

**National Institute of General Medical Sciences
Strategic Plan for Reducing Health Disparities**

**THE MISSION OF THE
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES**

The mission of the National Institute of General Medical Sciences (NIGMS) is to support basic biomedical research that is not targeted to specific diseases. NIGMS funds studies on genes, proteins, and cells, as well as on fundamental processes like communication within and between cells, how our bodies use energy, and how we respond to medicines. NIGMS attempts to ensure the vitality and continued productivity of basic biomedical research, while producing the next generation of scientific breakthroughs and training the next generation of scientists.

**OVERVIEW OF NIGMS STRATEGY
FOR ADDRESSING HEALTH DISPARITIES**

Throughout all of NIGMS's research and research training programs, emphasis is placed on increasing the participation of underrepresented minorities in the biomedical research enterprise. One important consequence of a more diverse research community is likely to be increased attention to areas of research that can reduce health disparities.

The areas of emphasis and the specific objectives that make up the NIGMS plan to reduce health disparities were suggested by members of the extramural science community through workshops, advisory council meetings, and other scientific meetings that NIGMS routinely holds to explore new areas of research and research training opportunities. A draft of the plan was reviewed by the National Advisory General Medical Sciences Council and placed on the NIGMS website for comments. Any feedback received has been used to revise the plan.

RESEARCH

Pharmacogenetics

Rationale. Pharmacogenetics is the effect of inheritance on drug action. Individual variability occurs in both the desired therapeutic effects of drugs, as well as in their toxicity (or side effects). In 1998, it was reported that adverse drug effects account for 100,000 deaths per year, as well as 5 to 10 percent of hospital admissions. Some of these problems can be prevented through simple adjustments in medication choices or amounts, once the basic underlying scientific principles are understood. The knowledge from basic research will help guide "personalized medicine"-the development of drug therapies intended to treat people as individuals.

Ethnogeographic differences in drug responses are known to exist between populations. The best known instances are associated with the enzymes of drug clearance. Genetic polymorphisms significantly affect the elimination of several major classes of important drugs in clinical use today, including antidepressants, antipsychotics, several cardiovascular drugs, antiepileptics, and anti-ulcer drugs. For some of the enzymes involved in drug clearance, much less is known. For example, it has been observed anecdotally that African-Americans frequently require higher doses of cyclosporine A, an immunosuppressant drug given for transplants and a substrate of an enzyme required to eliminate a very large proportion of medications in use today. However, the basis for the higher dosage requirement is not understood. These genetic differences can have serious clinical consequences, particularly in chronic dosing situations. Knowledge that is acquired by studying the effects of inheritance in any selected groups can also be used to improve the health of individuals with similar genetic characteristics who are members of other population subgroups.

Objective. NIGMS's Pharmacogenetics Initiatives are designed to discern the role that human genetic variation plays in drug responses. The goal of the Pharmacogenetics Research Network and Knowledge Base is to systematically collect and interpret information about inherited variations in humans that determine both therapeutic and adverse responses to medications. Basic scientific knowledge will be stored in an information repository (the PharmGKB) that is intended for research purposes. (For more information, see <http://www.nih.gov/nigms/funding/pharmacogenetics.html>)

Action Plan: Issue solicitations for proposals and award grants for 1) exploratory clinical studies to identify populations where functional genetic variation is believed to exist, and 2) the development of common resources for network usage, such as tissue sample banks, with samples obtained by appropriately informed consent.

Performance Measure: Solicitation of proposals and number of awards made. NIGMS has announced the availability of supplements to promote exploratory clinical studies and to develop common resources for network usage (see NIH Guide notice NOT-GM-01-004, April 3, 2001).

Outcome Measure: The outcome anticipated from these supplements is new knowledge regarding the relationship between genetic variation and differential responses to pharmacological agents. Significant findings from this research will be communicated through scientific conferences and publications.

The NIGMS Human Genetic Cell Repository

Rationale. The NIGMS Human Genetic Cell Repository contains cell lines and DNA samples that allow investigators to study the causes of a large variety of genetic disorders, some of which

affect minority populations disproportionately. Among these are samples for the study of adult onset diabetes, sickle cell anemia, and glucose-6-phosphate dehydrogenase deficiency. The Repository also contains the DNA Polymorphism Discovery Resource, a set of 450 cell lines established in collaboration with the National Human Genome Research Institute, designed to reflect the genetic diversity of the U.S. population.

Objective. This resource enables investigators to identify DNA sequence polymorphisms, which serve as an important starting point in the search for genes involved in the etiology of complex genetic disorders. Some of these complex genetic disorders, such as cardio- and cerebrovascular disease, hypertension, obesity, asthma, prostate cancer, end-stage renal disease, and systemic lupus erythematosus, occur disproportionately in African Americans. The Repository will facilitate research on complex genetic disorders, furthering our understanding of these diseases and improving diagnosis and treatment.

Action Plan: Provide a resource for investigators studying the etiology, diagnosis, and treatment of genetic disorders by continuing support for the Human Genetic Cell Repository.

Performance Measure: Renewal of the contract for the Human Genetic Cell Repository. The current contract for the Cell Repository will be maintained until 2003. NIGMS plans to continue funding the Repository beyond the current contract period.

Outcome Measure: Support for the Human Genetic Cell Repository is expected to facilitate research on genetic disorders, resulting in new knowledge published in scientific journals and presented at research conferences.

Complex Genetic Diseases

Rationale. Heritable traits, including genetic disorders and susceptibility to disease, tend to arise and concentrate in specific populations, often in response to an environmental stress. For example, there is strong evidence that the genes for genetic disorders, among them sickle cell anemia, Tay-Sachs disease, and cystic fibrosis, served in the past to protect populations from infectious diseases. Genetic and environmental differences between populations, both present and past, are part of the equation that explains health disparities.

Objective. As more data on genetic and environmental differences become available, the challenge will be to interpret them correctly. Studying the architecture of traits, particularly complex ones such as cardiovascular diseases, asthma, and obesity, that differ among populations requires the application of mathematical and statistical models that account for current genetic information and past population history. Current models only account for a fraction of the information needed to fully understand the genetics of traits related to health disparities.

Action Plan: Provide support for research to further understanding of the architecture of traits related to health disparities through mathematical and statistical approaches. Because this research is investigator-initiated, the portion of this that will be directly related to health disparities is not known in advance.

Performance Measure: The issuance of program announcements in this area and the funding of research on complex diseases.

Outcome Measure: The long-term outcome anticipated from these research grants is new knowledge to guide subsequent research and the development of more effective diagnostics and treatments. Significant findings from this research will be communicated through scientific conferences and publications.

INFRASTRUCTURE AND CROSS-CUTTING ISSUES (RESEARCH CAPACITY)

Rationale. One of the ways in which NIGMS addresses the issue of health disparities is through its programs to increase the number and capabilities of underrepresented minority biomedical scientists, some of whom can be expected to pursue research related to health disparities in minority populations. The focal point for this effort within the Institute is the Division of Minority Opportunities in Research (MORE). The MORE Division has three components: the Minority Biomedical Research Support (MBRS) Branch, the Minority Access to Research Careers (MARC) Branch, and a section that handles special initiatives.

The MBRS program has recently undergone reorganization and has experienced an increase in the number of institutions that are eligible for research and institutional development support due to their substantial minority student enrollments. Along with this increase in the number of potential applicants for MBRS grants has been a rise in the average size of requested grant awards, making these grants comparable in size to most NIGMS research grants. As a result, MBRS' needs have grown substantially, and NIGMS has allocated additional resources to it. The MBRS program comprises three subcomponents: Support of Continuous Research Excellence (the SCORE program), the Research Initiative for Scientific Enhancement (RISE), and the Initiative for Minority Student Development (IMSD).

Together, the MORE programs cover the educational spectrum from the undergraduate level to postdoctoral activities by providing support in two broad areas of need: institutional development and training and career development.

Institutional Development

Objective. The goal of MORE's institutional development support is to enhance the science curricula and faculty research capabilities at institutions with substantial minority enrollments.

Action Plan: Continue to provide support for institutional development through the MBRS program.

Performance Measure: Number of MBRS grants awarded for institutional development.

Outcome Measure: The expected outcomes of MBRS support and plans to evaluate these outcomes are outlined in applicants' funding proposals and they vary from institution to institution. These outcomes will be peer-reviewed when grantees submit renewal applications at the end of their funding period, and they are one consideration in providing continued funding for a program.

Ongoing Minority Training and Career Development

Objective. The goal of MORE's ongoing support for training and career development is to encourage minority students to pursue training for scientific careers and strengthen the research skills of minority students and faculty. The wide range of opportunities provided by these programs allow for the participation of all types of institutions in the MORE programs, from 2-year colleges to research-intensive institutions having doctoral programs.

Action: Encourage minority students to pursue training for scientific careers and strengthen the research skills of minority students and faculty through grants.

Performance Measure: Number of grants awarded for training and career development through several ongoing programs:

RISE. RISE seeks to enhance the research environment at minority-serving institutions through faculty and student development. The overall goal is to increase the interest, skills, and competitiveness of students and faculty in pursuit of biomedical research careers. The program offers support for faculty and student development activities, which can include on- or off-campus workshops, specialty courses, travel to scientific meetings, and research experiences at on- or off-campus laboratories. Support is available for evaluation activities, as well. RISE also offers some support for institutional development, which includes limited funds for the renovation or remodeling of existing facilities to provide space for an investigator to carry out developmental activities, limited equipment purchases, and the development of research courses.

IMSD. IMSD encourages domestic private and public educational institutions with fully

developed and funded research programs to initiate and/or expand innovative programs to improve the academic and research capabilities of underrepresented minority students and to facilitate their progress toward careers in biomedical research. The application may be directed toward the development of underrepresented minority scientists who are in any phase of their career development, from the undergraduate level through the Ph.D. Awards under this program use the institutional education project grant mechanism.

MARC Training and Fellowships. MARC supports special research training opportunities for students and faculty at educational institutions with substantial minority enrollments. MARC programs also enable grantee institutions to develop and strengthen their biomedical research training capabilities. As a result, these schools are able to interest students in, and prepare them for, pursuing doctoral study and biomedical research careers.

MARC accomplishes these goals through Undergraduate Student Training in Academic Research (U*STAR) institutional grants, predoctoral fellowships, faculty predoctoral and senior fellowships, a visiting scientist program, and grants for MARC ancillary training activities. Like MBRS, MARC announced one-time supplemental grants for communications and technology in FY 1998.

In addition to the programs described above, MARC has formed relationships with professional scientific societies to develop innovative programs aimed at increasing the number of underrepresented minority biomedical scientists. These societies include the American Society for Cell Biology, the American Society for Microbiology, the Society for Advancement of Chicanos and Native Americans in Science, and the Federation of American Societies for Experimental Biology. With MARC support, the societies have sponsored activities that engage minority students and faculty members in the biomedical sciences, including visiting scientist programs, summer research opportunities, and scholarships enabling attendance at national scientific meetings and conferences.

National Predoctoral Fellowships for Minorities. NIGMS also participates in an NIH-wide program providing predoctoral fellowship support for minorities. The National Research Service Award Predoctoral Fellowship for Minority Students provides up to five years of support for research training leading to the Ph.D. or equivalent research degree; the combined M.D./Ph.D. degree; or other combined professional degree and research doctoral degree in the biomedical, behavioral sciences, or health services research. These fellowships are designed to enhance the racial and ethnic diversity of the biomedical, behavioral, and health services research labor force in the United States. Accordingly, academic institutions are encouraged to identify and recruit students from underrepresented racial and ethnic groups who can apply for this fellowship.

IRACDA. In FY 1998, NIGMS announced a new program that is designed to facilitate the progress of postdoctoral candidates toward research and teaching careers in academia.

The Institutional Research and Academic Career Development Award (IRACDA) combines a traditional mentored postdoctoral research experience with an opportunity to develop teaching skills through mentored assignments at a minority serving institution (MSI). The goals of the program are to provide a resource to motivate the next generation of scientists at MSIs and to promote linkages between research-intensive institutions and MSIs that can lead to further collaborations in research and teaching.

Bridges to the Future. One special initiative supported by NIGMS is the Bridges to the Future Program, which is co-sponsored by NIGMS and the National Center on Minority Health and Health Disparities. The mission of the Bridges to the Future program is to make available to the biomedical science research enterprise and to the nation the intellectual talents of an increasing number of underrepresented minority group members. It does so by facilitating the transition of students from associate- to baccalaureate-degree granting institutions and from masters to doctoral degree-granting institutions. The program promotes effective inter-institutional partnerships that lead to improvement in the quality and quantity of underrepresented minority students being trained as the next generation of scientists. Examples of activities supported through the Bridges program include laboratory research experiences, mentoring and academic counseling programs, curriculum enrichment, visiting lectureships, and course development.

Research Supplements for Underrepresented Minorities. As part of an NIH-wide program, principal investigators holding NIGMS research grants may request supplemental funds to support minority scientists and students. The aim of these supplements is to attract and encourage minority individuals to pursue biomedical research careers. Any principal investigator at a domestic institution holding an active NIGMS research grant, program project grant, center grant, or cooperative agreement research program, with a reasonable period of research support (usually 2 years or more) remaining at the time of the supplemental award, is eligible to submit a request to NIGMS for an administrative supplement to the grant.

Outcome Measure: The expected long-term outcome of NIGMS's ongoing training and career development activities is greater participation of minority students in science. More specific goals and measures are outlined in applicants' funding proposals and vary from institution to institution. These outcomes will be peer-reviewed when grantees submit renewal applications at the end of their funding period, and they are one consideration in providing continued funding for a program.

National Research Service Award (NRSA) Institutional Research Training Programs

Objective. Encourage minority students to pursue training for scientific careers and strengthen the research skills of minority students through traditional NRSA training programs. All institute-supported training programs are required to establish acceptable minority recruitment

plans to encourage the participation of underrepresented minority students in traditional research training grants.

Action: Review the minority recruitment plans of all institute-supported training programs and ensure that they are acceptable. These recruitment efforts are an integral part of the Institute's ongoing research training programs. The costs of these efforts cannot be separated from NIGMS's total research training budget.

Performance Measure: Support for training and career development provided to only those institutions with acceptable minority recruitment plans.

Outcome Measure: Institutions' minority recruitment activities and progress are re-evaluated with each competing renewal application. The expected long-term outcome of this support is greater participation of minority students in science. NIGMS will monitor periodic assessments of the participation of minorities in science education and research performed by the National Science Foundation and the National Research Council.

New Training and Career Development Initiatives

Objective. Maintain the interest of post-baccalaureate participants in scientific research and promote and instill an interest in research on health disparities.

Action: Fund a new NIGMS program, the Post-baccalaureate Research Education Program, to encourage underrepresented minority students who hold a baccalaureate degree in the biomedically-relevant sciences to pursue a research doctorate after postponing their application to graduate school.

Performance Measure: Announcement of program to the extramural community and number of grants awarded to institutions for support of post-baccalaureate students.

Outcome Measure: Participation in this program is expected to facilitate the development of a cohort of researchers who will address health problems disproportionately affecting minorities and the medically underserved.

Objective. Encourage research on diseases and health conditions of importance to American Indians and Alaska Natives, develop a cadre of American Indian biomedical and behavioral scientists and health professionals who are able to compete successfully for NIH funding, and increase the capacity of both the research-intensive organizations and the Indian organizations to work in partnership to produce competitive research proposals.

Action: Provide funding for centers that will link the Native American community with organizations that conduct health research.

Performance Measure: Establishment of an interagency agreement with the Indian Health Service, and provision of support for this effort.

Outcome Measure: Support for this program is expected to result in the involvement of tribal organizations, research-intensive organizations, and Native American researchers in activities to stimulate research on diseases and health conditions of importance to American Indians and Alaska Natives, and to increase the quality of research proposals in these areas.

COMMUNITY OUTREACH AND INFORMATION DISSEMINATION

Outreach and Technical Assistance to Minority Serving Institutions.

Rationale. The recent restructuring of the MBRS program and new MORE initiatives resulted in an increase in the number and frequency of staff outreach visits to explain new program requirements, review incoming applications, and monitor ongoing programs. In addition, NIGMS staff make presentations at regional workshops targeted at minority serving institutions not currently funded by NIGMS to introduce the workshop participants to NIH and NIGMS and familiarize them with the Institute's efforts to recruit minorities into science careers. NIGMS has also provided technical assistance in writing grant applications for the RISE, MARC and Bridges to the Future programs. A total of six workshops were held throughout the U.S. in fiscal year 2001. NIGMS also provides outreach through several websites designed to provide information on ongoing NIGMS minority programs and initiatives. In addition to staff outreach efforts, NIGMS provides extramural funding for technical assistance activities performed by third parties, such as professional societies.

Objective. The purpose of this outreach is to assist institutions in establishing specific goals for their programs, designing plans for assessing and reporting the outcomes of their programs, and developing their ability to compete successfully for MARC and MBRS support.

Action Plan: NIGMS will continue to provide technical assistance to minority-serving institutions.

Performance Measure: Continued support for staff visits to minority-serving institutions, development of workshops for potential applicants, and performance of other communication activities at research conferences and workshops.

Outcome Measure: Support for technical assistance is expected to result in the involvement of minority-serving institutions in activities to develop their ability to successfully compete for MARC and MBRS support and strengthen their own evaluation processes.

The Pharmacogenetics Populations Advisory Group

Rationale. It is important and necessary to consider issues of stereotyping and stigmatization of communities, and any possible resulting harm to individuals (e.g. discrimination in access to various social benefits) that may arise from membership in an identified group.

Objective. Establish a way to consider possible areas of misunderstanding and the ramifications of pharmacogenetics research. Continue a dialogue on the likely benefits and potential risks of pharmacogenetics research, and steps that can be taken to minimize those risks.

Action Plan: A Pharmacogenetics Population Advisory Group has been formed and will be supported in fiscal years 2002 through 2006.

Performance Measure: Meetings of the advisory group held twice yearly.

Outcome Measure: Outcomes of this support will be an expanded role of the NIGMS Pharmacogenetics Populations Advisory Group, in conjunction with the Pharmacogenetics Research Network and Database, and bi-directional exchange of ideas and advice between members of the Advisory Group, or their designees, and collaborative centers funded through the Pharmacogenetics Research Network and Knowledge Base.

Ethical, Legal, and Social Issues in Genetic Research

Rationale. It is recognized that people of different ethnic and geographic backgrounds may have different alleles of genes that predispose them to complex genetic disorders, and identifying such genes would be valuable for diagnosis and development of therapies. However, studies on members of specific populations raise the possibility of discrimination, stigmatization, and stereotyping.

Objective. NIGMS has taken the lead in efforts to develop approaches that would permit investigators to conduct these important genetic studies while protecting the subjects and the populations from which they come from negative impact.

Action Plan: NIGMS held a meeting in July 1999 that led to the concept of special oversight groups that would assure that tissue samples are acquired and studied with due protections for the population. A large, follow-up meeting was held in the summer of 2000, and more regional meetings are planned in fiscal years 2002-2006 to seek input and advice from members of various ethnic groups.

Performance Measure: Continued support for regional meetings and the receipt of input and advice from members of population subgroups.

Outcome Measure. The outcome of these efforts will be greater understanding among researchers and subject populations, and the protection of subjects from any negative impacts in future genetic research studies.

NIGMS Health Disparities Budget
(Dollars in Millions)

Institute/Center	FY 2002			FY 2003		
	Research	Infrastructure	Outreach	Research	Infrastructure	Outreach
NIGMS	\$16.80	\$152.50	\$0.10	\$17.10	\$163.20	\$0.10