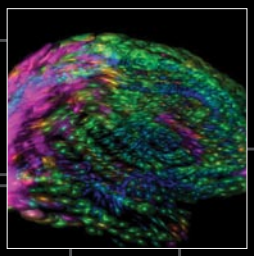
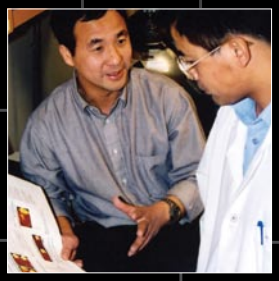
National Center for Research Resources




NCRR Strategic Plan 2009–2013

Translating Research from Basic Discovery to Improved Patient Care

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Center for Research Resources

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Acknowledgments and Next Steps

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, provided through the NCRR Web site or at the December 2007 Strategic Planning Forum, were essential for setting NCRR's future priorities to facilitate translational and clinical research. NCRR's *Strategic Plan 2009–2013: Translating Research from Basic Discovery to Improved Patient Care* 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 in research capacity, biological models, technology development, informatics approaches, workforce development, and partnership strategies.

To ensure that this *Strategic Plan* is effectively executed, NCRR is actively preparing an *Implementation and Progress Report* that will provide updates on how the action items are being met. NCRR will continue to enlist the help of the research community to produce the desired results in the coming years.

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Foreword

NCRR Guiding Principles

Foster the translation of basic science findings to human studies and clinical research advances to patients and communities.

Provide new opportunities for community engagement.

Encourage innovation for the creation of novel and cutting-edge technologies, animal models, and research tools.

Develop flexible and diverse resources that can readily respond to unanticipated research opportunities.

Support biomedically important resources that are unlikely to be supported by other federal agencies or private-sector organizations.

Employ shared and accessible resources that effectively leverage federal dollars.

Encourage investigators from diverse disciplines to train in multidisciplinary settings.

Barbara Alving, M.D., M.A.C.P.
Director, NCRR

Transcending geographic boundaries and research disciplines, the National Center for Research Resources (NCRR) supports unique and essential resources that help researchers funded through the National Institutes of Health (NIH) transform basic scientific discoveries into improved human health.

The next five years will be pivotal for NCRR as it seeks to energize the discipline of clinical and translational research across the country. This is NCRR's opportunity to expand and leverage existing activities and create new avenues that will address the evolving needs of the biomedical research community. This *Strategic Plan* is intended to provide NCRR with a solid foundation for moving forward.

This *Plan* reflects extensive discussions and advice from a broad spectrum of individuals, including biomedical scientists, high-level administrators in research institutions, members of professional organizations, and NIH senior program staff. Through a *Federal Register* notice, NCRR received more than 500 responses to six broad basic resource questions, which served as a framework for NCRR's December 2007 Strategic Planning Forum held in Rockville, Md.

At this two-day forum, more than 80 invited participants identified research trends and needs and also shared their recommendations for addressing critical problems in translational research. Forum participants represented a cross-section of investigators, clinicians, and other representatives of NCRR's core constituencies. Their wisdom, advice, and judgment, together with earlier comments from other interested individuals, serve as the basis for this strategic endeavor.

Implementation of the *Plan* will require that NCRR continue to develop and explore creative ways to partner with other federal government agencies and additional organizations, both public and private. NCRR also will continue to enlist the help of researchers and administrators across the biomedical research community to ensure successful implementation of the *Plan* and its continued evolution in response to new challenges and discoveries.

Sincerely,

Barbara Alving, M.D.

Barbara Alving, M.D., M.A.C.P.
Director, NCRR

About NCRR

NCRR unites innovative research teams with the power of shared resources, multiplying the opportunities to improve human health. Together, NCRR's four integrated and complementary areas of focus accelerate and enhance research along the entire continuum of biomedical science. The following highlights some of the major NCRR center programs and resources:

Biomedical Technology

Biomedical Technology Research Resources (BTRRs)
Create critical, often unique, technology and methods for application to a broad range of basic, translational, and clinical research. Foster synergistic interactions of technical and biomedical expertise, both within the resources and through intensive collaborations with other leading laboratories, to provide other biomedical researchers with training and access to new tools and methodologies.

Shared Instrumentation and High-End Instrumentation Grants
Provide funding to NIH-supported investigators to acquire expensive, commercially available equipment.

Comparative Medicine

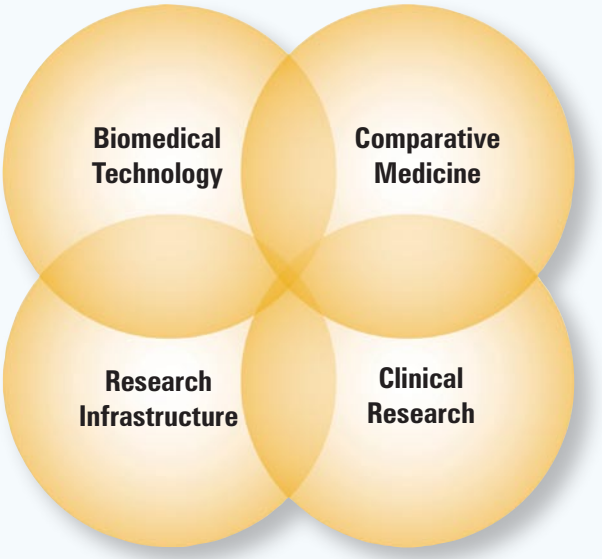
Comparative Medicine Resources
Support a broad array of high-quality animal models and biological materials; safeguard the health and welfare of laboratory animals; and provide career training opportunities in specialized areas of translational science.

National Primate Research Centers (NPRCs)
Foster the development of animal models, such as monkeys and baboons, facilitating research on diseases including HIV/AIDS, hepatitis, and cancer.

Research Infrastructure

Research Centers in Minority Institutions (RCMIs)
Develop and enhance the research infrastructure of minority institutions to expand their capacity for conducting basic, translational, and clinical research.

Institutional Development Award (IDeA)
Increase the capacity in states that historically have not received significant levels of competitive research funding from NIH through the following two programs:



- *Centers of Biomedical Research Excellence (COBREs)*
  Support thematic multidisciplinary centers that strengthen institutional research capacity by expanding and developing biomedical faculty capability and enhancing research infrastructure that encompasses the full spectrum of the basic and clinical sciences.
- *IDeA Networks of Biomedical Research Excellence (INBREs)*
  Support statewide networks of institutions with a multidisciplinary, thematic scientific focus to strengthen the research capabilities of biomedical faculty, and provide access to biomedical resources for promising undergraduate students.

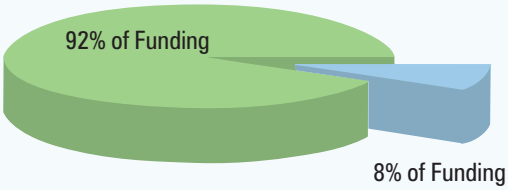
Clinical Research

Clinical and Translational Science Awards (CTSAs)
Support a national consortium of academic health centers that share a common vision to reduce the time it takes for laboratory discoveries to become treatments for patients and to engage communities in clinical research. Train the next generation of clinical researchers.

Science Education Partnership Awards (SEPAs)
Bring together biomedical and behavioral researchers, educators, community groups, and other interested organizations in partnerships to create and disseminate programs that give K–12 students and teachers and the general public a better understanding of life sciences.

Funding Comparison: Center *vs.* Research Project Grants

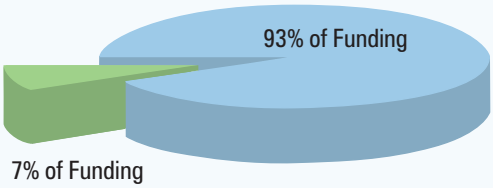
NCRR
FY 2008 (est.)



Center Grants = $760M

Research Project Grants = $69M

National Heart, Lung, and Blood Institute
FY 2008 (est.)



Center Grants = $141M

Research Project Grants = $2B

In contrast to other parts of NIH that mainly support individual investigator–initiated grants, most of NCRR's budget supports center grants that underwrite research infrastructure at academic medical centers and universities. These centers provide specially adapted research facilities, instrumentation, training, animal models, and expertise to more than 30,000 NIH-funded biomedical investigators across the country. The graphic above provides one example of the difference in support provided by NCRR in comparison to a categorical NIH Institute. Note that NCRR and the National Heart, Lung, and Blood Institute also support other types of grants, so the total of center plus research project grants is not their total budget.

Introduction

NCRR supports the continuum of biomedical research

Delivering new and effective treatments and disease prevention approaches to improve the nation's health depends on a research continuum to quickly and efficiently translate basic biomedical research findings into clinical practice and health care decision-making (see figure on next page). The National Center for Research Resources (NCRR), part of the National Institutes of Health (NIH), develops strategies for bringing basic research discoveries to human studies, optimizing the conduct of clinical research, and facilitating the transfer of new knowledge into clinical and community practice. NCRR is unique within NIH in that its programs align and reinforce the entire continuum by providing scientists with research tools and connections to other researchers and communities.

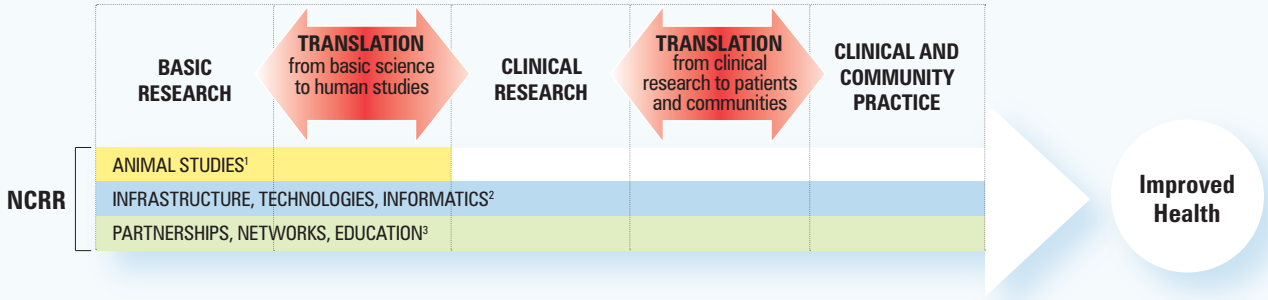
Translational research drives progress along the continuum and encompasses two separate processes. NCRR is fully involved in both translational steps. The first involves applying discoveries generated during research in the laboratory to the development of studies in humans. Such preclinical translational investigations are often carried out using animal models, cultures, samples of human or animal cells, or experimental systems, such as gene arrays, to study biological molecules, including DNA, RNA, and proteins. The second translational process takes results from studies in humans and applies them in clinical practice to improve people's health and jump-start the adoption of best practices in the community. NCRR's translational efforts often focus on overcoming roadblocks that impede the progress of clinical research by enabling more than 30,000 NIH-funded investigators to access its rich portfolio of research tools and facilities.

Clinical research encompasses human subjects research—studies that involve direct interaction between investigators and human participants or use of material of human origin, such as tissues, specimens, and data that retain participant identity information. Examples include clinical trials and studies of mechanisms of human disease, disease prevalence, and new technologies. Research networks and collaborations sponsored by NCRR help investigators quickly recruit participants for studies; provide the public with the widest possible access to clinical studies; and address the special health concerns of high-risk populations, minorities, rural communities, and individuals with rare or understudied conditions.

An evolving role for NCRR

In response to significant changes within NIH and throughout the research community, NCRR is increasingly engaged in fostering collaborative, cross-institutional research partnerships and building capacity for clinical and translational research. Not only does NCRR bring together innovative research teams, but it also equips

NCRR supports the continuum of biomedical research



1 Animal models are the bridge between basic science and human medicine. NCRR provides such models through specialized laboratory animals and research facilities. For example, NCRR supports eight National Primate Research Centers (NPRCs) to facilitate the translation of laboratory findings to clinical trials.

2 NCRR 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. For example, it funds the Biomedical Informatics Research Network (BIRN), a consortium that leverages and shares distributed tools, software, data, and expertise. BIRN and NPRC researchers are working together to apply the BIRN model for data storage and sharing to establish a nonhuman primate pathology database.

3 NCRR helps build partnerships and networks among grantees to create a matrix of research support in which the whole is much greater than the sum of the individual programs. The Clinical and Translational Science Award (CTSA) initiative has launched a consortium spanning basic, translational, and clinical research to bring effective prevention and treatment strategies more quickly into practice. Additionally, the collaborations fostered by the Research Centers in Minority Institutions (RCMI) and Institutional Development Award (IDeA) programs are building capacity at minority institutions and in underserved states to ensure that when research results are translated into practice they reach the many diverse communities that populate the United States. These programs and others include educational and career development components to help better prepare a cadre of biomedical investigators to carry out the nation's research agenda.

them with essential tools, such as scientific resources, facilities, technologies, and training, needed to tackle the nation's complex health problems.

For example, at a time when many researchers, deans, and professional societies cautioned that the current clinical research system needed a new direction, NCRR became the leader of an NIH effort to re-engineer the clinical research enterprise. The resulting Clinical and Translational Science Award (CTSA) program is forging a consortium of new partnerships among research institutions and sparking innovative approaches to build on and strengthen NCRR's long-standing investments in basic, translational, and clinical research. As the consortium matures, NCRR will encourage and facilitate partnerships among grantees from all its programs, forming a synergistic matrix of research resources and expertise.

As such, NCRR programs are accelerating and enhancing research across the full spectrum of human disease. The following sections describe NCRR resources and activities in the setting of strategic planning to continue and expand biomedical research along the entire continuum spanning basic research to community practice.

Building Capacity to Translate Biomedical Research into Practice

NCRR helps to build partnerships and networks among grantees to create a matrix in which the whole is much greater than the sum of the individual programs. Three of these programs demonstrate the range of NCRR-supported activities, including basic biomedical and behavioral research, integrated research infrastructure, mentoring and career development, and community outreach. Through the Clinical and Translational Science Award (CTSA) initiative, NCRR has launched a consortium to bridge basic, translational, and clinical research to bring effective prevention and treatment strategies more quickly into practice. The Institutional Development Award (IDeA) program supports and fosters health-related research at institutions in states where NIH support has historically been low, many of which have significant minority and medically underserved populations. NCRR's Research Centers in Minority Institutions (RCMI) program builds capacity at minority institutions to bring more minority scientists into mainstream research, enhancing studies of minority health and reducing health disparities.

Strategy 1

Support efforts that will encourage increased quality and efficiency in the conduct of basic, clinical, and translational research.

Focused efforts are under way to increase the quality and efficiency of clinical and translational research. This will allow researchers to develop new knowledge and thus provide new treatments more quickly and effectively to patients across the country.

Cynthia McEvoy, M.D., a neonatologist, and Daniel Marks, M.D., Ph.D., a pediatric endocrinologist, tend to newborn Diego in the neonatal intensive care unit of the Doernbecher Children's Hospital at the Oregon Health & Science University (a CTSA grantee) in Portland, Ore. Drs. McEvoy and Marks are collaborating on a study to look at the effects of maternal nutrition on prenatal development. The study is an extension of animal research that Dr. Marks conducted, which was supported through a pilot grant from NCRR's CTSA program. (Photo Credit: Rick Rappaport Photography)

Researchers in the laboratory of Donald E. Palm, Ph.D., at Florida A & M University College of Pharmacy and Pharmaceutical Sciences, investigate the molecular underpinnings of stroke and Parkinson's disease to identify new treatment modalities. In this photo, postdoctoral fellow LeeShawn Thomas, Ph.D. (left), and master's student Taaj Shelton prepare to examine the results of a Western blot, a technique used to detect the identity and size of a specific protein in a mixture of proteins. Florida A & M University is 1 of 18 locations that host the NCRR-supported RCMI program, whose mission is to expand the national capacity for research in the health sciences by assisting, through grant support, predominantly minority institutions that offer doctorate degrees in the health professions or health-related sciences to strengthen their research environment. (Photo Credit: Denise Gordon, Florida A & M University College of Pharmacy and Pharmaceutical Sciences)

Action Items:

CTSA NCRR will support the efforts of the CTSA consortium to:

- Develop best practices, training, tools, workflows, databases, and analysis tools that assist investigators in the development and performance of clinical and translational protocols to quickly and efficiently address important questions in multiple areas of science, while assuring high quality and appropriate protection of human participants.
- Develop metrics, workflow management, and communications to improve the efficiency of the clinical research process from start to finish.
- Provide investigators with integrated training, services, or tools for protocol and informed consent authoring and tracking, adverse event reporting, safety, and regulatory management and compliance.
- Share best practices that reduce institutional barriers and enhance inter-institutional collaboration.
- Ensure that collaborative clinical and translational research activities are facilitated and are in compliance with the institutional review board (IRB) requirements, and ensure protection of research participants.

RCMI NCRR will support the efforts of the RCMI program to:

- Provide support for resources to facilitate basic biomedical research in RCMI sites.
- Coordinate clinical and translational research activities by reorganizing the various RCMI clinical and translational research infrastructure-related activities into one integrated program called the RCMI Infrastructure for Clinical and Translational Research (RCTR).
- Provide investigators in minority institutions with integrated training, core resources, and tools to improve the clinical and translational research process.

- Use intra- and inter-institutional collaborations and partnerships to develop and share best practices for prevention, diagnosis, and/or treatment of diseases to reduce health disparities.

NCRR will increase the opportunity for multisite clinical and translational research among minority and other collaborating institutions through the RCMI Translational Research Network (RTRN). NCRR will support the efforts of the RTRN to:

- Provide infrastructure to facilitate secure data entry, management, and sharing across multiple sites in support of collaborative clinical and translational research, including attention to national standards.
- Serve as a national resource to facilitate multisite clinical and translational research in health disparity areas.
- Promote the inclusion and participation of underrepresented minorities in clinical and translational research and training.

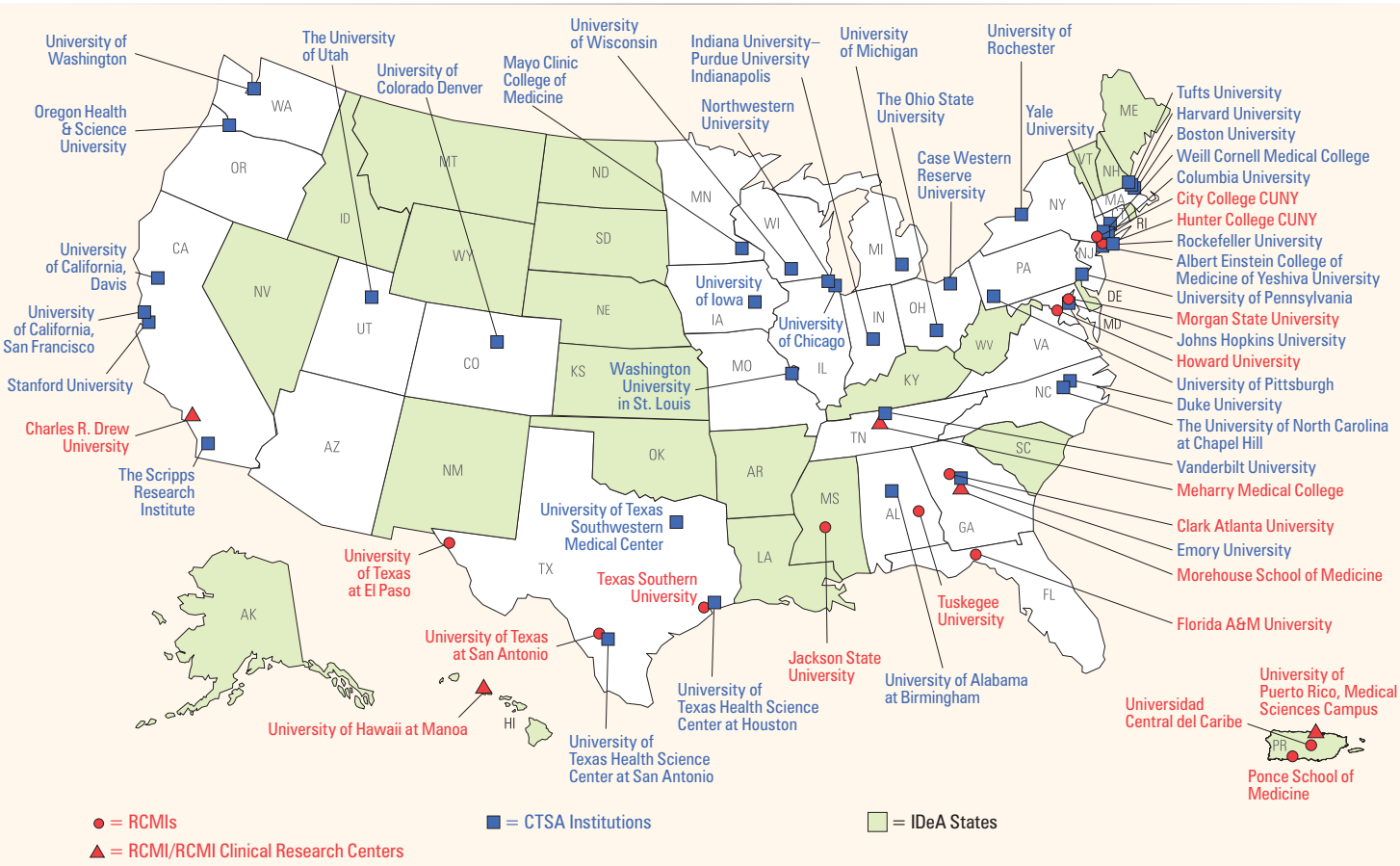
Strategy 2

Build research capacity in IDeA states.

NCRR will continue to support the two major activities of the IDeA program: the Centers of Biomedical Research Excellence (COBRE) and the IDeA Networks of Biomedical Research Excellence (INBRE). COBREs are thematic multidisciplinary centers that augment and strengthen institutional biomedical research capacity by expanding and developing biomedical faculty research capability and enhancing research infrastructure, including the establishment of core facilities needed to carry out the objectives of multidisciplinary, collaborative programs and facilitate the development of new disease-specific research centers or augment the capability of existing centers. INBREs support the development, coordination, and sharing of research resources and expertise to expand the research opportunities and increase the number of competitive investigators in the IDeA-eligible states. By doing so, the INBREs enhance the caliber of scientific faculty at research institutions and undergraduate schools, thereby attracting more promising students to biomedical research careers.

Action Items: NCRR will:

- Build active biomedical research environments in U.S. states that do not receive significant NIH support in order to improve access to modern, state-of-the-art biomedical research for students, researchers, and the general public in these states.
- Ensure that states without medical schools have an opportunity to develop research capacity to conduct basic biomedical research and that special populations within these states are included in clinical research.



Three programs of NCRR—CTSA, RCMI, and IDeA—provide the integrated research infrastructure, community engagement, and mentoring/career development needed to underpin successful clinical and translational research. This map will evolve over the next five years and beyond as the CTSA program grows and additional collaborations form among the three programs.

- *NCRR's **CTSA program** is creating academic homes for a new, unified discipline—clinical and translational science—at institutions across the country. Beginning in 2006 with 12 academic health centers located throughout the United States, the consortium will link about 60 institutions (www.CTSAweb.org).*

- *The **RCMI program** is bolstering research capacity and infrastructure in institutions whose enrollment is at least 50 percent students from communities underrepresented in the biomedical sciences, including African Americans, Hispanics, American Indians, Alaska Natives, Native Hawaiians, and Pacific Islanders. Five of the 18 RCMI-supported institutions have clinical research centers with a special focus on health conditions that affect racial and ethnic minorities.*

- *NCRR's **IDeA program** is helping states with historically low rates of success in obtaining NIH funding by providing grants to institutions and communities in 23 states and Puerto Rico for biomedical research and outreach to unique populations. The IDeA program is producing a pipeline of homegrown researchers who will become leaders in competing for federal research dollars, a process that will ultimately lead to reductions in health disparities.*

- Provide opportunities to address health disparities in medically underserved groups residing in IDeA states and to have members of these groups included in research conducted in non-IDeA states and nationally.
- Foster opportunities for communities and tribal health centers, especially in IDeA-eligible states, to have access to health research opportunities and be included in clinical and translational research.
- Promote technology transfer, entrepreneurship, and public-private partnerships to create and enhance vibrant translational research environments around IDeA-supported institutions.
- Ensure increases in research capacity and competitiveness in IDeA-eligible states.
- Provide opportunities for talented undergraduate students to participate in research training and research careers in the biomedical sciences.
- Provide opportunities for bioinformatics cores and cyberinfrastructure networks to support biomedical sciences through INBRE.
- Provide support for infrastructure and core facilities at COBRE institutions.
- Encourage collaborations among IDeA research resource centers to capitalize on each other's unique capabilities to solve complex research queries, and encourage consolidation of research resources that hold complementary technologies.

Strategy 3

Broadly and effectively engage communities in clinical and translational research.

Community outreach and engagement also are vital to ensure that research participants represent the rich diversity of the U.S. population, especially when addressing the special health concerns of high-risk populations and medically underserved and hard-to-reach communities. Working with community-based groups, such as voluntary and professional organizations, schools, women's health groups, and housing organizations, will help to ensure that research results reach communities.

Action Items:

CTSA

NCRR will support the efforts of the CTSA consortium and expand it to include the RCMI and IDeA academic research centers to:

- Engage patient advocacy groups, community groups, and their physicians in the research process from protocol idea through enrollment and study results dissemination.
- Engage the public in advancing health through recognition of the role of individuals in supporting and participating in clinical research and provide educational programs for the public on clinical research and its benefits.

- Foster bidirectional dialogues about community outreach, access, and dissemination of translational research results.
- Identify and establish partnerships to leverage additional support for community engagement activities.
- Develop evaluation outcomes and metrics for community engagement research.
- Convene workshops to accelerate the dissemination and translation of clinical research into practice.

IDeA

NCRR will continue to support a broad array of research, education, and training activities through the IDeA program to:

- Provide opportunities to address health disparities in medically underserved groups residing in IDeA states.
- Ensure that rural and remote communities and tribal health centers have access to health research and training opportunities.

RCMI and IDeA

NCRR will further build upon the unique resources of the RCMI and IDeA programs to:

- Capitalize on RCMI and IDeA grantees' experience to successfully integrate population-based approaches, research in health disparities, and establishment of trusted relationships with communities to improve the conduct of translational and clinical research.
- Create the necessary biomedical research workforce by engaging K–12 and undergraduate academic institutions in the RCMI and IDeA communities, thus providing additional career development opportunities.
- Increase collaboration among RCMI, IDeA, and CTSA grantees to address challenges among populations who face much higher rates of disease, premature death, and disability than other populations. Working together, these programs can address challenges that exist in clinical and community-based research to engage members of racial and ethnic minority groups and people living in rural or inner-city areas.

Strategy 4

Engage RCMI and IDeA communities as equal partners within, across, and beyond programs and institutions.

RCMI and IDeA institutions provide critical research resources and have greater accessibility to minority and underserved communities. By training and supporting researchers who are representative of their communities, these institutions ensure a greater understanding of the needs and challenges unique to their communities.

At the same time, RCMI and IDeA institutions can facilitate greater community involvement and participation in the research enterprise. By engaging as equal partners with other programs, these institutions will benefit from greater resources as well as provide valuable expertise and understanding in the research needs of their communities.

RCMI and IDeA

Action Item: NCRR will encourage equal partnerships between RCMI and IDeA institutions and CTSA and other NCRR programs through research collaborations, visiting professorships, work groups, and the sharing of resources and infrastructure.

Strategy 5

Demonstrate return on investment in basic, clinical, and translational science.

With such large investments across the research continuum, NCRR must demonstrate the return on such investment to its various stakeholders, including NIH partners, professional societies, the research community, Congress, and—ultimately—the public.

Action Items: NCRR will:

- Pursue a comprehensive national evaluation of the CTSA program to determine the effectiveness of the consortium to achieve its goal to transform clinical and translational science.
- Assess the contributions and impact of NCRR's diverse programs and research portfolio on facilitating and conducting biomedical research and advancing the disciplines of clinical and translational science.

The Center for Clinical and Translational Sciences (CCTS) is a collaboration of the University of Texas Health Science Center at Houston, the University of Texas M.D. Anderson Cancer Center, and the Memorial Hermann Healthcare System. Here, stroke researcher Nicole R. Gonzales, M.D., is testing a potential treatment for a hemorrhagic type of stroke. Dr. Gonzales is pictured with stroke survivor Joe Grant and his wife, Marie. Researchers also can utilize the services of the Genetics Core Lab, which provides DNA harvesting and banking, DNA genotyping, and DNA sequencing. Under the direction of Dianna Milewicz, M.D., Ph.D., the staff has the expertise to collect, analyze, and store data from biological materials. (Photo Credit: University of Texas Health Science Center at Houston)

Animal Models to Advance Translational Research

Scientists depend on laboratory animals and other nonhuman models for investigating biological processes, studying the causes of diseases, and testing promising new therapies. Nonhuman animal models also are indispensable for developing effective biodefense strategies and for investigating many other emerging health issues. NCRR supports research and research resources that develop and enhance access to a broad range of nonhuman animal models, including primates, rodents, zebrafish, worms, and cellular models. These programs include a network of eight National Primate Research Centers (NPRCs) with highly specialized facilities that foster the development of animal models such as monkeys and baboons and provide expertise in all aspects of nonhuman primate biology and husbandry. NCRR sponsors initiatives to improve the health and care of laboratory animals and also supports the Animal Facilities Improvement Program, which upgrades animal facilities, improves research animal care, and assists institutions in complying with the regulations and policies related to the use of laboratory animals.

Strategy 1

Expand and ensure the development of and access to animal models.

NCRR will provide the intellectual leadership to help guide the development and availability of critical animal models. This includes the need to:

- Continually evaluate the utility of and provide sustained support for valued traditional and nontraditional animal models.
- Evaluate and promote the application of new technologies (e.g., advanced imaging, stem cells) to animal resources.

Many major medical advances of the past century have been achieved, in part, because of translational research conducted in animal models. However, many serious diseases still threaten our well-being: many types of cancer, HIV/AIDS, Alzheimer's disease, and Parkinson's disease, to name a few. Finding ways to treat and prevent these and other ailments will involve the use of animals (such as rhesus macaques, a type of monkey, shown in the photograph) to lay the groundwork for clinical studies. The eight NCRR-funded NPRCs are catalyzing such translational research efforts. Closely affiliated with U.S. academic institutions and strategically located across the country, the NPRCs together have more than 27,500 animals representing more than 20 species of nonhuman primates, mostly macaques. (Photo Credit: iStockphoto)

Action Items: In this leadership role, NCRR will:

- Support the continued access to and availability of the highest quality—disease free or genetically defined—range of commonly used animal models for biomedical research.
- Evaluate the need for nontraditional species and their further characterization and utility for biomedical research.
- Continue to provide support for the Animal Facilities Improvement Program.
- Promote and facilitate the development of partnerships with NIH categorical Institutes and Centers (ICs) to pool resources. The development of partnerships will be carried out through:
  - Workshops and meetings organized in collaboration with NIH ICs to showcase the research models at NCRR-funded Animal Resource Centers that are available to investigators.
  - Coordination of efforts allowing resources to work together, resulting in the formation of more efficient programs for access to models and information.

Strategy 2

Create a "knowledge environment" to allow researchers to find out what disease model resources exist and their utility for the study of various diseases.

Preclinical research advances are changing the entire process of discovery of methods of treating human disease; for example, the increasingly common use of microarray analyses generates vast quantities of potentially disease-illuminating data that are useful to many investigators but frequently cryptic to those not associated with the actual data generation. Because of these advances, there is greater

Mice have been found invaluable by NIH researchers over the years. The mouse is particularly important because it is the only mammalian species in which researchers can delete one gene at a time from the genome. A trans-NIH initiative, the Knockout Mouse Project (KOMP), was conceived in 2003, and this project is aiming to eventually disrupt, or "knock out," each of the 20,000 or so genes in the mouse genome. The aim is to create 8,500 to 10,000 new lines of knockout mice, tripling the number that existed in 2007. The newly established repository, funded by NCRR, the National Human Genome Research Institute, and the National Institute of Allergy and Infectious Diseases, will make knockout mice available to researchers as live mouse lines, embryonic stem cell clones, frozen embryos, and sperm. Researchers then will be able to study the mice to develop better models of many human diseases. (Photo Credit: iStockphoto)

urgency for effective integration and application of disparate data sources. The problem is not simply a lack of resources or their archiving, but the lack of our current ability to analyze the data and to share the results across multiple institutions or disciplines. Many of these data are collected and maintained by individual investigators or laboratories that publish only selected results in scientific journals. Negative or nonprocessed data, as well as the processing tools to convert data into analytical formats, need to be made widely available. This approach will prevent unnecessary time being spent on studies that are performed multiple times. Nowhere is this data integration challenge of preclinical research more prominent than in informatics related to animal models.

Action Item: NCRR will lead the development of an informatics system related to animal models to bridge gaps that now exist in the ability to share and use information effectively. The following are a few of the important "knowledge environment" system characteristics:

- Easily extensible—evolves concurrently with technology.
- Links the mechanisms of action to human diseases.
- Relational among different animal models.
- Provides for nonintuitive data discovery (i.e., identifies relevant data from unanticipated sources).

Strategy 3

Further integrate biological material resources with clinical and translational research.

Since animal models bridge basic science with human medicine, synergies are currently emerging among the CTSAs, RCMIs, and NPRCs. These collaborations are helping to promote a pathway to move discoveries from the bench to the bedside.

The NCRR-funded Sea Urchin Genome Resource at the California Institute of Technology provided critical reagents and informatics support for sequencing the genome of the purple sea urchin, Strongylocentrotus purpuratus. *The sequencing was performed at the Baylor Human Genome Sequencing Center, funded by the National Human Genome Research Institute. The sea urchin genome, which consists of about 23,300 genes, is closer on the evolutionary scale to the genome of humans than to other invertebrate animal models that are often used by developmental scientists. Equipped with knowledge of the sequence and analysis of the 814 million DNA bases that make up this marine animal's genome, researchers will be able to perform functional studies in a simple animal model that shares a common ancestor with vertebrates. (Photo Credit: Laura Francis, National Oceanic and Atmospheric Administration)*

As the priorities of biomedical research shift from basic molecular and cellular research to translational research, the importance of having veterinarians skilled in translational medicine has increased. The challenge now is to identify, recruit, train, and retain veterinarians who can be principal investigators or other key members of research teams in a variety of initiatives. Through NCRR Institutional Research Training Grants, veterinarians are receiving essential training to prepare them for careers in biomedical research. The photograph shows Rachel Mo Peters, D.V.M., Ph.D., transferring samples to multiwell microtiter plates in a laboratory at Cornell University in New York. She earned her doctorate in comparative biomedical sciences under the university's training program sponsored by NCRR. (Photo Credit: Alexis Wenski-Roberts)

Action Item: NCRR will enable research scientists working at CTSA-, RCMI-, and NCRR-supported Animal Resource Centers to engage in productive, mutually beneficial collaborative research relationships that take full advantage of the knowledge and infrastructures of both the clinical and animal resource entities. These new partnerships will aim to utilize animal or biological materials for preclinical investigations leading to cutting-edge translational science programs. In addition to utilizing the specific models, the partnerships also may facilitate sharing of research cores, such as pathology, informatics, or statistics, thus helping to increase resource utilization and cost-effectiveness among the CTSA, RCMI, and NPRC grantees, as well as with other animal resources. Focus will be placed on collaborations that involve sharing of knowledge, expertise, or labor costs associated with researchers working together to accomplish a common mission.

Strategy 4

Increase the number of qualified research veterinarians and ensure that veterinarians are recognized partners on translational research teams.

Veterinarians play a critical and unique role in government, academia, and industrial organizations engaged in biomedical research. In particular, the One Medicine–One Health concept offers opportunities to encourage partnerships between human and veterinary medicine. There are considerable challenges in identifying, recruiting, training, and retaining veterinarians who can fill these research roles. With biomedical research priorities shifting from basic molecular and cellular research to translational research, the importance of animal models and, therefore, veterinarians skilled in comparative medicine has increased.

Action Item: NCRR will address the growing need for research-trained veterinarians by sponsoring career development programs that attract and train graduate veterinarians in such specialties as primate clinical medicine, laboratory animal medicine, and rodent pathology.

Strategy 5

Ensure an ongoing adequate infrastructure (facilities, animals, and workers) for animal research.

Primate centers need support to upgrade and expand the space they have, enabling them to move research forward and have the flexibility they need to provide more models targeted toward specific diseases, such as AIDS, avian influenza, and obesity. The same holds true for other research animal centers and resources. Appropriately designed facilities are needed to support research using these animal models. Adequate resources also are required to train clinical veterinarians to properly manage and care for these valuable research animal models, given their specialized veterinary care needs.

Action Items: NCRR will continue its effort to:

- Renovate and upgrade, through the Animal Facilities Improvement Program, current animal resource facilities that support biomedical and behavioral research in order to comply with the Animal Welfare Act and provide the appropriate environment suitable for housing the targeted animal models.
- Maintain liaison with the biomedical research community through outreach activities (e.g., workshops, seminars, participation in professional meetings or other similar activities) to remain up-to-date on current requirements for animal facilities.
- Develop incentives and funding sources designed to attract veterinarians into laboratory animal medicine, pathology, and other areas of clinical and translational research.
- Modulate the size and output of breeding colonies (including nonhuman primates) to match the demand for specific animal models.
- Develop cryopreserved archives of specific animal models, such as genetically modified rodents, to achieve cost savings.

Strategy 6

Continue enhancement of activities related to cryopreservation of animal germplasm and related technologies.

The ability to produce transgenic, knockout, and mutant lines of many animal species has provided biomedical researchers with many models for the study of human diseases. However, the requirements to maintain these strains as live animals can overwhelm the capacity of even the largest animal model resource center. Although cryopreservation of gametes and embryos is a proven method for the long-term maintenance of laboratory animals, there are wide differences in the success with which various forms of germplasm can be cryopreserved in various species. With researchers producing thousands of new strains, NCRR needs to critically assess the status of the cryopreservation of germplasm and embryos for cost-effective management of breeding colonies in NCRR animal resource centers.

Action Items: NCRR will:

- Encourage the development of innovative research in the areas of high-throughput and scalable animal germplasm cryopreservation methods.
- Support the development of multidisciplinary teams to establish new approaches to the collection, cryopreservation, and distribution of germplasm for high-priority translational species through workshops or meetings.
- Promote novel "high-risk/high-return" preservation technologies through the Small Business and Exploratory/Developmental Research Grant programs.

Strategy 7

Foster ways to prioritize need and determine the validity of animal models.

NCRR will, in collaboration with other NIH ICs, develop a priority list of needed validated animal models. Validation criteria should be defined and should include, at a minimum, the characteristics of the animal that make it useful as a model for the study of human disease and descriptions of mechanism-of-action studies that indicate whether the endpoint for the model is reached through the same pathway as for the human condition.

Action Item: NCRR will hold a workshop in partnership with grantees, other NIH ICs, or the pharmaceutical industry to determine:

- A priority list of needed models based on unmet medical needs.
- Which models require validation.
- Whether it is feasible to validate the use of particular animal models and, if so, what the validation criteria are.
- Mechanism(s) to create a pooled source of money that is targeted to models of high interest.

Clinical Research Applied to Patients

1950s

- Standardized memory tests for assessing amnesia
- Study of amnesic cases implicates the temporal lobe

Research with Nonhuman Primates

1960s–1990s

- Clarification of the role of the hippocampus in memory
- Development of recognition memory tasks for monkeys, including eye tracking

1990s–2000

- Mild cognitive impairment (MCI) identified as a precursor to Alzheimer's disease
- Determination that hippocampal pathology is linked to MCI

2000

- Discovery in monkeys that recognition memory tasks are especially sensitive to hippocampal damage

2006

- Memory tasks developed in monkeys adapted for early assessment of MCI
- Eye-tracking technology adapted from work in monkeys

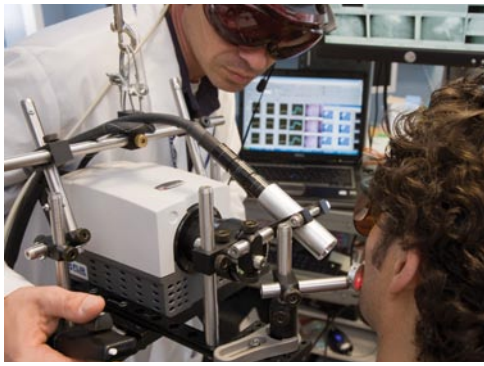
2008

- Research into the use of recognition memory tests and eye-tracking technology to rehabilitate memory impairment by guiding training and monitoring success: MCI, traumatic brain injury, HIV

Historically, research in neuroscience and neurodegenerative diseases has been translational in nature, essentially a dance between research in nonhuman primates and that in humans. Research using nonhuman primates serves as a basis for clinical research, and clinical research provides additional questions to explore in nonhuman primates. One technology that has arisen from work in nonhuman 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 mild cognitive impairment (MCI) and, of those with MCI, who will develop Alzheimer's disease. Other studies focus on the use of eye tracking to rehabilitate patients with brain injury or cognitive impairment. Moreover, the NCRR-funded NPRCs hold the promise of developing models for neurodegenerative diseases. (Courtesy of Stuart M. Zola, Ph.D., Yerkes National Primate Research Center. Photo Credit: Getty Images, Inc.)

III Technologies to Advance Translational Research

Technology underpins all of biomedical research—from basic discovery to clinical application. To solve structures of proteins or to study physiological mechanisms *in vivo,* biomedical researchers need advanced instruments, methods, and computing tools. In support of this effort, scientists, clinicians, and engineers work together at Biomedical Technology Research Resources (BTRRs) to create critical, often unique, technology and methods for application to a broad range of basic, translational, and clinical research. BTRR scientists also actively engage other biomedical researchers, providing them with training and access to these new tools. Thus, the broader research community benefits from these innovative technologies. The results of these interactions are disseminated both within the resources and through intensive collaborations with other leading laboratories. In addition to being rapidly and widely adopted by these individual laboratories, technologies developed in the BTRRs also are incorporated into state-of-the-art commercial products.



The NCRR-funded Laser Microbeam and Medical Program (Irvine, CA) develops medical laser technologies in which laser light is used to detect, diagnose, and treat abnormal biological tissue. By evaluating the effects of light aimed at a target, biological structures can be visualized and functional properties, such as hemodynamics, can be gauged. Here, a short pulse from a laser is directed to an area with a vascular abnormality on a patient's face. The light induces a small temperature rise in subsurface blood vessels, thereby allowing them to be imaged with a heat-sensitive camera. This procedure yields such information as depth, size, and density of the vessels, which can be used in planning treatment of vascular lesions. (Photo Credit: Paul Kennedy)

Strategy 1

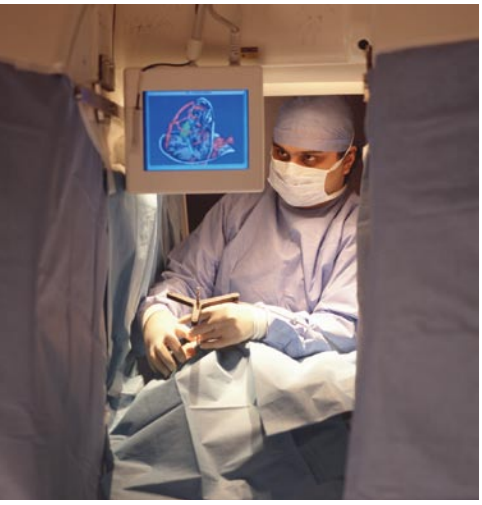
Expand and ensure the development of technologies to support translational research.

NCRR will provide the intellectual leadership to help guide the development and availability of critical biomedical technology resources. This includes the need to:

- Continually evaluate the utility of and provide sustained support for valued technologies.
- Evaluate and promote the application of new technologies to the translational process.
- Pursue new opportunities for technology development that have potential for a large impact in the clinical sciences (e.g., clinical proteomics and analysis of transient molecular complexes).

Action Items: In this leadership role, NCRR will:

- Support continued availability of and access to leading-edge technologies and evaluate the balance and quality of BTRR with periodic advice from an external advisory panel.
- Promote and facilitate the development of partnerships with NIH categorical ICs to leverage resources. NCRR plans to:
  - Convene workshops and meetings organized in collaboration with NIH ICs to assess community needs and showcase the technologies that are available to investigators.
  - Coordinate efforts among grantees to maximize efficiencies that enable greater access to technologies and information.



A neurosurgeon at Brigham and Women's Hospital in Boston, Mass., views a three-dimensional image of his patient's brain. This image, which was obtained through magnetic resonance imaging (MRI), shows the brain's internal structures in relation to the tumor (in green). The image, generated through several MRI scans, helps the surgeon determine the precise location of the tumor and thus minimize the invasiveness of the surgery. (Photo Credit: Photo Researchers, Inc.)

- Encourage the further development and translation of technology and basic research sponsored by the IDeA program, in collaboration with other NIH ICs.

Strategy 2

Further integrate biomedical technologies into clinical research activities.

It is imperative that biomedical technologies be employed to the maximum extent possible to facilitate and accelerate the movement of basic research to clinical applications. The success of this approach has been exemplified by BTRR scientists using laser spectroscopy in the operating room to help surgeons make better decisions more quickly. BTRR-created resources in glycomics were leveraged by a new National Cancer Institute program to translate discoveries into clinically useful biomarkers. Similarly, the CTSA program is beginning to access and leverage the translational expertise in the BTRR program.

Action Items: NCRR will:

- Support biomedical projects that will link technology centers and clinical and translational programs to increase convergence of missions. These projects will often involve training and education in addition to research.
- Foster relationships between CTSA and BTRR grantees that lead to joint proposals around a few clinically relevant issues. Alternatively, encourage BTRR grantees to cooperate with a COBRE, RCMI, or other clinical center around a specific focus, such as mass spectrometry.
- Encourage grantees to bring students together to work on a project that clearly links the aims of a technology with a clinical research activity.

Strategy 3

Develop affordable and flexible technologies that can be applied to translational research.

Many advanced technologies under development by BTRR researchers have the potential to help not only in the research setting but also for routine clinical use. Optical sensors, clinical mass spectrometry, glycomics, proteomics, and informatics technologies applied to image-guided therapy are a few examples of areas in which focused effort may allow research tools to be developed sufficiently to become standard approaches. Collaboration among BTRR and CTSA researchers will combine the technical and clinical expertise necessary to drive these advances.

Potential targets include:

- Data integration technology.
- Mass spectrometry–based diagnostic tests.

- Clinical applications of proteomics and glycomics.
- Validation of vibrational spectroscopy as a real-time diagnostic tool.
- Integration of imaging or microscopy approaches across a range of scales from sub-nano to micro.

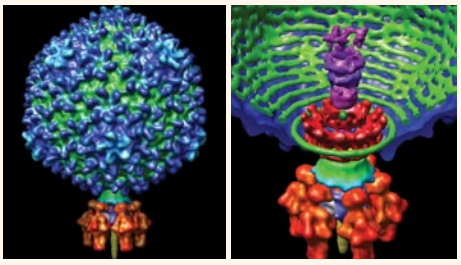
Action Items: NCRR will:

- Solicit applications for Small Business Awards (SBIR/STTR) to address technology needs not addressed through other means. By supporting these awards, NCRR will encourage partnerships between academics who understand the problems and the companies that develop the technologies.
- Continue and expand instrument development with emphasis on developing instrumentation with a high potential for clinical application.
- Continue to support the Shared Instrumentation Grant and High-End Instrumentation Grant programs, which provide NIH-funded investigators with cutting-edge research tools for their studies on human health and disease.
- Explore novel approaches for placing advanced instrumentation into the hands of more clinical researchers.
- Convene a workshop, with other federally-funded agencies, to explore instrument development opportunities for biomedical research.

Strategy 4

Develop additional areas of expertise and knowledge, especially at the crossroads of mathematics/physics and medicine.

Many advanced technologies that now serve medical science had their roots in mathematics and physics. Translational science often entails the rapid generation



These two photographs depict the P22 virus, a bacteriophage that infects the food-borne pathogen Salmonella. *The left photo shows the virus in full view, while the right photo, a cross section, reveals the mechanism that packs DNA into the virus. Studying the structure of viruses in detail is important for many reasons, among them the possibility of locating targets for drugs that might keep a virus from replicating. These studies of P22 replication were made possible through the use of a cryo-electron microscope at the National Resource for Automated Molecular Microscopy (NRAMM) in La Jolla, Calif. In recent years, the NCRR-funded NRAMM has developed innovative tools that automate the process of collecting images, which speeds the process and reduces labor. More than 50 studies have been conducted at NRAMM that involved the cryo-electron microscope. (Photo Credit: Gabriel Lander, the Scripps Research Institute)*

of large analytical datasets (e.g., genomic, proteomic, metabolomic) to be integrated and interpreted using informatics systems designed by mathematicians. Therefore, it is critical to forge new alliances to encourage mathematicians and physicists to work at the interface between basic science and clinical opportunity, with the ultimate aim of improving the nation's health.

Action Items: NCRR will:

- Work with its grantees to convene workshops, short courses, degree programs, and graduate-level courses that support knowledge convergence across disciplines.
- Foster the inclusion of students of mathematics, physics, and engineering in biomedical research experiences through the INBRE program.
- Encourage the development of the critical faculty required for awarding advanced degrees in bioinformatics, for instance, in the IDeA program.

Strategy 5

Provide investments in information technology to facilitate greater collaboration and participation in translational research by minority and minority-serving research institutions and minority and medically underserved populations and communities.

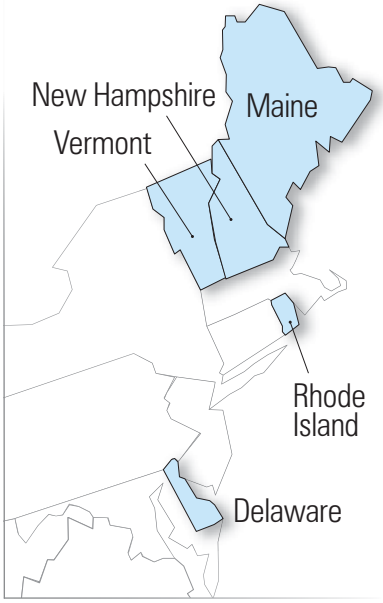
Coordinated investment in information technology infrastructure is critical to enabling and advancing the activities of partnerships and consortia, particularly in underserved communities. Information technology resources need to be maximized for collaboration within and across an institution's functional units, as well as to enable greater exposure to other clinical and translational research opportunities.

NCRR is committed to enhancing network connectivity so that research institutions in underserved states can participate in bandwidth-intensive science applications. Building on statewide INBREs, the IDeANet initiative provides regional access to national and international high-speed networks, computational resources, and bioinformatics software tools and training. IDeANet's initial effort, dubbed the Lariat Project, established high-speed links to the Internet2 and National LambdaRail backbones for a consortium of universities in six largely rural western states. In addition, RTRN is facilitating the participation of the five RCMI Clinical Research Centers in collaborative clinical and translational research by providing the technology infrastructure and data management resources to support these studies.

Action Items: NCRR will:

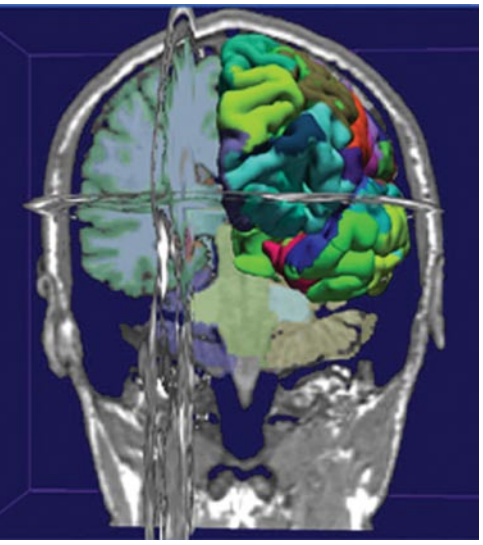
- Expand the IDeANet initiative to other regions across the country to enhance network connectivity at additional IDeA-eligible institutions, including primarily undergraduate institutions and minority-serving institutions. In addition, IDeANet will eventually provide critical network infrastructure to IDeA and RCMI investigators across the nation, enabling collaboration and connections to other networks, such as NCRR's Biomedical Informatics Research Network (BIRN) and the CTSA consortium.
- Expand RTRN to enhance the clinical informatics resources available to additional RCMI sites that are engaged in clinical and translational research.
- Facilitate partnerships with other federal agencies, such as AHRQ, HRSA, USDA, DOE, NSF, VA, DoD, FCC, and IHS, to leverage investments in network connectivity and health information technology. These partnerships will also foster increased collaboration among researchers, health care providers, and patients to speed translation of research into practice.

Northeast Network Initiative



The Northeast Network Initiative, launched in fiscal year 2007, is a collaborative research effort in five IDeA states to improve access to nationwide research networks and resources. NCRR is committed to enhancing the connectivity of networks so that research institutions, especially in underserved states, can participate in bandwidth-intensive science applications. NCRR's support for network upgrades will enhance participation in NCRR programs at IDeA institutions located in these five states.

IV. Informatics Approaches to Support Research



The NCRR-supported Morphometry Biomedical Informatics Research Network (mBIRN) is pooling and analyzing data across neuroimaging sites to explore potential relationships between anatomical differences and specific dysfunctions of memory. This image of brain morphology reveals segmentation of white and gray matter and cortical parcellations generated by the FreeSurfer software tool and interactive visualization by 3-D Slicer. The data were collected by mBIRN as part of a multisite, multivendor magnetic resonance calibration effort to improve the accuracy and statistical power of large-scale brain imaging clinical studies. (Photo Credit: Steve Pieper, Isomics, Inc., and Surgical Planning Laboratory, Brigham and Women's Hospital)

Informatics is an overarching theme that permeates all the strategies and areas in this *Plan*—clinical and translational research, animal models, technology development, and advancing underserved communities. All investigators require new informatics knowledge and tools that will allow them to:

- Collect, manage, and analyze the large amounts of data that are increasingly needed to address their questions.
- Share and combine their raw data in understandable ways with other investigators in all areas of research to move research forward more quickly.
- Ensure confidentiality and privacy of human data at all levels.

NCRR is committed to working with other agencies, NIH ICs, and industry to bring informatics knowledge and tools to researchers at all levels. Several NCRR-supported programs currently provide informatics resources.

- Eleven different BTRRs focus on informatics; each produces and distributes software for data analysis or simulation and modeling of biological systems.
- BIRN uses emerging technology advances to enhance collaborative efforts that integrate data, expertise, and unique resources across the country.
- Several bioinformatics core facilities supported by the IDeA program's INBRE initiative provide critical access to bioinformatics resources and training opportunities for undergraduate and graduate students in a wide variety of urban, rural, and minority-serving academic institutions.
- Many of the IDeA program's COBREs include bioinformatics core facilities to assist with data management, analysis, and sharing for proteomics, genomics, and other research applications.
- Many institutions supported through the CTSA initiative are sharing knowledge and tools to solve common problems and are committed to making data and software available.

NCRR will continue to support and address integration of informatics research and solutions in all its programs and centers. In addition, NCRR will pursue integration across the various domains of knowledge and research within NCRR and its partners at other NIH ICs, other federal agencies, industry, and foundations. Issues of integrity, durability, availability, and security of data will continue to play a critical role in this era of fast-moving technologies and analysis tools.

Strategy 1

Facilitate information sharing among biomedical researchers.

Connectivity to the Web and wide access to informatics tools enable information sharing and communication across geography and disciplines, as Google and other informatics resources have clearly shown. PubMed Central will make the results of NIH-supported published biomedical research widely available. Sharing of raw data has become commonplace in some fields, including the human genome sequence, as well as those of many other species. Other genetic and phenotype data are being collected and made available through the National Library of Medicine. Additionally, many NIH ICs, other federal agencies, and private organizations make data available for research. Many tools for data analysis also are broadly and freely available from NIH, investigators, and organizations. However, there are areas for progress in data availability and, in particular, in sharing of metadata associated with the data (i.e., data that increase the usability and quality of the data).

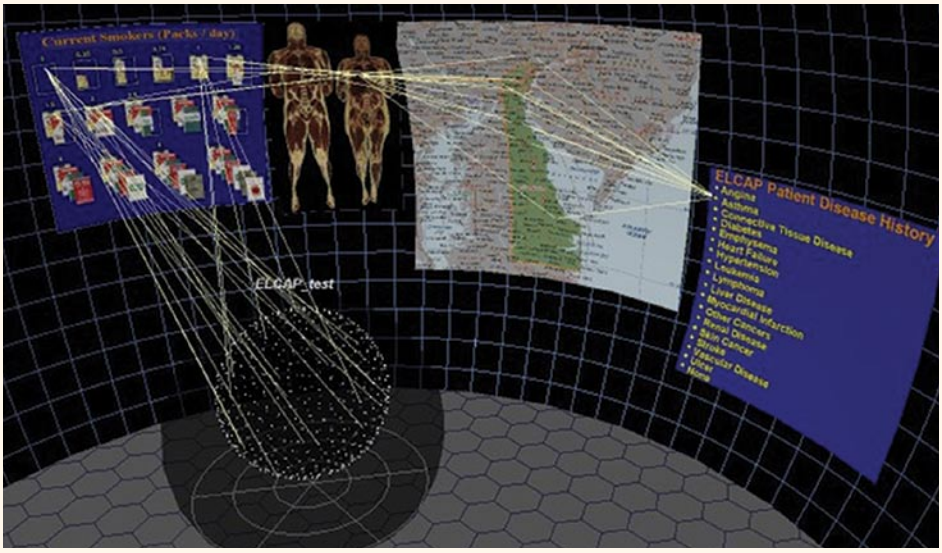
Sharing of de-identified raw clinical data and clinical research data is also common, including from the Centers for Medicare and Medicaid Services, NIH studies, and foundations. Careful attention is required to assure privacy and confidentiality in sharing and use of human data for research. Differing and conflicting regulations and approaches have made sharing of clinical data more difficult.

Many challenges still exist to facilitate information sharing for biomedical research:

- Issues related to accessing and querying text data are well advanced; however, approaches and tools for querying other types of data are much less well developed. This includes image, gene, structural, clinical, and digital data.

In 2006, Vanderbilt University used institutional resources to establish a DNA specimen and databank repository that is available to all Vanderbilt and Meharry Medical College investigators. Informatics support for requests to retrieve, genotype, and analyze these biobank samples and their associated de-identified clinical information will be provided through competitive funding requests from Vanderbilt University's CTSA program. This repository is a potent example of cross-program NCRR collaboration, given that Meharry Medical College has been a long-standing recipient of RCMI funding to support the infrastructure of shared resources. This image depicts a scientist in a laboratory logging samples in test tubes into a computer database; the inset shows the barcode scanning system used for cataloging biological samples. (Photo Credit: Dana C. Johnson, Vanderbilt University Medical Center)

- Collection of metadata associated with the data from all sources is critical for semantic and syntactic interoperability, that is, for the meaning of the data to be understood and for combination with other data. Increasingly, it is also important for data to be understood by a computer, or computable, because vast datasets do not permit analysis by humans. Challenges exist in capturing the associated data, because they may not exist in databases. Whereas data that are carefully defined with standard vocabularies and ontologies are required in some cases, many data can be very useful with less granular information.
- Data models, structures, and formats also are critical for the sharing of data. Lack of industry standards for machine data and lack of agreement, particularly in emerging research areas, make sharing difficult. There are ongoing efforts in many communities related to these issues.
- Clear and common agreements on policy and technology requirements for sharing of human data would facilitate sharing of these data.



University of Delaware researchers collaborate with physicians at the Christiana Care Health System to develop innovative methods for visualizing complex biomedical data. This image, created by Karl V. Steiner, Ph.D., at the Delaware Biotechnology Institute, shows work based on a study conducted by Thomas Bauer, M.D., a thoracic surgeon at the Helen F. Graham Cancer Center, as part of the "International Early Lung Cancer Action Program (I–ELCAP)." The data are displayed using Starlight, a visualization-based information system developed by Battelle that allows for interactive, visual analysis of epidemiology patterns. The image displays multivariant correlations of such topics as patient disease history, diagnosis, age, gender, body mass index, home location, and smoking patterns. The project was supported, in part, by NCRR through the Delaware INBRE program. (Photo Credit: University of Delaware)

- Access to tools for management and analysis of the data is necessary. Many tools and computer cycles can be made widely available using a grid-based computational structure.

Action Items: NCRR will:

- Work to implement policies that encourage or require investigators to share data collected with NIH support and to describe their data-sharing plans in detail in their applications.
- Work with academic institutions, patient advocacy groups, NIH ICs, and other agencies to develop procedures that facilitate the sharing of human data for research by its centers and programs while protecting confidentiality and privacy.
- Continue to support and modernize the BIRN and RTRN data-sharing infrastructure and attempt to facilitate the use of that infrastructure in a variety of research communities.
- Continue to support COBRE and INBRE bioinformatics core facilities, computational resources, and network connectivity upgrades at IDeA-eligible institutions.
- Explore ways to work with NSF, DOE, other agencies, and industry to develop tools to analyze large amounts of data and to develop tools to query heterogeneous datasets.

Strategy 2

Encourage institutions to provide informatics-based approaches to basic, clinical, and translational investigators and their research teams to support all aspects of their research.

The transformation of clinical and translational science requires a visionary approach to management and sharing of information, which can only be accomplished with ubiquitous access to tools and processes by investigators to enhance the quality, availability, security, collection, and analysis of data. It is recognized that the informatics needs identified today for clinical and translational research will be rapidly augmented by new demands. Therefore, the supporting infrastructure needs to be flexible to respond to new challenges as they arise and scalable to accommodate increases in demand and the amount of data.

The performance of clinical and translational research requires a systematic approach to defining hypotheses and selecting a study design, including, in many cases, appropriate statistical power, that assures the study questions can be answered without putting human participants at inappropriate risk. In addition, clinical research requires multiple reviews by regulatory bodies and, in some cases, oversight by a data and safety monitoring board. This process can be complicated

and may require multiple revisions of the protocol prior to implementation. At many institutions, investigators do not have tools to assist in this process nor in the performance of the study. Informatics-based approaches have been very helpful in tracking protocol development and approvals and also in assuring that the quality of the study and its ability to be implemented are not impeded in the process.

Action Items: NCRR will:

- Encourage NCRR-supported institutions to collaborate on the implementation, adaptation, development, and application of tools for clinical and translational investigators and their research teams.
- Provide forums for exchange of information between researchers, informaticists, institutional information technology personnel, and others on clinical and translational research process and workflow and interfaces with clinical care, animal models research, and basic structural and physiologic databases.
- Support development of informatics approaches that will be flexible to respond to new challenges as they arise and scalable to accommodate increases in demand and the amount of data.
- Develop ontologies and repositories to allow mapping between nonhuman models and human diseases.

Strategy 3

Maximize the use of informatics-based approaches to conduct clinical research.

Significant deficiencies exist in the approaches to support clinical studies and trials at academic institutions. Process and workflow modeling of clinical study development—from hypothesis formation through protocol and informed consent development; regulatory approvals; study implementation, including data collection; case report form design; data validation; analysis; and administrative and budgetary management—should facilitate the design and utilization of novel approaches. Informatics-based approaches grounded in the processes and workflows of clinical researchers and those involved in research with human participants will increase safety, quality, and ability to efficiently conduct such studies at academic institutions.

Action Items: NCRR will:

- Encourage the modeling of clinical research study development, regulatory approval, implementation, conduct, analysis, and dissemination with attention to standard practice of research by researchers and staff to aid the selection of appropriate informatics-based approaches that facilitate quality, safety, and usability.

- Use informatics-based approaches and institution policies to ensure the security and privacy of all human participant clinical research data of all investigators.
- Evaluate and facilitate the dissemination of tools that support data collection and validation.
- Develop tools to link pharmaceutical knowledge and applicable systems biology principles.
- Assure availability of flexible and easy-to-use systems that fit researchers' and their staff's work needs and environments to allow reporting in real time of adverse events related to research.

Strategy 4

Support the development of educational training competencies in informatics for biomedical researchers.

The challenges of conducting biomedical research currently and in the future require that researchers have an understanding of a set of core competencies in informatics. While many informatics training programs exist in the country, supported by the National Library of Medicine, there are few training programs in clinical and translational science and veterinary medicine that include informatics as a part of their curricula. However, these scientists will need to have a working knowledge of basic concepts regarding standards, ontologies, database theory, and knowledge management to use the tools and approaches required to design, conduct, and analyze research projects. The challenge is to increase the number of "multicapable" scientists working at the interface between basic science and the basic knowledge that comes from new technologies; having scientists who can think about this translates into emerging clinical opportunities.

Action Items: NCRR will:

- Sponsor workshops and provide institutional support for short courses, degree programs, and graduate-level courses.
- Integrate clinical informatics into curricula developed through Clinical Research Education and Career Development awards through the RCMI program.

Strategy 5

Develop an online resource knowledge community for biomedical researchers.

To establish effective collaborations and partnerships and use the most effective tools, researchers must have access to and knowledge of state-of-the-art resources, technologies, and people in relevant areas. Many online resource and collaboration networks are arising, driven by this need. However, information about many NIH-supported resources is fragmented and difficult to locate, even via Internet searches. NCRR provides many resources in its multiple programs that could be further utilized.

Action Item: NCRR will pursue the development of a Web-based knowledge community of NCRR resources that encourages access by all biomedical researchers. NCRR will explore tools that allow users to interactively query the resources and community, analyze spatial information, and explore relationships.

V. Building the Research Workforce

NCRR offers training and mentoring programs that benefit researchers, clinicians, veterinary scientists, and a range of disciplines needed to move basic research to clinical practice. For example, through the CTSA program, NCRR is supporting advanced degrees in clinical and translational science. BTRRs offer training in specialized technologies. The RCMI program, in collaboration with seven other NIH ICs, supports curriculum-dependent programs in minority institutions to train investigators in clinical and translational research leading to a master of science degree in clinical research or a master of public health degree in a clinically relevant area. COBRE and INBRE support and stimulate the development of a pipeline for the next generation of biomedical researchers and health professionals at all levels. Such investments contribute to the workforce development in IDeA states. Within comparative medicine, several programs are addressing the need for veterinarians in research. Many of these programs are designed to address a shortfall of well-trained scientists to support a broad range of research. In addition, NCRR supports science education for the general public and students to enhance their understanding of health issues and career opportunities.

Strategy 1

Ensure a multidisciplinary clinical research workforce.

Clinical and translational science is only effective if multiple disciplines come together to solve complex biomedical problems. Therefore, training programs for multidisciplinary teams are needed that will expose them to clinical research de-

The technology development team for the Resource for Macromolecular Modeling and Bioinformatics (seated clockwise: Gila Budescu, D.Sc., Ph.D., Jim Phillips, Ph.D., Kirby Vandivort, M.S., and Robert Brunner, Ph.D.; Klaus Schulten, Ph.D., stands at the screen) is pictured at work in a software development meeting. The goal was to develop software that permits scientists to share views of molecular models in real time over the Internet—facilitating the true team science that NCRR seeks to support. For example, a researcher in Boston might prepare a perspective on a protein's active site to highlight the protein's function and mechanism. With this software, the image could be shared with colleagues anywhere in the world. Here, the development team discusses image quality and how to make the software user friendly. (Photo Credit: John Stone, provided courtesy of the NIH Resource for Macromolecular Modeling and Bioinformatics, Beckman Institute, University of Illinois at Urbana-Champaign)

Mr. Edem Blavo (left) and Mr. Ifedapo Adeniyi, students at Clark Atlanta University, presented their research at a poster session at a National Symposium on Prostate Cancer. The symposium is hosted by the RCMI-supported Center for Cancer Research and Therapeutic Development (CCRTD). Because many investigators at RCMI institutions, including CCRTD, study diseases that disproportionately affect minorities, the program serves the dual purpose of bringing more minority scientists into mainstream research and enhancing studies on minority health. (Photo Credit: Curtis McDowell, Clark Atlanta University)

sign, epidemiology, biostatistics, pharmacology, biomedical informatics, ethics, behavioral science, engineering, law, and health economics.

Action Item: NCRR will encourage investigators from diverse disciplines, including medicine, pediatrics, surgery, dentistry, nursing, engineering, veterinary medicine, and pharmacology, to train in multidisciplinary settings so they can participate as members of an integrated research team.

Strategy 2

Promote the recruitment, training, advancement, and retention of new investigators in clinical and translational research careers.

To ensure that there will be a next generation of clinical and translational scientists, new training opportunities and approaches need to be available to young investigators. These opportunities need to be linked to core competencies and to opportunities for gaining advanced degrees. Taken together, these steps could evolve into national standards to define the discipline of clinical and translational science.

Discussions of pipeline issues often focus on graduate and professional schools, when efforts should begin far earlier. One of the main missions of the IDeA program's INBRE initiative is to support the student pipeline through outreach to faculty and students in undergraduate institutions, tribal colleges, community colleges, and high schools. These programs also encourage and support students from diverse populations.

Effective mentoring is a key requirement for the education of researchers and plays a central role in passing on the skills needed to translate findings from the clinic into diverse and complex community settings. Mentoring also can help build additional skills and talent among researchers who are working in areas that face the challenges of rural and sparse populations.

Action Items: NCRR will:

- Develop initiatives through the CTSA consortium to:
  - Improve scholar retention and apply metrics to assess the transition of clinical scholars to independence.
  - Establish national core competencies for degree-granting programs in clinical and translational science.
  - Create a uniform policy guideline for mentored career development awards.
- Encourage grantees to share novel approaches to research training and mentoring with each other for greater dissemination and adoption.
- Continue to support comprehensive mentoring programs within the IDeA program's COBRE and INBRE initiatives to train investigators across the scientific spectrum, from basic to clinical to community-based clinical and translational research.

Strategy 3

Expand opportunities to train biomedical researchers in advanced technologies.

Investigators at BTRRs create critical, unique technologies and methods and apply them to a broad range of basic, translational, and clinical research. This approach is accomplished through a synergistic interaction of technical and biomedical expertise, both within the resources and through intensive collaborations with other leading laboratories.

BTRRs serve a unique purpose in the broad context of NIH-funded research. They represent a critical mass of technological and intellectual resources with a strong focus on service and training for investigators as well as dissemination of technologies, methods, and software. Their goal is to promote the widespread and routine application of the cutting-edge technologies they develop across the full spectrum of research.

Action Items: Through the BTRR program, NCRR will:

- Extend its training courses in mass spectrometry, proteomics, and other techniques to investigators, such as in the RCMI and IDeA communities.

- Provide training opportunities to broaden the skills of new investigators in the application of advanced methods.
- Develop possible training collaborations between CTSA and BTRR grantees.
- Bridge the gap from modeling and simulation to clinical study by ensuring the availability of trained individuals from diverse backgrounds, working across disciplines.

Strategy 4

Increase the number of qualified research veterinarians and ensure that veterinarians are recognized partners on translational research teams.

Veterinarians play a critical and unique role in government, academia, and industrial organizations engaged in biomedical research. In particular, the One Medicine–One Health concept offers opportunities to encourage partnerships between human and veterinary medicine. There are considerable challenges in identifying, recruiting, training, and retaining veterinarians who can fill these research roles. With biomedical research priorities shifting from basic molecular and cellular research to translational research, the importance of animal models and, therefore, veterinarians skilled in comparative medicine has increased.

Action Item: NCRR will address the growing need for research-trained veterinarians by sponsoring career development programs that attract and train graduate veterinarians in such specialties as primate clinical medicine, laboratory animal medicine, or rodent pathology.

Strategy 5

Encourage students to pursue biomedical research careers and educate the public about healthy living.

The two major goals of the Science Education Partnership Award (SEPA) program are to 1) increase the pipeline of future scientists and clinicians, especially from minority, underserved, and rural K–12 students, and 2) to engage and educate the general public on the health-related advances made possible by NIH-funded research. By creating relationships among educators, museum curators, and medical researchers, SEPA encourages the development of hands-on, inquiry-based curricula that inform participants about such timely issues as obesity, stem cells, and infectious diseases. In addition, SEPA provides professional development for teachers and mentoring opportunities for students.

Action Items: NCRR will:

- Form partnerships to educate the public, provide opportunities for mentoring, and encourage young people to pursue careers in biomedical research.
- Augment outreach efforts to inform high schools about opportunities to participate in SEPA.
- Encourage science museums, which reach a wide audience, to educate the public in the benefits of NIH-supported research.

A fourth-grade student is examining a plastic replica of a human brain as she takes part in a class with a special speaker, neuroscientist Eric Chudler, Ph.D., of the University of Washington in Seattle. Dr. Chudler studies the brain and Parkinson's disease, and with a SEPA from NCRR, he is exploiting the potential of the Internet to deliver science education materials directly to classrooms, media centers, libraries, and homes. Since 1991, NCRR has used its SEPA program to fund innovative science education to improve understanding of health and biomedical research by supporting projects that increase the scientific literacy of children, young adults, and the public at large. SEPA projects, both K–12 and science center and museum based, have been implemented in more than 30 states, Puerto Rico, and more than a dozen American Indian/Alaska Native/Native Hawaiian (AI/AN/NH) communities, and they reach tens of thousands of people every year. (Photo Credit: Doug Ramsay/Snohomish County Tribune)

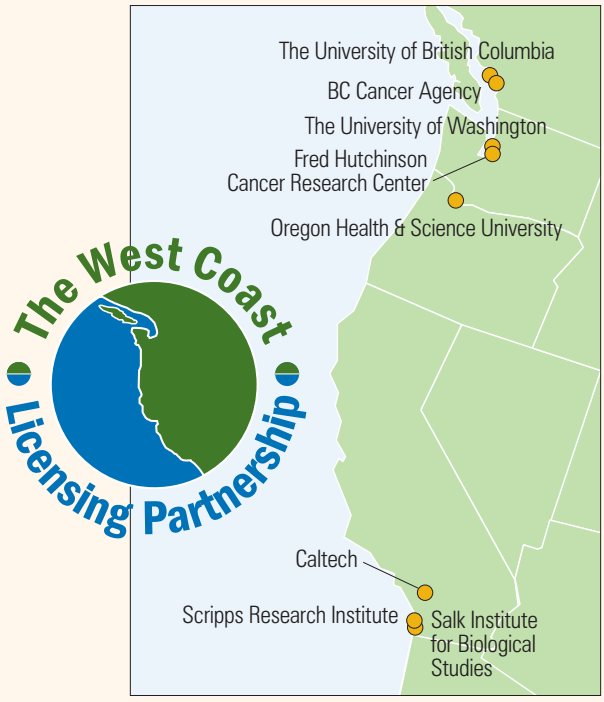
VI. Partnerships to Maximize Research Investments

The relationships among academic institutions, federal-funding sources, industry, and the community are vital to the discovery and dissemination of innovations. The advanced technologies, methods, and interactions that are developed, refined, and adopted through NCRR programs may be among the most important resources for the strategic and efficient use of precious capital and, ultimately, the commercial dissemination of discovery. Therefore, it is essential that these relationships be fostered in a strategic manner to optimize potential return on scientific opportunity and investment.

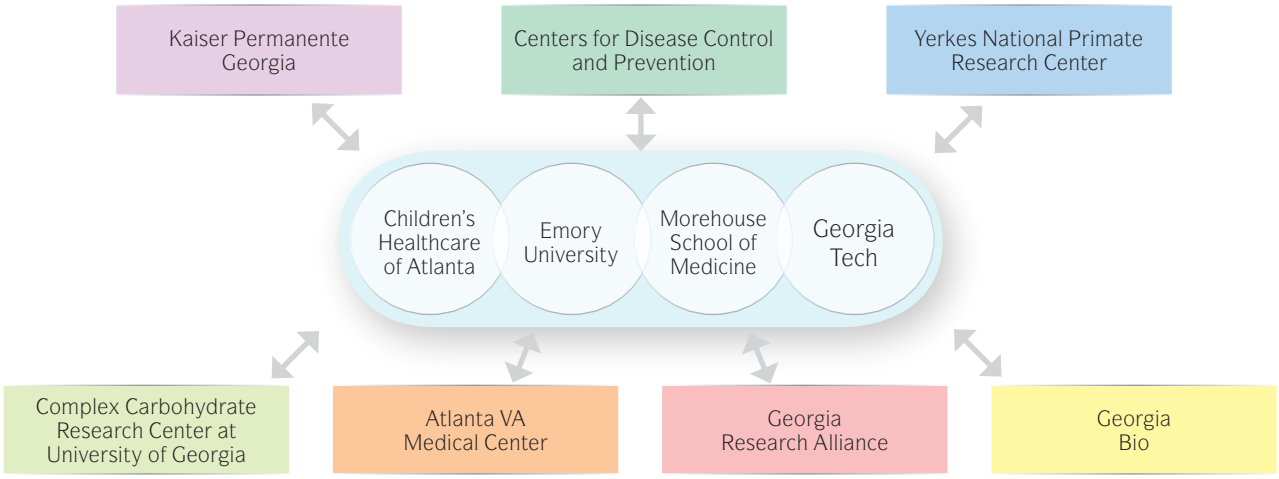
Strategy 1

Encourage NCRR-funded grantees to collaborate within and across programs to capitalize on unique capabilities to solve complex clinical and translational research problems.

Today's climate of financial constraints and limited resources encourages organizations with similar interests to collaborate to achieve their goals. Together, NCRR resource centers often can accomplish tasks that are mutually beneficial and can do so in a cost-effective manner, especially if undertaking them can attain an economy of scale.



Oregon Health & Science University (OHSU), an NCRR-supported CTSA grantee, is one of eight institutions willing to bundle a subset of its technologies for marketing and licensing through the West Coast Licensing Partnership, which was formed in 2006. Operating under a memorandum of understanding, each partner is able to package a bundle of technologies from the collective portfolio of the eight partners. The benefits are many. For example, nonexclusive licensing makes research tools globally accessible through the eight institutions. All the institutions save time and money through the negotiation of multiple licensing agreements, and the bundled technologies yield net cost savings compared with licensing individual tools and technologies. The menu of technologies includes animal models, biomarkers, medical imaging, and medical devices, but the partnership foresees several new bundles of animal models becoming available soon for the study of neurodegenerative diseases, neuroendocrinology, and stress and anxiety disorders. More information is available at www.westcoastlicensing.com.



The partnerships of the Atlanta Clinical and Translational Science Institute (CTSI) capitalize upon the strong clinical, translational, training, and basic discovery programs at the CTSA grantee Emory University as well as the health disparities, training, and community outreach focus of its RCMI partner, the Morehouse School of Medicine. By 1) capitalizing on the engineering and bioinformatics achievements of Georgia Tech, the nonhuman primate resources available through the Yerkes NPRC, and the excellence in pediatrics of Children's Healthcare of Atlanta and 2) collaborating with the private nonprofit Georgia Bio organization, the Georgia Research Alliance (a state-sponsored academic-industry partnership), and the Complex Carbohydrate Research Center (an NCRR resource for medical glycomics and integrated glycotechnology), the Atlanta-CTSI is poised to become a leader in clinical and translational research. In addition, this strategic multi-institutional alliance is creating dynamic community, public health, informatics, and population studies programs through partnerships and collaborations with Kaiser Permanente of Georgia, the Centers for Disease Control and Prevention, and the Atlanta Veterans Affairs Medical Center. More information is available at www.med.emory.edu/research/ctsa.

Action Items: NCRR will:

- Find innovative ways to foster collaboration as the CTSA consortium reaches 60 members by 2012. Encourage support for the formation of clusters within and beyond the CTSA consortium to promote shared programs, activities, data, and practices on a manageable scale and at greater efficiency.
- Further enhance efforts to form consortia in the NPRC and IDeA programs.
- Create opportunities through funding mechanisms, training sessions, and visits to initiate collaboration among various NCRR resources. Possible examples include the following:
  - Foster collaborations between NPRCs and other NIH-supported or research-focused nonhuman primate facilities and strengthen mutant mouse model resource cooperative centers.
  - Enhance collaborations between NCRR's SEPA awardees and grantees supported by other NCRR and NIH programs.
  - Facilitate collaborations among grantees and across programs by developing an aggregated database that would assist users in sharing resources and in identifying common research interests.

Strategy 2

Facilitate the creation and implementation of public-private partnerships.

A major goal of NCRR clinical research programs is to stimulate alliances of medical research and research training efforts and to promote sharing of information and best practices that will lead to improved translation of research into clinical practice.

Action Item: NCRR will support activities to:

- Facilitate a joint industry RCMI/IDeA forum to help initiate public-private partnerships.
- Facilitate collaborations in the IDeA and RTRN programs by providing technology-transfer assistance and advice.
- Foster the development of additional biotechnology companies initiated through the activities supported through COBRE.

NCRR is committed to engaging groups who are at increased risk of disease or are living in areas that historically have been medically underserved. Through its community-based clinical and translational research undertaken through the CTSA, IDeA, and RCMI programs and via collaborations with other government agencies, NCRR is ensuring that populations experiencing higher rates of premature death and disability are represented in research populations and have access to cutting-edge research. Bidirectional communication is the best means of ensuring that communities' needs are reflected in the nation's research agenda, developing appropriate and relevant guidelines and best practices, and finding the most effective conduits for bringing new research into the clinic. (Photo Credit: iStockphoto)

Since its establishment in 1982, the SBIR program at NIH has fostered the participation of a variety of small businesses in federally supported research and development within the biomedical sciences, and it has encouraged commercialization by the private sector of technology developed through federal support. With an SBIR grant, awarded by NCRR's Division of Biomedical Technology, physician Geoffrey Hart, M.D., and biomedical engineer David Chastain at the consulting firm Design Continuum came up with a solution to an important problem: giving needed anesthesia to apprehensive, suffering children without increasing their fear or discomfort. They designed and developed the PediSedate—a medical device that looks like a brightly colored toy but is actually a system for delivering anesthetic gas and monitoring vital signs. The child-sized headset connects to a CD player or a handheld video game, both of which can have a calming effect on the pediatric patient, while one of the earpieces monitors oxygenation of the blood. The snorkel itself monitors respiration, delivers mixed oxygen and nitrous oxide through a semitransparent purple mouthpiece, and scavenges exhaled gas. (Photo Credit: Continuum)

- Facilitate the development of technology-transfer offices at RCMI and COBRE grantee institutions to encourage wider use of the Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) initiative.
- Identify common funding gaps and opportunities in medical research that can be solved via collaboration among academic health centers and private-sector and government partners.
- Seek databases or other electronic tools that would facilitate "peer-to-peer" transfer of research materials among CTSA researchers. An additional possible activity is for CTSA entities to develop approaches to pool and aggregate "Intellectual Property" and research resources, such as biomedical materials.
- Share common language and identify rate-limiting steps used in public-private partnership agreements. Topics for consideration include agreement/consent standardization, tracking, master agreement clauses and provisions, and models of public-private partnership used in member institutions and by government agencies.
- Collect and disseminate "partnering curriculum" used by member institutions with the aim of developing entrepreneurial awareness and skill sets among translational researchers.

Strategy 3

Develop partnerships with other government agencies, foundations, and businesses in the areas of biomedical technology and advanced instrumentation.

Scientists are seeking wider applications of breakthrough biomedical technologies developed with NCRR-funded resources. As difficult as it is to develop useful new methods or instruments, it is also challenging to transform them into finished, easy-

to-use products and put them in the hands of researchers and clinicians worldwide. This process can often be expedited through partnerships with private industry, philanthropic organizations, or other government entities. NCRR is exploring all of these collaborative approaches as a means of efficiently bringing technologies into mainstream use.

Action Items: NCRR will:

- Initiate discussion with other government technology centers through such organizations as the Federal Laboratory Consortium for Technology Transfer—the nationwide network of federal laboratories that provides the forum to develop strategies and opportunities for linking laboratory mission technologies and expertise with the marketplace.
- Initiate discussion with private foundations, such as the Robert Wood Johnson Foundation and the Ewing Marion Kauffman Foundation, to develop partnerships in the area of biomedical technologies and devices.
- Forge alliances with small- and medium-sized biotechnology companies and large pharmaceutical companies by encouraging grantees to engage their respective technology offices in these efforts.
- Offer a forum for NCRR grantees to develop partnerships with small companies for technology development. An example of a possible initiative would be to facilitate CTSA organizations to attend major conferences to promote the CTSA and other NCRR programs. Exhibit space also would be purchased to highlight these programs at select major conferences.

Strategy 4

Promote public-private partnerships through the SBIR/STTR grant programs.

NCRR participates in two federal grant programs that provide funding to small businesses—the SBIR program and the STTR program. Both programs seek to increase the participation of small businesses in federally supported research and development (R&D) and to increase private-sector commercialization of technology developed through federally supported R&D. Both of these programs provide opportunities to integrate public and private initiatives.

Action Items: NCRR will:

- Increase marketing and outreach of the NCRR SBIR/STTR programs.
- Focus the SBIR/STTR programs on NCRR's top technology priority areas with commercial potential.
- Issue SBIR/STTR Funding Opportunity Announcements with direct focus on translational research activities.

- Encourage partnerships between academics who know the problems and the companies that make the technologies by bringing the two groups together to facilitate workshops.

Strategy 5

Enhance partnerships between NCRR grantees and other NIH Institutes and Centers.

NCRR resources support more than 30,000 investigators who have primary funding from other NIH ICs. It is imperative that NIH program staff understand the infrastructure that underlies NCRR-funded research and, at the same time, that NCRR grantees understand the other NIH ICs' research endeavors and resources.

Action Items: NCRR will:

- Increase awareness of NCRR programs through workshops to trans-NIH communities.
- Conduct outreach to NIH intramural and extramural program staff to determine how to leverage and partner with NCRR grantees—for example, involving CTSA, RCMI, and IDeA grantees in multicenter clinical trials.
- Foster opportunities to improve the efficiency and quality of clinical trials management.

Strategy 6

Develop partnerships among government agencies that support community engagement activities.

One of the ways that NCRR supports biomedical research is by engaging communities in clinical and translational science. To achieve its purpose, translational research must include members of racial and ethnic minority groups and people living in rural and inner-city areas, who face much higher rates of disease, premature death, and disability than other populations. The key to this engagement, regardless of the type of program or population served, is two-way communication that establishes partnerships among researchers, health practitioners, and their community members.

Action Item: NCRR will further enhance relationships with the AHRQ, CDC, HRSA, IHS, and other government agencies by sponsoring workshops and other joint activities.

Conclusion

NCRR serves a unique role within NIH. Through its support, investigators across the nation who are working on all types of diseases and conditions have access to the facilities, technologies, and training they need to solve the most complex biomedical problems. The strategies and action items outlined in this *Plan* will serve to further accelerate the pace of discovery and continue to enhance biomedical research along its entire continuum—from basic research and animal models of disease to clinical trials and community practice.

Participants at the NCRR Strategic Planning Forum, December 3–4, 2007

Christian Abee, D.V.M.
Professor and Chairman
Michale E. Keeling Center for Comparative Medicine and Research
University of Texas M.D. Anderson Cancer Center
Bastrop, TX

Frank Arnett, M.D.
Executive Director
Center for Clinical and Translational Sciences
University of Texas Health Science Center at Houston
Houston, TX

Lisa Begg, Dr.P.H., R.N.
Director of Research Programs
Office of Research on Women's Health
National Institutes of Health
Bethesda, MD

Rachel Behrman, M.D., M.P.H.
Director
Office of Critical Path Programs
U.S. Food and Drug Administration
Rockville, MD

Robert Bilder, Ph.D.
Professor in Residence of Medical Psychology and Neuropsychology
Neuropsychiatric Institute
University of California, Los Angeles
Los Angeles, CA

Lynn Bosco, M.D., M.P.H.
Medical Officer
Office of Behavioral and Social Sciences Research
National Institutes of Health
Bethesda, MD

Josephine Briggs, M.D.
Senior Scientific Officer
Howard Hughes Medical Institute
Chevy Chase, MD

Judy A. Brown, Ed.D.
Executive Director
Center for Interactive Learning
Miami Science Museum
Miami, FL

Nancy Brown, M.D.*
Associate Dean for Clinical and Translational Scientist Development
Division of Clinical Pharmacology
Vanderbilt University School of Medicine
Nashville, TN

Thomas Budinger, M.D., Ph.D.
Professor of Bioengineering, Electrical Engineering, and Computer Science
University of California, Berkeley
Lawrence Berkeley National Laboratory
Berkeley, CA

D. Bruce Burlington, M.D.
Consultant
Gaithersburg, MD

Cathy Carlson, D.V.M., Ph.D.
Professor of Veterinary Population Medicine
College of Veterinary Medicine
University of Minnesota
St. Paul, MN

Wah Chiu, Ph.D.
Professor of Biochemistry and Molecular Biology
Baylor College of Medicine
Houston, TX

Christopher Chute, M.D., Dr.P.H.
Professor and Chair of Biomedical Informatics
Department of Health Sciences Research
Mayo Clinic
Rochester, MN

Janice Clements, Ph.D.
Vice Dean for Faculty and Professor
School of Medicine
Johns Hopkins University
Baltimore, MD

Barry Coller, M.D.
Professor of Medicine
Laboratory of Blood and Vascular Biology
Rockefeller University
New York, NY

James Collins, Ph.D.*
Assistant Director of Biological Sciences
National Science Foundation
Arlington, VA

Valérie Copié, Ph.D.*
Associate Professor of Chemistry and Biochemistry
Montana State University
Bozeman, MT

Kenneth Cornetta, M.D.*
Joe C. Christian Professor and Chairman
Department of Medical and Molecular Genetics
Indiana University School of Medicine
Indianapolis, IN

Becky Costello, Ph.D.
Director of Grants and Extramural Activities
Office of Dietary Supplements
National Institutes of Health
Bethesda, MD

Catherine Costello, Ph.D.
Professor of Biochemistry
Boston University School of Medicine
Boston, MA

Allan Czarra
Deputy Director
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Bethesda, MD

Michael P. Davis, M.S.
Director
Office of Program Planning and Analysis
National Eye Institute
National Institutes of Health
Bethesda, MD

Don Detmer, M.D.
President and Chief Executive Officer
American Medical Informatics Association
Bethesda, MD

Mark Ellisman, Ph.D.
Professor of Neurosciences and Bioengineering
National Center for Microscopy and Imaging Research
Director of Center for Research in Biological Systems
University of California, San Diego
La Jolla, CA

Emma Fernández-Repollet, Ph.D.
Vice President for Research
University of Puerto Rico Medical Sciences Campus
San Juan, PR

Jay Fox, Ph.D.
Professor of Microbiology
University of Virginia
Charlottesville, VA

Elaine Gallin, Ph.D.
Program Director of Medical Research
Doris Duke Charitable Foundation
New York, NY

Isabel Garcia, D.D.S., M.P.H.
Deputy Director
National Institute of Dental and Craniofacial Research
National Institutes of Health
Bethesda, MD

David Guzick, M.D., Ph.D.
Dean
School of Medicine and Dentistry
University of Rochester Medical Center
Rochester, NY

Tsegaye Habtemariam, D.V.M., Ph.D.
Dean and Professor of Epidemiology
College of Veterinary Medicine, Nursing, and Allied Health
Tuskegee University
Tuskegee, AL

Patricia Hand, Ph.D.
Administrative Director
Mount Desert Island Biological Laboratory
Salisbury Cove, ME

Clare Hastings, Ph.D., R.N.
Chief Nursing Officer
Nursing and Patient Care Services
National Institutes of Health Clinical Center
Bethesda, MD

James Heubi, M.D.*
Professor and Associate Chair of Pediatrics
Associate Dean for Clinical Research
Cincinnati Children's Hospital Medical Center
University of Cincinnati College of Medicine
Cincinnati, OH

John Higginbotham, Ph.D., M.P.H.
Associate Dean of Research and Health Policy
Rural Health Institute for Clinical and Translational Science
School of Medicine
University of Alabama at Tuscaloosa
Tuscaloosa, AL

Roland F. Hirsch, Ph.D.*
Program Manager
Office of Biological and Environmental Research
Life and Medical Sciences Division
U.S. Department of Energy
Washington, DC

Keith Hodgson, Ph.D.
Professor of Photon Science
Stanford Linear Accelerator Center
Stanford University
Stanford, CA

Kevin Johnson, M.D., M.S.*
Associate Professor and Vice Chair of Biomedical Informatics
Vanderbilt University Medical Center
Nashville, TN

Cynthia Keppel, Ph.D.*
Director
Jefferson Laboratory
Center for Advanced Medical Instrumentation
Hampton University
Hampton, VA

Barbara Knowles, Ph.D.*
Vice President of Education, Training, and External Collaborations
The Jackson Laboratory
Bar Harbor, ME

Kurt Kroenke, M.D.
Professor of Medicine
Indiana University School of Medicine
Indianapolis, IN

Henry Lewis, III, Pharm.D.*
Dean and Professor
College of Pharmacy and Pharmaceutical Sciences
Florida A&M University
Tallahassee, FL

Kent Lloyd, D.V.M., Ph.D.
Professor and Associate Dean
School of Veterinary Medicine
University of California, Davis
Davis, CA

Bertram Lubin, M.D.
President
Children's Hospital Oakland Research Institute
Oakland, CA

Russell Luepker, M.D., M.S.
Mayo Professor
Division of Epidemiology and Community Health
School of Public Health
University of Minnesota
Minneapolis, MN

Bettie Sue Masters, Ph.D.*
Robert A. Welch Distinguished Professor in Chemistry
University of Texas Health Science Center at San Antonio
San Antonio, TX

Patrick Mastin, Ph.D.
Branch Chief
Cellular, Organ, and Systems Pathobiology Branch
National Institute of Environmental Health Sciences
National Institutes of Health
Research Triangle Park, NC

Bonnie Mathieson, Ph.D.
Health Science Administrator
Office of AIDS Research
National Institutes of Health
Bethesda, MD

Alan McLaughlin, Ph.D.
Director
Division of Applied Science and Technology
National Institute of Biomedical Imaging and Bioengineering
National Institutes of Health
Bethesda, MD

Nancy Miller, Ph.D.
Senior Science Policy Analyst
Office of Science Policy
National Institutes of Health
Bethesda, MD

Beverly Mitchell, M.D.
Deputy Director
Stanford Cancer Center
Stanford, CA

Howard Moss, M.D.
Associate Director for Clinical and Translational Research
National Institute on Alcohol Abuse and Alcoholism
National Institutes of Health
Bethesda, MD

John Murray, M.D., Ph.D.
Associate Vice President for Clinical Research and Professor of Medicine
Meharry Medical College
Nashville, TN

Philip Needleman, Ph.D.
Former Professor and Chairman
Department of Pharmacology
Washington University School of Medicine
Former Chief Scientist and Head of Research and Development
Monsanto/Searle/Pharmacia
Creve Coeur, MO

Keith Norris, M.D.
Vice President for Research
Charles R. Drew University
Lynwood, CA

Eugene Orringer, M.D.
Executive Associate Dean for Faculty Affairs
School of Medicine
University of North Carolina at Chapel Hill
Chapel Hill, NC

Marguerite Pappaioanou, D.V.M., Ph.D.
Executive Director
Association of American Veterinary Medical Colleges
Washington, DC

Mark Pauly, Ph.D.*
Professor of Health Care Systems
Wharton School
University of Pennsylvania
Philadelphia, PA

Joan Reede, M.D., M.P.H., M.S.
Dean
Office for Diversity and Community Partnership
Harvard Medical School
Boston, MA

Thomas Rosol, D.V.M., Ph.D.*
Dean
College of Veterinary Medicine
Ohio State University
Columbus, OH

Mona Rowe, M.C.P.
Associate Director
Office of Science Policy, Analysis, and Communication
National Institute of Child Health and Human Development
National Institutes of Health
Bethesda, MD

Susan Shurin, M.D.
Deputy Director
National Heart, Lung, and Blood Institute
National Institutes of Health
Bethesda, MD

Cheryl Silver
Acting Chief
Strategic Planning and Evaluation Branch
Office of Strategic Planning and Financial Management
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Bethesda, MD

Jean Slutsky, P.A., M.S.P.H.
Director
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality
Rockville, MD

M. Susan Smith, Ph.D.
Senior Scientist and Professor
Oregon National Primate Research Center
Oregon Health & Science University
Beaverton, OR

Robert Star, M.D.
Acting Director
Division of Kidney, Urologic, and Hematologic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Bethesda, MD

Joel Stiles, M.D., Ph.D.
Director
Pittsburgh Supercomputing Center
Carnegie Mellon University
Pittsburgh, PA

Nancy Sung, Ph.D.
Senior Program Officer
Burroughs Wellcome Fund
Research Triangle Park, NC

Arthur Toga, Ph.D.*
Professor
Department of Neurology
School of Medicine
University of California, Los Angeles
Los Angeles, CA

Daniel Wattendorf, M.D.
Department Chief
Medical Innovations
Modernization Directorate
Office of the Air Force Surgeon General
Falls Church, VA

Frank Waxman, Ph.D.
Professor
Department of Microbiology and Immunology
University of Oklahoma Health Sciences Center
Oklahoma City, OK

David Weir, Ph.D.
Director
Delaware Biotechnology Institute
University of Delaware
Newark, DE

Linda Weiss, Ph.D.
Chief
Cancer Centers Branch
National Cancer Institute
National Institutes of Health
Bethesda, MD

M. Roy Wilson, M.D., M.S.*
Chancellor
Health Sciences Center
University of Colorado at Denver
Denver, CO

Mary Woolley, M.A.
President
Research!America
Alexandria, VA

Keith Yamamoto, Ph.D.
Professor of Cellular and Molecular Pharmacology
University of California, San Francisco
San Francisco, CA

Sheila Zimmet, J.D.*
Associate Vice President for Regulatory Affairs
Georgetown University Medical Center
Washington, DC

Stuart Zola, Ph.D.*
Director
Yerkes National Primate Research Center
Emory University
Atlanta, GA

*National Advisory Research Resources Council Member

NCRR Commonly Used Acronyms

AFIP Animal Facilities Improvement Program
BIRN Biomedical Informatics Research Network
BTRR Biomedical Technology Research Resources
COBRE Centers of Biomedical Research Excellence
CRECD Clinical Research Education and Career Development
CTSA Clinical and Translational Science Award
GCRC General Clinical Research Center
HEI High-End Instrumentation
ICs NIH Institutes and Centers
IDeA Institutional Development Award
INBRE IDeA Networks of Biomedical Research Excellence
NPRC National Primate Research Center
R&D Research and Development
RCMI Research Centers in Minority Institutions
RCTR RCMI Infrastructure for Clinical and Translational Research
RFIP Research Facilities Improvement Program
RTRN RCMI Translational Research Network
SBIR Small Business Innovation Research
SEPA Science Education Partnership Award
SIG Shared Instrumentation Grant
STTR Small Business Technology Transfer

Other Federal Acronyms

AHRQ Agency for Healthcare Research and Quality
CDC Centers for Disease Control and Prevention
DoD U.S. Department of Defense
DOE U.S. Department of Energy
FCC Federal Communications Commission
FLC Federal Laboratory Consortium for Technology Transfer
HRSA Health Resources and Services Administration
IHS Indian Health Service
NSF National Science Foundation
USDA U.S. Department of Agriculture
VA U.S. Department of Veterans Affairs

NCRR Glossary

Animal Facilities Improvement Program (AFIP): This program upgrades animal facilities, improves research animal care, and assists institutions in complying with the regulations and policies related to the use of laboratory animals.

Biomedical Informatics Research Network (BIRN): This program uses emerging technology advances to enhance collaboration efforts that integrate data, expertise, and unique technologies from research centers across the country.

Biomedical Technology Research Resources (BTRR): This program creates critical, often unique, technologies and methods for application to a broad range of basic, translational, and clinical research and fosters synergistic interactions of technical and biomedical expertise, both within the resources and through intensive collaborations with other leading laboratories, to provide other biomedical researchers with training and access to new tools and methodologies.

Clinical Research Education and Career Development (CRECD): This program trains clinical investigators at minority institutions to conduct sound clinical research and be competitive in obtaining external research support.

Clinical and Translational Science Award (CTSA): Through a national consortium, CTSAs are improving how biomedical research is conducted across the nation. The consortium's goals are to reduce the time it takes for laboratory discoveries to become treatments for patients and to train the next generation of clinical researchers.

Federal Laboratory Consortium for Technology Transfer (FLC): FLC is the nationwide network of federal laboratories that provides the forum to develop strategies and opportunities for linking laboratory mission technologies and expertise with the marketplace.

General Clinical Research Centers (GCRC): This program offers clinical investigators specialized research environments that provide the infrastructure necessary to conduct patient-oriented research.

High-End Instrumentation (HEI): This program provides a mechanism to acquire expensive equipment ($750,000 to $2 million) that is too costly to be purchased through the SIG program.

Institutional Development Award (IDeA): This program fosters health-related research and increases the competitiveness of investigators at institutions in 23 states and Puerto Rico with historically low aggregate success rates for grant awards from NIH. The two major initiatives of the IDeA program are the Centers of Biomedical Research Excellence (COBRE) and the IDeA Networks of Biomedical Research Excellence (INBRE).

- **Centers of Biomedical Research Excellence (COBRE):** The COBRE initiative supports thematic multidisciplinary centers that strengthen institutional research capacity by expanding and developing biomedical faculty capability and enhancing research infrastructure that encompasses the full spectrum of the basic and clinical sciences.
- **IDeA Networks of Biomedical Research Excellence (INBRE):** The INBRE initiative establishes a multidisciplinary research network that strengthens the lead and partner institutions' biomedical research expertise and infrastructure while providing research support to faculty and students, including those from community and tribal colleges.

- **IDeANet:** This initiative will broaden access to high-performance computational resources for data-intensive science applications and provide bioinformatics software tools and training to investigators across participating states.
- **Lariat:** This initiative to develop and implement a plan to provide a high-speed telecommunications network for biomedical researchers will enable scientists and educators in Alaska, Hawaii, Idaho, Montana, Nevada, and Wyoming to take advantage of the wealth of remote research resources and expertise available to scientists in other areas of the country.

National Primate Research Center (NPRC): The major goal of the NPRC program is to facilitate the use of nonhuman primates (NHPs) as models of human health and disease for basic, translational, and clinical biomedical research. It provides animals, facilities, and expertise in all aspects of NHP biology and husbandry through funding to eight institutions.

Research Centers in Minority Institutions (RCMI): The goal of the RCMI program is to develop and enhance the research infrastructure of minority institutions to expand their capacity for conducting basic, translational, and clinical research. It provides grants to institutions that award doctoral degrees in health-related fields and have student populations that are 50 percent or greater African American, Hispanic, American Indian, Alaska Native, Native Hawaiian, or Pacific Islander.

RCMI Infrastructure for Clinical and Translational Research (RCTR): This program includes the reorganization of various RCMI clinical and translational research infrastructure-related activities into one integrated program.

RCMI Translational Research Network (RTRN): This program provides opportunities for multisite clinical and translational research among minority and other collaborating institutions throughout the nation.

Research Facilities Improvement Program (RFIP): This program helps to expand, remodel, renovate, or alter existing research facilities or construct new research facilities. These facilities must support basic and/or clinical biomedical and behavioral research, and they may also support research training.

Small Business Innovation Research (SBIR): This program supports domestic small business concerns to engage in research or research and development that has the potential for commercialization.

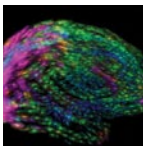
Science Education Partnership Award (SEPA): The two major goals of this program are 1) to increase the pipeline of future scientists and clinicians, especially from minority, underserved, and rural kindergarten to grade 12 students, and 2) to engage and educate the general public on the health-related advances made possible by NIH-funded research.

Shared Instrumentation Grant (SIG): This program provides a cost-effective mechanism for groups of NIH-supported investigators to obtain commercially available equipment that costs between $100,000 and $500,000.

Small Business Technology Transfer (STTR): This program supports innovative research in the United States that results in commercial products or services that benefit the public. An STTR grant requires research partners at universities and other nonprofit research institutions to have a formal collaborative relationship with the small business concern.

On the Cover:

Scientists at the NCRR-funded Sea Urchin Genome Resource at the California Institute of Technology used a two-pronged strategy to sequence the genome of the purple sea urchin, Strongylocentrotus purpuratus. *These scientists based their approach on whole-genome shotgun sequencing and a library of bacterial artificial chromosomes (BAC), clones that carry inside them very large pieces of the sea urchin's DNA. The sea urchin genome, which consists of about 23,300 genes, is closer on the evolutionary scale to the genome of humans than to other invertebrate animal models that are often used by developmental scientists. Equipped with knowledge of the sequence and analysis of the 814 million DNA bases that make up this marine animal's genome, researchers will be able to perform functional studies in a simple animal model that shares a common ancestor with vertebrates. (Photo Credit: Laura Francis, National Oceanic and Atmospheric Administration)*



Brain imaging is providing valuable insights into the effects of disease on the human brain. NCRR's BIRN initiative is supporting brain-mapping research to chart brain structure and function in hundreds or even thousands of human subjects throughout the lifespan. The ability to create maps of variability across populations provides a description of similarity and differences. This brain image depicts group variability as ellipsoidal shapes or tensors. Each tensor shows the magnitude (size) and direction (shape) of the variability. The statistics contained within the map illustrate both local and global patterns. (Photo Credit: Arthur W. Toga, Ph.D., Laboratory of Neuro Imaging, UCLA School of Medicine)

John Gore, Ph.D., director of the Vanderbilt Institute of Imaging Science in Nashville, Tenn., received funding from NCRR to support the purchase of a 7-tesla human magnetic resonance imaging (MRI) and spectroscopy system. This instrument provides the highest level of MRI available for humans and is one of only several such instruments in the United States. It provides a more sensitive measure of changes in brain activity and gives higher resolution, providing researchers even more detailed pictures of the brain. (Photo Credit: Dana C. Johnson, Vanderbilt University Medical Center)

Ke Jian Liu, Ph.D., (left) and Shimin Liu, M.D., Ph.D., prepare a research poster for presentation. Their IDeA-supported studies are being conducted at the University of New Mexico's Integrative Program in Central Nervous System Pathophysiology Research. The researchers are evaluating blood flow and oxygenation in the brain following stroke. IDeA funding provides opportunities and resources for helping scientists develop their talents to the fullest, encouraging high-quality research drawing on the talents of investigators from a variety of academic disciplines, and enhancing the ability of junior investigators to compete independently for research support. (Photo Credit: Cathleen Rineer-Garber, University of New Mexico Health Sciences Center)

The technology development team for the Resource for Macromolecular Modeling and Bioinformatics (seated clockwise: Gila Budescu, D.Sc., Ph.D., Jim Phillips, Ph.D., Kirby Vandivort, M.S., and Robert Brunner, Ph.D.; Klaus Schulten, Ph.D., stands at the screen) is pictured at work in a software development meeting. The goal was to develop software that permits scientists to share views of molecular models in real time over the Internet—facilitating the true team science that NCRR seeks to support. For example, a researcher in Boston might prepare a perspective on a protein's active site to highlight the protein's function and mechanism. With this software, the image could be shared with colleagues anywhere in the world. Here, the development team discusses image quality and how to make the software user friendly. (Photo Credit: John Stone, provided courtesy of the NIH Resource for Macromolecular Modeling and Bioinformatics, Beckman Institute, University of Illinois at Urbana-Champaign)

Kenneth Ataga, M.D., a specialist in sickle cell disease at the University of North Carolina at Chapel Hill School of Medicine, performs clinical studies that help move discoveries from the laboratory bench to the patient. With the help of an NCRR Career Development Award, Dr. Ataga is investigating the relationship between the occlusion of blood vessels, the hallmark of sickle cell disease, and the coagulation activation of patients' blood. (Photo Credit: Dan Sears/UNC News Services)

A young participant in a sleep study talks with Carole Marcus, M.D., and her colleague at The Children's Hospital of Philadelphia (CHOP). Dr. Marcus, the director of the Sleep Center at the hospital, is the coprincipal investigator of a CTSA grant awarded to the University of Pennsylvania, The Children's Hospital of Philadelphia, the Wistar Institute, and the University of the Sciences in Philadelphia. The CTSA consortium enables multiple partnerships, such as these in Pennsylvania as well as others across the nation, that will transform clinical and translational research and bring new scientific advances to health care. (Photo Credit: The Children's Hospital of Philadelphia)

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