trials with minimal or low risk, a single individual can perform safety monitoring, but for studies or trials involving significant risk, a data and safety monitoring board is required. Since the RSA positions were established in 2001, the number of data and safety monitoring plans and boards has increased at the GCRCs, probably indicating that RSAs are enhancing human subject protection. RSAs interact with potential participants and enrolled clinical research volunteers to enhance the research subjects' understanding of clinical research and their role as research participants. Through periodic workshops, the RSAs keep clinical investigators informed about their scope of responsibilities. The ultimate goal of the RSA program is to regain and maintain the public's trust in clinical research by facilitating the conduct of safe, ethical, and respectful clinical research.

- Create **high-throughput national resources for genotyping and phenotyping**, including standardized approaches for clinical phenotyping. Develop and validate new phenotyping methods.
- Strengthen **collaborations among clinical investigators and basic scientists** to foster translational research. Host hands-on, science-based workshops for established and promising new investigators across disciplines to increase communication and understanding.
- Facilitate **characterization and classification of individuals with rare diseases** through innovative, geographically dispersed networking. Incorporate common vocabulary and laboratory standards with robust scalable informatics, including tools for analysis and data integration. Support the application of new technologies, including microarrays, to study rare diseases.
- Provide research tools and networking across the GCRCs and MSI–CRCs to facilitate **efficient recruitment of individuals with rare diseases**. Extend these strategies to assure adequate representation of underserved ethnic minorities in all appropriate clinical research studies.

- Increase the capacity of clinical research centers associated with Research Centers in Minority Institutions (RCMIs) **to study the causes of health disparities** in racial and ethnic minority populations. Develop prevention and intervention research programs targeted to minority populations and promote collaborations between minority institutions and institutions with more extensive research programs.
- To restore the public's trust about the safety of research participants in clinical research studies, encourage adoption of and adherence to **high ethical standards for research** conducted by investigators at institutions, hospitals, and other research organizations. The standards need to encompass organizational responsibility; conflicts of interest; Federal, state, and local regulations, policies, and guidelines; oversight; dissemination of research results; as well as continuing education of investigators and clinical research personnel on current standards. Such standards should be effectively articulated and promoted and would provide institutional accountability. This process may be further strengthened through a process of voluntary accreditation, similar to that for AAALAC (American Association of Accreditation of Laboratory Animal Care).
- Further evolve the **Research Subject Advocate (RSA) program**. Consider extending the RSA model to clinical research studies outside of the GCRC, as a complement to existing institutional activities for human subject protection. Arrange workshops for investigators and other clinical research staff who interact with research subjects. Encourage participation by staff at nearby institutions.

Focus on Health Disparities

NCRR supports clinical research studies on health disparities, or diseases that disproportionately affect racial and ethnic minority populations. NCRR has joined with the National Institute of Mental Health to establish three Comprehensive Centers on Health Disparities. These Centers will further 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. The funding also is intended to support a vigorous and stimulating scholarly environment that will inspire students and research fellows to pursue careers that focus on health disparities. In addition, NCRR supports a Stroke Prevention and Intervention Research Program that focuses on minorities, as well as a mentored clinical research career development program to provide clinical research training for doctoral and postdoctoral candidates in minority institutions.

- Develop an **Internet-based network to facilitate collaborative research** among basic and clinical investigators at the RCMIs, institutions eligible for IDeA funding (see sidebar on page 19), NCRR resources, and other sites. The RCMInet will foster research collaborations within the RCMI institutions, as well as with others outside this network. The RCMInet will provide remote access to virtual laboratories, scalable computing and national databases. The network must be compatible with other NCRR networks to optimize research opportunities.
- Increase **MSI–CRC investigators' participation in national clinical trials** sponsored by other NIH components. Facilitate this effort by linking the studies through a coordinating center equipped with clinical trials software and hardware, biostatistical expertise, and data management and analysis. Support a data safety monitoring board through the coordinating center.

INFORMATICS AND COMPUTATIONAL BIOLOGY

Goal

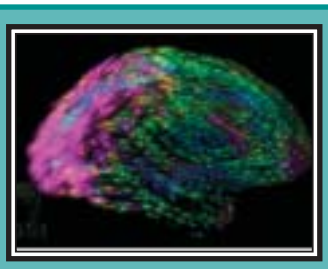
Promote the development of and access to cutting-edge informatics and computational resources, including network infrastructure, computer hardware, software, and database technologies.

Biomedical researchers increasingly depend on sophisticated computational resources for modeling biological processes and collecting, managing, and analyzing data. The future of biomedical research will involve collaborations by many scientists in diverse locations linked through high-speed computer networks that enable submission, analysis, and sharing of data. Through this process, scientists can tackle complex problems that are beyond the reach of individual investigators. By establishing the Biomedical Informatics Research Network (BIRN) and other complementary computational resources, NCRR helps make this vision of the future a reality.

Objectives

- Create **national centers for biomedical computing** to develop computational tools and to educate researchers in computing. These centers will be components of a national supercomputing network that scientists across the country can access in order to share and analyze data using a common set of software tools.
- Exploit **high-capacity computer networks** to:
  - Link genomic, proteomic, and metabolomic databases with other databases (e.g., clinical phenotypes).
  - Link less research-intensive institutions with the rest of the biomedical community to foster collaborations and to provide access to computational tools and virtual laboratories that facilitate the acquisition and analysis of research data.
- Integrate the **Mutant Mouse Regional Resource Centers' database** with similar mouse databases, such as those at The Jackson Laboratory and the International Mouse Resource, to facilitate investigator access to all existing models and data relevant to each validated genetic mutant through a single access point.

- Extend the **Biomedical Informatics Research Network** to more investigators and institutions to further enhance neurobiology research. Extend the infrastructure model and software tools to other research communities outside of neuroimaging. Partner with other large informatics projects to enhance interoperability and seamless integration for users. Facilitate integration of cutting-edge computing and informatics advances into biomedical research.
- Develop **user-friendly interfaces and provide training for biologists** who may lack expertise in computer science yet need access to powerful computational tools.



Team Science and Data Sharing

Scientists are often considered to be solitary individuals, working alone in a laboratory or, at most, with a small group of technicians and graduate students. However, as biomedical science and research projects become broader in scope, this traditional view is being joined by another image, that of the scientist as member of a large interdisciplinary research team. This trend toward team science originated in fields such as genomics and proteomics as an offshoot of the large-scale effort to sequence the human genome. The field of neuroscience also is moving toward large-scale or more complex science, with neuroscientists developing tools to correlate gene expression and highly detailed digital brain images at higher resolutions with lower variances than ever before.

NCRR facilitates team science through development of nationwide, high-performance computer networks. One example is the Biomedical Informatics Research Network (BIRN), which links many NCRR-supported Biomedical Technology Resource Centers that host imaging technologies with their institutional GCRCs. Initially, researchers with access to BIRN and newly developed imaging algorithms are concentrating on neuroimaging studies of mice and humans. Because of the network, researchers can combine images of research subjects and data from multiple laboratories. Eventually, scientists will have the tools to compare neuroimaging data with cellular- and molecular-level data in both mice and humans.

NCRR's Rare Diseases Clinical Research Network also facilitates team science by linking multiple rare disease clinical research sites across the country. Although each site may recruit only a small number of patients with a rare disease, the network allows researchers to efficiently and effectively collaborate, thus enhancing the value of data obtained from interactions with participants who have rare diseases.

- **Develop and improve biomedical software**. Biomedical research teams have independently developed codes for software, but support is needed for the maturation and maintenance of these codes, an important step toward creating shareable software.
- Promote **development and incorporation of informatics (e.g., computational, grid, and Web) standards** into research resources in partnership with relevant standards communities.
- Facilitate development of data-mining methodologies and enhance **user-friendly access to data-mining tools**. Promote development of software algorithms to identify commonalities in biomedical data.
- Develop ontology-based strategies and analytical techniques for **linking disparate types of databases**.

NONHUMAN MODELS FOR BIOMEDICAL RESEARCH

Goal

Enhance the development of and access to nonhuman models that are critical to understanding human health and responding to emerging health threats.

Scientists depend on laboratory animals and other nonhuman models for investigating biological processes, studying the causes of diseases, and testing promising new therapies. Nonhuman models also are indispensable for effective biodefense strategies and many other emerging health issues. NCRR supports research and research resources that develop and enhance access to a broad range of nonhuman models, including nonhuman primates, rodents, zebrafish, worms, and cellular models. NCRR also sponsors initiatives to improve the health and care of laboratory animals.

Objectives

- Establish resources and improve the techniques for **characterizing, standardizing, and cryopreserving important animal models**, including gametes and embryos. Such technology is available for mice and zebrafish and should be developed for other animals, particularly nonhuman primates. The quality of animal-model characterization varies greatly across institutions, and only a few facilities are highly successful at freezing and storing viable embryos.

- **Increase the number of nonhuman primates available for biomedical research**, and evaluate other methods to address the shortage of nonhuman primates. The need for these animals has risen substantially and is expected to escalate even more due to their essential role in biodefense, gene transfer research, and the increased risk of transmission of infectious agents to air travelers from remote areas around the globe.
- Address the critical shortage of Indian-origin rhesus monkeys by establishing robust breeding colonies and **enhancing the usefulness of other nonhuman primate species** for biomedical research. Develop new and test existing reagents that investigators need to characterize the immune response, genome organization, pedigree structures, and gene expression in these potential alternative nonhuman primate models.
- Establish a database with information provided through a **network among National Primate Research Centers (NPRCs)** and other investigators that would allow scientists to locate nonhuman primates with particular characteristics.

- Develop and enhance the availability of **stem cell lines from nonhuman primates**. Characterize the effects of micronutrients and other factors on stem cell differentiation in culture, and investigate the therapeutic potential of stem cells in nonhuman primate models of disease.
- Establish **centers for genotyping and phenotyping animal models** and maintain a database with relevant information that can be readily accessed.
- Promote **standard nomenclature for identifying genes and proteins** found across animal species.
- Develop **genome libraries for more organisms**, such as invertebrates, lower chordates, and endangered nonhuman primate species. As more genomes are sequenced, comparisons of DNA sequences among animals may provide unexpected insights into gene function and regulation.
- Develop **methods for comparing different models** (e.g., how a knockout mouse relates to a primate model).
- Develop novel **high-throughput drug-screening strategies** with animal models and cell cultures. Place approved screens in centralized locations for general access.

Mutant Mice in High Demand

The mouse is one of the most commonly used research models to study human disease processes. It is small, easy to handle, and breeds rapidly. In the 1990s, researchers developed a method to create "knockout" mice; that technique selectively disables one or more genes and has created thousands of valuable new mouse models. However, researchers who create these unique genetically altered animals often lack the facilities or staff to maintain and distribute the mice to other scientists.

More than 10 years ago, NCRR initiated support for a national resource for mouse genetic mutants at the Jackson Laboratory. However, the number of genetically altered rodents has expanded considerably with the sequencing of several dozen genomes. To accommodate this need, NCRR established the Mutant Mouse Regional Resource Centers. Created in 2001, the program consists of four regional centers and a central facility that processes animal submissions and orders from researchers. Once accepted, new mouse models are rederived by embryo transfer into pathogen-free mice, which are then bred in pathogen-free facilities and distributed to scientists in return for a nominal fee.

EMERGING TECHNOLOGIES AND INSTRUMENTATION

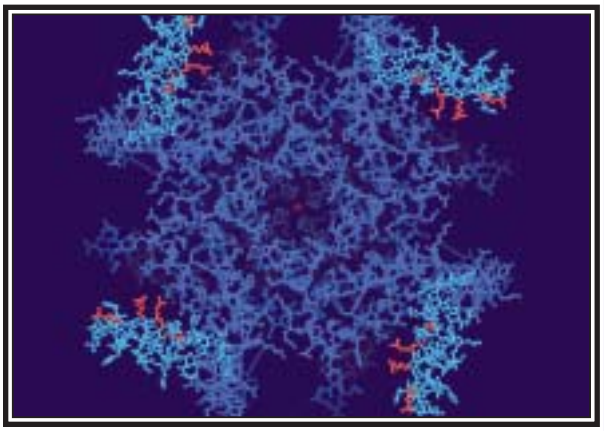
Goal

Promote the development of and access to cutting-edge technologies, techniques, and instrumentation.

Biomedical scientists today use many complex technologies, including mass spectrometry, macromolecular crystallography, and advanced imaging tools. They urgently need improved or new technologies to study the thousands of proteins that interact with one another to make a cell function as a tightly modulated unit. This new area of research, known as proteomics, includes structural characterization of proteins, analysis of protein expression and interactions within the cell, and the use of biomedical informatics to make sense of the large volume of resulting data. To enhance investigator access to state-of-the-art instruments, methodologies, and computational tools, NCRR supports Biomedical Technology Resource Centers and other shared technology-related resources at institutions across the country. A major focus of research is the development of new biomedical technologies and the application of existing technologies for use in health research.

Objectives

- Create **national technology centers for networks and pathways** to develop novel proteomics and other complementary technologies that are applicable to dynamic systems. Consider incorporating the "Virtual Cell" as a model system for discerning protein-protein dynamics within the cell and validating the predicted model experimentally.
- Develop technologies to delineate the composition and **three-dimensional structures of macromolecular complexes** as well as their intracellular functions.
- Develop **techniques to explore molecular interactions**. These techniques may include new methods based on existing instruments and tools, such as mass spectrometry, microscopy, and computational modeling, or new types of microarrays.
- Expand the **utility of microarray investigations** through standardization, quality control, and development of specialized microarrays. The present diversity of microarray systems and technologies used in genomics and proteomics complicates comparisons of datasets.
- Develop and improve novel technologies, instruments, and **tools for genomic, proteomic, and metabolomic studies**, including electron cryomicroscopy for studying protein interactions and the functions of protein complexes; techniques to make robotic technologies faster, more accurate, and less expensive; and software to analyze the data generated with innovative technologies.



- Ensure the availability of **shared state-of-the-art instrumentation** to meet the needs of the biomedical research community. Many of the instruments required for today's complex research projects are too expensive to be purchased with individual research grants.
- Promote **interactions between users and developers of technologies** to improve their application in laboratory and clinical settings.
- Encourage academic institutions to recognize and create **faculty positions for technical specialists** who develop new instrumentation, and instruct scientists in the use of technologies that are outside their disciplines (e.g., teaching a neuropsychologist how to use DNA microarrays or brain-imaging equipment).
- Ensure that **modern imaging technologies are available** to clinical investigators as well as investigators working with model systems, ranging from cell lines through nonhuman primates.

A Pressing Need for Advanced Instruments

Biomedical scientists today use equipment unheard of only a decade ago. Such equipment can be expensive, beyond the reach of most researchers or even academic institutions. To help provide scientists and their institutions with state-of-the-art technologies, NCRR established the Shared Instrumentation Grant (SIG) Program in 1982. The program enables institutions to purchase research equipment priced between $100,000 and $500,000. The program is cost-effective because SIG-purchased instrumentation must be shared by at least three NIH-supported scientists. The instruments typically are placed in central core facilities that provide technical expertise and educate scientists in the use of the instruments. Between 1993 and 2003, the SIG Program awarded 1,082 grants, for nearly $300 million.

Because some instruments are too costly to be purchased through the SIG Program, NCRR established the High-End Instrumentation (HEI) Program in 2002. This program supports the purchase of instruments that cost at least $750,000; awards of up to $2 million may be made. If the cost exceeds that level, then the applicant institution must identify the source for the differential cost of the equipment. NCRR received an overwhelming number of grant applications when the program was first launched, which demonstrates a strong need for instruments in this price range.

The SIG and HEI Programs have greatly benefited scientists nationwide. As one participant at NCRR's Strategic Planning Forum noted, "A single SIG award may ultimately end up serving 10 or more R01-funded investigators, many of whom may be unaware that the instrument was purchased through an NCRR grant."

RESEARCH CAPACITY BUILDING: Resources, Networks, and Facilities

Goal

Build a strong biomedical research infrastructure, and facilitate multidisciplinary collaborations among scientists.

Advances in biomedical science depend on the availability of state-of-the-art research environments. At their best, such environments not only provide the tools and technologies needed to conduct research but also facilitate collaborations among scientists with diverse areas of expertise. NCRR supports programs for constructing new or renovating existing research laboratories, upgrading laboratory animal facilities, and enhancing the research capacity of minority institutions and institutions located in states with historically low success in obtaining NIH grant funding.

Objectives

- Create **centers for interdisciplinary research** that will focus on developing new approaches to solving significant biomedical problems, particularly those that have been resistant to more traditional approaches.
- Explore new, **flexible approaches to provide distributed research resources**, technologies, informatics tools, data management, and other clinical research tools within and across clinical research facilities that will enhance their capacities.
- Enhance NCRR's **Research Facilities Improvement Program**. Institutions often lack sufficient funds to expand research facilities and build new research space.

- Consider establishing a program to **guarantee loans for institutions to fund construction and renovation** of biomedical research laboratories. A Federal program of this type would enable institutions to borrow money at lower commercial interest rates and for more years.
- Encourage **construction of facilities that promote interdisciplinary collaborations**. Novel collaborations sometimes arise from casual conversations between researchers from different departments. Buildings in which scientific laboratories are located should be designed and staffed in such a way as to facilitate these types of interactions (Carnegie model, for example).
- Improve and expand **facilities that house nonhuman primates**. These facilities may be used for quarantine of species imported for research.
- **Evaluate all new NCRR programs** and periodically assess the effectiveness of long-standing NCRR-supported programs. Modify existing programs to ensure they provide sufficient capacity to address investigators' needs.

Enhancing Research Capacity in Underserved States

Historically, half of the states in the United States have received 95 percent of the NIH biomedical research grant support. Other states have typically received few NIH grant awards because investigators submit only a small fraction (8 to 10 percent) of the entire pool of NIH grant applications. Without adequate funding, these underserved states cannot develop a competitive infrastructure that includes modern research laboratories, recruitment of competitive scientists, and acquisition of sufficient instruments and technical resources to compete successfully for competitive research funding.

To help these states compete, NIH created the Institutional Development Award (IDeA) Program, which NCRR administers. The program led to the establishment of Centers of Biomedical Research Excellence (COBRE) in IDeA-eligible states. COBREs are multidisciplinary research centers with a specific research theme. They not only provide opportunities and resources for conducting high-quality research, but they also enhance the competitiveness of junior investigators to compete independently for NIH research support.

In 2001, NCRR launched the second IDeA program—the Biomedical Research Infrastructure Network (BRIN) program—designed to build collaborative partnerships between and among institutions in IDeA-eligible states. The BRIN coordinates and distributes research resources and expands research opportunities by increasing the pipeline of outstanding students who may become the future competitive investigators in these states. The BRIN provides funding to strengthen the basic science departments of undergraduate institutions to recruit top-notch science faculty and students. A BRIN network includes a doctoral degree granting institution or research institute along with several baccalaureate institutions and, in some cases, includes minority-serving institutions and community colleges. In FY 2004, the BRIN program was renamed the IDeA Networks of Biomedical Research Excellence.

TRAINING AND EDUCATION

Goal

Strengthen the Nation's human capital in the biomedical sciences through training and education.

Biomedical scientists must receive specialized training and a broad-based education that requires years of development before they become independent researchers. NCRR has established career-enhancing training programs for investigators who conduct basic research or evaluate new therapies in clinical trials. Many of these programs are designed to address a shortfall of well-trained scientists, including research clinicians, mouse pathobiologists, and specialists in genomics and proteomics. In addition, NCRR supports science education for the general public and students to enhance their understanding of health issues and career opportunities.

Objectives

- Promote **cross-disciplinary training at all levels** for investigators, technical specialists, and students. Cross-disciplinary training is critical for many disciplines, including biology, computational science, and genomic and proteomic research.
- **Support individuals with highly technical skills**, such as biologists with backgrounds in computer science, engineering, or other disciplines, who provide critical technical service for investigators.
- Establish flexible training mechanisms that enable new and established researchers **to gain skills and expertise in the latest technologies** to capitalize on new research opportunities.
- Provide a **bridge between the K23 and R01 grants** by significantly enhancing the level of research support to clinical investigators through a K mechanism that provides more robust support of faculty investigators who previously held K23 support. This new or modified K program would provide competitive support to physicians who are conducting meritorious clinical research.
- Continue to support **programs for medical students and early-career development for physicians** to acquire training and career development in clinical investigation. Encourage students to pursue clinical research careers.

- Increase the number of research-trained pathologists, microbiologists, veterinarians, parasitologists, and protozoologists for **infectious disease, vaccine development, and biodefense research**. Assess the need for training clinical investigators in these areas.

- Provide support for **science education opportunities** through partnerships among dedicated scientists, educators, community organizations, academic institutions, museums, public school systems, and others. Ensure that cutting-edge science education projects are innovative and broadly distributed. Translate research findings so that the information can be readily understood by individuals at various educational levels, helping them make healthier life style choices.

Concern About Dwindling Proportion of Physician Scientists

Because of their experience and skill in working with patients, physicians are valuable members of the clinical research team. Unfortunately, the relative proportion of physicians interested in conducting clinical research has declined for the past three decades. In the 1970s, physicians accounted for nearly 40 percent of the total applicants for NIH clinical research grants; today, physicians account for less than 25 percent of applicants. Several factors have been cited as contributors to this shrinking proportion of physician applicants. The major factor is that the number of investigators who submit NIH grant applications and hold Ph.D.s has grown at a substantially greater pace than that for physicians. Several other factors undoubtedly contribute to the lack of a substantial increase in the proportion of physician investigators, including the level of debt of recent graduates; the additional years of research training needed to become an independent clinical investigator; the modest support for junior faculty positions and uncertainties about faculty promotion; and the perception that basic research is often valued more than clinical research. However, objective data are lacking as to how much each of the foregoing factors contribute.

NCRR has established two programs to attract more medical students, physicians, dentists, and other health professionals to clinical research. The Mentored Clinical Research Scholar Award (K12) is a pilot program that provides support allowing recently trained physicians and dentists to develop their research skills with the guidance of a mentor who is an established clinical researcher. The Mentored Medical Student Clinical Research Program provides supplemental funding for GCRCs to introduce medical students to potential careers in clinical research.

NCRR also participates in two NIH training programs for clinical investigators: the Mentored Patient-Oriented Research Career Development Award (K23), which supports individuals who have completed their clinical training and have made a commitment to conduct clinical research, and the Midcareer Investigator Award in Patient-Oriented Research (K24), which allows outstanding clinical investigators to devote time to clinical research and mentor beginning clinical investigators. NCRR also participates in the NIH Loan Repayment Program, which enables clinical investigators to receive two-year contracts to conduct clinical research. In return for each year of service, NCRR repays up to $35,000 of an educational loan. Such programs are expected to create a new generation of physician scientists who have been rigorously trained and are well prepared to contribute to the Nation's clinical research enterprise.

RESEARCH PARTNERSHIPS

Goal

Pursue strategic alliances with NIH components, other Federal agencies, industry, foundations, and other interested groups to provide access to essential biomedical research resources.

Today's climate of financial constraints and limited resources encourages organizations with similar interests to collaborate to achieve their goals. Together, organizations often can accomplish tasks that are of mutual benefit and can do so cost effectively, especially if the undertaking can attain an economy of scale. NCRR also avoids duplication of efforts by collaborating with other NIH components.

Objectives

- Identify and **overcome the barriers to strategic alliances**, and establish models for private-public partnerships. Barriers involve patents and intellectual property rights, material transfer agreements, and real and apparent conflicts of interest.
- Encourage **collaborations among NCRR-funded research resource centers** to capitalize on each other's unique capabilities to solve complex research queries. Consider consolidation of research resources that hold complementary technologies.
- Work in partnership with Federal agencies to identify and **overcome regulatory barriers to research**.
- Collaborate with other agencies to **streamline the process of bringing biotechnology products to market.**
- Provide access to **nationally distributed research resources** for both NIH intramural and extramural investigators; encourage collaborative studies when the undertaking is of mutual benefit.

COMMUNICATIONS

Goal

Inform the biomedical research community and the public about research resources and scientific advances.

An important component of NCRR's mission is to inform biomedical scientists of the research resources available to enhance their investigations. NCRR provides this critical information through its web site; the *NCRR Reporter*, a quarterly magazine; and other publications. Because of the wide-ranging needs of the biomedical research community, NCRR is exploring additional avenues to enhance investigator awareness of available research resources, their capabilities, and how to access them. These new communication efforts will not only help to inform and educate the research community but also bring together investigators for collaborations and training in leading-edge technologies.

Objectives

- Create a **"resource of resources" database that is easily accessible via the Internet**; the site should list all available NIH-supported resources by category and how to access them. Explore with other Federal agencies and private research organizations the inclusion of additional available resources, including databases and repositories.
- Enhance **outreach by NCRR resource centers to the scientific community**. Host onsite hands-on workshops for researchers; widely disseminate information about available technologies via scientific journals and meetings.
- **Document the value of NCRR resources to the research community**. Collect data on utilization by researchers and their satisfaction. Consider evaluating cost-effectiveness through economic models.
- Encourage the GCRCs to collaboratively develop brochures to **inform and educate the public and potential research participants about clinical research**, including clinical studies and trials and the role of the GCRC.

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September 10-11, 2003

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PHOTO CAPTIONS

Clinical Research Resources and Networks

Page 8 - Dr. Bonnie Ramsey (left) is director of the Therapeutics Development Network, which unites the efforts of eight GCRCs that conduct investigations involving patients with cystic fibrosis. Dr. Ramsey is instructing a cystic fibrosis patient on how to inhale an antibiotic through a nebulizer. (Photo by William Stickney, University of Washington)

Page 9 - Pediatric endocrinologist Dr. Thomas Carpenter (right) is the Research Subject Advocate (RSA) at the Children's GCRC at Yale University. RSAs help clinical researchers adhere to the complex policies and regulations that protect the safety and privacy of human research subjects. (Photo by Terry Dagradi, Yale University)

Page 10 - Meharry Medical College researcher Dr. ZhongMao Guo (left), an RCMI-sponsored faculty member, explains an experiment to second-year Ph.D. student George Jules. In 2003, Meharry was one of three institutions that received NIH funding to create a Comprehensive Center on Heath Disparities. Dr. Guo and his colleagues are examining the relationship between hypertension and oxidative stress in African Americans. (Photo courtesy of Meharry Medical College)

Page 11 - NCRR supports 10 Islet Cell Resource (ICR) Centers that isolate, purify, and characterize human pancreatic islets for subsequent transplantation into patients with type 1 diabetes. Dr. Camillo Ricordi, director of the ICR at the University of Miami, examines islet cells before transplanting them into a patient. (Photo courtesy of Dr. Ricordi)

Informatics and Computational Biology

Page 12 - The Visualization Studio at the Delaware Biotechnology Institute allows up to 10 people to interact with images of large molecules and sections of tissues, such as the inner ear (pictured). To see the images in three dimensions, participants wear stereo glasses. Ultrasonic sensors mounted in the ceiling track the motion of the lead investigator's head and a handheld 3-D wand, allowing team members to feel as if they are in the middle of the picture. (Photo by Eric Crossan)

Page 13 - Advanced computing technologies allowed researchers at the University of California, Los Angeles, to combine brain images of 20 normal elderly persons into this composite image, which shows normal anatomical variation in the brain. This baseline data, with each color representing a different degree of variability, allows scientists to distinguish normal anatomical variation from abnormal brain loss, such as that seen in Alzheimer's disease. The Biomedical Informatics Research Network facilitates transmission of brain images from many people to a central location, where they are used to produce composite brain images such as this. (Photo courtesy of the Laboratory of Neuro Imaging; University of California, Los Angeles)

Nonhuman Models for Biomedical Research

Page 14 - Rhesus macaques are critical animal models for evaluating potential human therapies, gaining insight into disease processes, and investigating emerging health threats. Through the eight National Primate Research Centers, NCRR supports research, resources, and scientific access to macaques and other nonhuman primates. (Photo by Jeff Miller, University of Wisconsin-Madison)

Page 15 - The Mutant Mouse Regional Resource Centers preserve genetically modified mice and distribute them to biomedical researchers. (Photo courtesy of Johns Hopkins University)

Emerging Technologies and Instrumentation

Page 16 - Potassium channels are multiprotein complexes embedded in the cell membrane that play important roles in nerve conduction, muscle contraction, and other bodily processes. This computer-generated model shows the channel's central passageway that selectively allows potassium ions to exit the cell. The channel's three-dimensional structure was deciphered using NCRR-supported instrumentation and resources. (Photo courtesy of The Rockefeller University)

Page 17 - NCRR established the Shared Instrumentation Grant and High-End Instrumentation programs to help scientists and their institutions purchase expensive state-of-the-art technologies, like this spot-picking robot, which rapidly collects protein samples for analysis. (Photo by Martin Vloet, University of Michigan)

Research Capacity Building: Resources, Networks, and Facilities

Page 18 - With NCRR funding to the Nebraska Center for Virology, students Veenu Minhas (in back) and Saul Phiri work with human cells infected with the herpesvirus that causes Kaposi's sarcoma, a blood vessel cancer endemic in equatorial Africa. (Photo courtesy of Dr. Charles Wood, University of Nebraska)

Page 19 - Funded by NCRR's Centers of Biomedical Research Excellence Program, Drs. Ke Jian Liu (left) and Shimin Liu discuss their research on blood flow and oxygenation in the brain following stroke. (Photo by Cathleen Rineer-Garber, University of New Mexico Health Sciences Center)

Training and Education

Page 20 - As the scientific demand for genetically engineered mice increases, so does the need for experienced mouse pathologists. An NCRR training program allows students like Dr. Prasad Nadella (left) to gain experience under the mentorship of a veterinary pathologist. Here he works with visiting assistant professor Dr. Ramiro Toribio (right) to examine an electrophoresis gel of DNA from genetically modified mice. (Photo by Jerry Harvey, Ohio State University)

Page 21 - NCRR has established programs to attract more medical students, physicians, dentists, and other health professionals to clinical research. As program director of the GCRC at Stanford University, Dr. Branimir Sikic (standing next to patient) oversees the training of future clinical investigators. (Photo by Arturo Beckles, Stanford University)

Communications

Page 23 - NCRR's print and Web publications describe research resource opportunities, highlight scientific advances supported by NCRR, and explain NCRR grant programs.

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