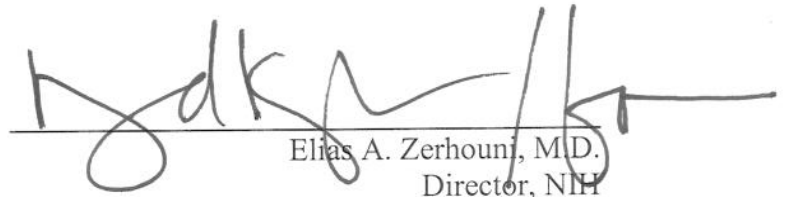


DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

(See list of Institutes and Centers in the Table of Contents)

IMPLEMENTATION OF INSTITUTE AND CENTER STRATEGIC PLANS



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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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IMPLEMENTATION OF INSTITUTE AND CENTER STRATEGIC PLANS

Executive Summary

In House Report No.109-515, the Committee on Appropriations requested that the National Institutes of Health (NIH) prepare and submit a report on how NIH Institute and Centers (ICs) implement their strategic plans. The report that follows is submitted in response to the request.

Every NIH IC has unique uses for its strategic plans. However, because ICs share in common the function of supporting outstanding research using similar research priority setting and funding mechanisms, IC plans also share common features and uses. By developing and articulating consensus on today's most pressing research questions, NIH strategic plans influence the research directions and methods proposed by investigators in un-solicited applications. By the same token, strategic plans inform NIH decisions about areas of research that require stimulation (achieved through a variety of means including Program Announcements and Requests for Applications). Finally, strategic plans influence NIH decisions on which applications to fund. Each of these roles is echoed in the IC-specific reports that follow.

The IC-specific reports are preceded by a brief introduction that quotes the House Report language to which NIH is responding and provides an overview identifying the most common themes in IC implementation of strategic plans. Following the IC-specific reports, Appendix 1 provides lists of NIH strategic plans, and Appendix 2 provides an overview of NIH priority-setting and award processes.

IMPLEMENTATION OF INSTITUTE AND CENTER STRATEGIC PLANS

Introduction

In its report on the Fiscal Year 2007 budget for the Department of Health and Human Services, the House Appropriations Committee Report includes language requiring each National Institutes of Health (NIH) Institute and Center (IC) to report how it implements its strategic plans. The language reads as follows:

“Priority setting—The Committee recognizes the role of serendipity in science, but continues to believe that thorough and thoughtful strategic planning is a far superior alternative. The Committee commends each IC that has undertaken a strategic planning process in conjunction with the best and brightest minds in the extramural community. Accordingly, the Committee directs each IC to develop a report, to be submitted no later than February 15, 2007, that identifies, by IC, measures to be taken to ensure that awards made via the peer review process in fiscal year 2007 and beyond reflect the strategic plans that have been published by each IC in conjunction with the extramural community. The Committee expects that such reports will identify specific steps such as mechanisms to ensure that strategic directions, as identified in strategic plans, are included in the peer review process for unsolicited grant applications as well as an increased emphasis on the use of requests for applications (RFAs) that identify specific research themes to achieve the strategic goals of each IC, as identified in the strategic plan. Furthermore, the Committee expects that each IC will adopt a tactical approach to implementing strategic plans so as to maximize the significant public investment with the ultimate aim of curing diseases.” (House Report No. 109-515, pages 122-123)

The following report has been prepared by the National Institutes of Health of the Department of Health and Human Services in response to this request.

This introduction provides an overview to identify the most common themes in IC implementation of strategic plans. Every NIH IC has unique uses for its strategic plans. However, because ICs share in common the function of supporting outstanding research using similar research priority setting and funding mechanisms, IC plans also share common features and uses.

A helpful way to understand the commonalities in NIH research funding and priority setting is through analogy. The NIH research enterprise is like a free-market economy in which individual initiative is informed by forecasts, modulated by incentives, and shaped by the choices of consumers. In the free-

market of scientific ideas, NIH strategic plans function as vision documents that influence the scientific directions investigators choose to pursue, the incentives NIH decides to offer, and the funding choices NIH makes.

Most NIH-research activities are investigator-initiated. By developing and articulating consensus on today's most pressing research questions, NIH strategic plans influence the research directions and methods proposed by investigators in their applications. By the same token, strategic plans inform NIH decisions about areas of research that require stimulation (achieved through a variety of means including Program Announcements and Requests for Applications). Finally, strategic plans influence NIH decisions on which applications to fund. Each of these roles will be echoed in the IC-specific reports that follow.

The role of strategic planning and its implementation varies across ICs. Differences in the missions of ICs lead to differences in the degree of specificity with which future research plans can be articulated. Differences in IC missions also lead to differences in the extent to which ICs utilize various means to stimulate research applications and mechanisms to fund research as they implement their strategic plans. For example, strategic planning and strategic plan implementation differ across ICs that primarily fund basic research, those that are more disease/organ/life-stage focused, those with a strong technological concentration, and those with large roles in infrastructure development. These differences, including the breadth and dynamics of IC research portfolios, lead each IC to use a unique combination of strategies to influence the nature of the research applications it receives (state of the science reports, solicitations, etc.) and means to fund research (individual-investigator awards, program projects, centers, contracts, etc.).

Following the IC-specific reports, Appendix 1 provides a list of IC-wide strategic plans. Because strategic plans take a variety of forms and have varying scopes, IC plans specific to diseases/disorders and to scientific areas are included in the list. Appendix 1 also lists Trans-NIH strategic plans.

Appendix 2 provides an overview of NIH priority-setting and award processes. Many IC specific reports will refer to the processes mentioned above. Appendix 2 is available as a reference so that the ICs need not include redundant explanatory text.

National Cancer Institute (NCI) Response to Congressional Report Language on Strategic Plan Implementation

Strategic Plan Development

NCI's integrated strategic planning process is based on the practical premise of thinking, planning, and doing. The myriad of strategic ideas, which form the starting point, funnel down to a finite number of strategic initiatives designed to achieve the full impact of cancer research toward reducing the cancer burden. NCI recently completed a process to develop a long-range strategic plan that involved a series of internal retreats to chart the strategic direction for the National Cancer Program. The leadership invited a wide range of internal and external individuals and groups to think about the problem of cancer and possible solutions and to submit their ideas to NCI as proposed initiatives. Meanwhile, NCI leadership worked with staff in NCI divisions, centers, and offices to identify critical paths and priorities for cancer research. Informed by this analysis, the NCI Executive Committee (EC) assessed more than 200 proposed initiatives, considering available resources and the potential impact on the cancer burden. The internal leadership was guided by input from a variety of advisory boards and groups with diverse memberships from the scientific, medical, advocacy, and consumer communities. The EC selected eight priorities which comprise the Objectives of the NCI Strategic Plan.¹ The first version of the Strategic Plan has been disseminated widely to NCI stakeholders, including the nationwide community of researchers, public health workers, healthcare providers, patients, advocates, and policy-makers. It is being used to inform decision-making at all levels of the Institute and throughout the cancer community, helping to shape research proposals and set funding priorities.

Although the Strategic Plan sets long-range goals, *The Nation's Investment in Cancer Research*, also called the Bypass Budget, outlines specific steps that will ensure that the Strategic Plan is a living document that will evolve within its broad objectives. Since it is prepared annually, the Bypass Budget defines milestones for each fiscal year and ties directly to the eight Objectives of the Strategic Plan. NCI's implementation strategies, that encourage participation of the full cancer community, ensure that the good ideas embodied within the strategic and operational plans are formed into achievable initiatives that stimulate

¹ NCI has a long history of using strategic priorities to guide cancer research. Some of the many activities mentioned in this report were initiated before the publication of the current Strategic Plan; however they were designed to support NCI strategic priorities that were incorporated into our present Strategic Plan.

progress in attacking the cancer burden. Importantly, the Strategic Plan also serves as an organizer for measuring and reporting on progress made through the support of cancer researchers and organizations. The following examples illustrate the significant strides NCI is making in implementing our strategic priorities.

Operational and implementation plans cascade down from our long-range Strategic Plan. For example, the Strategic Plan highlights the need for more integrated and efficient clinical trials and translational research structures. The Institute recently completed, and has begun to implement, recommendations from the Clinical Trials Working Group (CTWG). The working group, with broad representation from the cancer community, examined the existing clinical trials infrastructure and developed initiatives to create a more integrated and efficient system. The implementation/restructuring plan contains five themes and takes into account our disease-specific priorities in the form of steering committees. The first to be formed are in gastrointestinal, gynecologic, and head and neck cancers. Currently, the Institute is examining the translational research enterprise through a similar, refined process that builds upon the lessons learned with the CTWG. The desired outcome is an implementation plan that will help the Institute better organize its investment to further translational research and meet its strategic objectives.

The Relationship between the Strategic Plan and Extramural Research Funding

The Role of Expert Review in Setting and Implementing Research Directions. NCI has a robust planning process which compares the Strategic Plan Objectives to our portfolio of research to identify gaps and opportunities. NCI then initiates funding opportunities known as Program Announcements (PAs) or Request for Applications (RFAs), to ensure that NCI research addresses these gaps and opportunities. Within the Institute, program staff identify potential funding opportunities, often by convening scientific conferences or workshops to assess research needs with the assistance of expert extramural scientists. Scientific concepts are further validated by an internal approval process that requires agreement of NCI senior leadership and, for RFAs, approval of the NCI Board of Scientific Advisors, an external advisory committee. If an RFA does not attract enough quality grant applications, then set-aside funding is not expended. When the RFA attracts more quality applications than the set-aside will support, NCI has the option to increase the amount allocated to support the initiative.

The Use of Exception Funding to Target Research Priorities. NCI allocates approximately 10 percent of the budget available for new and competing renewal grants for funding grants beyond the established payline. This “exceptions funding” provides another means for the Institute to fill in gaps in the research portfolio and ensure support of strategic priorities. The competition for exception funds is intense and each NCI division examines the requests in an internal evaluation process guided by criteria agreed upon by the leadership.

The Relationship between the Strategic Plan and the Intramural Funding Process

Although funded through a different process, intramural projects are aligned with NCI’s Strategic Plan using several strategies, including internal administrative funding decisions and an external review by the Board of Scientific Counselors (BSC), an advisory committee focused on intramural activities. The Intramural Research Program budgets are designed to support value-added research that complements the extramural cancer research portfolio and addresses the strategic planning goals of NCI and NIH. Furthermore, the Institute uses the BSC peer review to ensure that NCI uses its resources wisely, and supports science that has the greatest potential to make a significant contribution to cancer research, medicine, and public health.

The Strategic Plan in Action: Case Studies from NCI Programs Moving Plans into Action

As a leader of the National Cancer Program, the NCI provides vision and leadership to the nationwide cancer community. Success in reducing the cancer burden will depend on the integration of activities across a seamless continuum and will require partnerships and translating findings to the clinic and community. Our strategic objectives are stratified on two fronts:

- **To preempt cancer at every opportunity** by understanding the causes and mechanisms of cancer, accelerating progress in cancer prevention, improving early detection and diagnosis, and developing effective and efficient treatments.
- **To ensure the best outcomes for all** by understanding the factors that influence cancer outcomes; improving the quality of cancer care; improving the quality of life for cancer patients, survivors, and their families; and overcoming cancer health disparities.

Examples cited below demonstrate NCI's progress in taking the framework of the Strategic Plan and putting it into operation to impact people's health and lives.

Overcoming Cancer Health Disparities. NCI has initiated several activities to address research needs and implementation strategies on health disparities. A recent NCI-wide workshop was convened with registrants from virtually every NCI division, office, and center. Their expertise in biomedical and social sciences was focused on two primary goals: 1) build synergy around NCI efforts to reduce cancer health disparities by enhancing communications, stimulating interactions across the Institute, and leveraging strengths through information sharing and 2) propose strategies for strengthening collaborations across NCI to reduce cancer health disparities. Participants identified objectives and proposed action plans that provide a basis for the newly formed NCI Health Disparities Implementation/Integration (I²) team that will move beyond the planning stage to implement strategies to reduce cancer health disparities.

Improving the Study of Cancer Biology. NCI organized a special Think Tank in the area of integrative cancer biology. This need for an integrative approach to cancer research is emphasized in NCI's Strategic Plan. An RFA was issued in December 2003 that resulted in the funding of nine integrative cancer biology centers. The research covers the continuum from understanding the fundamental properties of the cancer cell through clinical applications. This Integrative Cancer Biology Program (ICBP) is the NCI's primary effort in the area of systems and computational biology. Though still in the development phase, these centers have already achieved new insights and identified potential targets associated with cancer as well as built basic computational models showing the migration and metastasis of cancer cells.

Large, collaborative projects uncover genetic and environmental factors in the causes of cancer. Uncovering the role of genetic, environmental, and lifestyle factors in cancer risk to inform strategies for cancer control is a strategic priority of the Institute. To address this need in the most efficient and cost-effective manner, NCI established the Cohort Consortium, an international collaboration of intramural and extramural investigators responsible for 23 independent population cohorts encompassing 1.2 million individuals. By pooling the data and samples from such large numbers of study participants, researchers can begin to examine the role of genetic and environmental factors in the cause of cancer.

NCI knocks down barriers to developing new cancer tests. The Program for the Assessment of Clinical Cancer Tests (PACCT) was designed to ensure that development of the next generation of laboratory tests is efficient and effective in

cancer detection, diagnosis, and prognosis. The Program is guided by a multidisciplinary Strategy Group of scientists from academia, industry and NCI staff. PACCT activities and accomplishments are in line with NCI's Strategic Objectives to promote collaborative, multidisciplinary research for validating biomarkers of early detection and screening and to develop better diagnostic and screening tools for early detection, risk assessment, and recurrence.

*Energy Balance.*² In 2001, the Secretary of DHHS identified overweight and obesity as a public health priority. Scientists at the NCI have long been studying various aspects of nutrition, physical activity, and energy balance. Now, NCI's Strategic Plan sets a high priority on this topic of research. NCI created a working group in 2002 as a forum for sharing information among nutrition experts from across NCI and for fostering transdisciplinary research related to energy balance and cancer. This led to the creation of the Centers for Transdisciplinary Research on Energetics and Cancer (TREC). TREC fosters collaboration among transdisciplinary teams of scientists to accelerate progress toward reducing cancer incidence, morbidity, and mortality associated with obesity, low levels of physical activity, and poor diet. These activities are components of NCI's larger energy balance research focus, which complements the trans-NIH Obesity Task Force.

Development of Nanotechnology Centers. NCI developed the *Cancer Nanotechnology Plan* with input from a broad cross-section of the cancer research and clinical oncology communities. NCI gathered input for the plan during a series of symposia that brought together cancer researchers and technology developers to focus on the potential of nanotechnology for cancer diagnosis, treatment, and prevention. After assessing the needs of the community and determining how to best facilitate collaboration, NCI released an RFA for Centers of Cancer Nanotechnology Excellence to address cancer nanotechnology platforms in a consortia or network of laboratories and research facilities.

A common language for comparing research portfolios. NCI has developed a coding system called the Common Scientific Outline (CSO) to code all NCI initiatives, resources, applications, and awards. The CSO is organized around seven broad areas of scientific interest in cancer research. These categories and their sub-categories align with NCI's Strategic Plan to enable efficient and effective analysis of NCI's research portfolio. The CSO is also used by international partners to make wise funding choices and to have a positive impact on the progress of research on cancer. Unless groups are able to 'speak' a

² Energy balance refers to the integrated effects of diet, physical activity, and genetics on growth and body weight over an individual's lifetime.

common language to promote collaboration and cooperation we will not be able to conquer cancer.

Examples of Internal and External Collaborative Models to Implement Priorities

The NCI Strategic Plan specifies, “Our success will depend on our ability to integrate our activities across a seamless continuum of discovery, development, and delivery; partner with others to leverage resources and build synergy; and ensure that what we learn in the clinic and community transforms future discovery.” The following examples highlight some achievements.

Integration across NCI. In May 2004, the NCI began forming Integration/Implementation (I²) teams to advise NCI senior leadership in key scientific investment areas. This enterprise-wide strategic planning approach integrates both extramural and intramural activities to achieve transformational rather than incremental progress. The I² teams include representatives from across NCI and direct efforts in NCI’s strategic priorities through the development of a resource management plan that takes into account current investments based on a formal portfolio analysis, future needs, scientific opportunity, and potential partnerships. The first three I² teams address the research areas of imaging, bioinformatics, and lung cancer. The lung cancer I² team led to the establishment of the NCI Lung Cancer Program. A new Health Disparities I² Team has been initiated and others may be formed for important cross-cutting, high-priority activities.

Vaccines for Cancer Prevention. Cancer prevention is a high priority for NCI and one of the objectives in the Strategic Plan. Early population studies established a link between the human papillomavirus (HPV) infection and cervical cancer. Based on this association of cancer with an infectious agent, researchers began finding ways to boost the body’s immune response to prevent the cancer-causing infection. This year, a vaccine that is 100 percent protective against the development of cervical cancer and genital warts caused by four subtypes of HPV was approved by the FDA and a second vaccine is being reviewed. These vaccines show how basic discoveries arising from population studies, molecular biology and immunology can be applied to solve significant public health problems and perhaps, in this case, eliminate cervical cancer as a threat to women’s health.

Partnering in Disease-Specific Research. NCI uses several different models of external collaborations designed to implement NCI’s strategic priorities in

disease-specific research. These collaborations promote the cross-cutting priorities of multi- and interdisciplinary research and shared resources. Individually, the collaborations address many other strategic priorities, such as understanding the causes and mechanisms of cancer, improving the quality of cancer care, and ensuring the best outcomes for all. Examples include partnering with other cancer related organizations, facilitating outside funding opportunities, and promoting productive meetings to address our priorities.

- The Strategic Plan highlights the need to ensure the best outcomes for everyone. In 2005-2006, NCI partnered with the Lance Armstrong Foundation (LAF) to assess the special research and cancer care needs of the Adolescent and Young Adult age groups and to solicit recommendations for a national agenda to improve cancer care and outcomes among these patients. More than 100 experts from diverse disciplines participated in formulating recommendations, which have moved into the implementation phase. A similar process is also being initiated with representatives of melanoma research to develop a collaborative, community-oriented melanoma action plan.
- A Public Private Partnership has been developed to improve lung cancer screening and diagnosis. The Foundation of NIH, in collaboration with NCI, other federal partners, and eight industrial companies, is creating a public database of lung CT and X-Ray images that can be used to improve computer aided diagnosis and advance the clinical management of lung cancer. This partnership further supports NCI's efforts to improve diagnosis and outcomes.
- The Leukemia/Lymphoma Molecular Profiling Project (LLMPP) is a consortium of scientists from around the world who looked at the gene profiles of a type of lymphoma that showed different responses to therapy in different patients. The group identified three subtypes of this lymphoma and is using the data to develop a clinical test to inform treatment decisions. LLMPP addresses the strategic priority of early detection and diagnosis.
- Supporting the priority to ensure the best outcomes for all, NCI convened a multidisciplinary committee to review the pancreatic cancer research field and make recommendations concerning the most needed and promising directions for future NCI investment. The group provided priority recommendations in six major areas. NCI performed a retrospective analysis of progress in pancreatic cancer since the report. During the last 5 years, NCI funding for pancreatic cancer increased by more than 200%. The number of pancreatic cancer research projects grew substantially in five of the six Progress Review Group priority areas. In the coming years, NCI will continue to work toward translating research

results into practice to make a difference for those affected by pancreatic cancer.

- NCI is partnering with the National Human Genome Research Institute to study three cancers in the pilot phase of The Cancer Genome Atlas project. These cancers -- lung, brain, and ovarian cancer – account for more than 210,000 cancer cases each year in the United States. This partnership addresses the priority area of understanding the causes and mechanisms of cancer.

The Pipeline of Planning Continues. NCI uses a variety of collaborative meetings, workshops, and conferences to move science planning into an implementation stage as evidenced in the following examples.

State of the Science meeting on Tobacco Use. NCI worked closely to implement an NIH State of the Science meeting on Tobacco Use: Prevention, Cessation, and Control. NCI's Strategic Plan identifies tobacco use prevention research as critical to accelerating progress in cancer prevention. The workshop resulted in a statement prepared by independent panels of health professionals and public representatives on the basis of literature review, presentations, and open and closed deliberations. NCI staff are developing strategies to respond to this statement and move priority areas forward in tobacco use prevention and cessation. Several funding opportunity announcements are under development in areas such as smoking cessation and weight gain, and understanding and preventing co-occurring health risk behaviors among U.S. youth.

SPOREs foster bi-directional feedback to help set priorities. The Specialized Programs of Research Excellence (SPOREs) are a unique funding mechanism because they focus on specific diseases to promote translational and interdisciplinary research. Each year, the SPORE directors meet to share ideas and progress in two ways—within their disease area and across disease sites. These interactions help the investigators and the Institute set and shift priorities in disease-specific research.

Integration of Research Across the Cancer Continuum. Patient access to optimal state-of-the-art therapies may soon be the greatest determinant of mortality from cancer. To address the issue of access for all, NCI has developed a research pilot project, the NCI Community Cancer Centers Program (NCCCP), designed to study the best ways to bring science to patients in the communities where they live. This program also has the potential to harness electronic medical records and interconnected informatics systems, to create a national cohort of cancer patients. The NCCCP cross-cuts the NCI strategic objectives and demonstrates how

specific initiatives are moving into integrative approaches that span the research continuum.

National Heart, Lung, and Blood Institute (NHLBI) Response to Congressional Report Language on Strategic Plan Implementation

Under the direction of its new leadership, the National Heart, Lung, and Blood Institute (NHLBI) embarked in 2005 upon an intensive, community-based effort to develop a scientific working plan for the next 10 years. The new strategic plan is expected to be published in the spring of 2007.

Current Planning Process:

The first step (Level I) of the new strategic planning process comprised 23 thematic meetings held April through August of 2006. The meetings incorporated input from approximately 500 investigators, who were asked to identify scientific areas for which the NHLBI is well positioned to make major contributions and to recommend operational policies to facilitate conduct of high-priority scientific research.

In October 2006, a Level II meeting brought together members of the National Heart, Lung, and Blood Advisory Council, chairpersons of the Level I meetings, and other leaders from the research community. Their task was to review the reports of the Level I meetings, synthesize and prioritize objectives and strategies, determine methods for measuring progress toward achieving objectives, and recommend approaches for fostering development of the research workforce. Participants were asked to give particular consideration to efficient and cost-effective strategies to achieve the objectives that were identified.

Level III, scheduled for completion in February 2007, has entailed development of a draft plan to reflect the vision of the research community. The plan includes specific implementation steps, focusing on areas where the NHLBI can be most effective in driving and/or facilitating research that addresses high-priority goals. Comments on the draft plan have been solicited from patient advocacy groups, professional societies, and other members of the scientific and lay communities. Thus, the final version will reflect the collective vision and wisdom of the Institute's diverse stakeholders.

Dissemination of the Plan:

The new strategic plan will be made available on the NHLBI public Web site, and summaries will be published in leading scientific journals. It will be distributed widely at meetings of professional societies and public advocacy groups and at scientific conferences and workshops. A version of the plan oriented to non-scientific audiences will also be prepared and distributed to other interested parties.

Because the strategic plan is especially relevant to scientists who are in the developmental stages of their research careers, NHLBI staff will distribute the plan whenever they meet or otherwise communicate with trainees or newly independent investigators. One such opportunity is an annual workshop, organized by the Institute's Division of Lung Diseases in conjunction with the American Thoracic Society meeting, at which NHLBI staff and new investigators discuss potential career development pathways. This past year, workshop attendees participated in the Level I planning process by offering recommendations for research objectives and suggestions for addressing training needs.

The plan will also be distributed to NHLBI-related public interest organizations. Each year since 2000 the Institute has invited representatives from about 100 organizations to attend a special meeting in Bethesda designed to enhance public input and involvement in NHLBI activities. These meetings have set the stage for a number of collaborative activities between the Institute and its public interest organizations, and have enhanced the organizations' role in educating their constituencies about NHLBI-sponsored clinical studies.

Previous Strategic Planning Process:

The new strategic plan will supplant its predecessor, which covered fiscal years 2005-2009 and has been highlighted on the Institute's public web site. That plan identified important scientific opportunities within the Institute's mandate, as well as selected action steps that could be taken to address them. Its recommendations were derived from numerous and extensive discussions with representatives of the scientific community and Institute advisory committees and working groups. Action steps comprised two categories: specific initiatives under development for potential release in FY 2005 and additional action steps under consideration for future years to stimulate interest in the identified opportunities.

Implementation of the Plan:

The new strategic plan will be implemented in many of the same ways as the Institute's previous plans.

Investigator-initiated research: The plan will drive investigator-initiated research by informing investigators of the Institute's highest-priority objectives so they can tailor their research accordingly. Since the plan is being developed in close consultation with the research community, it is likely that many of the directions it sets will already be familiar and it is hoped that investigators will be encouraged by the Institute's efforts to respond to the opportunities and needs identified by its

constituency. Trainees and new and mid-level investigators especially will be served by the plan—it will inform them of the likely scientific direction over the next decade at a point in their careers when they are fine-tuning their research ideas and plans.

About 70 percent of NHLBI extramural research funds are used to support investigator-initiated research. The payline is determined based on the amount of money the Institute and NIH make available for competing research projects, minus set-asides for awards made pursuant to requests for applications (RFAs) and other Institute priorities. With few exceptions, grants are selected for funding in the order of the priority score received in scientific merit review; the NHLBI uses a payline that is 5 percentile points higher for young investigators.

NHLBI-initiated research: As with previous strategic plans, Institute scientific staff—using the strategic plan as a blueprint of research priorities—will identify areas where additional investment may be warranted. They will review the Institute’s portfolio (and consider the research programs of other NIH components and federal agencies as well) to determine the extent to which a strategic objective is being addressed. They will consult with scientific experts in the field and members of other constituency groups via working groups, conferences, and other meetings. Promising initiatives will be further developed in consultation with Institute leadership. When appropriate, other NIH components will be approached regarding possible cosponsorship.

All initiatives, whether designed as RFAs, requests for contract proposals (RFPs), or program announcements (PAs), undergo concept review by NHLBI advisors—the Institute’s Board of Extramural Experts (BEE) and the National Heart, Lung, and Blood Advisory Council—before being released to the research community. The BEE, comprising scientists appointed by the NHLBI who have significant stature in the cardiovascular, lung, blood, and sleep research communities, is charged with evaluating the NHLBI research and training portfolios on an ongoing basis. The Council is established by law; its members represent scientific and health disciplines and the general public, and are appointed by the DHHS secretary. It reviews all Institute initiatives before they are announced to the community and all grants and cooperative agreements proposed for funding. While the strategic plan serves as the blueprint for Institute-led activities, several additional factors affect which initiatives will be implemented—portfolio balance, budgetary considerations, and additional priorities developed by the Institute in consultation with its advisory groups.

Trans-NIH Strategic Plan:
The Strategic Plan for NIH Obesity Research

The Strategic Plan for NIH Obesity Research provides a guide for the development of new NIH-supported obesity research in areas of greatest scientific need, opportunity, and challenge. The plan was formulated by the NIH Obesity Research Task Force (ORTF), which is co-led by the director of the NHLBI and the acting director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). It reflects input from experts in the external obesity research community, leaders of voluntary and professional health advocacy organizations, and the public. It is a comprehensive document that addresses the biologic and environmental causes of obesity, as well as bases for improved treatment and prevention.

To facilitate dissemination of the plan, the ORTF created an NIH Obesity Research Web site, which provides free electronic copies. Print copies are available through the NIH Weight-control Information Network. Since publication of the plan, staff members have worked to disseminate it to the research community and other stakeholders in a number of ways. For example, the plan has been publicized by the ORTF leaders in major biomedical research journals, and in 2005 it was highlighted at a meeting of the NHLBI advisory council. NHLBI staff members have distributed print copies of the plan to investigators who participated in the NHLBI Think Tank on Enhancing Obesity Research, to members of professional societies, and to representatives of other federal agencies. Print copies also are routinely given to ad hoc visitors to the NIH engaged in research or programmatic obesity-related activities. The obesity web site address has been provided to potential NHLBI grantees, as well as to investigators on data and safety monitoring boards for NHLBI obesity-related studies.

The ORTF, which has primary responsibility for monitoring the implementation of the strategic plan, meets on an ongoing basis to discuss member ICs' plans for new obesity initiatives. By sharing information, the ICs can focus effectively on identifying gaps in the plan's implementation while avoiding duplication of effort. In addition, the ORTF periodically has formed ad hoc subgroups to discuss and develop initiatives in areas of relevance to the plan. As one of the co-leads of the ORTF, the NHLBI director also monitors progress on implementing the plan. As part of the monitoring process, the NHLBI tracks new NIH obesity initiatives and maps them to the strategic plan themes. Implementation of the plan also depends on keeping the scientific community apprised of new NIH obesity initiatives. Therefore, the ORTF provides an up-to-date list of obesity-related NIH funding

opportunities and relevant upcoming NIH-sponsored meetings via the NIH Obesity Research web site.

National Institute of Dental and Craniofacial Research (NIDCR) Response To Congressional Report on Implementation of Strategic Plans

NIDCR's strategic planning process is vibrant, ongoing, and longstanding.

Our most recent five-year plan is in effect through the end of Fiscal Year 2008, at which time it will be re-evaluated to assess the need for updating and/or revision. The current plan was vetted extensively during its development and finalization, with input obtained from outside organizations, professional associations and sister governmental agencies outside the NIH. A copy can be found on the NIDCR website, found at www.nidcr.nih.gov.

One indication of how important the strategic planning process has become to achieving this Institute's mission is that recently we took the plan one step further and developed a formal implementation strategy for the strategic plan. This implementation plan was developed with broad input from the extramural research community, from intramural scientists, and from NIH staff. For each programmatic area, staff initially performed an analysis of gaps and scientific opportunities in the existing portfolio. Following these analyses, twelve separate groups covering each of ten programmatic areas, as well as mucosal immunology and training and career development issues were convened. Participants included scientific content experts, members of the National Academies, the National Science Foundation, the Howard Hughes Medical Institute, other NIH Institutes, the National Advisory Dental and Craniofacial Research Council, members of the Board of Scientific Counselors, and NIDCR program staff.

Additional outside input was obtained during the development of both the strategic and implementation plans through calls for public comment posted on the NIDCR website and publicized widely through professional associations, newsletters, and e-mail listservs. Similar methods are used on an ongoing basis to help the Institute stay on-track with its mission while maintaining currency and relevance to the public we serve. One example is the development cycle for NIDCR research initiatives, which include outside experts on development teams and widely disseminated calls for public comment from a variety of interested individuals and organizations.

The beneficial outcome of this activity is that mission-relevant priorities are clearly identified and articulated, and are used to provide guidance and inspiration to the scientific community and our own professional staff. For example, NIDCR's FY 2008 research initiatives track closely with the priorities identified in our strategic and implementation plans:

FY 2008 Initiative	Relevance to Strategic Plan Priorities
Oral Health Disparities Centers: Competing Renewal	<ul style="list-style-type: none"> ▪ Goal 2.C.: Further the understanding of how genetic, biologic, social, behavioral and environmental factors interact to contribute to disease susceptibility or resistance in diseases such as head and neck cancer, caries, periodontal diseases, and conditions such as craniofacial defects or syndromes, birth defects, and chronic and disabling pain. ▪ Goal 6: Eliminate health disparities in oral, dental and craniofacial diseases and conditions among underserved populations and groups.
A Systems Biology Approach to Salivary Physiology	<ul style="list-style-type: none"> ▪ Goal 1 (A): Support studies that address the genome, the transcriptome and the proteome of dental, oral and craniofacial diseases and disorders; and ▪ Goal 1 (B): Support research to understand the molecular mechanisms of cell signaling related to the development and progression of oral, dental and craniofacial diseases and disorders.
Osteoimmunology: Cross-Talk between Immune System and Bone	<ul style="list-style-type: none"> ▪ Goal 1 (A): Support studies that address the genome, the transcriptome and the proteome of dental, oral and craniofacial diseases and disorders; and ▪ Goal 1 (B): Support research to understand the molecular mechanisms of cell signaling related to the development and progression of oral, dental and craniofacial diseases and disorders.

Our strategic planning process helps create a rational pipeline by which we can move basic research into the translational arena and respond nimbly to new developments – all without unduly restricting scientific innovation. As examples, two endeavors that were designed to develop the clinical research infrastructure necessary to pursue the overarching objectives of Goal Two of our strategic plan are described below. For the reader’s convenience, our overarching Strategic Initiatives are summarized on the following page

NIDCR Strategic Initiatives

- Goal 1:** Advance the understanding of the normal and abnormal processes underlying oral, dental and craniofacial diseases and disorders through the development and application of new technology and research tools.
- Goal 2:** Develop new or improved approaches and methods for preventing, diagnosing, treating and eventually eliminating oral, dental and craniofacial diseases and disorders.
- Goal 3:** Ensure an adequate and well-trained research workforce that reflects the current and emerging needs of science and includes sufficient numbers of investigators from diverse disciplines and from underrepresented groups.
- Goal 4:** Support research infrastructure and enhance the development of new approaches for conducting inter- and cross-disciplinary research.
- Goal 5:** Enhance the translation of research results into clinical practice and communicate science-based health information to ensure that NIDCR-supported research leads to improved health.
- Goal 6:** Eliminate health disparities in oral, dental and craniofacial diseases and conditions among underserved populations and groups.
- Goal 7:** Ensure the adequacy of systems to document and monitor the extent and impact of oral, dental and craniofacial diseases, disorders and conditions.

A few years ago, NIDCR implemented a strategy to develop and sponsor more Phase III clinical trials. The strategy called for a step-wise progression and development of clinically relevant ideas, beginning with grants to collect pilot data, followed by a planning grant, and culminating in development of a complete, multicenter Phase III clinical trial. Recently, a clinical trial has been funded that went through all of the requisite steps - concept to planning grant to pilot study to clinical trial. NIDCR is now well positioned to support the most mature and testable ideas in a scientifically rigorous manner that will directly benefit the public's health.

Another example is NIDCR's Practice Based Research Networks (PBRN) program. Each of three regional networks conduct approximately 15 to 20 studies, comparing the benefits of different treatment strategies and materials under a range of patient and clinical conditions, and generating useful data on diseases, treatment trends, and the prevalence of less common oral conditions. The NIDCR's significant investment in this relatively new research network has already proven useful: we currently are facing an urgent public-health concern regarding a type of drug known as bisphosphonates. Thousands of Americans use these drugs, either to prevent osteoporosis or to control their cancer pain. There

are a growing number of reports that bisphosphonates can cause a serious condition called osteonecrosis in some patients. This condition results in the breakdown of the jaw bone; it is extremely difficult to treat, and the sequelae can be life-altering. Answers about the extent of the problem and how to address it are needed sooner rather than later. With the PBRNs already established, NIDCR was well-positioned to quickly mount a clinical study designed to gather relevant information that is expected to lead to useful information regarding the development of osteonecrosis.

Traditional R01 grants remain the lifeblood of the Institute’s research portfolio, and are fundamental to achieving our mission. NIDCR is able to achieve a balance that encourages investigators to steer their energies in directions that are congruent with our priorities and strategic plan while leaving room for investigators with novel insights to gain a place at the table as well. The “steering mechanisms” we most often use are Requests for Applications (RFA) that cluster around a particular research initiative and Program Announcements (PA) that state our ongoing research interests. In addition to the rated scientific merit as reflected in the priority score or percentile, in making funding decisions we give consideration to the need to fill significant scientific gaps in the Institute's research portfolio, potential scientific overlap with grants already supported, whether the applicant is a new investigator and the level of other support available to the applicant. To assist in this, NIDCR maintains a “Discretionary Pool” of funds used to support applications falling outside the pay line that the Institute determines should be funded for programmatic reasons as previously described.

We recently completed our annual review of particularly noteworthy peer-reviewed publications emanating from NIDCR support. Of the six publications chosen to be highlighted as examples of the type of strong science-based advances supported by our institute, half were submitted in response to an RFA and half were investigator-initiated. All were congruent with our priorities and strategic plan.

Subject of the Research (link to press release where available)	Application submitted in response to an RFA/PA and/or Initiative	Congruent with the NIDCR Strategic Plan
A disposable microfluidic cassette for DNA amplification and detection	Yes: DE02-002	Goals 1, 2, and 4
Fluoride varnish efficacy in preventing Early Childhood Caries	Yes: DE97-002	Goals 2, 5 and 6
Short- and long-term efficacy of brief cognitive-behavioral therapy for patients with chronic temporomandibular disorder pain: a randomized, controlled trial	No – Investigator-initiated	Goals 2, 5, and 7
Three articles elucidating new molecular targets identified for diabetes-related periodontitis (http://www.nidcr.nih.gov/NewsAndReports/ScienceNewsInBrief/ChronicPeriodontitis.htm http://www.nidcr.nih.gov/NewsAndReports/ScienceNewsInBrief/StudyTakesCloserLookatAcquiredImmunity.htm)	No – Investigator-initiated	Goals 1 and 3
RvE1 protects from local inflammation and osteoclast-mediated bone destruction in periodontitis (http://www.nidcr.nih.gov/NewsAndReports/ScienceNewsInBrief/Resolvins.htm)	Yes: DE04-006	Goals 1, 4 and 5
The cells and logic for mammalian sour taste detection (http://www.nidcr.nih.gov/NewsAndReports/ScienceNewsInBrief/SourTaste.htm)	No – Investigator-initiated	Goals 1, 4, and 5

While NIDCR funds the overwhelming majority of oral health-related research at NIH, the Institute also engages in partnerships when the opportunities emerge. The clear delineation of priorities and objectives provided by our strategic plan enhances the institute's ability to recognize appropriate opportunities for partnership. Two examples are the Specialized Programs of Research Excellence (SPORE) for Head and Neck Cancer conducted in partnership with the NCI, as well as discoveries regarding the logic of mammalian sour taste (described above) which resulted from a collaboration between NIDCR intramural scientists and an NIDCD-funded team at the Howard Hughes Medical Institute in San Diego.

In summary, NIDCR's strategic plan creates a framework within which high-quality research addressing important oral health problems can be organized, while providing a rational means of communicating priorities to the extramural community. Simultaneously, it allows for sufficient scientific innovation that newly emerging areas of discovery are not overlooked, and affords the opportunity for outside experts to weigh in on our current and future directions.

**National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
Response to Congressional Report Language on Strategic Plan
Implementation**

INTRODUCTION

The mission of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) encompasses a broad spectrum of diseases, including diabetes, endocrine, and metabolic diseases; digestive diseases, nutrition, and obesity; and kidney, urologic, and hematologic diseases. Because of the diverse nature of NIDDK's programs, the Institute has found that strategic planning is most efficient and effective when it is focused on disease-specific, organ-specific, or program-specific areas of research. Planning is an inherent part of the NIDDK management function. The planning process often culminates in the production of a document. Several such documents currently help to serve as scientific guideposts for future program development efforts as the Institute pursues its mission to reduce illness and death attributable to the diseases within its research purview. Core elements of NIDDK's strategic planning efforts include:

- Obtaining critical input from other NIH Institutes, Centers, and Offices, and external stakeholders—including non-NIH scientists, scientific professional organizations, advocacy groups, patients and the public;
- Identifying the burden of illness and state-of-the-science in the areas being addressed;
- Assessing basic and clinical research gaps and challenges, as well as infrastructural issues; developing research themes; and framing goals, objectives and/or strategies to capitalize on scientific opportunities over a time horizon of several years; and
- Distributing planning documents broadly. Plans are typically posted in draft form on the NIH website for a public comment period then posted again in final form. They are also made available in hard copy through NIDDK information clearinghouses, and distributed at scientific meetings and conferences. Press releases announce completion of planning documents, which are also widely distributed among NIH components and to individuals who participated in the process.

The NIDDK employs an array of mechanisms to ensure that the plans are actively pursued and that they remain dynamic. The NIDDK website is a major venue for bidirectional sharing of information with the scientific research community and the public. Strategic plans are posted and promoted on the NIDDK website to encourage research applications from investigators in the areas of opportunity

identified through the planning process. The Institute's development of research solicitations (Requests for Applications, Program Announcements, and Requests for Proposals)—which have received concept clearance from the National Diabetes and Digestive and Kidney Diseases Advisory Council—is largely focused on capitalizing on the research opportunities identified through strategic planning processes. The NIDDK also reserves funds for the support of agreed-upon "Special Emphasis Areas," many of which are consistent with strategic planning processes. In addition, scientific conferences and workshops review progress toward strategic planning goals, periodically reassess the state-of-the-science, and seek advice on newly emerging discoveries and technological approaches that will affect future research directions. The following are examples of NIDDK strategic planning efforts.

Conquering Diabetes: Highlights of Program Efforts, Research Advances and Opportunities—A Scientific Progress Report on the Diabetes Research Working Group's Strategic Plan. Completed in 2002, this strategic planning document recounted steps taken by the NIH to implement the recommendations of "***Conquering Diabetes: A Strategic Plan for the 21st Century***," a five-year plan issued in 1999 by the independent, congressionally-established Diabetes Research Working Group (DRWG), with broad input from the scientific and lay communities. The 2002 NIDDK update also identified research advances and new opportunities that occurred following the issuance of the 1999 plan.

Implementation Activities: The 2002 update documented the influence of the DRWG's Plan on decision-making by the NIDDK, as well as other NIH Institutes and Centers (ICs) with interests related to diabetes research. The update highlighted key steps taken by the NIH to implement the scientific recommendations of the *Plan* and the NIH research agenda, identifying advances in all of the five priority areas of extraordinary research opportunity identified in the Plan. It enumerated the 57 Requests for Applications (RFA), 29 Program Announcements (PA), and 3 Requests for Proposals (RFP) that were issued to pursue goals in the DRWG's Plan between its publication in 1999 and the 2002 planning update. Of the 57 RFAs that were issued, two-thirds were supported by more than one NIH IC. Similarly, two-thirds of the 29 PAs issued were supported by multiple ICs. Moreover, 31 conferences and workshops were held during that period, focused on the goals in the DRWG's Plan. In addition, the NIDDK has issued 24 RFAs and 20 PAs, and has convened 28 scientific conferences, since 2002 related to the five extraordinary opportunities and other important areas of opportunity and challenge identified by the DRWG. In addition, the primary federal diabetes research coordinating mechanism—the NIDDK-led statutory Diabetes Mellitus Interagency Coordinating Committee—provides a forum for

discussion and formulation of potential initiatives related to the DRWG Plan and 2002 Progress Report.

The DRWG Plan (and Progress Report) also has had important implications for expansion of planning efforts in related areas of research. The science of other major strategic plans described in this document—the Strategic Plan for NIH Obesity Research (2004) and the Strategic Plan for Type 1 Diabetes (2006)—were two of the five areas of “extraordinary opportunity” highlighted in the DRWG Plan.

Advances and Emerging Opportunities in Type 1 Diabetes Research: A Strategic Plan. Completed in 2006, this 10-year Strategic Plan was spearheaded by the NIDDK under the auspices of the statutory Diabetes Mellitus Interagency Coordinating Committee (DMICC), with broad stakeholder input.

Implementation Activities: The DMICC will serve the important function of assessing progress toward attaining the goals and objectives in the Strategic Plan. The NIDDK will continue to encourage support of the Plan’s goals by informing the scientific community and soliciting their input through scientific meetings, conferences, and planning and evaluation meetings. Overall, the successful pursuit of the research objectives presented in the Plan requires the collaboration of multiple NIH ICs, other government agencies, the private sector, and the research and advocacy communities.

Even as this new Plan was in development, the NIDDK began to use it as a scientific guidepost for the priority-setting process for the type 1 diabetes research field. For example, an initiative was released in April 2006 to facilitate biomarker development in diabetes complications, a scientific area identified in the Plan as critically important for propelling progress. In addition, the research objectives the Plan identifies will be considered when assessing progress and future directions of many ongoing collaborative research efforts addressing type 1 diabetes and its complications, such as the Type 1 Diabetes Genetics Consortium, the Type 1 Diabetes TrialNet, the Beta Cell Biology Consortium, and the Epidemiology of Diabetes Interventions and Complications Study.

Trans-NIH Action Plan for Liver Disease Research. Completed in 2004, this 10-year strategic Plan was spearheaded by the NIDDK under the auspices of the Liver Disease Subcommittee of the statutory Digestive Diseases Interagency Coordinating Committee (DDICC).

Implementation Activities: Strategies for successfully implementing the Plan include: (1) encouraging its use in grant applications in communications between NIDDK and potential applicants, and in the publication of RFA's and PA's to encourage research; (2) promoting collaborations between research funding entities (including industry); and (3) promoting specific initiatives based on the Action Plan among NIH components and other relevant Federal agencies. Effective coordination is made possible through the mechanism of the DDICC.

To monitor progress in attaining the Plan's 214 goals, organized under 16 topic areas, the NIDDK prepared a *Research Progress Review* that evaluates 2005 research activities.

(http://www.niddk.nih.gov/fund/divisions/ddn/ldrb/Progress_reviews.htm).

Accomplishments were documented for each of the 214 goals, including initiatives that complement a robust NIH investigator-initiated research portfolio. The *Progress Review* cites 13 PAs and RFAs that are relevant to the Action Plan, including "Endoscopic Clinical Research in Pancreatic and Biliary Diseases;" "Etiology, Prevention, and Treatment of Hepatocellular Carcinoma;" "Hepatitis C Cooperative Research Centers;" and "Development of Assays for High Throughput Drug Screening." The *Progress Review* also summarizes 23 clinical and epidemiologic studies relevant to the Plan's goals. In addition, over 120 relevant articles were published in distinguished journals.

Partnerships are considered critical to implementation. Within the NIH, 18 ICs and Offices currently support and collaborate on liver and biliary disease research. Of the 13 PAs and RFAs cited in the *Progress Review*, nearly two-thirds are supported by two or more Institutes and over a third of the studies and announcements cited have multi-Institute support. Many of these program initiatives, such as the "Biliary Atresia Research Consortium" and the "Drug-Induced Liver Injury Network," are designed to foster collaborations among external institutions as well. In addition, the NIDDK has developed partnerships with pharmaceutical companies in the planning and implementation of clinical trials designed to test the efficacy of new treatments.

Strategic Plan for NIH Obesity Research. This long-range Strategic Plan was completed in 2004 by the NIH Obesity Research Task Force, under the leadership of the NIDDK and National Heart, Lung, and Blood Institute (NHLBI), with

crucial input from experts in the external obesity research community, representatives of professional and voluntary health advocacy organizations, and the public.

Implementation Activities: The NIDDK's implementation of the Plan includes both IC-specific and trans-NIH activities. When developing concepts for research solicitations, the NIDDK considers the goals of the Plan, as well as the strategies and opportunities noted in the Plan for achieving the goals. Concepts for research solicitations to implement the Plan are discussed in the NIDDK's Obesity Research Working Group; with representatives from other NIH ICs at Task Force and other meetings; and with external experts, for example, National Advisory Council members and the NIDDK's Clinical Obesity Research Panel. Meetings of the Task Force also foster synergistic partnerships among the many represented ICs, avoid duplicative efforts, and help identify gaps in research activity. The Task Force has also formed *ad hoc* subgroups of staff from multiple ICs to develop collaborative research efforts consistent with the Plan's recommendations. The Task Force also maintains, on its website, up-to-date information on NIH research solicitations and upcoming meetings.

Since publication of the Plan in August of 2004, the NIDDK has sought to help realize its goals through leading or co-sponsoring 11 RFAs and 32 PAs. Additionally, the NIDDK also led or participated in 5 conferences or workshops. Examples of specific NIDDK-led initiatives include: "Site Specific Approaches to Prevention or Management of Pediatric Obesity;" "Long-Term Weight Maintenance: Basic and Clinical Studies;" "Translational Research for the Prevention and Control of Diabetes and Obesity;" "The Obese and Diabetic Intrauterine Environment: Long-term Metabolic or Cardiovascular Consequences in the Offspring;" and "Diet Composition and Energy Balance."

Renal Disease Research Plan. This 5- to 10-year strategic Plan was developed in 1999 by the NIDDK and the Council of American Kidney Societies, with major input from over 100 non-federal scientists, as well as patients. This Plan provided the foundation for a related strategic planning activity—a *Strategic Planning Meeting for Polycystic Kidney Disease (PKD)*, which the NIDDK convened in 2002. Speakers and participants included federal and non-federal scientists and physicians, and representatives of patient advocacy groups.

Implementation Activities: The Plan and the recommendations from the PKD planning meeting provide important guideposts for future directions in kidney disease research generally, and PKD research specifically, by identifying priorities in renal research and the mechanisms required to implement those

priorities. Thus, the Plan spurred the issuance of RFAs, PAs and meetings of kidney disease experts convened to heighten awareness of the Plan's goals. A host of major basic and clinical NIDDK initiatives have been derived from both planning efforts, with the endorsement of the NIDDK's National Advisory Council, to better understand the cause and clinical course of kidney diseases, and to develop better diagnostic methods and therapies. Since 1999, the NIDDK has issued 13 RFAs and 16 PAs, including several on PKD, related to the areas of scientific opportunity identified in the Plan. In addition, these planning activities have stimulated focused follow-on efforts, such as scientific meetings and conferences (19 convened since 1999), to review and discuss the state-of-the-science and revisit and update opportunities and challenges for future research. Significant research progress has resulted from these initiatives. The following formal initiatives emanated from these planning activities and incorporate the Plan's overarching priorities:

- Epidemiologic studies of chronic kidney disease and its relationship to cardiovascular disease (in adults) and cognitive function (in children)—such as the Chronic Renal Insufficiency Cohort Study (CRIC); a prospective cohort study of chronic kidney disease in children (CKiD);
- More clinically relevant models of renal injury, including the Animal Models of Diabetic Complications Consortium (AMDCC);
- Genetic susceptibility studies including the Family Investigation of Nephropathy of Diabetes (FIND) study, and Genetics of Kidneys in Diabetes Study (GoKinD);
- Renal development and genomics, including the GenitoUrinary Development Atlas (GUDMAP); and
- Improving treatments for renal diseases—including the Acute Renal Failure Trial Network (ATN) Study; the Consortium for Radiologic Imaging Studies of Polycystic Kidney Disease (CRISP), and CRISP II and the HALT PKD clinical trials; the Dialysis Access Consortium; the Focal Segmental Glomerulosclerosis in Children and Young Adults Interventional Study; the Folic Acid for Vascular Outcome Reduction in Transplantation (FAVORIT) study; and Frequent Hemodialysis Network (FHN).

These are just a few examples of the strategic planning efforts of the NIDDK and their positive impacts on program development.

National Institute of Neurological Disorders and Stroke (NINDS) Response to Congressional Report Language on Strategic Plan Implementation

Planning at the NINDS:

The mission of the NINDS is to reduce the burden of neurological disorders through research. Because of the enormous number and variety of disorders that affect the brain, spinal cord, and nerves of the body, the Institute plans at multiple levels of analysis. NINDS strategic planning develops a broad vision of scientific and program priorities across the breadth of the Institute's mission. Building on the strategic plan, the NINDS plans for specific diseases, for training of physician scientists, and for health disparities in neurological disorders. At the most detailed level, every grant proposal that the NINDS accepts presents concrete specific aims that are significant for the Institute's mission and provides a detailed research plan to accomplish these goals. Finally, to address issues that go beyond the mission of NINDS alone, the Institute plans together with other NIH Institutes and the NIH Office of the Director through the NIH Roadmap, the NIH Blueprint for Neuroscience Research, the CounterACT chemical counterterrorism program, and other activities.

The NINDS began formal strategic research planning in 1999, following discussions with the National Advisory Neurological Disorders and Stroke (NANDS) Council. In the course of the strategic planning process, more than 100 scientific and medical leaders addressed cross-cutting scientific topics that hold promise for preventing neurological diseases, delaying their onset, designing treatments, or restoring function after illness or injury. In addition to soliciting comments from the research community and the public on the draft plan, the NINDS met with representatives of patient groups to discuss the findings, to raise other issues, and to recommend how the Institute might seek public input on an ongoing basis. Following consultation with the NANDS Council, the Institute posted the final version of the plan "Neuroscience at the New Millennium" on its website. The NINDS publicizes its strategic and other plans in scientific and medical journals, at conferences of scientific, clinical and patient voluntary groups, and by extensive informal contacts between NINDS scientific and clinical staff and the research and patient communities.

The Millennium plan set broad goals for basic, translational, and clinical research programs that provided a framework for more specific NINDS planning. Planning on specific diseases, on minority health disparities, and on physician-scientist training has not only set priorities for those concerns, but also has strongly reinforced the importance of the cross-cutting priorities of the strategic plan. Current NINDS disease research plans focus on ataxia telangiectasia, brain

tumor, epilepsy, muscular dystrophy, Parkinson's disease, tuberous sclerosis, stroke, and drug development for spinal muscular atrophy. The NINDS also attends to Institute of Medicine (IOM) reports that assess the state of science and set research goals for neurological disorders that include, in recent years, multiple sclerosis, sleep disorders, transmissible spongiform encephalopathies, and spinal cord injury. The Institute participates in planning for diseases led by other components of the NIH to bring its expertise to problems such as autism and the nervous system complications of diabetes.

Complementing strategic and disease planning, the NINDS supports scientific workshops that assess current understanding and research priorities for disease-related subtopics, cross-cutting research themes, emerging technologies, and clinical issues. Workshops often pursue in more depth issues that were raised by earlier planning, such as non-motor problems in Parkinson's disease or animal models to improve drug screening for epilepsy. These meetings engage the community in setting a research agenda, which stimulates interest and collaboration; the discovery of the first gene that can cause Parkinson's disease and an interdisciplinary team effort to develop gene therapy for this disease are two examples of collaborations catalyzed by workshops. When initiatives are appropriate, workshops help the Institute to shape them to be most effective. Recent NINDS workshops have focused on topics in HIV/AIDS, multiple sclerosis, tuberous sclerosis, neurofibromatosis, Batten disease, vascular cognitive impairment, stroke, fragile X syndrome, spinal muscular atrophy, autism, hydrocephalus, Down syndrome, non-epileptic seizures, and Parkinson's disease, among other disorders. Major scientific meetings scheduled for 2007 include a meeting that will bring together researchers who study a wide spectrum of peripheral neuropathies and a reprise of the conference that launched the Epilepsy Benchmarks planning process, which will assess progress and future directions.

Although the NINDS plans for diseases and scientific issues each year through formal planning exercises, scientific workshops, and the constant attention of its scientific and clinical staff, the Institute has not revised its broad strategic plan since 2000. Following consultation with the NINDS Council in 2006, the NINDS began a new strategic planning process. A steering committee, including members of the NINDS Council, will guide planning, which will be informed by analysis of ongoing programs and will engage the public, the medical community, and researchers. The new strategic planning process is starting with translational research, defined here as preclinical therapy and diagnostics development. The choice of translational research reflects both the intense interest in Congress and the public in translating scientific advances to therapies and the dramatic growth of NINDS translational research programs since the last strategic plan. After a

thorough consideration of translational research, the strategic planning process will take up clinical and basic research, and then integrate across basic, translational, and clinical research from the perspective of diseases. The Millennium plan, as the Institute's first strategic plan, set a broad vision for the NINDS. The present strategic planning will be organized around focused questions that will guide the program choices NINDS will make in the coming years.

Plan Implementation

The NINDS implements plans in several ways. The most direct route is via targeted grant and contract solicitations or program announcements. Since 2000, the Institute has issued more than 125 requests for applications, requests for proposals, targeted supplement programs, and program announcements (many with set asides or special review) that address priorities of the NINDS and trans-NIH strategic or disease plans. Some initiatives target cross-cutting issues, such as the blood-brain barrier, stem cells, deep brain stimulation, gene therapy, and mechanisms of neurodegeneration. Others address disease specific planning recommendations. Among the many specific actions in response to the Parkinson's Disease Research Agenda, for example, the NINDS set up a program to solicit from the international research community candidate drugs that might slow Parkinson's disease, systematically evaluate the existing data on these drugs, and test the most promising drugs in clinical trials at a network of 40 clinical centers. The network of 7 Specialized Program of Translational Research in Acute Stroke (SPOTRIAS) centers address stroke planning priorities for the development of acute stroke therapies from preclinical research through early phase clinical trials. Actions to implement brain tumor planning recommendations include grant solicitations on brain tumor dispersal, the blood-brain barrier, and the neurovascular system. In response to the muscular dystrophy research plan, the NINDS recently has focused initiatives on translational research for muscular dystrophy and on understanding rare forms of muscular dystrophy. Following the priorities set by the Epilepsy Benchmarks process, the Institute has held a series of workshops, followed by solicitations, to develop better animal models to test drugs that stop the development of epilepsy, and treat pediatric, geriatric, and treatment resistant epilepsy. Other NINDS disease initiatives focus on ALS, brain tumor, dystonia, epilepsy, multiple sclerosis, muscular dystrophy, neuroAIDs, pain, Rett syndrome, restless legs syndrome, spinal cord injury, spinal muscular atrophy, stroke, traumatic brain injury, transmissible spongiform encephalopathies, tuberous sclerosis, and vascular dementia.

The NINDS also addresses strategic planning priorities by establishing flexible programs that engage the expertise and creativity of the scientific community. One major theme that recurs throughout the Millennium plan and disease specific plans is the need to translate insights from basic research to therapies. In 2002, the NINDS established the Cooperative Program for Translational Research to address this continuing priority. This program supports preclinical research to develop therapies for any disease within the Institute's mission; it requires collaboration, tailors peer review to the objectives of therapy development research, and monitors progress with milestone-driven funding. In 2005, the Institute renewed the program through 2008 with increased efforts to engage small businesses and an additional focus on shared resource centers. Currently there are more than 50 ongoing cooperative projects on drug, stem cell, or gene therapies for more than 20 diseases, including ALS, Batten disease, epilepsy, Huntington's disease, muscular dystrophy, Parkinson's disease, tuberous sclerosis, traumatic brain injury, and stroke. Expanding clinical trials is another strategic planning goal that the NINDS has addressed through a comprehensive program. The Institute currently supports more than 140 phase I, II, and III clinical trials, which plan to enroll more than 30,000 people. An active subcommittee of the NINDS Council now provides program and priority-setting advice on Institute clinical research activities, including clinical trials, and the Institute has implemented grant mechanisms for planning large trials and for pilot trials; procedures to optimize trial design; enhanced peer review; improved databases for tracking of trials; and a web-based "toolkit," of resources on design, implementation and oversight for investigators.

Strategic and disease specific plans stress the importance of empowering investigators by providing access to the increasingly sophisticated technology and resources necessary for research. For this reason, resource programs are another important element of NINDS planning implementation. In 2003, the Institute established the NINDS Human Genetics Repository to collect, store, characterize, and distribute DNA samples and cell lines, as well as standardized clinical data, for the research community. The Repository serves as a national resource for the discovery of genes relevant to neurological disorders and addresses goals of the NINDS strategic plan and plans for stroke, epilepsy, and Parkinson's disease, as well as priorities from workshops on motor neuron diseases and Tourette syndrome. Similarly, because the strategic plan and disease plans highlighted the need for resources to study gene activity, the NINDS established a network of Microarray Centers and GENSAT, the Gene Expression Nervous System Atlas. Both of these productive programs have now been extended under the auspices of the NIH Blueprint for Neuroscience Research, which is a framework for trans-NIH cooperation on research in the brain and nervous system. Other NINDS

programs provide resources for drug screening, medicinal chemistry, genetically engineered mice, and for core resources to support collaborative research. Tools and resources are also a major thrust of the NIH Blueprint for Neuroscience Research and of several NIH Roadmap activities that are relevant to the NINDS mission. Computational neuroscience, imaging, drug screening, and structural analysis of membrane proteins are among the many examples.

Finally, although the NINDS targets initiatives to public health needs and scientific opportunities that are not otherwise addressed, the Institute relies heavily on unsolicited investigator-initiated research. This emphasis reflects the strong and consistent recommendations of the NINDS Council. The marketplace of research is especially suited to addressing the diverse challenges and opportunities that neurological disorders present. It is not happenstance that many highly ranked unsolicited grants respond to Institute priorities. The NINDS informs the research community about strategic and diseases plans, scientific workshops engage the research community in setting agendas to move forward, and plan priorities are also likely to be the focus of successful proposals simply because they reflect a consensus among the research community about what is most important for progress. From unsolicited grant proposals, the NINDS director, NINDS scientific staff, and the NINDS Council also identify meritorious “High Program Priority” grant proposals that score outside of the normal funding range but are especially important for the Institute’s goals. All NINDS research, whether solicited or not, is rigorously evaluated by peer review and by the NINDS Council for significance, quality, and relevance to the Institute’s mission.

National Institute of Allergy and Infectious Diseases NIAID Response to Congressional Report Language on Strategic Plan Implementation

The National Institute of Allergy and Infectious Diseases (NIAID) conducts and supports basic and applied research to better understand, treat, and prevent infectious, immunologic, and allergic diseases. For more than 50 years, NIAID research has led to new therapies, vaccines, diagnostic tests, and other technologies that have improved the health of millions of people in the United States and around the world and saved millions of lives.

The scope of the NIAID research portfolio has expanded considerably in recent years in response to new challenges such as bioterrorism, emerging and re-emerging infectious diseases, and the increase in this country of asthma prevalence among children. The growth of NIAID programs has also been driven by unprecedented scientific opportunities in the core NIAID scientific disciplines of microbiology, immunology, and infectious diseases. Advances in these key fields have led to a better understanding of the human immune system and the mechanisms of infectious and immune-mediated diseases.

Research Planning

Because of the breadth of research that NIAID supports – research on over 300 infectious and immunologic diseases, along with the need to conduct research globally, and the need to help translate the fruits of basic research into products that ultimately benefit the public – NIAID conducts extensive analysis and planning at multiple levels, each of which builds on the level above in increased detail. NIAID’s planning process was cited as a model by the Institute of Medicine in its 1998 report, *Scientific Opportunities and Public Health Needs: Improving Priority Setting at the National Institutes of Health*.

The highest planning level at NIAID is strategic planning, which develops and communicates a broad vision of scientific priorities across of the Institute’s research mission areas. Building on the strategic plans and the strategic planning process, NIAID next develops more detailed plans and research agendas that articulate the research priorities of specific NIAID missions, such as the biodefense and emerging infectious diseases mission area, and for specific diseases, such as AIDS, influenza and autoimmune diseases.

The next level in the planning process is the cascading development of ever-more detailed plans to “operationalize” and implement the higher-level plans. Planning at this level includes development of plans and activities to entice the scientific community to conduct research in critical, high-priority areas; to transition

promising research into promising new drug and vaccine candidates; and to provide incentives for the private sector to develop new drugs and vaccines that benefit the public. For instance, since FY 2000 NIAID has supported 371 research initiatives, each with its own goals and plan which were developed to support the higher-level plans. At the most detailed level are the plans of the individual research grants and contracts. Like every other Institute or Center at NIH, every grant or contract proposal that NIAID funds includes specific aims aligned with NIAID's research mission and provides a detailed plan to accomplish its goals.

Throughout its planning process, NIAID consults extensively with its stakeholders--a diverse group that includes scientific experts, professional societies, and patient advocacy groups--on the development of long-range NIAID strategic plans, as well as specific research initiatives.

In 2000, NIAID completed an intensive strategic planning effort, which included advice from a task force of infectious and immunologic disease experts. The product of that effort was *NIAID: Planning for the 21st Century*, a strategic plan that described broad-based priorities to guide NIAID programs, policies, and initiatives. NIAID expects to release an updated version of the plan by Summer 2007.

Since completing the 2000 strategic plan, NIAID has completed several mission- and disease-specific planning activities, most notably in the area of biodefense. In the wake of the 2001 terrorist attacks, NIH embarked on a systematic strategic planning process by convening the Blue Ribbon Panel on Bioterrorism and Its Implications for Biomedical Research, composed of distinguished scientists and other experts. Based on the Panel's advice and extensive discussions with other Federal agencies, NIAID developed three key documents to guide its biodefense research program and facilitated the development of trans-NIH strategic plans and research agendas for the development of countermeasures against radiological and nuclear threats and countermeasures against chemical threats.

NIAID has also convened scientific workshops, program reviews, and blue ribbon panels to evaluate progress and to determine future needs and opportunities in areas of research within the Institute's purview. For example, NIAID convened the NIAID Influenza Blue Ribbon Panel on September 11 and 12, 2006. The Panel reviewed the current NIAID influenza portfolio and research gaps and areas of scientific opportunity previously identified by NIAID staff, and identified additional scientific opportunities and approaches to guide NIAID's influenza research agenda.

Implementation of Strategic Plans and Research Agendas

NIAID implements its strategic plans and research agendas through several mechanisms, including targeted research initiatives, partnerships with industry, development of research resources, and the NIAID intramural research program. Unsolicited, investigator-initiated research is an important element of the NIAID research portfolio.

NIAID strategic priorities are addressed most directly through targeted research initiatives for basic, translational, and clinical research in scientific areas that present an emerging opportunity or a growing need. Between fiscal years 2000 and 2006, NIAID supported a total of 371 research initiatives.

To ensure that research initiatives are aligned with NIAID strategic priorities, they are developed through an annual planning process. The process aims to maximize public benefit by (1) paying close attention to current public health needs and anticipating changes in those needs; (2) capitalizing on scientific opportunities, especially those with potential to reduce the burden of disease; (3) ensuring the capacity for future work by sustaining a broad array of basic research and nurturing scientific talent; (4) collaborating within and beyond NIH; and (5) using federal resources to leverage and complement the activities of other sectors. Throughout the planning process, concepts for research initiatives are reviewed and refined multiple times as input from various sources is considered. After approval by the National Advisory Allergy and Infectious Diseases Council, NIAID staff members develop initiative concepts into program announcements (PAs), which are announcements requesting grant applications in a stated scientific area, and into grant and contract solicitations (e.g., RFAs and RFPs).

Over the years, NIAID-supported initiatives have enabled the development of many drugs and other therapeutics, vaccines, and diagnostics that have dramatically improved public health. For example, NIAID initiatives aimed at stimulating the development of drugs to treat HIV/AIDS have contributed to the development of more than 20 antiviral drugs. AIDS drugs have saved more than 3 million years of life in the United States. In the area of biodefense, targeted initiatives have led to the rapid development of and clinical testing of next generation vaccines against smallpox and anthrax and a vaccine against Ebola.

NIAID's implementation of its *Strategic Plan for Biodefense Research* has been aided by the enactment of the Project BioShield Act of 2004. Project BioShield provides NIH additional flexibility in awarding contracts, cooperative agreements, and grants for research and development of critical medical countermeasures. The BioShield Act also provides NIH with streamlined personnel authority, which

has allowed NIAID to hire highly qualified individuals to fill key positions related to product development. Lastly, Project BioShield provides NIAID with additional authority for the construction of research facilities, which NIAID has used to award grants for the construction of biocontainment laboratories. Research activities currently funded under these authorities include the development of therapeutics directed against the CDC Category A agents that cause anthrax, smallpox, tularemia, plague, botulism, and viral hemorrhagic fevers; medical countermeasures against radiological or nuclear terrorist attacks; and assays for influenza therapeutics.

NIAID partnerships with the private sector are important for the translation of knowledge gleaned from basic research into drugs, vaccines, and diagnostics. NIAID and private companies, acting in concert, can accelerate research and development of new preventive, therapeutic, and control strategies for high-priority diseases for which commercial markets currently provide insufficient incentive for corporate investment (e.g., diseases caused by agents of bioterror, HIV, TB, malaria, SARS). Powerful mechanisms have been established that both “push” and “pull” science toward needed medical countermeasures—basic research provides the push and new incentives to industry for product development provide the pull. Some of the mechanisms used to foster partnerships with the private sector include contracts to support evaluation, testing and development of high-priority medical countermeasures, Public Private Partnership grants, Small Business and Innovation Research grants, Small Business Technology Transfer grants, Challenge Grants, and Cooperative Research and Development Agreements. Recent partnerships with the private sector have included clinical testing of several pandemic influenza vaccines, development of biodefense diagnostics, a clinical trial of an HIV vaccine, an alliance to develop TB drugs, and development of immunotherapeutics for treatment of viral infectious.

NIAID strategic plans and research agendas emphasize the need to provide research resources and infrastructure to the research community to help speed the development of new drugs and other therapeutics, vaccines, and diagnostics. NIAID-supported research resources include the development of centralized sources of expertise in various fields, such as *in vivo* and animal model development; production of standardized and validated reagents and tests; development and humanization of antibodies, bioinformatics, diagnostic validation, vaccine production; clinical trials networks for the testing of vaccines, therapeutics, and prevention strategies; and construction of biocontainment facilities. A list of research resources available to the NIAID research community is available at <http://www3.niaid.nih.gov/research/resources/>.

NIAID's strategic plan, *NIAID: Planning for the 21st Century*, calls for the continued support of investigator-initiated research, a central pillar in NIAID research endeavors. The NIAID planning process acknowledges that the product development pipeline starts with a considerable investment in unsolicited research that allows science opportunities to be determined by individual scientists looking at new ideas and insights across a broad spectrum of research. This cutting edge, creative basic research becomes the foundation other basic and applied research is built upon. At times, NIAID steers the direction of unsolicited research through Institute-sponsored workshops and published research plans intended to encourage new research proposals in the scientific community.

Over the years, NIAID's investment in unsolicited investigator-initiated research has paid major dividends in the form of remarkable new insights into the immune system, immunologic disease, the immune response to infection, the physiology and genetics of infectious microbes, and the pathogenesis of infectious disease. Though the majority of unsolicited investigator-initiated research is not targeted towards product development, the fruits of this research are what ultimately drive the development of new approaches to solving important clinical and public health problems.

National Institute of General Medical Sciences (NIGMS) Response to Congressional Report Language on Strategic Plan Implementation

The mission of the National Institute of General Medical Sciences (NIGMS) is to support research and training in basic medical sciences and related natural or behavioral sciences that lays the foundation for advances in disease diagnosis, treatment, and prevention. Most of this support consists of research grants funding investigator-initiated proposals for cutting-edge biomedical research. Each year, NIGMS-supported scientists make major advances in understanding fundamental life processes. In the course of answering basic research questions, these investigators also increase our knowledge about the mechanisms and pathways involved in certain diseases. Strategic planning, in this context, involves identifying broad research themes and scientific opportunities in the biomedical sciences that are either currently available or likely to emerge in coming years.

Both in 1998 and again in 2002, NIGMS solicited the advice of the scientific community to help assign priorities and set the Institute's research agenda in future years. The discussions held in 1998 generated many ideas that blossomed into very successful scientific programs. Among these are the "glue grant" program, the complex systems initiatives, the Protein Structure Initiative, and the NIH Pharmacogenetics Research Network. As the 5-year NIH budget-doubling period drew to a close in 2002, the Institute again convened a meeting of representatives from the scientific community to take stock of progress, resources, and opportunities and to identify the most important and then-emerging areas of biomedical research. The 2002 meeting led to a March 2003 report *Funding Priorities and Initiatives of the National Institute of General Medical Sciences*, which serves as the NIGMS strategic plan.³ NIGMS will be holding a similar meeting in 2007 to help develop principles to guide NIGMS research support in the years to come.

In addition to these periodic discussions with the scientific community to identify broad research themes, NIGMS holds a number of scientific workshops each year to identify current research opportunities and develop more specific plans for individual initiatives. The results of these workshops are documented in reports presented to the National Advisory General Medical Sciences Council, which must give approval for any initiative that might be needed.

³ <http://publications.nigms.nih.gov/reports/priorities.html>

The Role of *Funding Priorities and Initiatives of the National Institute of General Medical Sciences* in Guiding NIGMS Support for Research

The research priorities identified by scientific experts in planning meetings such as those convened by NIGMS influence future research activities in several ways. The reports of these meetings are widely disseminated among the community of biomedical scientists who are keenly aware of and attentive to emerging opportunities and the stated priorities of funding agencies. The mere communication of these research opportunities can be a major influence on the direction of investigator-initiated research, as investigators seek to develop successful proposals for research funding.

These stated priorities also influence the Institute's grant funding decisions. While the results of peer review are always a major consideration in the funding of research proposals, the peer review score is not the only factor considered when Institute staff and Advisory Council members recommend specific grant applications for funding. Among the other factors taken into account is scientific program need. Meritorious proposals, but with somewhat poorer peer review scores, may still be funded if they are designated by the National Advisory General Medical Sciences Council as being of high program priority.

Discussion among scientific experts can also identify areas of research in which a more active role of the Institute is required to stimulate the submission of research proposals. For such areas, it may be necessary for the Institute to issue a program announcement or request for applications. Several such research themes were identified as current or emerging in the 2003 report and funding has been allocated to these initiatives in recent years. For example:

- ***Modeling/Complexity.*** The 2003 report called for a stronger emphasis on systems biology approaches. NIGMS created a set of initiatives to promote quantitative, interdisciplinary approaches to studying complex biological systems. For the past several decades, biomedical research has largely focused on identifying and characterizing individual molecules. Now, with an avalanche of biological data arising from gene sequencing projects and the availability of other new technologies, biologists are eager to explore the intertwined networks that underlie complex processes such as cell behavior, embryonic development, and the progression of multifaceted disorders like heart disease. Because such work relies on computational modeling, this effort seeks to enlist the expertise of mathematicians, physicists, engineers, and computer scientists. Descriptions of efforts to recruit quantitative scientists,

opportunities for training, and areas of special research interest in this area are available at <http://www.nigms.nih.gov/Initiatives/SysBio>.

- ***Interdisciplinary Science.*** Recognizing the increasing need for collaborative research, NIGMS created an initiative to "glue" together large groups of scientists pursuing some of the biggest unsolved problems in basic biomedical research today. The purpose is to support the formation of large research teams drawn from different institutions and scientific disciplines to tackle problems that are not likely to be solved by individual research laboratories. As in all NIGMS-supported research, peer review is used to evaluate the success of these efforts. Evaluations conducted in 2005 and 2006 resulted in the phasing out of one of these collaborative efforts and a 5-year renewal of three others.
- ***Tool Development/Access.*** In conjunction with the NIH Roadmap for Medical Research, NIGMS established the Exploratory Centers for the Development of High Resolution Probes for Cellular Imaging in 2004 to support multi-investigator teams to develop new technologies that enable higher sensitivity biological imaging in living cells. Each of the nine centers will focus on different strategies for probe development, cellular delivery, probe targeting, and signal detection to improve detection schemes by a factor of 10 to 100. The ultimate goal is to develop probes and imaging systems that can be used to routinely achieve single molecule sensitivity for imaging dynamic processes in living cells.

NIGMS Partnerships in Strategic Planning

NIGMS considers the biomedical research community its primary partner, both in helping to set research agenda and conducting the research that NIGMS supports. As part of its planning activities, NIGMS also identifies areas in which partnerships with other funding agencies can either avoid duplication of effort or create synergistic effects that will advance science more rapidly. Within NIH, NIGMS coordinates with other institutes and centers in a variety of ways, but this collaboration is perhaps best exemplified by the active role played by NIGMS in implementing the NIH Roadmap for Medical Research.

NIGMS leads the Bioinformatics and Computational Biology and the Structural Biology Roadmap initiatives, and is responsible for major components of the Molecular Libraries and Imaging and the Interdisciplinary Research initiatives. In FY 2005, NIGMS also became the administrative home for the NIH Director's Pioneer Award program. This award complements NIH's traditional,

investigator-initiated grant programs by supporting exceptionally creative scientists who take innovative approaches to major challenges in biomedical research.

NIGMS also participates with 14 other NIH institutes and centers in the NIH Neuroscience Blueprint. By pooling resources and expertise, the Blueprint benefits from economies of scale, confronts challenges too large for any single institute or center, and develops research tools and infrastructure that serve the entire neuroscience community. This approach allows the broad implementation of best practices developed at a single institute or center, the coordination of planning at the early concept stage, the expansion of access to neuroscience resources, and the creation of multi-institute working groups to focus on cross-cutting scientific issues.

**National Institute of Child Health and Human Development (NICHD)
Response to Congressional Report Language on Strategic Plan
Implementation**

Introduction

The mission of the National Institute of Child Health and Human Development (NICHD) is to ensure that every child is born healthy and wanted; that women suffer no harmful effects from reproductive processes; that all children have the chance to achieve their full potential for healthy and productive lives, free from disease or disability; and to ensure the health, productivity, independence and well-being of all people through optimal rehabilitation.

To achieve its mission, the NICHD conducts and supports basic, clinical and translational research and training programs that span a broad spectrum-- from studies of gene expression and metabolic pathways involved in development, to studies of the influence of economic and social structures on the well being of mothers, children and families. NICHD research begins at the bench and progresses through clinical trials and studies of clinical practice.

The NICHD uses a combination of strategies to achieve a balanced portfolio of research projects and training programs that addresses the most pressing issues relevant to its mission. When setting research agendas, the NICHD actively seeks input from numerous authoritative sources, both within and outside of the federal government. This feedback helps the NICHD fulfill its mission while considering the needs of different communities and constituencies affected by its research.

Long-Range Planning at the Institute Level

The NICHD has a long history of setting research priorities at the Institute level. The latest of these overall strategic plans developed the framework for a trans-NICHD planning process. This was followed by six separate and more targeted plans representing the major scientific areas of interest to the Institute (see Appendix 1). Each plan was developed with significant input from scientific experts outside of the Institute and the federal government. Drafts of these plans were posted on the NICHD Website and public input was sought. The final plans were widely distributed to stakeholders, including all of the medical research institutions across the nation. Copies of the plans were available to the general public via the NICHD clearinghouse and posted on the Web for wider dissemination. These plans, combined with ongoing program planning (see below) and investigator-initiated research provide the foundation for the Institute's scientific activities and accomplishments.

Long Range Planning at the Program Level

To more fully address the Institute's broad research interests, the NICHD recently expanded its planning to include more specific and targeted activities at the Branch level. This affords the Institute greater flexibility to respond to rapidly changing research requirements and emerging scientific opportunities and places planning closer to the level where funding decisions are made.

Branch Reports to Council

Each NICHD Branch quadrennially reports its activities to the National Advisory Child Health and Human Development Council (Council). Previously, these reports focused on accomplishments; now, they include a major section describing future research directions. Development of the future directions begins with an extensive review and analysis of the Branch's current research portfolio, and training and funding trends. To increase accountability and transparency, an outside panel consisting of scientific experts, Council members, patient advocates, and representatives from professional organizations and interested communities are invited to provide input. The draft reports are reviewed by Council and posted on the Web for further feedback. The final reports are widely distributed to interested communities via mass mailings. They are also available through the NICHD clearinghouse and readily accessible through the newly designed NICHD Website.

The Branches use these future directions to guide development of initiatives, plan research agenda-setting meetings, make future funding decisions, and encourage research collaborations and resource sharing. The Branches will report back to Council on their progress half way through the reporting period. To date, three Branch reports plans have been completed under this process and three others are in various stages of production (see Appendix 1).

- Since the Mental Retardation and Developmental Disabilities (MRDD) Branch Report was published in June 2005, the Branch has initiated several activities in response to the suggestions of its expert panel. These include, among others: 1) meeting with the 15 MRDD Research Center Directors and launching a secure Web Portal to facilitate research collaborations and knowledge sharing among the MRDD Centers; 2) evaluating the P30 funding mechanism as a means to define and achieve new MRDD Program goals; 3) drafting two trans-NIH RFAs to solicit applications for P30 and R01 grants in Autism research; and 4) issuing an RFP and awarding two contracts for novel technologies in newborn screening.

- The Developmental Biology, Genetics and Teratology (DBGT) Branch has already initiated several activities in response to the future directions outlined in its Branch Report (in production). These include: 1) reassigning a portion of its portfolio to another Branch with similar projects to simplify grants management; 2) arranging for certain NICHD-supported scientists to use microarray analysis instruments in NINDS-funded facilities, thus leveraging overall NIH research costs. In addition, a PA has been approved to stimulate research in genetic epidemiology of human structural defects.

Research Agenda Setting Meetings

The NICHD uses scientific workshops to develop research agendas targeting priorities identified through strategic planning and other efforts. These meetings bring together experts, including notable scientists from the extramural community, as well as practitioners, advocates, and community representatives to review the state of the science and to inform the research community of emerging opportunities and shifting research priorities. Through such meetings, a consensus is reached on potential research directions, partnerships and consortiums formed, and barriers to scientific progress addressed. The resulting research agendas are disseminated to the investigative community in various formats and inspire investigator-initiated applications and NICHD-initiated solicitations. For example:

- The NICHD sponsored a workshop to stimulate innovative research approaches to study the causes and treatment of vulvodynia. The report of this workshop was distributed to researchers in the field, members of the American College of Obstetricians and Gynecologists and the National Vulvodynia Association. A PA has been prepared in response to the findings.
- The NICHD and the NIH Office of Medical Applications of Research sponsored a State-of-the-Science conference to examine evidence on how frequently caesarean deliveries are scheduled for women without medical or obstetrical indications for the procedure, and how these “maternal request” procedures compare with vaginal deliveries in terms of child health and development and maternal health outcomes. The conference produced recommendations concerning critical knowledge gaps that will help define future research priorities and inform clinical practice.

Cross-Cutting Planning

NICHD staff participate in many trans-NICHD and trans-NIH coordinating committees to bridge and enhance the research mission of the broader scientific community. These committees address research issues of mutual interest to

inform Institute- or NIH-level priorities, avoid duplication of effort, and leverage research and management resources. The NICHD collaborates with other ICs to develop and support joint PAs and RFAs and to plan and fund scientific meetings and workshops in cross-cutting areas of interest. For example:

- As the result of trans-NIH discussions and consultation, the two existing Autism networks [Studies to Advance Autism Research and Treatment (STAART) and Collaborative Programs of Excellence program in Autism (CPEA)] are being consolidated into one Autism Centers of Excellence program. This will maximize coordination and cohesion of NIH sponsored efforts in autism research without diminishing the financial commitment. A RFA was issued and the most meritorious applications will be funded in 2007.
- As a member of the NIH Obesity Research Taskforce, the NICHD contributed to developing a cross-cutting strategic plan for coordinating obesity research activities across the NIH. Based on the plan, the NICHD joined several other Institutes in issuing RFAs and funding grants to investigate the link between metabolic syndrome and childhood obesity, and to test the effectiveness of prevention strategies in community settings.

Dissemination

The NICHD uses a variety of formal and informal dissemination methods to convey our research goals to the scientific community. This contact encourages scientists to submit proposals that address the Institute's targeted priority areas and to prepare their labs to address emerging opportunities.

NICHD scientific program staff attends a number of professional association meetings, at which they discuss research priorities via formal presentations and informal discussions.

Research priorities are also disseminated through the Friends of the NICHD, a broad coalition of professional organizations, advocacy groups and others with interest in the NICHD's scientific areas. Member organizations further broadcast the information to their membership. The individual program officers also interact directly with researchers in the field and encourage research proposals that target identified areas of scientific interest to the Institute.

Initiative and Funding Decision

An annual operational planning process brings together all of the priorities identified in the Institute's various planning activities into one organized and viable implementation plan. The process begins with scientific program staff

proposing new project ideas based on the goals and priorities identified through the strategic plans, research agenda setting meetings, and by relevant directives. Concepts are proposed to Council for their feedback and approval. Selected concepts are developed into conferences, RFAs, RFPs, or PAs. These proposals, along with recurring projects due for renewal, are prioritized based on program priorities and budgets, and presented to the Institute leadership for consideration. The Institute Director then selects, rejects, or defers projects and conferences based on overall Institute priorities, ongoing funding obligations, scientific portfolio balance, and budgetary constraints.

The Budget and Grants Management Offices recommend an overall funding strategy and payline to the Institute Leadership at the beginning of the fiscal year, which is fine-tuned before each Council round. This strategy includes a method for selecting projects for funding that are beyond the payline if they address critical research priorities. The funding decisions also give special consideration to new investigators. The Council provides guidance and approval of the final implementation plan.

The results of this overall strategic/operational planning process are strategic directions that are well-informed and target the highest priorities of the Institute. This planning process ensures that issues critical to the NICHD's broad scientific mission are adequately addressed, public health concerns are considered, and emerging scientific opportunities are exploited. This process also allows the Institute to maximize returns from the national investment in its research and improve the health of the nation.

National Eye Institute (NEI) Response to Congressional Report Language on Strategic Plan Implementation

Background on NEI Strategic Planning

For over 30 years, the National Eye Institute (NEI) has set its research priorities through a strategic planning process that culminated in the publication of a series of national plans for vision research at roughly three to five year intervals. This process actively involved the National Advisory Eye Council (NAEC), members of the vision research community, scientific experts from other fields of research, outside public groups, and professional and advocacy groups. This involvement included assessing progress, identifying needs and opportunities, and developing strategies for research conducted and supported by the NEI. It should be stressed, however, that the NEI and the NAEC have never viewed these plans as master plans or blueprints for research, but rather as a means of drawing attention to areas of research need and opportunity. The first priority has been and continues to be funding the highest quality investigator-initiated research applications that help achieve the goals and objectives outlined in the strategic plans. To that end, the principal factor considered in determining which applications are funded continues to be the scientific and technical merit of the applications, as evaluated through the peer review system, combined with the programmatic considerations of the NEI and NAEC and the availability of funds.

The first plan, Vision Research Program Planning, was published in 1975 and established the formal planning process that would guide the development of subsequent plans for the next 30 years. These plans resulted from a dynamic process, in which changes in approach, structure, and format were made in an attempt to improve the process and be responsive to the changing needs of the field and existing public health challenges. A core component, however, in the development of each plan has been the convening of expert panels to review and make recommendations on NEI research programs. These panels were also tasked to determine where progress was made by identifying the most important research accomplishments that were achieved since publication of the last plan. Not only was this assessment key to evaluating the progress that has been made in achieving the goals and objectives in the previous plan, it is also a vital first step in their next tasks of identifying the future needs and opportunities in each program and ultimately in setting realistic goals and objectives for each program.

During the development of the most recent strategic plan, the National Plan for Eye and Vision Research (2004), the vision research community was asked, within their field or fields of expertise, to review the previous plan and to provide

an update of most important areas of research progress or accomplishment; to assess the current relevancy of the objectives; and to recommend additions or deletions based on broad areas of scientific need and opportunity. This information was provided to the panels of experts representing each of NEI's programmatic areas for consideration in preparing the draft reports of their recommendations. The draft reports were reviewed by the NAEC and scientific, professional, and philanthropic and advocacy organizations who conduct or support vision research prior to finalization by NEI staff and publication of the complete strategic plan. The plan was then made accessible through printed copies and by posting electronic versions on the NEI website (<http://www.nei.nih.gov/strategicplanning/>).

Strategic Plan Publication and Distribution

The earliest NEI strategic plans were available as printed documents only. They were mailed to all grantee and members of scientific, professional, and advocacy organizations that conduct or support vision research. Copies of the plans were also made available at scientific and professional meetings at information booths where current and potential grantees could talk with NEI program staff about their research interests and the opportunities available for vision research. These meetings included the annual meetings of the Association for Research in Vision and Ophthalmology, the Society for Neuroscience, the American Academy of Ophthalmology, the American Optometric Association, and other scientific meetings that NEI grantees and intramural scientists attend to present the findings of their research.

With the advent of the worldwide web and improved methods of electronic communication, the NEI was able to broaden its involvement of the vision research community in its priority setting efforts. Grantees were contacted by email, through the U.S. Postal service, and by posting of these communications on the NEI website and were allowed to play a role, as discussed above, in identifying accomplishments, making recommendations on research needs and opportunities, and suggesting strategies for meeting critical needs or taking advantage of unique opportunities. With the most recent plan, the National Plan for Eye and Vision Research (2004), the draft expert panel reports were posted on the NEI website and were reviewed by the full NAEC and approximately 60 organizations that conduct or support vision research. The final plan was posted on the NEI strategic planning website and the availability was announced electronically to NEI grantees. Additionally, a media campaign was conducted to ensure current and potential grantees were aware that printed or electronic copies could be obtained from the NEI. The plan continues to be available at annual

scientific and professional meetings attended by current and potential NEI grantees from broad areas of science that underpin vision research. In this way the strategic plan serves a role similar to a program announcement. This has allowed the NEI to attract researchers from other scientific disciplines who can bring their special expertise to vision research. It has had the further advantage of creating new opportunities for participation in a variety of trans-NIH research activities, including the Roadmap initiatives, the Neuroscience Initiative, and numerous diabetes studies that were recommended as research priorities within NEI's strategic plan.

Implementation Activities

The NEI has long relied on investigator-initiated research as the primary means of implementing the program planning priorities identified in its strategic plans. For basic or fundamental research, the emphasis on investigator-initiated research has been achieved primarily through use of the research project grant mechanisms. For applied clinical research, the emphasis on investigator-initiated research has been achieved through cooperative agreements. This has allowed the vision research community to maintain scientific creativity in responding to program priorities identified in the national plans and has resulted in the submission of remarkably creative grant applications that are consistently of high scientific quality.

The NEI leadership and the NAEC have long held the view that the planning process does not necessarily determine the course of scientific discovery, but rather hastens the rate at which it occurs. Even though program planning panels representing the vision research community have identified the priority areas that they consider the most important areas of research, the advent of new technologies or scientific insights always presents the possibility of additional scientific opportunity not foreseen during the plan's development. For that reason, the scientific quality of the research, as ascertained through the peer review process, is the prime determinant of whether the application ultimately receives funding. Thus, the program priorities are based upon the collective wisdom of the scientific community, and yet the competitive funding process remains responsive to new and innovative ideas and approaches from that community.

A further role of the program priorities during implementation of the plan is in consideration of a small number of applications that have been judged to have significant scientific merit in addressing a designated priority or supporting a program goal or objective, and yet did not receive a score within the funding

range. Council may designate these applications as having high program relevance and recommend them to the NEI Director for funding. It should be emphasized, however, that the designation of high program relevance is not used in cases where study sections have recommended that the application not be given further consideration. It is again important to note, however, that new technologies or scientific insights may create additional scientific opportunity not envisioned during the plan's development, and therefore, the scientific quality of the research remains the primary determinant of funding.

The NEI periodically reviews and updates the plan's priorities so that the plan stays abreast of progress in the various research areas. The NEI recently published an assessment of progress in vision research that occurred during and subsequent to the period of the doubling of the NIH budget. This document, Progress in Eye and Vision Research: 1999 – 2006, highlights some of the most important research advances upon which future progress can be built. Additionally, the NEI engages in an ongoing effort to conduct or support workshops, conferences, or symposia in critical or emerging areas of science to explore how they might be applied to diseases of the eye and disorders of vision. Reports from such forums are being posted on the NEI website at <http://www.nei.nih.gov/strategicplanning> and will assist future program planning panels in the periodic evaluation and updating of the needs and opportunities in vision research and the refinement of the NEI's goals and objectives.

Scientific experts within and outside of the vision research community have participated in the formal planning panels, as well as the workshops and conferences that help update the plans' recommendations. By encouraging scientific input from broad areas of science and attending scientific meetings to distribute the plans and talk with potential grantees within and outside vision research, the NEI not only has attracted grantees from other scientific disciplines who bring their special expertise to vision research, it has also created the opportunities for participation in a variety of trans-NIH research activities. Many of the areas of research highlighted in the Roadmap initiatives, the Neuroscience Initiative, and numerous diabetes studies have been recommended as research priorities within NEI's strategic plans.

Points and Modes of Influence on Decision-making

Role of the Strategic Plan in Reviews, Program Announcements, and Requests for Applications: The strategic plan is organized by disease, disorder, or ocular tissue into research programs and other NEI sponsored activities. Currently, a portfolio review of one of NEI's programs or subprograms is conducted at each meeting of

the NAEC. The portfolios are reviewed generally according to these programmatic divisions or according to areas of science, such as genetics or immunological diseases, which cut across programmatic divisions. During the portfolio review, an overview of the research area is presented by an outside expert in the field and the NEI program director for the area under review addresses the research content and funding for the program. The NAEC members are then given the opportunity to comment or provide recommendations related to the program. Council members are encouraged to identify areas which are not receiving adequate support or making sufficient progress, as well as to suggest topics for workshops, conferences, or symposia in critical or emerging areas of science. These reviews inform the strategic planning process by reviewing the scientific content and accomplishments of programs or activities within the strategic plan and ensuring that prescribed priorities are being accomplished. Similarly, during the formal development of the strategic plan the panels are provided information on the programmatic content and funding within the program and are asked to evaluate how well the program is meeting established goals and objectives and to recommend changes in priorities where necessary.

Because the strategic plans are developed with the support and involvement of the NAEC and members and supporters of the vision research community, the NEI experience has been that the strategic plan, itself, has served a similar function to a program announcement. Because vision researchers have been so responsive to the needs and opportunities identified in the strategic plans, NEI has purposefully chosen to limit the issuances of program announcements (PAs) or requests for applications (RFAs). When these solicitations have been issued, e.g., NEI Translational Research Program on Therapy for Visual Disorders (PAR-05-110) or Therapeutics Delivery for Neurodegenerative Diseases (RFA-EY-07-001), they have been issued to stimulate research in an area identified in the strategic plan or in collaboration with other NIH components to address areas of common interest that also are prioritized in the strategic plan. The NAEC participates with the NEI leadership in discussions regarding the possible issuance of PAs or RFAs.

Role of the Strategic Plan in Funding Applications: As stated above, a relatively small number of applications that have been judged to have significant scientific merit in addressing a designated priority or supporting a program goal or objective, and yet are not within the funding range, may be brought up by NEI program staff for special NAEC consideration. Council may designate these applications as having high program relevance and recommend them to the NEI Director for funding. Additionally, grantees frequently cite the current plan within their grant application, highlighting the research goals or objectives their proposals address.

The Role of Partnerships in Strategic Plan Implementation

The NEI, the NAEC, and the vision research community have maintained a unique partnership in addressing the most pressing visual health needs through the development and publication of NEI's strategic plans. This partnership included NAEC members, NEI staff, members of the vision research community, and supporters of vision research in numerous scientific, voluntary, and philanthropic organizations throughout the country. Involvement of these groups in the strategic planning process ensured that the groups upon whom the NEI depended for implementation were knowledgeable of the most pressing needs and opportunities in the field.

The NEI has also used the National Eye Health Education Program (NEHEP) partnership in the review and implementation of strategic planning priorities. This partnership involves over 60 public and private organizations concerned with eye health education. Although the primary purpose of the partnership was to collaborate on the development of eye health education programs, the public and private groups represented are the same organizations involved in the implementation of the strategic plan recommendations.

National Institute of Environmental Health Sciences (NIEHS) Response to Congressional Report Language on Strategic Plan Implementation

Both the development and implementation of the most recent NIEHS Strategic Plan (published May 2006) demonstrate the approach of our Institute towards pursuing specific strategic research directions in order to maximize the return on our overall research investment in environmental health science.

Building a Consensus and Groundwork for the NIEHS Strategic Plan

The current NIEHS Strategic Plan, titled *New Frontiers in Environmental Sciences and Human Health*, took form through a nearly year-long process of discussions with more than 400 scientific and public leaders from academia, government, medical professions, community advocacy groups, and the general public. It was drafted with input from a national web survey, the participation of 90 science and health professionals during a two-day strategic planning forum, discussions with members of the NIEHS Public Interest Liaison Group, numerous opportunities for public review and comment on draft documents, and much input from NIEHS staff and members of the NIEHS National Advisory Environmental Health Sciences Council.

The vision of our Strategic Plan is broad – to prevent disease and improve human health by using environmental sciences to understand human biology and human disease. Putting this vision into practice will require that the Institute focus attention on understanding all possible aspects of the etiology and pathogenesis of complex diseases. The strategic plan provides a matrix of challenges and goals that will guide NIEHS development over the next several years, and accelerate the application of our science to improvements in human health.

Seven goals are identified by the NIEHS Strategic Plan in the areas of clinical research, basic research, integrative research programs (see especially the Director's Challenge and DISCOVER Program below), global and community-linked research, biomarker development, training and partnerships. The strategic plan thus becomes a structure that the Institute and its grantees can build on. The Plan serves as an overarching guide to fulfillment of the Institute mission.

Communicating and Distributing the Strategic Plan to the Research Community

Putting our Strategic Plan into action requires the help and efforts of the full environmental health sciences community, both researchers and stakeholders. Thus distribution of the Plan and wider communication and understanding of the

Plan's goals represent the first, critical step towards implementation. The new NIEHS Strategic Plan was rolled out on May 1, 2006. It was distributed as a supplement to *Environmental Health Perspectives*, the NIEHS journal, and is available online at <http://www.niehs.nih.gov/external/plan2006/>. Printed copies were distributed widely to Congress and Congressional staff; to the scientific community, including grantees of NIEHS and of other institutes; and to interested members of the public. Printed copies are available on request. The Director and other Institute senior scientists and officials are making presentations outlining the goals and implementation of the Strategic Plan in a number of forums. Talks and/or workshops have been held or are planned for the National Academy of Sciences' Institute of Medicine Roundtable on Environmental Health Sciences, Research and Medicine; at the Annual Meeting of the Society of Toxicology and other national scientific meetings; and at major research universities. The Plan has been advertised and publicized widely in the scientific press.

Efforts to communicate the NIEHS Plan to the research community are helped enormously by the fact that many of the ideas in the Plan were the result of dialogue with the research community as the Plan was being created. A consensus direction was embodied in the Plan which marries the vision of the NIEHS leadership with the best ideas and expertise to be found across the scientific community. Implementing the Plan becomes that much easier since the Institute and its associated research enterprise begin the process on much the same page.

Designing Initiatives, Directing Our Research Investment to Fulfill the Plan

The goals of the Strategic Plan influence greatly the NIEHS's decision-making regarding research investment. Plan goals are the single most important consideration in designing new research initiatives; they also come into play in considering investigator initiated applications. Once these applications have been ranked for scientific excellence through the peer review process, NIEHS commonly funds grants taking into consideration many additional factors: whether the applicant is a new, young investigator; if the project shows high program relevance or addresses gaps in the portfolio; if there is the promise of especially high-payoff research, for instance. All of these considerations are made with the Strategic Plan in view. At the September 2006 meeting of the NIEHS Advisory Council, the Council expressed an interest in helping staff identify applications within this "gray zone" that Council members feel are particularly worthy of funding. The Council has established a work group that will do this for the next Council meeting in February 2007.

NIEHS is developing a number of new, more directed initiatives that address goals of the Strategic Plan. The NIEHS Advisory Council will be commenting on the relevance of new initiatives and the funding plans for those initiatives in meeting the objectives of the Strategic Plan. NIEHS will be informing its Council of funding decisions for all the new initiatives for which they have provided input. New ideas based on the goals of the Plan were outlined at a recent scientific retreat; several high profile scientific initiatives in various stages of implementation exemplify the efforts of the NIEHS to translate its strategic plan goals into action.

- *Integrative Research:* The Strategic Plan's focus on integrative research is the genesis of the DISCOVER Program, which stands for Disease Investigation through Specialized Clinically Oriented Ventures in Environmental Research. NIEHS is excited by the opportunities presented by this new grants program, which supports centers where teams of researchers will focus on integrating mechanistic environmental health research with patient-oriented and population-based studies relevant to human disease. This research will facilitate the application of fundamental findings toward the development of improved clinical or public health practice. Since the release of the DISCOVER RFA, NIEHS has worked hard to communicate and promote this program to the extramural community. A dedicated webpage was developed to provide DISCOVER-related information for potential applicants. NIEHS staff held several Applicant Information Meetings (both in person and Videocast) to provide a forum to discuss the goals and objectives of the DISCOVER program and to answer questions from the scientific community. In order to advertise the DISCOVER Program to scientists not familiar with NIEHS and its new Strategic Plan, solicitations were sent to NIH investigators currently leading active Centers programs funded by other Institutes in disease-related areas that are relevant to the mission of NIEHS. In addition to DISCOVER, the Institute is also developing a new "fusion" grant concept that will promote interdisciplinary and multi-disciplinary research by linking R01 investigators in a shared overall project or set of projects to bring different perspectives and expertise to environmentally relevant problems. (Other integrative research models are being tested as part of the Director's Challenge, described below under Intramural Initiatives.)
- *Exposure Biology:* Recently, the NIH received considerable endorsement from the scientific community, Congress, and the Administration for a bold new trans-NIH initiative, the Genes and Environment Initiative (<http://www.niehs.nih.gov/oc/news/gei.htm>), to accelerate research discoveries on the role of genes and the environment in human disease. NIEHS has earned a lead role in this initiative, through the NIH Exposure

Biology Program, to promote the development and application of new technologies to precisely measure human exposure in population genomics studies. This program reaches directly towards one of the goals of the NIEHS Strategic Plan. Following the hosting of a multidisciplinary workshop, the Environmental Airway Disease Project was launched in FY06 as the initial research project under this program. Additionally, five RFAs were released in early FY07 to recruit the extramural community into this effort. They will be applying new technologies to our ability to definitively assess an individual's real-world exposure, the internal or biological dose of this exposure, as well as incorporating information on factors that modify response to environmental agents. The outgrowth of this research effort will be the development of 10 – 25 new exposure assessment technologies over the next five years that will be a great improvement in sophistication and precision over current exposure assessment techniques.

- *Community-based Research:* In response to the devastation wrought by Hurricane Katrina, and consonant with Strategic Plan goals relating to the support of community-based research and partnering, NIEHS, in conjunction with the National Center for Minority Health and Health Disparities, the New Orleans Department of Health, and other public and private partners, is launching a new research study called HEAL (Head off Environmental Asthma in Louisiana). The HEAL project will assess the impact on asthma in New Orleans children of environmental health conditions that were caused and exacerbated by Hurricane Katrina, as well as implement an intervention program to address these problems. An important component of the project will be a clear plan for informing the New Orleans community about the goals, implementation, and outcomes of the study. A community advisory group, comprising representatives of diverse community interests, will provide a conduit for community members to present and discuss their needs and concerns related to the HEAL project, as well as their preferences for dissemination of study results to the participants and the community at large.
- *Training and Career Development of Science Professionals:* In pursuit of the Strategic Plan goal of expanding the pool of high-caliber environmental health sciences researchers, NIEHS has established the Outstanding New Environmental Scientist (ONES) program to support the development of independent investigators and recruit talented emerging scientists into this field. Grantees were recently invited to present their work in seminars to encourage interaction with Institute intramural scientists. Other initiatives are under development to promote the training of physician-scientists with expertise in environmental health, and, at the beginning of the training pipeline, to attract undergraduate and high school students into environmental health sciences by providing exciting laboratory experiences.

- *Intramural Initiatives and the Director's Challenge:* Several of the goals of the Strategic Plan are also driving new efforts internally within the NIEHS and its intramural program. The NIEHS Director has set aside funds to support integrative, interdisciplinary intramural research that exhibits special potential through the Director's Challenge program. The program supports intramural scientists in conducting innovative research to unravel the mechanistic underpinnings of complex human diseases, and in rapidly translating these findings in epidemiologic and clinical populations. Recipients of the Director's Challenge will develop an interdisciplinary research theme that integrates patient-oriented or public health research with basic biological and mechanistic studies to understand how environmental exposures modulate or regulate physiological processes that may lead to human disease. By fostering collaborative and integrative research, the Director's Challenge is intended to increase the relevance of basic scientific discoveries in environmental health and public health applications to ultimately improve human health. Also, to expand and facilitate clinical research at NIEHS, in keeping with one of the goals of the Strategic Plan, the Institute is constructing a Clinical Research Unit on campus, a 14,000 gross square foot out-patient facility on site where physicians and other researchers can see patients without commuting to other institutions. NIEHS has developed a new Office of Translational Research and recruited a senior scientist to lead it.

As the narratives above demonstrate, NIEHS has made tremendous progress converting its Strategic Plan into action. As we move into the future, we anticipate even greater changes in our ability to translate environmental health findings into strategies that address and reduce the burden of complex human diseases. We will move beyond the current paradigm, where the public health applications of NIEHS research play out primarily in the regulatory arena. In future this research will also be brought to bear in the clinic where NIEHS-generated insight on the basic biology of human diseases will result in improvements in our ability to treat previously recalcitrant conditions such as asthma, neurodegenerative disease, cancer, and heart disease.

National Institute on Aging (NIA) Response to Congressional Report Language on Strategic Plan Implementation

The mission of the National Institute on Aging is to:

- Support and conduct biological, clinical, and behavioral and social research with respect to the aging process, diseases associated with aging, and other special problems and needs of older Americans.
- Foster the development of research and physician scientists in aging.
- Communicate information about aging and advances in aging research with health care providers, the public, and the scientific community.
 - With the goal to promote the health and independence of our older citizens.

We carry out this mission through an extensive extramural research grant program and a vibrant intramural research program. To facilitate effective stewardship, we work to ensure that decisions for funding investigator-initiated research and special initiatives such as Requests for Applications are carried out in the context of a strategic planning framework that addresses current and projected public health needs and takes full advantage of scientific and technological opportunities for advancing the field of aging research. We identify new strategic directions through constant monitoring of the health needs of our older citizens, analysis of our NIA research portfolio and scientific resources, and regular consultation with a network of stakeholder communities.

Identifying and Communicating Our Strategic Directions

The NIA Strategic Plan outlines the goals and objectives of the Institute. It serves as a tool for communicating our mission and strategic directions, a point of reference for discussion about future directions and funding decisions, and a framework for systematically mapping the Institute's scientific portfolio and tracking progress toward our goals.

We are currently in the process of updating our Strategic Plan. The strategic directions outlined in our *Action Plan for Aging Research: Strategic Plan for Fiscal Years 2001-2005* (www.nia.nih.gov/AboutNIA/StrategicPlan) remain current and will provide a consistent framework for the updated Plan, focusing on four goals:

- Increase our understanding of healthy aging.

- Improve the health and quality of life of older people.
- Reduce health disparities among older people and populations.
- Enhance resources to support high quality research.

We are engaging broad participation to update the Plan beginning with NIA staff and involving members of the National Advisory Council on Aging (NACA) as well as extramural researchers, professional societies, and advocacy groups for their ideas and review. We anticipate completing the update by May 2007.

Our intention is to post the updated Strategic Plan on the NIA Web site with hyperlinks to connect the goals and objectives of the Plan with descriptions of the research programs, initiatives, and scientific advances that support them. This approach will greatly enhance our ability to use the Plan in a dynamic way and to make it as widely available as possible. We hope that this resource will prove valuable to our own staff, staff at other NIH Institutes, Centers, and offices, and our external stakeholders by informing them in real time about our research activities and the progress we are making.

We will provide printed copies of the core Plan for distribution to members of the research community, professional societies, advocacy organizations, and other stakeholders upon request.

Implementing Our Strategic Plan

In the coming years, our Strategic Plan will continue to serve as a reference for operational planning, priority setting, and decision making. We will use it to help:

- Define unmet public health needs and research gaps.
- Allocate resources through grants and intramural programs.
- Take advantage of opportunities to strengthen collaboration with public and private partners.
- Assess progress in meeting priority goals, objectives, and strategies.

The NIA organizational structure is designed to most effectively achieve the goals outlined in our Strategic Plan. Our budgetary framework reflects that organizational structure. NIA senior leaders oversee implementation of the Strategic Plan. They guide and coordinate activities and support the NIA Director in making decisions on research concepts, workshops and conferences, and other planning and policy issues.

We use several forums for open discussion among the NIA leadership and scientific staff. For example, the NIA holds twice yearly planning retreats to engage Institute staff in articulating and discussing needs, opportunities, and priorities for moving the field of aging research forward. Within budgetary guidelines, concepts presented at these retreats result in the development and announcement of Requests for Application, Program Announcements, or Requests for Proposals for research contracts. In addition, the retreats provide an opportunity for staff to review current research directions in light of new discoveries or opportunities. Our challenge is to strike a balance between the vision expressed in the Strategic Plan and the press of “free market” ideas and research guided by peer review and represented by investigator-initiated research.

Trans-NIA working groups also play a significant role in identifying strategies for implementing our strategic plan. The groups frequently collaborate to hold workshops involving large numbers of people from our stakeholder communities to explore potential or to solicit advice about how to approach work in specific research areas. Two recent examples of workshops supported by NIA-wide efforts are a workshop on inflammation and its interaction with aging and an upcoming workshop on facilitating translational research across our programs, a critical activity for achieving the objectives of our Strategic Plan.

NIA staff also participate in a number of NIH-wide planning activities such as the Neuroscience Blueprint, the Trans-NIH Strategic Plan to Eliminate Health Disparities, the Task Force on Obesity, and several NIH Roadmap related efforts. We often take advantage of opportunities to build synergy and leverage resources through partnerships with other NIH Institutes, Centers, and offices and with private funders on initiatives such as the Alzheimer’s Disease Neuroimaging Initiative and the Paul B. Beeson Career Development Awards in Aging Research.

Peer Review Activities

Following the established NIH guidelines and procedures described in Appendix 2, the NIA approval process for funding most grant applications is in order of percentile or priority score as determined by first level peer review. Each year, the NIA Director also allocates a percentage of competing dollars for use by program staff in choosing applications for consideration from a discretionary zone or percentile range. Decisions on these applications are made explicitly in terms of Institute priorities as outlined in the Strategic Plan.

The National Advisory Council on Aging (NACA) (for extramural research) and the NIA Board of Scientific Counselors (for intramural research) also play vital roles in the Institute's decision making. They conduct periodic reviews of NIA research programs and these reviews are used extensively to inform future planning and priority setting. In addition, NACA provides second-level peer review of extramural grant proposals for research and training projects before final funding decisions are made. Recommendations made by NACA are based on both scientific merit and the relevance of the proposed research to NIA's mission and goals. NACA members use the NIA Strategic Plan as a key reference in making their recommendations.

After each NACA review, the NIA Director makes the final funding decisions for the Institute. These decisions are driven by the needs and opportunities as identified in the Institute's Strategic Plan. Each decision requires a balanced approach that takes into account the importance of innovation and synergism through investigator-initiated research and work in unexplored or under-explored areas stimulated through such mechanisms as new Requests for Applications or Program Announcements.

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) Response to Congressional Report Language on Strategic Plan Implementation

Introduction

In June of 2006, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) publicly posted its Long-Range Research Plan for fiscal years 2006 to 2009. The plan serves as a broad scientific outline for NIAMS, and the investigative and lay communities, by identifying compelling research opportunities that will inform the Institute's priority-setting process. Over time, the plan will help propel research progress related to the understanding, diagnosis, treatment, and, ultimately, prevention of arthritis, musculoskeletal, and skin diseases. With 20 years of scientific accomplishments behind us – and unprecedented research challenges before us – the plan provides a collective perspective on key priority areas. While the plan is not meant to be comprehensive, as the mission of NIAMS is broad-ranging, it will help guide our assessment of emerging scientific opportunities and public health needs that the Institute is positioned to address.

How Was the NIAMS Long-Range Plan Developed and Distributed?

The plan was developed with significant input from extramural investigators, representatives of research societies and health voluntary organizations, and NIAMS scientific staff. To lay the foundation for the plan, the Institute sponsored a series of roundtable discussions with outside scientists who are experts in our key mission areas. The input from these meetings was used to develop a draft plan that included both cross-cutting areas of science – such as behavioral and biopsychosocial research, biomarkers discovery and development, and regenerative medicine – and program-specific sections.

Scientific staff from the Institute analyzed and refined the draft plan before it was presented to the NIAMS Advisory Council for review and comment. The revised draft was then made available on the Institute's website for public comment. Special notices were sent to the Institute's funded investigators, as well as scientific and patient groups with a particular interest in the NIAMS' activities, to ensure that we received broad input on the draft plan. All public comments were reviewed and analyzed, and appropriate changes were made. The final plan was presented to the NIAMS Advisory Council and posted publicly on the website, again with targeted notices to our investigative and lay communities. The Institute Director and other senior scientific staff regularly highlight the plan

in conference presentations and at meetings with colleagues from research organizations and patient groups.

How Does the Plan Affect the Institute's Priority-Setting and Decision-Making?

One of the most significant areas of common need identified in our plan relates to research translation, and how the Institute can best stimulate and support it. To this end, the NIAMS has recently launched a new Centers of Research Translation (CORT) program, to help bridge the gap between laboratory bench and patient bedside. CORTs are designed to bring together basic and clinical research in a way that helps translate fundamental discoveries into new diagnostics and treatments. The Institute has funded four new centers as part of this program, and we are currently soliciting applications for a second round. The new centers will focus on the following areas: the first will study the biological basis of fracture healing and the efficacy of a potential new treatment for healing of fragility fractures in the elderly; the second will investigate the role of different cell types in lupus pathogenesis, develop markers of disease activity and severity, and explore new targets for therapies; the third will study the molecular contributors to a genetic form of rickets, and work toward developing new treatments; and the fourth will explore the molecular basis of scleroderma to understand its underlying causes using functional genomics and gene networks.

While the scientific opportunities and research needs that are highlighted in our plan do not necessarily lead to specific new initiatives, they do help guide areas that we emphasize in funding solicitations, including cross-cutting areas. For example, in our most recent announcement for Rheumatic Diseases Research Core Centers – which provide resources for established, currently funded investigators, often from different disciplines, to adopt a multidisciplinary approach to common research problems, and to ensure greater productivity than we would expect from separate research projects – we listed several areas of potential emphasis that are discussed in our plan. These include, but are not limited to: exploring mechanisms of autoimmunity underlying rheumatic diseases, including environmental factors that contribute to the development of these conditions; investigating the genetic basis of rheumatic diseases, including in animal models and defined clinical populations; studying mechanisms underlying organ damage, including inflammatory processes; and identifying new risk factors and developing technological approaches to evaluate them, in order to predict disease susceptibility more reliably.

In addition, the long-range plan helps to inform our decision-making about joining initiatives led by other Institutes and Centers in areas that intersect with our scientific interests. To illustrate this, we recently partnered with the National Institute of Dental and Craniofacial Research and the National Cancer Institute to solicit research projects focusing on basic and translational studies of osteonecrosis of the jaw, an oral complication associated with bisphosphonate use. Bisphosphonates are prescribed to alleviate bone pain in certain cancer patients, and to reduce bone loss in osteoporotic or osteopenic individuals. Although there is a growing knowledge base on the effects of bisphosphonates on bone quality and strength, there is a gap in our understanding of how they may interfere with bone healing and repair at the genetic, molecular, cellular, and tissue levels. These new initiatives are seeking to address that gap, in order to develop knowledge that will serve as the basis for the prediction, prevention, diagnosis, and treatment of this condition.

Finally, the long-range plan also influences choices about topics to address at our annual roundtable discussions and scientific retreat, held as part of our overall planning process. It affects Institute decisions about select pay of research proposals beyond our payline, and acceptance of unsolicited applications over \$500,000 in annual direct costs. Further, priority areas in the plan help inform activities of trans-NIH working groups that involve the Institute. For example, at the most recent meeting of the Lupus Federal Working Group – which NIAMS leads on behalf of the Department of Health and Human Services – our plan was highlighted as a document of interest to other agencies, as well as research societies and health voluntary organizations. Similarly, the discussion at the last meeting of the Federal Working Group on Bone Diseases, held in October 2006, included a session on potential collaborations across NIH Institutes and Centers. Relevant sections of the NIAMS plan were shared with Working Group members to help stimulate ideas for possible future efforts.

How Does the Plan Help Facilitate Collaborations and Partnerships?

There are a number of ways that the long-range plan facilitates collaborations and partnerships in fields of high priority for the Institute. To the extent that areas of shared scientific interest are highlighted, the plan provides a platform for pursuing joint efforts with other Institutes and Centers. For example, we have a strong partnership with the National Institute of Neurological Disorders and Stroke and the National Institute of Child Health and Human Development in muscular dystrophy research and training. This includes support for Senator Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers, which promote side-by-side basic, translational, and clinical research; provide resources that can

be used by the national muscular dystrophy and neuromuscular communities; and offer training and advice about muscle diseases for researchers and clinicians. We are also pursuing collective efforts to encourage translational research in all forms of muscular dystrophy, and to stimulate career development opportunities for muscle disease researchers. Taken together, these activities are designed to facilitate the development of new and more effective treatments for muscular dystrophy, and to increase the number and quality of investigators in basic, translational, and clinical research focused on this disease.

We are also building on insights from the plan to nurture emerging areas of science that may need stimulation by the Institute. For example, we have recently created a new extramural research program that is focused on musculoskeletal development, tissue engineering, and regenerative medicine, and we are exploring potential initiatives in these areas with other Institutes and Centers. While these initiatives are still under development, their overall aim would be to better understand the mechanisms by which connective tissues are originally generated. These insights could then be translated into tissue engineering approaches for the repair and regeneration of connective tissues in clinical applications. In addition, work would be needed to integrate developmental mechanisms with the remodeling processes that occur normally in mature tissues. Such efforts would require considerable collaboration between basic biologists and tissue engineering specialists. Ultimately, functional tissue restoration and regeneration have the potential to reduce major sources of disability in society, as millions of Americans are affected by conditions that could benefit from such advances, including osteoarthritis, degenerative disc disease, and sports injuries to the musculoskeletal system.

With respect to research training, the long-range plan articulates a broad need to develop a cadre of clinician scientists who are positioned to pursue epidemiology, clinical trials, and health outcomes research across our mission areas. To facilitate this, the Institute has recently partnered with the Orthopaedic Research and Education Foundation and the American Skin Association to encourage applications for individual National Research Service Award post-doctoral fellowships. These fellowships would support up to two years of advanced training in the relevant methodologies to obtain a Master's of Public Health and/or a doctoral degree in epidemiology to qualify the fellows to pursue careers in these areas as they relate to musculoskeletal or skin diseases. The overall goals of these initiatives are to increase the number of clinically-trained orthopaedic surgeons and dermatologists who are prepared to make advances in epidemiology, clinical trials, and health outcomes research, and to enhance the visibility of these disciplines at U.S. academic health centers.

Conclusion

The NIAMS mission covers a broad and diverse spectrum of research and training responsibilities, as bones, muscles, joints, and skin are central components of the body. The Institute's Long-Range Research Plan for fiscal years 2006 to 2009 is one of many tools we use to guide our planning and priority-setting in times of tremendous scientific opportunity. Other cross-cutting documents – such as our Strategic Plan for Reducing Health Disparities, the NIH Muscular Dystrophy Research and Education Plan, and the NIH Autoimmune Diseases Research Plan, to name a few – also help shape our decision-making and resource-allocation choices, as well as our collaborative efforts. Collectively, they provide critical guideposts to ensure that we are taking full account of the needs and gaps that are most challenging for our research communities. Our ability to address these effectively will, over time, benefit the millions of Americans who are affected by both the common and rare diseases we study.

**National Institute on Deafness and Other Communication Disorders
(NIDCD) Response to Congressional Report Language on Strategic Plan
Implementation**

We depend on our ability to communicate effectively to function in our modern society. Yet, approximately one of every six Americans experiences some form of communication disorder. Strategic Planning at the National Institute on Deafness and Other Communication Disorders (NIDCD) is driven by this compelling public health need and recent growth of new human communications research opportunities. The NIDCD solicits advice through a series of continuous planning, expert advisory, evaluation, and analysis activities to prepare the Institute to seize and capitalize on research opportunities that can benefit the health of Americans.

On October 28, 1988, the NIDCD was established by Public Law 100-553. The mission of the NIDCD is to conduct and support research and research training in the normal and disordered processes of hearing, balance, smell, taste, voice, speech, and language. These processes of sensing, interpreting, and responding are fundamental to the way we perceive the world and to our ability to communicate effectively and efficiently. Basic and clinical research to understand the normal processes and disorders of human communication are motivated by intrinsic scientific interest, by the goal of allowing more individuals to reach their potential, and by reducing costs, both tangible and intangible, to individuals and to the nation.

The NIDCD Strategic Plan (Plan) presents a series of goals and objectives that serve as a guide to the Institute in prioritizing its research investment to keep current with the state-of-the-science and advances in diagnosis and treatment of communication disorders. Due to an expansion of new discoveries in human communications research and the availability of new tools to identify study targets, the NIDCD implemented a new process in 2002 to update the Plan. This new method is designed to accelerate discovery by collecting broad-based scientific advice from experts charged with setting clear priorities amidst numerous competing opportunities. To keep current with the state-of-the-science and advances in the field, the Plan is reviewed and updated by the National Deafness and Other Communication Disorders (NIDCD) Advisory Council every three years. The NIDCD invites the public to provide input on the draft Plan using the NIDCD Public website. The next update of the Plan will be completed in FY 2009.

The Plan serves as a guide to the NIDCD staff and the NDCD Advisory Council. In these instances, the Plan becomes a key decisive tool when considering investigator-initiated research grant applications for High Program Priority (HPP) funding, developing Program Announcements/Requests for Applications/Requests for Contract Proposals. Furthermore, the Plan is often distributed by staff at NIDCD-sponsored workshops or research conferences, so the research community can be better aware of the priorities of the Institute. Investigators also submit focused or directed applications for research projects that directly address priorities within the Plan. The current Plan includes the following four Strategic Plan Priorities (SPPs), which include areas that offer extraordinary research opportunities in the field of human communication sciences:

- Determine the Molecular and Epidemiological Bases of Normal and Disordered Communication Processes
- Study the Development, Deterioration, Regeneration, and Plasticity of Processes Mediating Communication
- Study Perceptual, Cognitive, and Sensorimotor Processing in Normal and Disordered Communication
- Develop and Improve Devices, Pharmacologic Agents, and Strategies for Habilitation, Rehabilitation, and Prevention of Human Communication Disorders

In order to track and evaluate our research portfolio, the NIDCD matches each funded research project with the appropriate SPP. By doing so, the NIDCD staff can, at any time, analyze the research portfolio to demonstrate how well the funded NIDCD research portfolio corresponds with the Plan SPPs and other designated trans-NIH needs or priorities. Using these analyses, the NIDCD and the NDCD Advisory Council can assess the level of emphasis in the portfolio and/or identify research gaps. In general, the analyses exemplify the Institute's important contributions to the body of knowledge needed to help individuals with communication disorders and to advance research in all aspects of human communication.

The NIDCD believes that the scientific merit of a grant application, as judged by initial peer review, is the single most important criterion in the determination of funding. As evidence, 80% of the funds available at each NDCD Advisory Council meeting are used to support grants of the very highest technical merit,

independent of discipline or NIDCD program area. The remaining 20% of funds are used to support additional meritorious applications designated as HPP by the NDCD Advisory Council or NIDCD program staff on the basis of meeting one, or more, of the following HPP nomination criteria: to fill scientific gaps or deficiencies in the grant portfolio (including meritorious applications in areas identified as priorities in the Plan), to foster the entry of new investigators into the field, to foster innovative research, and to increase the diversity of principal investigators and grantee institutions in the portfolio.

In addition, the NIDCD relies on partnerships with other NIH Institutes, federal agencies, and the public to effectively implement the priorities of the Plan. For example, the NIDCD continues to seek guidance and advice from the public, through professional and lay organizations with an interest in research within the mission of the NIDCD and the SPPs. The priorities within the Plan can also encourage collaboration and coordination of research or health information dissemination with outside partners and other NIH institutes and centers. For example, the NIDCD participates in many Interagency Committees used to foster collaboration among federal agencies whose missions include human communications research. In addition, the NIDCD convenes chartered *ad hoc* advisory committees and working groups as needed to obtain recommendations on areas of scientific importance and opportunity. The NIDCD also has a Health Disparities Strategic Plan for Fiscal Years (FYs) 2004-2008 and a Ruth L. Kirschstein National Research Service Award (NRSA) Training Program Plan. The NIDCD employs multiple methods to prioritize its efforts and to identify the most promising scientific opportunities in order to advance human communication research.

National Institute of Mental Health (NIMH) Response to Congressional Report Language on Strategic Plan Implementation

NIMH supports innovative research that will profoundly transform the diagnosis, treatment, prevention, and ultimate cure for mental disorders. Mental disorders are brain disorders and that means that progress requires a deeper understanding of the brain and behavior. Our commitment to basic brain-behavior science has never been greater. Along with the rest of NIH, we are also committed to translating the discoveries from basic science to clinical practice. Our clinical research vision focuses on the four Ps of medical research: increasing the capacity to Predict who is at risk for developing disease; developing interventions that Pre-empt the disease process; use knowledge about individual biological, environment, and social factors to better Personalize interventions; and, ensure that clinical research involves Participation from the diversity of people and settings involved in health care. The need for transformative, innovative research is urgent; each year, one in every 20 adults in the United States experiences a disabling mental illness,⁴ while nearly one in 10 experiences a serious emotional disorder during childhood.⁵

Priority Setting at NIMH

To achieve these goals, NIMH has developed several strategic plans and, more recently, has engaged in extensive priority-setting for the Institute (see Appendix 1 for a complete list). In developing these plans and setting priorities, NIMH:

- Solicited and obtained input from our various stakeholders – patients and their advocates, physicians/scientists and their professional societies, Congress, and the National Advisory Mental Health Council (NAMHC), which includes members from academia and the general public;
- Convened workgroups of the NAMHC to review our portfolios in basic science, clinical trials, and mental health services research to recommend priority areas for future investment;
- Identified funding priorities with each extramural program division, based on review of existing and new science in the portfolio.

⁴ Kessler, RC, Chiu, WT, Demler, O, Merikangas, KR, Walters, EE. Prevalence, severity, and comorbidity of 12-month DSM-IV disorders in the National Comorbidity Survey Replication. *Archives of General Psychiatry*. 2005; 62, 617-627.

⁵ “Prevalence of serious emotional disturbance in children and adolescents.” *Mental Health, United States, 1996*. Center for Mental Health Services, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, 1996.

In this effort, we have attended to three overarching factors: relevance, traction, and innovation. Relevance refers to research most applicable to the NIMH mission, which is to reduce the burden of mental and behavioral disorders through research on mind, brain, and behavior. Traction refers to the capacity for rapid progress in areas where new tools, such as whole-genome analysis or high resolution and high-speed imaging, can yield definitive answers to long-standing, relevant questions. Innovation refers to projects that frequently are considered too risky. However, we live in an era of ‘discovery science’, with tools at the ready like never before to identify the major candidate genes, cells, and systems involved in emotion, cognition, and behavior. This work, while risky, also has significant potential to advance understanding and treatment for mental disorders. Unless NIMH places a priority on innovation, these unprecedented opportunities may not receive the support they deserve.

As a result of our priority-setting discussions with stakeholders, NIMH is committed to the following goals for innovative research and research training over the next five years:

- Support integrative science of brain and behavior that provides the foundation for understanding mental disorders and their treatments.
- Develop more reliable, valid diagnostic tests and biomarkers for mental disorders.
- Define the genetic and environmental risk architecture of mental disorders.
- Develop interventions to prevent occurrence and/or reduce relapse of mental disorders.
- Develop more effective, safer, and equitable treatments that have minimal side effects, reduce symptoms, and improve daily functioning.
- Conduct clinical trials that will provide treatment options to deliver more effective personalized care across diverse populations and settings.
- Create improved pathways for rapid dissemination of science to mental health care and service efforts.

To reach these goals, NIMH refocused its extramural research division in the fall of FY 2004 to better emphasize translational research spanning bench, to bedside, to practice. In turn, each of the extramural research divisions used these Institute goals to develop areas of high priority that further refined and specified for the research community the types of scientific questions of greatest interest to the Institute.

Institute goals and priorities are disseminated and communicated to the research community in a variety of ways including: presentations at numerous scientific meetings; postings on the NIMH web site; presentations to local, state, and national advocacy and professional organizations; a tri-yearly newsletter with up-to-date information on Institute workshops and initiatives circulated to extramural grantee and posted on the NIMH website; and, person-to-person technical assistance provided by NIMH program staff in interaction with grantees, contractors, and applicants.

Planning Activities for Implementing Priorities

In addition to general communication and dissemination, Institute and extramural research division priorities have become central to the development of yearly workshops, conferences, scientific reviews, and programmatic initiatives. Each fall, the Institute re-evaluates the status and progress of high priority areas by asking the research divisions to develop action plans for implementing priorities in the upcoming fiscal year. Yearly action plans subsequently are reviewed by and discussed with Institute leadership to identify the most critical opportunities for advancing Institute goals. Examples of action items in these plans include, but are not limited to: convening workshops and meetings to bring together leaders in the scientific community to help identify next-steps in cutting-edge research; convening inter-agency meetings to identify areas of synergy and ways to improve across-agency harmonization; identify and pursue opportunities for developing public-private partnerships; and, develop funding opportunity announcements to encourage and/or solicit research on high priority topics.

Each spring, the Institute initiates planning for the next fiscal year. Institute leadership and programmatic staff in the extramural research divisions meet to brainstorm and discuss potential initiatives to be developed into Program Announcements and Requests for Applications (RFAs) or Proposals (RFPs). Thorough vetting is essential as discussion among the scientific staff identifies the priority being targeted, potential cross-initiative and priority synergies, and overall scientific enthusiasm for accelerating advancements. Institute leadership subsequently uses this information when making decisions about the initiatives to be pursued in the next fiscal year.

As a final step, initiatives involving RFAs are presented and discussed with the National Advisory Mental Health Council. This too provides an important source of input about scientific opportunities addressed by the initiative, as well as the match between the initiative and Institute priorities.

The Importance of Flexibility in Funding Decisions

It is important to remember that even within this context of priority setting, it is equally important for the Institute to be open and nimble in order to take advantage of the sometimes rapid and unanticipated opportunities in biomedical research. With all of the expert and considered opinion that goes into the development of our strategic plans and priorities, it is critical that NIMH remain open to and encouraging of unsolicited research applications, as they can and do frequently address provocative and recently emerging areas of research that hold great promise for advancing our mission. In early 2006, the Institute conducted an assessment and determined that approximately 80% of the newly funded research project grants (RPGs) matched one or more of the divisional priorities. This assessment demonstrates that the research community, while aware of and engaged in pursuing research on Institute priorities, also remains inspired to pursue potentially provocative and “outside of the box” mental health research.

NIMH’s commitment to maintaining a healthy balance of research addressing areas of high-priority and newly emerging opportunities is reflected further in our overall funding strategy for FY 2007. In general, NIMH intends to support up to three-fourths of new and competing research applications that fall below the 20th percentile. Council and program staff may selectively recommend payment of grants that fall in this range, as well as beyond, based on: Institute priorities; balance in the existing research portfolio; and, availability of funds. In addition, NIMH considers newly independent investigator status as a priority in funding decisions. This means that a research grant from a new investigator may be funded out of order and at percentile scores equal to or higher than grants not selected for payment from established investigators.

NIH Blueprint for Neuroscience Research

NIMH also serves as co-lead with the National Institute of Neurological Disorders and Stroke (NINDS) for the NIH Blueprint for Neuroscience Research. The NIH Blueprint is a trans-NIH program of cooperative activities among the NIH Office of the Director and 15 NIH Institutes and Centers that support research on the nervous system. The purpose of the NIH Blueprint is to enhance data sharing and provide enabling resources to accelerate research in the neurosciences. Beginning in 2005, the NIH Blueprint has engaged in annual planning exercises to identify areas where investment or coordination of ongoing activities can have a major impact. Based on this process, the NIH Blueprint themes developed for the next few years include: neurodegeneration from disease and aging (FY07); development of the nervous system throughout the lifespan (FY08); and

plasticity, the remarkable capacity of the nervous system to change in response to environmental cues, experience, injury, and disease (FY09).

For each theme, the NIH Blueprint hosts workshops with consultants from the extramural science community to generate recommendations for specific initiative topics relevant to the year's theme. Workshop recommendations are then evaluated by the NIH Blueprint Institute Directors using the following criteria: relevance to providing research tools and infrastructure to the entire neuroscience community; ability to build on existing programs of supported research without redundancy; and, innovation. Initiatives that best match these criteria are used to form project teams comprised of program staff from multiple Institutes to develop and carry out implementation plans. The project teams implement most recommendations by developing new RFAs or RFPs, although they are able to address some recommendations by modifying or coordinating existing programs, without new research funds.

National Institute on Drug Abuse (NIDA) Response to Congressional Report Language on Strategic Plan Implementation

In September 2000, NIDA published its first Strategic Plan, *Bringing the Power of Science to Bear on Drug Abuse and Addiction*. Given recent revolutionary advances in drug abuse research, NIDA is presently undergoing a strategic planning process to update this Strategic Plan for the coming years. This process includes gathering recommendations from the National Advisory Council on Drug Abuse (the NIDA Council) and from ongoing dialogue with our various stakeholder groups to establish achievable goals and objectives.

NIDA sets research priorities according to significant public health needs and emerging drug abuse trends, key scientific opportunities, and gaps in our current knowledge base. To stimulate targeted research in these areas, NIDA issues both Requests for Applications (RFAs) and Program Announcements (PAs), which alert researchers to our scientific priorities. Meritorious applications (both investigator-initiated and solicited) are selected through the NIH two-tiered peer review process, with funding decisions based on scientific merit and on whether an application responds to identified research needs.

The Strategic Planning Process at NIDA

In recent years, NIDA again called in a large group of knowledgeable and interested parties to guide our strategic direction. From 2004–2005, seven workgroups comprising NIDA council members and diverse outside experts were convened to make recommendations to the Director for how NIDA could best respond to urgent public health needs and simultaneously build a strong scientific infrastructure to help ensure that resulting research is used by trained health care professionals. The seven workgroups representing priority research areas included:

- Workgroup on HIV/AIDS
- Blue Ribbon Task Force on Health Services Research at NIDA
- Medications Development Work Group
- Clinical Trials Network Work Group
- Basic Science Review Work Group
- Work Group on NIDA's Approach to Grant-Making
- Minority Health Disparities Work Group

Workgroup recommendations stemmed from thorough program reviews and discussions with NIDA staff. These recommendations were presented to the NIDA Director, who developed a responsive implementation plan and vetted it

through the NIDA Council for incorporation into NIDA's Strategic Plan. In addition to soliciting cutting-edge research through RFAs and PAs addressing identified areas of need, NIDA is tackling research priorities through a Strategic Plan on Reducing Health Disparities, which focuses on minority health disparities in the prevention and treatment of drug abuse and addiction.

Identifying and Disseminating NIDA Strategic Priorities

To further inform NIDA's strategic direction as well as disseminate our research priorities, NIDA maintains an ongoing dialogue with stakeholders, including substance abuse researchers and practitioners in the field, State substance abuse treatment and prevention directors, a variety of constituent groups, and the NIDA Council. This dynamic outreach process "seeds" ideas for further research needs, which are then fed back into NIDA's strategic planning process via Council membership, constituent groups, and Institute staff, creating an instructive feedback loop that ensures inclusion of emerging needs in our calls for research and training priorities.

Below are brief descriptions of our multifaceted outreach efforts:

- *Monitoring of drug abuse trends.* NIDA monitors national and regional substance abuse trends to allow us to respond strategically to emerging public health needs. For example, NIDA's Community Epidemiology Work Group (CEWG), a network of researchers from major metropolitan areas across the United States, meets semi-annually to discuss ongoing community-level surveillance of the nature and patterns of drug abuse, emerging trends, characteristics of vulnerable populations and social and health consequences.
- *Conferences and symposia.* NIDA holds a variety of meetings to solicit potential scientific research from the field and to generate interest in particular areas identified as a priority.
 - Our Blending conferences are a good example. Regularly scheduled Blending conferences bring scientists together with community practitioners, State representatives, and substance abuse directors to discuss the latest research, identify research gaps and needed dissemination products, and inform strategies to surmount noted barriers. NIDA has held six successful blending conferences, the most recent in October 2006, where interactive discussion highlighted translational strategies to move innovative research from bench to bedside to community.

- NIDA attends and sponsors symposia at annual meetings of science and health associations, such as the Society for Neuroscience, the College on Problems of Drug Dependence, the American Society for Addiction Medicine, the American Association of Child and Adolescent Psychiatry, the American Psychological Association, the American Psychiatric Association and more. These meetings serve as a venue to convene expert scientists in the field to discuss emerging and cutting-edge areas of research.
- NIDA convenes independent scientific meetings/workshops on an ongoing basis to highlight emerging research areas and identify new avenues of research emphasis.
- *Meetings with constituent groups.* NIDA has many constituent groups working nationwide, with whom we regularly interact both to share our latest research results and to receive input on our research priorities.
 - For example, CADCA—Community Anti-Drug Coalitions of America—holds an annual meeting, at which NIDA will typically sponsor symposia highlighting specific drug abuse issues deemed important. This meeting also features a presentation of our priorities delivered by the NIDA Director. Through this forum, NIDA imparts scientific information to the coalition community, receives input on the information’s relevance to their membership, and gains insight into new areas of research that should be pursued.
 - As part of continuing efforts to blend research and science, NIDA held a pivotal meeting in 2005, in which several drug abuse prevention and treatment provider organizations and networks participated. This meeting, which grew out of recommendations by NIDA’s 2004 Blue Ribbon Task Force on Services Research, sought to stimulate meaningful community participation in NIDA-supported research by service providers. An RFA was subsequently issued to this end.

Dissemination of the Strategic Plan: NIDA’s new Strategic Plan will be advertised and made available on our website as well as displayed and distributed at the various meetings to which the NIDA exhibit booth travels each year. In addition, the Strategic Plan will be advertised through our *NIDA Notes* publication and via our list-serve to multiple constituency groups. NIDA’s website also provides a mechanism by which we receive and respond to inquiries from the public, which are also incorporated into our future strategic planning.

The Role of NIH–Wide Partnerships in Strategic Plan Implementation

NIDA’s Strategic Plan also plays a role in coordinating research with partners across NIH by highlighting mission overlap and spurring development of joint research initiatives. Sharing and receiving information across other NIH Institutes is accomplished through partnering on RFAs and PAs; through collaboration on the Neuroscience Blueprint, a consortium to support research that extends across the missions of all 15 neuroscience Institutes; and through participation in NIH Roadmap initiatives that most closely align with NIDA’s mission.

National Institute on Alcohol Abuse and Alcoholism (NIAAA) Response to Congressional Report Language on Strategic Plan Implementation

The *NIAAA Strategic Plan for Research, 2007-2011*, presents a new organizing principle for alcohol research studies and describes research opportunities to deepen and broaden our understanding of alcohol use and alcohol use disorders. The division of the Strategic Plan into life stages and cross-cutting themes has provided the Institute with a framework to focus planning activities on critical areas of research. This plan was approved by the NIAAA Advisory Council on Alcohol Abuse and Alcoholism in June 2006 and will be updated to reflect research and technological advances.

The *NIAAA Strategic Plan for Research* is being disseminated widely. It is posted on NIAAA's web site

<http://pubs.niaaa.nih.gov/publications/StrategicPlan/NIAAASTRATEGICPLAN.htm> and has been highlighted in presentations by the Institute Director and other staff at major scientific conferences such as the Research Society on Alcoholism. By identifying opportunities and areas of major scientific interest through the Strategic Plan, and by promoting them widely among the scientific community, NIAAA is stimulating the submission of research projects addressing the Institute's research priorities.

The Strategic Plan has been informed by a range of activities. NIAAA has convened a series of Extramural Advisory Board (EAB) meetings to review the NIAAA portfolio in specific areas of research, decide where existing research is sufficient, and identify opportunities to advance the field. Integration of work between interdisciplinary teams and Divisions within the Institute, and the EAB consisting of experts outside the institute, has resulted in a number of research recommendations. The Strategic Plan has incorporated recommendations from past EAB deliberations that have been approved by the NIAAA Advisory Council. In addition, the EAB meetings, and activities that result from their recommendations, are a central component of the implementation of the Strategic Plan.

The Strategic Plan now guides the Institute in developing research initiatives and identifying budget priorities. Annual Planning and Budget Retreats are held in which NIAAA Teams and Divisions propose research initiatives, in the form of Requests for Applications (RFAs), Requests for Proposals (RFPs) and Program Announcements (PAs), that are put forward for approval by the NIAAA Director in consultation with Senior Staff. RFAs may be used to encourage focused scientific investigation, for example, in areas that are understudied, of significant

interest to the public, have the ability to enhance clinical practice and/or improve healthcare. They may also be used to encourage collaboration between entities that do not currently work together such as college and university officials and prevention researchers. This collaborative arrangement provides a mechanism for the Institute to work with awardees to achieve their mutual goals, such as those found in NIAAA's *Underage Drinking: Building Healthcare System Responses* projects. The Annual Planning and Budget Retreats are followed by a Mid-year Review that focuses on updates in budget policies as well as implementation of recommendations from EAB reviews of the NIAAA research portfolio in accordance with the Strategic Plan.

In some circumstances research projects that are of particular interest to NIAAA receive a priority score during the review process that puts them outside the normal funding range. In recognition that the Institute has the prerogative to fund projects beyond the payline, NIAAA sets aside a Director's Reserve calculated as a portion of the competing RPG funds. Research projects that address areas of interest within the Strategic Plan and are deemed meritorious by the Institute may be funded through the Director's Reserve.

Partnerships within and beyond NIH provide NIAAA an opportunity to implement some of the goals contained within its Strategic Plan. For example, NIAAA has identified underage drinking as a priority of the Institute. Therefore, when the U.S. Surgeon General announced his decision to issue a *Call to Action* on Underage Drinking, NIAAA provided the scientific foundation for the document and worked in close collaboration with the Office of the Surgeon General and the Substance Abuse and Mental Health Services Administration. NIAAA's focus on medications development in the Strategic Plan has resulted in additional research funding in this area as well as an emphasis on building relationships with the pharmaceutical industry, encouraging companies to invest in the development of medications for alcohol dependence.

Dividing the Strategic Plan by life stage provides a perspective on the development of alcohol use and problems. Notably NIAAA has put a significant focus on the mechanisms by which individuals change their drinking behavior, especially the transition away from harmful drinking. To fully understand this process will require input from multiple scientific disciplines and NIAAA is exploring innovative mechanisms similar to those used in the Defense Advanced Research Projects Agency (DARPA) to foster this type of research.

The *NIAAA Strategic Plan for Research, 2007-2011* informs every aspect of the work within the Institute. The plan is being widely disseminated and will

continue to influence research within the alcohol field to answer critical questions about alcohol's impact on health throughout the lifespan.

National Institute of Nursing Research (NINR) Response to Congressional Report Language on Strategic Plan Implementation

Introduction

Strategic planning plays a vital role in the development and assessment of the research portfolio of the National Institute of Nursing Research (NINR). Commensurate with the National Institutes of Health's (NIH) longstanding commitment to investigator-initiated research, NINR uses its Strategic Plan to communicate its research priorities to the scientific community, highlighting the critical areas of public health research in which needs are most acute and for which the Institute can make its biggest impact. In addition, careful strategic planning enhances NINR's ability to continually evaluate its past and current activities, monitor emerging research trends and public health needs, and adapt to the ever-changing research environment as circumstances dictate.

In October 2006, NINR released its new five-year Strategic Plan, entitled, "Changing Practice, Changing Lives." Developed in close consultation with representatives of the extramural community, this new Plan details NINR's scientific priorities. NINR will focus its research on health promotion and disease prevention; improving quality of life through self-management, symptom management, and caregiving; eliminating health disparities; and leading critical research on the end of life. The Plan also highlights four cross-cutting strategies for advancing nursing science, including: advancing the integration of the biological and behavioral sciences; promoting the design and use of new patient care technologies; improving nursing science methods; and developing the next generation of investigators. The full text of the Strategic Plan elaborates on each of these areas, and can be found on NINR's website at www.ninr.nih.gov.

Development and Distribution of NINR's Strategic Plan

Development of NINR's Strategic Plan

The formal process of developing NINR's Strategic Plan began in June 2005 at NINR's annual planning retreat. Institute staff and external scientific advisors took stock of NINR's research portfolio, goals, and accomplishments, and assessed priority areas discussed in the previous Plan for their relevance to continuing scientific and public health needs. Likewise, these experts identified gaps in current research, as well as opportunities for new research in emerging areas of science. A subcommittee of the National Advisory Council for Nursing

Research (NACNR), composed of Council members and key NINR staff, was convened to develop this analysis into a formal Plan. The NACNR was updated on the Plan's progress at its regular meetings throughout the following year. A draft of the Plan was posted on the NINR website to obtain public comments, and professional and patient groups were also invited to comment. Stakeholders, including representatives of major professional societies, deans, individual scientists, and students, provided helpful comments, many of which were incorporated in the final version of the Plan that was approved by the NACNR at its May 2006 meeting. The final Plan was distributed to members of the NACNR in September 2006, and was released to the general public at NINR's 20th anniversary research symposium on October 11, 2006.

Distribution of NINR's Strategic Plan

NINR's Strategic Plan is perhaps the most important means for communicating the Institute's research goals and priorities to the extramural community and to other stakeholders. This communication encourages investigators to fully consider NINR objectives when developing their own research proposals. Therefore, effective distribution of the Plan to stakeholders is essential. The Institute has published the Plan in three formats: as a posting on NINR's website, as an electronic file on CD-ROM, and in hard copy as a booklet. Since its initial release, the Plan has been distributed through multiple means. NINR has e-mailed a link to the Plan on its website to all of its principal investigators in the extramural community. Copies of the Plan are being mailed to stakeholder groups. Over 800 copies of the Plan were handed out on CD-ROM to participants at the October 2006 Council for the Advancement of Nursing Science meeting in Washington, DC, and NINR will continue to distribute the Plan at similar forums in the coming months and years. The Plan will also be highlighted in the many speeches and presentations given by the NINR Director. Institute program directors will provide guidance on the Plan's research priorities in various forums to investigators interested in applying for funding. In the future, NINR will continue to seek out new and innovative means for ensuring that our strategic priorities, in the form of our Strategic Plan, are effectively and broadly communicated to all researchers and stakeholders.

The Role of Strategic Planning in NINR Decision-making

NINR employs its Strategic Plan in many facets of Institute decision-making, from developing new funding opportunities, to determining NINR's potential role in trans-NIH initiatives, to ongoing portfolio evaluation. The organization of NINR's research portfolio reflects the research priorities detailed in the new Plan.

Extramural research program areas, as outlined in NINR's Congressional Budget Justification, correspond to the priority and cross-cutting research areas listed in the Plan. In this way, NINR seeks to ensure that resource allocations follow strategic priorities.

Developing New Announcements of Funding Opportunities

The majority of the NINR research portfolio consists of projects conceived and proposed by individual investigators. This investigator-initiated research dependably ensures that most of NINR's strategic goals are met; however, a small subset of those goals requires the specific stimulation of research applications in order to build that critical area of science. In these situations, NINR, like the other NIH Institutes and Centers (ICs), uses *Requests for Applications* (RFAs) and *Program Announcements* (PAs) to communicate this need to the scientific community. NINR employs RFAs to target specific types of research when tightly circumscribed programmatic objectives need to be met. The use of RFAs comes with a commitment of dedicated funds, thereby alerting the community to the importance of these studies. In contrast, PAs are used to signal Institute interest in broader research areas. While PAs do not provide a specific commitment of dedicated funds, they tell the community that the research applications will be regarded as highly relevant to the Institute's mission when reviewed alongside investigator-initiated applications. Employing funding opportunity announcements together with a robust investigator-initiated research portfolio works to assure overall scientific balance consistent with the goals of the Strategic Plan.

Funding initiatives are developed by NINR program staff and are subject to the approval of the NACNR. NINR's Strategic Plan provides a critical blueprint for the development of new initiatives. All new funding announcements are expected to be closely aligned with the strategic objectives set forth in the Plan. NINR will, however, allow for the possibility that new and re-emerging opportunities not necessarily covered by the Plan may appear that require urgent attention by the Institute. Under such circumstances, NINR will respond as quickly as possible.

Participation in Trans-NIH Initiatives

Trans-IC, collaborative research is a cornerstone of NINR's strategy. NINR participates in several trans-NIH initiatives, including NIH Roadmap initiatives, the NIH Pain Consortium, and the NIH Public Trust Initiative, as well as serving as the lead IC for end-of-life research. The decision to participate in these efforts,

and to what extent, is made with close consideration of the priorities outlined in our strategic planning process.

Ongoing Evaluation of Portfolio

In the same way that NINR's previous Plan was used to analyze past performance, the new Plan will be used to continually assess NINR's current portfolio and ensure the sustained alignment of funded research with scientific priorities. All funded grants will be assessed for their applicability to one or more of the research priority areas listed in the Plan. This type of analysis highlights the degree to which resources have been sufficiently allocated by NINR to its priority areas of research. Most importantly, it can highlight investigator-initiated research in new and exciting areas of science that the Institute may want to further develop.

Conclusion

Strategic planning is a critical part of the research process at NINR. The Institute views its Strategic Plan as its central means of communicating research priorities to the scientific community, and as essential to NINR program planning and evaluation. While continuing to recognize the essential role of investigator-initiated research in advancing medical science, NINR is committed to the full integration of strategic planning into its decision-making, further enhancing the Institute's ability to fulfill its vital mission of establishing the scientific basis of care for all individuals across the lifespan.

National Human Genome Research Institute (NHGRI) Response to Congressional Report Language on Strategic Plan Implementation

Since its inception, the National Human Genome Research Institute (NHGRI) has been guided by a series of strategic plans that have laid out ambitious goals and have provided measurable objectives that the Institute has used to gauge progress. Each of these plans was developed through a broad, dynamic planning and assessment process that involved a large number of experts from a variety of relevant disciplines plus members of the public. The Institute has then used the strategic plans to establish specific goals and to set a research agenda to achieve them. Building upon the successful implementation of three previous five-year plans, the NHGRI contributed significantly to the Human Genome Project's completion of the sequencing of the entire human genome in April 2003.

At the same time, NHGRI continued to make significant progress toward a number of additional goals as identified in those strategic plans that were also central to the institute's mission. These included technology development to reduce the cost and increase the amount of information produced by genomics; interpretation of the information content of the human genome and of human genome variation, enabling the application of genomic knowledge to biomedical research problems; analysis of the genomes of important model organisms; fostering research in the ethical, legal and social implications (ELSI) of genomic discoveries; developing strategies for reducing health disparities by disseminating genomic information to the public and health professionals; and providing support to train and educate the next generation of genomic investigators.

In anticipation of the completion of the Human Genome Project and the attainment of the major goal of the 1998-2003 strategic plan, NHGRI began in 2001 another planning effort to create a bold new vision for its future research agenda. This effort involved two major meetings *and* a series of more than a dozen more specialized planning workshops. These meetings and workshops, in total, brought together more than 600 of the world's top minds in many areas of basic, translational and clinical research, along with many public representatives, to envision the most effective ways to use the vast wealth of DNA data generated by the HGP to find practical applications in biology and medicine in the future. The results of the 2001-2 planning effort were brought together in a document that was reviewed and approved by the National Advisory Council for Human Genome Research. The document was then published as a centerpiece article, entitled "A Vision for the Future of Genomics Research" in the influential journal *Nature* in April 2003, coinciding with both the 50th anniversary of James Watson and Francis Crick's seminal publication of the structure of DNA and the

completion of the sequence of the human genome. The plan has, subsequently, been distributed widely in scientific meetings, public events, and formal presentations. It remains a starting point for most presentations made by the Director, NHGRI and senior staff of the Institute to communicate NHGRI's priorities to the scientific community and to the general public. It is also the basis for advice given by NHGRI program staff to prospective applicants considering submission of applications for research proposals to the NHGRI.

Since 2003, the plan, which is known within NHGRI as "The Vision Document," has been used as the primary source of NHGRI's program planning and scientific decision-making. While the landscape described in the document for the future of genomic research was intentionally broader than the specific interests of NHGRI, it provides a vital background for the establishment of specific NHGRI priorities and areas for funding. The key to making the Vision Document into a workable decision-making tool was a scientific coding system developed by the Institute's Division of Extramural Research. The coding system includes all of the elements of the plan, thus allowing all of the Institute's grant, cooperative agreement, and contract portfolio to be described in terms of the objectives of the strategic plan. This system has been used in many ways to inform the NHGRI's decision-making processes.

- It has enabled the Institute staff, from Director on down, to know on a continuing basis how the NHGRI's research budget has been invested and how that investment addresses the opportunities identified in the Vision Document.
- It allows the Institute staff to understand the balance among funded program areas and to determine whether specific objectives described in the Vision Document are being addressed.
- It is used to ensure that the overall strategic plans of the Institute are implemented in individual funding decisions by allowing funding decisions to take into account the distribution of funds at any given point in time that are being spent on the several aspects of the strategic plan. This means that the Institute's scientific priorities can be implemented in funding decisions on a dynamic, up-to-the-minute basis.
- It provides Institute staff with essential guidance in the development of new programs (announced as RFAs and specific Program Announcements) because those can be specifically tailored to address the unmet needs identified by the strategic planning process. All such new programs must specifically identify which goal or goals of the Vision Document are addressed. For example, the ENCODE program to identify all sequenced-based functional elements in human DNA was implemented

to address the first Grand Challenge (I-1) discussed in the Vision Document, “Comprehensively identify the structural and functional components in the human genome.” Similarly, a program recently initiated to characterize structural variation in the human genome is one component of the Institute’s effort to address Grand Challenge I-3, “Develop a detailed understanding of the heritable variation in the human genome.”

- It also provides the Institute staff with an intellectual structure against which any new idea that is suggested for development by the NHGRI, whether that idea comes from the outside scientific community, from the Institute’s established advisory structure, or from Institute staff can be vetted, to see whether the proposed idea does or does not fall within the scope of NHGRI’s interests and how it falls within the Institute’s priorities. This is used, on an on-going basis, to assess the priority of potential new initiatives.
- Finally, it provides the Institute with a basis for developing and participating in trans-NIH activities that are relevant to the overall goals described in it. Examples include the public-private Genetic Analysis Information Network (GAIN) and the Genes, Environment, and Health Initiative (GEI), both of which will contribute to progress toward Grand Challenge II-1, “Develop robust strategies for identifying the genetic contribution to disease and drug response.” Another important example is the NIH Roadmap Molecular Libraries and Imaging Initiative which bears on Grand Challenge II-4, “Use new understanding of genes and pathways to develop powerful new therapeutic approaches to disease.”

On a frequent basis, at least yearly and more frequently if necessary, the NHGRI research portfolio, organized according to the elements of the Vision Document, is presented to the National Advisory Council for Human Genome Research. At the same time, any proposals for new initiatives are also presented to the Council. As a result, the advice that the Council provides to the Institute is also be framed in terms of the objectives of the Vision Document.

In 2006, the NHGRI leadership, in particular the Division of Extramural Research, examined the question of whether it was time to revisit the Institute’s overall strategic plan, as described in “The Vision for the Future of Genomic Research” document. After extensive staff examination and deliberation, and an in-depth consideration of the staff’s recommendations by the National Advisory Council for Human Genome Research (NACHGR), a number of conclusions were reached:

- considerable progress has been made in many of the areas described in the Vision Document;
- essentially all of the components of the Vision are still relevant and represent significant opportunities for genomics to make major contributions to the understanding of basic biomedical science and to applying that knowledge to improving approaches to diagnosis, treatment and prevention of disease;
- in the area of strategic planning, the Institute's primary need is for establishing clearer priorities among the many possible research opportunities for the extramural research program, so that the opportunities for the potential contributions of genomics to improving the nation's health and revolutionizing the practice of medicine are maximized;
- There are additional opportunities for informing the scientific community and the public about the NHGRI's research priorities, for example by using the Institute's web site (www.genome.gov) to present continuous updates on Institute funding priorities, and by more frequently revising the Institute's overarching Program Announcement to address emerging opportunities.

**National Institute of Biomedical Imaging and Bioengineering (NIBIB)
Response to Congressional Report Language on Strategic Plan
Implementation**

The NIBIB was signed into law on December 29, 2000. Over the next few years, the NIBIB held several workshops to obtain scientific community input to determine future research and training programs. In December 2002, a "Workshop on Future Research Directions" was conducted to identify where the Institute can make a major impact on health care or biomedical research in the next five to ten years. An "NIBIB Workshop on Bioengineering and Biomedical Imaging Training" was also conducted to solicit input from relevant extramural and intramural scientific communities during the development of its research training programs. While these workshops were not designed to formulate a detailed blueprint for research, they were useful in identifying the most pressing needs and opportunities in biomedical engineering and imaging. Between 2002 and 2004, the NIBIB hosted several more workshops that focused on specific science program areas stemming from the original planning workshops to evaluate ongoing research and delineate specific research directions for the NIBIB to pursue. For example, in September 2002 the NIBIB held a planning workshop to identify the needs, opportunities and issues associated with research in image-guided interventions. Recommendations from these workshops were used in the development and release of the NIBIB's first ten Requests for Applications (RFAs).

Since January 2004, the NIBIB has embarked on a strategic planning process that has culminated in the publication of its first 5-year Strategic Plan. This process actively involved the NIBIB National Advisory Council, an NIBIB working group of senior management, and professional and advocacy groups to assess progress, identifying needs and opportunities, and developing strategies for research conducted and supported by the NIBIB. A National Advisory Council Strategic Planning Subcommittee was created and charged with identifying priority areas of research within the NIBIB mission, while considering research currently supported by the Institute as well as NIH-wide scientific initiatives.

When the NIBIB was first established, NIH Institutes identified and transferred grants to the NIBIB which were within the scope of the NIBIB mission. In February 2004, in an effort to evaluate the current NIBIB research portfolio, determine the areas of scientific opportunities, assess future directions, NIBIB staff began a series of staff retreats. Over the next year, NIBIB senior management and members from the National Advisory Council Strategic

Planning Subcommittee defined broad scientific areas for NIBIB-supported research for its first Strategic Plan.

In 2005 the NIBIB released a draft strategic plan and solicited comments from individuals and representatives of public and private organizations as well as scientific organizations. The final draft of the plan was reviewed by the National Advisory Council and was published shortly thereafter.

The Strategic Plan is continuously reviewed to ensure that the NIBIB is targeting the most compelling public health needs and the research opportunities in the NIBIB's mission areas that address those needs.

Strategic Plan Implementation Activities

The NIBIB is an Institute within the NIH devoted to merging the physical and biological sciences to develop new technologies that improve health. Unlike many other NIH Institutes, the NIBIB's mission is not limited to a single disease or group of illnesses; rather it focuses on the development of new technologies broadly relevant to many diseases. This mission is broader in scope and impact than most of the other NIH Institutes and Centers. Fulfilling our mission requires accessing the resources and capabilities of a segment of the scientific community that traditionally has not received funding from the NIH – the physical, engineering, and computational science communities. Investigators in these fields are often unaware of funding opportunities and are typically not familiar with NIH grant-making procedures and policies. The NIBIB has taken several steps to address these issues. First, the NIBIB has established a New Investigator Pay Plan to improve the success of new investigators receiving R01 awards. Under this policy, new investigators to the NIH will be selected for funding if their scores are within 5 percentile points of the NIBIB stated pay line for any given fiscal year. The NIBIB has also cosponsored a "Conference on Research at the Interface of the Life and Physical Sciences: Bridging the Sciences" with the National Science Foundation to obtain input from the scientific community on how to bridge the life and physical sciences. The NIBIB currently gives special consideration for funding to research grant applications that bridge and integrate the life and physical sciences.

In response to recommendations in our Strategic Plan and feedback from the NIBIB National Advisory Council, Institute staff is actively engaged in educating the NIH peer review members about the emphasis on technology development rather than more traditional disease-oriented research. Often, applications describing high-risk technology development may suffer somewhat in the review

process because of the uncertainties inherent in the research as well as the relative inexperience of the scientists in the NIH grant application process. Consequently, while these applications score relatively well, they often miss the Institute's payline. The NIBIB is addressing this situation by conducting a series of regional outreach Grantsmanship seminars to target physical scientists and investigators new to the NIH. The objective of this one-day seminar is to provide information on the Institute's research and training funding opportunities; NIH application, review, and grant-making processes and policies. In addition, the NIBIB has established a goal each year to identify and fund two and perhaps more R01 applications that propose high-risk research. This will be done as part of the Institute's yearly efforts to identify applications for "select pay" (i.e., meritorious applications that miss the established payline). To continue this effort to target highly innovative research the NIBIB launched the Quantum Grants program in 2006. The NIBIB Quantum Grants will support multi-investigator, interdisciplinary teams to develop technological methods to address a specific health care problem which may entail significant risk but with high potential payoff.

As a leader in the development of novel technologies and the translation of those technologies into applications for the benefit of public health, the NIBIB supports cooperation and collaboration among scientific disciplines and biomedical organizations. The NIBIB's Strategic Plan explicitly identifies the development and cultivation of partnerships between public organizations and private industry as an essential activity to accelerate the application of research advances to improve health and quality of life. In support of this activity, the NIBIB is working with key biomedical industries to explore several options for public-private partnerships that include interactive forums and collaborative research projects. The forums will enable communication and cooperation among government, industry, and research organizations with the objective of accelerating the translation of research advances and novel technologies to patient applications. Collaborative research projects will be aimed at addressing industry-wide issues and challenges that are preventing significant improvements in healthcare. It is anticipated that these projects will provide research and possibly training funding opportunities for the scientific community.

The Strategic Plan includes several goals for strengthening interdisciplinary research and training within the mission areas of the NIBIB. Implementation makes use of a variety of mechanisms including investigator-initiated awards, Program Announcements, RFAs, and intramural research. The NIBIB specifically sets aside funds for select pay of applications that fall within the areas of opportunity identified through the strategic planning and implementation process.

These target areas go through periodic review with the NIBIB National Advisory Council. The Institute also has a policy of individually reviewing all large applications for program relevance. Decisions about Program Announcements and RFAs are linked to the Strategic Plan at the conceptualization phase and also at the final approval phase. In addition, the NIBIB has recruited a Scientific Director for the intramural program, established an Office for Public-Private Partnerships, established a trans-agency liaison to take leadership in bridging the physical and life sciences, and expanded its expertise in bioinformatics.

As the NIBIB moves forward the Strategic Plan and strategic planning process will continue to play an integral role in responding to scientific advances and opportunities and maximizing the impact of our resources. With its first Strategic Plan published, the NIBIB has developed a process to more rapidly identify and bring emerging areas of science to bear on problems. The NIBIB will hold an annual one day meeting of the National Advisory Council Strategic Planning working group to assess progress made within specific program areas on implementation of the strategic plan, to determine the most critical or promising areas of research need or opportunity, and to develop goals and objectives that address these areas. The Institute will also continue to conduct workshops, conferences, or symposia in emerging areas of technology development. Reports from these events will assist with the program planning and updating of the needs and opportunities and the periodic refinement of NIBIB's goals and objectives. The highest priority for the funding of research has been and continues to be supporting the highest quality of research that will help achieve the goals and objectives as determined in our strategic planning process.

National Center for Research Resources (NCRR) Response to Congressional Report Language on Strategic Plan Implementation

Background

The National Center for Research Resources (NCRR) develops and supports critical research technologies and resources which underpin and advance health-related research supported by the NIH and other biomedical research organizations. The NCRR provides laboratory scientists and clinical researchers with environments and tools that they can use to conduct research related to the prevention, detection, and treatment of a wide range of diseases. This support enables discoveries that begin at the molecular and cellular level, move to pre-clinical and animal-based studies, and then are translated to clinical research, resulting in cures and treatments for both common and rare diseases.

To ensure that research resources meet current and evolving needs, NCRR staff must continually interact with investigators and administrators across the biomedical research community. Scientific trends and research needs change at an astonishing pace, yet effective research resources for addressing investigator needs cannot be generated overnight and must be established before lack of essential research tools becomes a barrier to research progress.

It is this need to stay ahead of the trends in biomedical research and anticipate the needs of investigators that guided the development of NCRR's current strategic plan entitled "NCRR's 2004-2008 Strategic Plan: Challenges and Critical Choices." This is NCRR's third such plan. For more than a decade, NCRR has involved the scientific community in its strategic planning process. In 1994, NCRR was among the first NIH components to publish a strategic plan based on extensive input from the scientific community. That initial five-year plan and its successor, published in 1998, have informed and guided NCRR's priorities for developing the requisite technologies, models, algorithms, and research resources to facilitate research.

Strategic Plan Development

When NCRR began to formulate its current plan in 2003, the Center published a notice in the *Federal Register* requesting input from biomedical scientists, high-level administrators in research institutions, scholarly organizations, and NIH senior program staff on four broad, basic resource questions. Over 600 responses were received and were representative of a broad cross-section of the research community. This initial input served as a framework for NCRR's Fall Strategic

Planning Forum, held in Arlington, Virginia, in September 2003. To ensure that the Forum generated fresh ideas and addressed new areas, at least half of the 70 participants at the forum had no prior history as former NCRR grantees or resource users. During the two-day forum, distinguished members of the biomedical research community identified scientific trends and needs and also shared their recommendations for addressing critical problems researchers in the extramural community were facing.

Based on this input, NCRR developed its strategic plan, which includes NCRR's guiding principles and provides goals and objectives related to clinical research resources and networks; informatics and computational biology; nonhuman models for biomedical research; emerging technologies and instrumentation; research capacity building; training and education; research partnerships; and communications.

Strategic Plan Distribution

The strategic plan was published in early 2004 and initially distributed to over 1,000 individuals, including grantees, advisory council members, Forum participants, constituency groups, NCRR review group members, NIH IC Directors and senior leadership, and those that requested copies when they responded to the Federal Register Notice. The *NCRR Reporter*, a quarterly publication with over 4,000 subscribers, also announced the publication of the strategic plan in the Spring 2004 edition. Additionally, the strategic plan was posted on NCRR's Web site and received over 1,600 hits within the first three weeks in which it was posted. Subsequently, additional copies of the strategic plan have been distributed at NCRR-sponsored meetings and it remains available on NCRR's Web site.

Wide distribution of the strategic plan ensures that the research community is aware of the areas in which NCRR will focus over the next five years. This gives researchers the ability to anticipate and prepare for future NCRR funding opportunity announcements and also lets them know that their needs for research resources will be addressed.

Strategic Plan Implementation

NCRR holds periodic staff retreats, the last three being in August 2005, April 2006, and October 2006, to discuss the future directions of the Center, including ways to address the goals and objectives of the strategic plan. As a result, NCRR has implemented many of the broad goals and objectives outlined in its strategic

plan, primarily through new or expanded initiatives. Developing an initiative is often preceded by a workshop and results in a proposed funding opportunity announcement. The initiatives are also reviewed and approved by NCRR's Advisory Council and are included in NCRR's annual budget justification, which is sent to Congress. Other goals and objectives in the plan are sometimes addressed by a change in policy or a specific action by NCRR, not just through funding opportunity announcements.

The following are a few specific examples of objectives (in italics) in the strategic plan followed by the actions taken to address them:

Strengthen collaborations among clinical investigators and basic scientists to foster translational research. On October 12, 2005, NCRR solicited applications for institutional Clinical and Translational Science Awards (RFA-RM-06-002). The goal is to create a national consortium that will transform how clinical and translational research is conducted, ultimately enabling researchers to provide new treatments more efficiently and quickly to patients. Twelve awards were made in FY 2006, along with 52 planning grants (RFA-RM-06-001), and a subsequent application request for additional CTSAAs was released on August 22, 2006 (RFA-RM-07-002).

Promote development and incorporation of informatics standards into research resources in partnership with relevant standards communities. On February 10, 2006, NCRR announced that it would track developments and inform the clinical research community in the area of clinical research information technology through a two-year contract with the MITRE Corporation. MITRE is providing a series of targeted research reports on the rapidly changing informatics landscape, as well as providing strategic advice. MITRE is investigating current informatics used for clinical research, proposing and analyzing future approaches, monitoring trends, and forecasting the evolution of related technologies developed by both public and private entities. Information, best practices, analysis and recommendations are being provided in periodic research reports, which are posted on NCRR's homepage. The reports are expected to help guide strategic planning efforts across NIH and among its grantees.

In addition, on May 9, 2006, NCRR co-sponsored a workshop with the Agency for Healthcare Research and Quality (AHRQ) and the non-profit organization FasterCures entitled, "Ensuring the Inclusion of Clinical Research in the Nationwide Health Information Network." Since the emphasis of the Nationwide Health Information Network NHIN work is on the information needs of clinicians providing direct patient care, the purpose of the workshop was to develop a list of

key steps needed to include clinical and translational research in the NHIN activities.

Provide support for science education opportunities through partnerships among dedicated scientists, educators, community organizations, academic institutions, museums, public school systems, and others. The inclusion of this objective in the strategic plan further affirmed the need for NCCR's Science Education Partnership Award (SEPA) program, which is designed to improve life science literacy throughout the Nation. These grants 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. This program has had several funding opportunity announcements, with the most recent being released on September 13, 2006 (PAR-06-549).

Establish centers for genotyping and phenotyping animal models and maintain a database with relevant information that can be readily accessed. To address this objective, NCCR recently held a workshop on April 19-20, 2006 entitled, "Genetic Tools for Optimizing the Use of Rhesus Macaques for Translational Research." The purpose of the workshop was to define the next generation of genetic tools needed to optimize the use of rhesus macaques in translational research. This topic was deemed to be timely by NCCR, because the rhesus is the most widely used nonhuman primate for translational studies directly related to human health. A set of first-generation genetic tools have been developed, and the rhesus genome sequence has now been determined. Thus, there is a need to define the next generation of genetic tools. The workshop resulted in a set of recommendations that will be addressed with future funding opportunity announcements.

Create national technology centers for networks and pathways to develop novel proteomics and other complementary technologies that are applicable to dynamic systems. NCCR issued two funding opportunity announcements (RFA-RM-04-005 and RFA-RM-04-019) and made four awards for National Technology Centers for Networks and Pathways. The primary goal of these centers is to develop new technologies to study the dynamics of molecular interactions within cells. To build on this, additional funding opportunity announcements (PA-06-128 and PA-06-129) were released on January 4, 2006 to solicit Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) applications for the development of broadly applicable research tools that address the core technical challenges in proteomics and glycomics.

Create national centers for biomedical computing to develop computational tools and to educate researchers in computing. This was another objective that NCRRLed that also met the goals of the New Pathways to Discovery component of the NIH Roadmap for Medical Research. NCRRL issued funding announcements (RFA-RM-04-003 and RFA-RM-04-022) to create National Centers for Biomedical Computing (NCBC). The seven centers that were awarded, in conjunction with individual investigator awards, are creating a networked national effort to build the computational infrastructure for biomedical computing in the nation. The NIH NCBC is devoted to all facets of biomedical computing, from basic research in computational science to providing the tools and resources that biomedical and behavioral researchers need to do their work. In addition to carrying out fundamental research, the NIH NCBC is playing a major role in educating and training researchers to engage in biomedical computing.

Strategic Plan Implementation Status

The above activities are just a few examples of the actions taken by NCRRL to meet the goals and objectives put forth in NCRRL's strategic plan. NCRRL continually monitors the status of its strategic plan by determining which activities have met the goals and objectives of the plan. Unmet objectives and strategies for meeting them are always being considered as funding plans for the future are being developed. To varying degrees, almost all of the objectives in the current strategic plan have been or are in the process of being met. Since most of the goals and objectives are relatively broad, a multi-faceted approach is required, and NCRRL will continue to strive to meet and further build on the objectives of the plan as it reaches the end of the plan's five-year period. As the plan comes to an end in 2008, NCRRL will initiate another strategic plan development process that will guide NCRRL into the future.

**National Center for Complementary and Alternative Medicine (NCCAM)
Response to Congressional Report Language on Strategic Plan
Implementation**

Strategic Plan: Creation, Publication, and Distribution

Established by Congress in 1998, NCCAM has the lead at the National Institutes of Health for research on the safety and efficacy of complementary and alternative medicine (CAM). NCCAM's second strategic plan, for 2005-2009, is entitled *Expanding Horizons of Health Care*. This plan was developed with advice from individuals representing the scientific community, CAM and conventional medicine practitioners, and the public. NCCAM undertook a year-long process to create an agenda for future research and research training that helped form the strategic plan. As part of this planning process, NCCAM convened a think tank that brought together leading scholars and policy makers, held stakeholder forums on both the East and West coasts, and assembled a national planning workshop with over 80 individuals from the CAM and conventional scientific communities. The draft plan was put on the NCCAM website for comment during October and November 2005. In all, NCCAM received input from over 2,500 individuals and professional organizations.

The second strategic plan became available in December 2004 in print and online at <http://nccam.nih.gov/about/plans/2005/>. Free copies are available from the NCCAM clearinghouse (1-800-644-6226 or info@nccam.nih.gov). The plan was distributed to NCCAM's advisory council, reviewers, other government agencies, researchers, health professional schools, including schools of dentistry and nursing, as well as the broad community of CAM stakeholders. Copies are also distributed at scientific and professional meetings, lectures, and public events. To date, NCCAM has distributed over 7,000 print copies of the strategic plan and over 1,400 copies on CD. By making this document broadly available, NCCAM hopes to encourage applications that address the areas and goals of the strategic plan.

Implementation of the Strategic Plan

The strategic plan guides the implementation of NCCAM's mission, namely supporting research in the context of rigorous science; training CAM practitioners in research and conventional research scientists in CAM; conducting outreach by the dissemination of authoritative information to the public and professionals, including the dissemination of the strategic plan; and providing appropriate governance of the Center by effective management of the public's investment in

CAM research. The goals of NCCAM's strategic plan are consistent with its mission as well as the aims recommended by the Institute of Medicine report, *Complementary and Alternative Medicine Use in the United States* (2005).

In enumerating its goals for supporting research, the NCCAM strategic plan emphasizes the following areas of CAM research:

- Biologically based practices (e.g., botanicals, dietary supplements)
- Mind-body medicine (e.g., meditation)
- Manipulative and body-based practices (e.g., chiropractic, yoga)
- Whole medical systems (e.g., traditional Chinese medicine)
- Health services research (e.g., practice-based research networks)
- Energy medicine (e.g., Reiki)
- Ethical, legal, and social implications of CAM research and integrated medicine
- International research.

The strategic plan also enumerates examples of research topics or questions for each area of the CAM research goal, such as establish the efficacy of selected mind-body and biologically based practices to maintain health, prevent disease, and treat conditions of public health importance; determine the pharmaceutical and pharmacokinetic properties of selected biologically based products; study manipulative and body-based practices to determine their potential therapeutic or wellness benefits; elucidate mechanisms of action operative in manipulative and body-based practices; explore models of organized health care delivery that integrate CAM with conventional care.

NCCAM's extramural research awards are made using the strategic plan as a guidepost, evaluated through the standard NIH peer review process, and reviewed by the National Advisory Council for Complementary and Alternative Medicine (NACCAM).

Program announcements (PAs) and requests for applications (RFAs) issued by NCCAM reflect the areas of emphasis in the strategic plan. For example, in FY 2005, NCCAM, in conjunction with NIDDK, issued an RFA for Phase I/II clinical studies of silymarin (milk thistle) to determine the efficacy and optimal dose for treating chronic hepatitis C and nonalcoholic steatohepatitis (NASH). This initiative, which resulted in five awards in FY 2006, addresses research within the strategic plan's biologically based practices area of emphasis. Similarly, in FY 2006, NCCAM issued a PA on the biology of manual therapies to foster basic research on the mechanism of action underlying biomechanical, immunological, endocrinological, and/or neurophysiologic consequences of

manual therapies. This initiative addresses the strategic area of manipulative and body-based practices.

NCCAM also accepts investigator-initiated grant proposals. Because of the way NCCAM defines CAM and how NIH referral guidelines are written to direct CAM-related grants to NCCAM, these applications are consonant with areas of emphasis included in the strategic plan.

Most applications for NIH funding are sent to the NIH Center for Scientific Review (CSR) study sections for an experts' evaluation of scientific merit. However, NCCAM Special Emphasis Panels review applications for developmental grants (R21), Phase III, and multi-site clinical trial applications assigned to NCCAM by CSR as well as applications submitted in response to NCCAM RFAs and PAs. Consistency with the goals of the NCCAM strategic plan is not a review criterion, but the review provided by the NCCAM Advisory Council considers the balance of the overall grant portfolio, which encompasses all of the eight areas referenced above.

NCCAM seeks to balance its research investment across the areas of emphasis, depending on scientific opportunity and public health needs. The eight research priorities in NCCAM's strategic plan are not represented equally in the Center's research portfolio. Research on biologically based CAM therapies dominates, and mind-body medicine is becoming a higher priority. These two CAM domains predominate because they cover a vast array of modalities, including dietary supplements, and are in widespread use by the American public with only limited information about their effectiveness and safety. In addition, the nature of these therapies allows them to be more easily tested using the tools, methodologies, and hypotheses currently available to researchers, such as animal models and diagnostic imaging.

Challenges to Implementation

In implementing its strategic plan, NCCAM encounters challenges unique to the study of CAM modalities.

Research Capacity. The scientific evaluation of CAM is an emerging research discipline. Conventional biomedical investigators, with extensive research expertise, must be attracted to CAM research. In addition, to be successful NIH applicants, CAM professionals must be trained to conduct CAM research using the same methodologies and practices as other NIH-supported researchers.

To build and sustain CAM research capacity and to train CAM investigators, NCCAM has funded several Centers of Excellence for Research on CAM and Centers for Dietary Supplements Research on Botanicals that support major research projects at experienced research institutions across the United States. In addition, NCCAM supports Developmental Centers for Research on CAM to promote collaborations among CAM schools (e.g., chiropractic, osteopathy, and acupuncture) and conventional biomedical research institutions. Furthermore, the Center funds several training and career development awards for researchers interested in building careers in CAM research.

Product Quality, Formulation, and Outcomes Measurement. In spite of the widespread use of CAM therapies such as dietary supplements, little is known about product quality, appropriate dosing ranges, and product formulations. In addition, in order to rigorously study prevalent CAM interventions, such as dietary supplements, mind-body practices, and manual therapies, new measurement tools must be developed to accurately determine the appropriate dose, patient adherence, and clinically relevant outcomes.

To address these fundamental research issues, NCCAM has implemented a policy requiring all biologically based products used in NCCAM-funded research to demonstrate standardization, purity, and quality. Products are reviewed by an advisory body to the NCCAM Advisory Council. In addition, several NCCAM initiatives and a workshop are stimulating the development of novel tools to evaluate the potential of CAM therapies.

Next Steps

NCCAM's second strategic plan was based, in part, on an analysis of lessons learned from its first strategic plan. In keeping with this process, NCCAM is planning a mid-course evaluation of its second strategic plan, which in turn will be used to inform a more in-depth evaluation of this plan. This analysis will involve looking at the investment in research across areas of emphasis, noting where success has been made and where additional progress is still needed. Importantly, future initiatives (PAs and RFAs) will be developed in accordance with areas enumerated in the strategic plan.

Below are several NCCAM initiatives for FY 2007. Because NCCAM is small, the Center relies on partnerships with other NIH Institutes, Centers, and Offices to support initiatives related to the areas in its strategic plan. As noted above, NCCAM partnered with NIDDK in a clinical study of milk thistle for liver disease. In addition, NCCAM, with support from NIA, NINDS, NHLBI, and

ODS, is funding a very large study of *Ginkgo biloba* to prevent cognitive decline among the elderly. The NIH Office of Dietary Supplements supports several important collaborations with NCCAM on biologically based practices, including the Botanical Research Centers Program. NCCAM has recently partnered with the Bernard Osher Foundation to begin a research training initiative in complementary medicine.

In addition to providing structure for NCCAM's program development, the strategic plan affords information and guidance to other organizations seeking to develop research, research training, and outreach in this important area of science.

FY 2007 NCCAM Initiatives

In FY 2007, under the Continuing Resolution, NCCAM will support several new initiatives consistent with the priorities of its strategic plan for 2005-2009:

Strategic Plan Goal: Support research on biologically based practices and mind-body medicine

Implementation: Clinical studies are designed to assess the efficacy of mind-body and biologically based practices. However, to establish efficacy, it is necessary to ascertain compliance with protocol. In FY 2007, NCCAM will issue an RFA soliciting R44 (Phase II SBIR) applications to develop innovative tools and technology, including assays and sensors, to (1) detect biologically active CAM agents, their constituents or metabolites in body tissues or fluids; (2) assess adherence to study protocols for mind-body medicine, including meditation and Tai Chi; and (3) validate adherence measures using patient-reported use and clinical outcomes in clinical studies. This research will provide valuable tools for future clinical studies of biologically based and mind-body interventions as well as information on the pharmacokinetic properties of biologically based products.

Strategic Plan Goal: Support health services research

Implementation: To explore models of organized health care delivery that integrate CAM with conventional care, NCCAM will issue a program announcement using the R21 mechanism to solicit proposals to assess the potential of existing community-based health care delivery networks (e.g., HMOs, practice-based research networks) to increase scientific knowledge about the safety, efficacy, and cost effectiveness of CAM. Research funded by this PAR will take advantage of existing federally funded primary care research networks that cover large patient populations in diverse care settings and have access to electronic data records systems to measure patients' outcomes.

Strategic Plan Goal: Support research on manipulative and body-based practices

Implementation: To further understanding of mechanisms of action of manipulative and body-based practices as well as their potential for therapeutic or wellness benefits, NCCAM will issue an RFA to solicit R43 (Phase I SBIR) applications to encourage the development of (1) diagnostics, protocols, assays, imaging technologies and methods to determine the potential mechanism of action or biological effects of manual therapies, such as chiropractic and massage; and (2) novel approaches to the diagnosis, monitoring, prevention and treatment of neuro-musculoskeletal conditions that are treated by manual therapies.

**National Center on Minority Health and Health Disparities (NCMHD)
Response to Congressional Report Language on Strategic Plan
Implementation**

In establishing the NCMHD, the Congress required in Public Law 106-525 that the Director of the NIH, the Director of the NCMHD, and the Directors of the other NIH Institutes and Centers in collaboration establish a comprehensive plan and budget for the conduct and support of all NIH minority health disparities research and other health disparities research activities. The law contained a number of requirements for the NIH Health Disparities Strategic Plan (NIH HD Plan), including:

- The Plan must be developed in consultation with the NCMHD National Advisory Council.
- The Plan must establish priorities among health disparities activities.
- The Plan must establish objectives regarding these activities, describe the means for achieving the objectives, and designate an anticipated completion date for the objectives.
- The Plan must promote coordination and collaboration among the NIH Institutes and Centers.
- The Plan must serve as a broad, binding statement of policies regarding health disparities research and other health disparities research activities of NIH.

Components of the NIH HD Plan

The overarching Goal Areas of the Plan include: (1) Research; (2) Research Infrastructure; and (3) Community Outreach. Within these three goal areas, the Plan establishes Priorities, or “Areas of Emphasis.” The Plan also includes Objectives for accomplishing these priorities. Each Objective includes: Action Plans, Timelines, Performance Measures to track and report on progress, and Outcome Measures to demonstrate accomplishment and ultimate impact.

Current Status of the NIH HD Plan

The final NIH Strategic Research Plan and Budget to Reduce and Ultimately Eliminate Health Disparities, Fiscal Years 2002-2006, was approved by the NIH Director, the NIH IC Directors, the NCMHD Advisory Council, and the HHS Secretary. The final Plan was submitted to the Congress in the winter of 2003 and is now posted on the NCMHD website. For the first time, NIH had developed a comprehensive Strategic Plan that provided detailed priorities, objectives and

action plans to guide all NIH activities in health disparities Research, Research Infrastructure, and Community Outreach.

Implementing and Updating the NIH HD Plan

Within its submission to the NIH HD Plan each IC describes the implementation steps to be taken and time frames to be followed to achieve its goals and objectives aimed at eliminating health disparities. In accordance with these action plans, the ICs implement their health disparities initiatives utilizing the full range of NIH funding and support mechanisms. Below are several examples IC objectives and implementation steps:

- **NCCAM Objective:** Fund research on complementary and alternative medicine (CAM) and its role relative to health disparities, including use, cost, and outcomes. **Action:** In collaboration with the National Center for Health Statistics of the Centers for Disease Control and Prevention, NCCAM developed a supplemental module on CAM use that was incorporated into the National Health Interview Survey (NHIS) in 2002. Because NHIS oversamples African Americans and Hispanic Americans, the survey collected much-needed information on CAM use in these groups.
- **NCI Objective:** Support Centers for Population Health and Health Disparities to conduct transdisciplinary, multi-level, integrated research to elucidate the complex interactions of the social and physical environment, mediating behavioral factors, and biologic pathways that determine health and disease in populations, leading to an understanding and reduction of health disparities. **Action:** To stimulate trans-disciplinary population based research to understand the causes of health disparities in cancer outcomes, access, and care. The NCI, in collaboration with the NIEHS, the NIA and OBSSR, supports this network of eight Centers for Population Health and Health Disparities, which are working to understand the complexity of health disparities rather than single factor relationships. Employing a community-based participatory research approach, these Centers engage and include community stakeholders in the planning and implementation of health research. This initiative employs NIH's most advanced and innovative population science to address the problem of health disparities.
- **NHLBI Objective:** Support research to develop new or improved approaches for diagnosing and treating heart, lung, and blood diseases and sleep disorders that contribute to health disparities. **Action:** **New**

Initiatives: *Pulmonary Complications of Sickle Cell Disease:* Elucidate mechanisms of the pulmonary complications of sickle cell disease (e.g., acute chest syndrome, a complex of symptoms including severe chest pain, dyspnea, and fever; and chronic sickle cell pulmonary disease, characterized by perfusion and diffusion lung abnormalities); and develop new treatments; *Sickle Cell Disease Clinical Research Network:* Establish a network of clinical centers to address critical issues in the care of persons with sickle cell disease by developing a registry and completing phase I-III clinical trials (with an emphasis on phase III trials).

- **NIAID Objective:** Support research to study the factors that affect the recruitment of women and minorities into HIV/AIDS clinical trials. **Action:** Through a Program Announcement, *Enrolling Women and Minorities in HIV/AIDS Research Trials*, NIAID is soliciting applications to study innovative and practical approaches to access, enroll, and study minority women and young adult populations in HIV/AIDS research trials in the United States, targeting the underserved, particularly in urban areas.

The NCMHD assists the ICs by providing co-funding support each year to selected IC activities. In addition, in fiscal year 2007 the NCMHD in collaboration with the other NIH ICs will convene forums to identify “best practices” to further enhance IC activities.

From the beginning the NIH viewed the NIH HD Plan as an evolving document. To assist the ICs, the NCMHD has continued to make funding available to enable them to convene meetings of outside experts and the public to review and assess their health disparities agendas. The NIH is now developing an updated version of the NIH HD Plan, again based upon public comment.

The NCMHD Strategic Plan

The NCMHD strategic plan, which is contained within the NIH HD Plan, is based upon the requirements of the Center that are contained in Public Law 106-525, including the establishment and continuation of NCMHD-specific programs. As required by the NCMHD strategic plan, the NCMHD has implemented the three programs authorized by Public Law 106-525: the Centers of Excellence Program; the Research Endowment Program; and the Loan Repayment Program. The NCMHD Advisory Council peer reviews all Center scientific programs and grant proposals to ensure that they comport with the Center’s strategic plan. Like the NIH HD Plan, the NCMHD strategic plan has three overarching goal areas,

including: (1) Research; (2) Research Infrastructure; and (3) Community Outreach.

Research

In the area of health disparities research, the **NCMHD Centers of Excellence Program** has been key in leading the NCMHD effort in supporting biomedical and behavioral research. The program is creating new partnerships to enable institutions at all levels of capability to maximize their health disparities research, research training and community outreach efforts. The 73 **NCMHD Centers of Excellence Program** grantees have created more than 100 unique partnerships focused on health disparities, with entities such as hospitals; tribal groups; health plans; health centers; community and faith-based organizations; civic and non-profit health organizations; and local, city, and state governments. The research conducted by NCMHD Centers of Excellence will help to increase understanding of the underlying causes of health disparities through projects such as: *Perceived Discrimination in Healthcare among American Indian/Alaska Natives*; *Religious Outlook on Organ and Tissue Sharing*; *Inflammation and Asthma*; *Impact of Coronary Heart Disease Risk Perception on Health Behaviors*; and *Physical Activity Assessment in Multi-Ethnic Women*.

Research Infrastructure

In the area of research infrastructure and capacity building, the **NCMHD Loan Repayment Programs** promote a diverse scientific workforce by increasing the number of qualified health care professionals who conduct health disparities and clinical research. Since its establishment, the Loan Repayment Programs have made more than 1000 new awards to researchers in research disciplines such as epidemiology, pharmacology, linguistics, etiology, health policy, and behavioral science. Through the **NCMHD Minority Health and Health Disparities International Research Training (MHIRT) Program**, 24 academic institutions have developed international training opportunities in health disparities research for faculty and students. MHIRT participants are engaged in research areas such as cancer epidemiology, reproductive biology, parasitology, and ethnopharmacology in countries such as Ethiopia, Ghana, Jamaica, the Dominican Republic, Australia, and Spain. The NCMHD commitment to enhancing research capacity at academic institutions is best demonstrated through its **Research Endowment Program** and its **Research Infrastructure in Minority Institutions (RIMI) Program**. The NCMHD provides endowment grants to eligible institutions to build minority health and other health disparities research and training capacity. The Endowment Program has funded 16 institutions to

strengthen teaching programs in the biomedical and behavioral sciences; establish endowed chairs and programs; obtain state-of-the-art equipment for instruction and research; and enhance the recruitment and retention of student and faculty from health disparity populations. The RIMI Program is building research capacity in 21 predominantly minority-serving academic institutions.

Community Outreach

In the area of community outreach, the **NCMHD Community-Based Participatory Research (CBPR)** Program supports 25 institutions nationwide. This program engages the community in all phases of the research process and is directed to a specific disease/health condition in a particular minority population. The CBPR is a novel approach for the biomedical research enterprise, and we anticipate its potential in addressing health disparities through projects such as: *Project GRACE: A Participatory Approach to Address Health Disparities in HIV/AIDS among African American Population; Partnership to Overcome Obesity in Hawaii; Project AsPIRE (Asian American Partnership in Research); The Healing of the Canoe* (is aimed at planning, implementing and evaluating a community-based and culturally competent intervention to reduce health disparities and promote health in the Suquamish Tribe reservation community); and *Partnership for a Hispanic Diabetes Prevention Program in Washington*.

Partnerships

Fostering partnerships is a key component of the multi-faceted NCMHD strategic approach to eliminating health disparities. The NCMHD funds a broad range of collaborations with the other NIH ICs, the Department of Health and Human Services, and other federal agencies. Through these co-funded projects, the NCMHD magnifies its reach by leveraging the existing strengths, resources, and research potential of its key federal research partners through an extensive array of research and training initiatives. Since its creation in 2001, the NCMHD has provided more than \$300 million to support several hundred research, training, community outreach and capacity-building projects. Some of the collaborative initiatives that the NCMHD has funded include:

- the *Jackson Heart Study* (with NHLBI), which examines cardiovascular disease in African Americans;
- the *Sister Study* (with NIEHS), a national study that investigates environmental and genetic causes of breast cancer that recently launched a Hispanic component;
- the *Hispanic Community Health Study* (with NHLBI and others), the

- largest epidemiological study of health and disease in Latin American populations living in the United States;
- the *Health Disparities Bench-to-Bedside Program* (with the NIH Clinical Center), which encourages new collaborations between basic and clinical investigators, the translation of scientific findings into clinical applications, and enhanced recruitment and retention of racial and ethnic minorities in NIH clinical research studies; and
 - the *Bridges to the Future Program* (with NIGMS), which facilitates the transition of students from associate- to baccalaureate-degree granting institutions and from masters- to doctoral-degree granting institutions.
 - the *Tribal Epidemiology Centers Program* (with the Indian Health Service), which provides epidemiologic analysis, interpretation, and dissemination of information and the development and implementation of disease control and prevention programs aimed at eliminating health disparities experienced by American Indians and Alaska Natives.

Conclusion

As indicated in the NIH HD Plan, the NIH total actual expenditures in health disparities for fiscal years 2003 through 2005 are: approximately \$2.4 billion, \$2.6 billion, and \$2.7 billion, respectively. Through the vision of the future embodied in the NIH HD Plan, the NIH continues to renew its commitment to build a solid and diverse national biomedical research enterprise of individuals and institutions dedicated to eliminating health disparities.

Fogarty International Center (FIC) Response to Congressional Report Language on Strategic Plan Implementation

The Fogarty International Center (FIC) is currently in the process of developing a five year strategic plan. In June 2006, a new permanent director, Dr. Roger Glass was appointed to the Center. One of his first actions was to initiate a strategic planning process at the Center. The most recent FIC Strategic Plan covered the years 2000-2003 and its expiration coincided with the departure of the previous permanent FIC director. During the interim, the previous plan continued to guide the center in its programmatic decisions. Efforts are underway to analyze the FIC investment portfolio, and to conduct an environmental scan looking at the current set of global health research investments in developing countries (using The World Bank classification based on Gross National Income per Capita). A gap analysis will form the basis of an FIC needs assessment. FIC stakeholders and partners are engaged in an effort to guide investments over the next five years.

The timeline for development of the FIC strategic plan is one year, with the anticipated date of publication July 2007. During this time, FIC will hold stakeholder conferences, internal planning retreats, and encourage stakeholder input through a web comment opportunity. FIC stakeholders include NIH institutes, U.S. government agencies (including The National Science Foundation, Centers for Disease Control and Prevention, and U.S. Agency for International Development), multilateral organizations (such as the World Health Organization and the Pan American Health Organization), FIC trainees and FIC award recipients and their foreign collaborators. The FIC Advisory Board is also actively engaged. The previous strategic plan is currently available through the FIC website and will be replaced when the new one is ready.

FIC has a method in place to routinely evaluate its extramural programs. After receiving five years of funding, each FIC program undergoes a process evaluation utilizing an expert committee who closely follows the FIC Framework for Evaluation (Framework). The Framework contains questions and metrics for analyzing scientific programs in the areas of program planning, program management, partnerships and communication, and scientific results. Strategic planning as it relates to the program is examined in the "program planning" section of the Framework.

Indicators of performance include evidence of:

- a planning process and a plan for the program
- program relevance to NIH, the different ICs at NIH and to HHS strategic plans

- stakeholder involvement in planning (numbers, duration, roles)
- integration of stakeholder input into planning
- re-evaluation of program goals over time

Outcome evaluations of 10-15 year old programs are conducted by external consultants using the same Framework. The results are then used to strengthen existing programs, make mid-course adjustments and to inform management decisions. Programs may be terminated for several reasons. For example, the funding gap has been filled by other agencies (e.g. AIDS FIRCA), or when the program goals have been met (e.g. International Research Fellowship Program and Scholars in Residence Program) or when another IC is willing to take over sponsorship of the program (Minority International Research and Training Grant).

Since 2000, development of programs at FIC has followed the 2000-2003 FIC strategic plan and FIC mission (e.g. International Tobacco and Health Research and Capacity Building Program, Brain Disorders in the Developing World: Research across the Lifespan, and International Collaborative Genetics Research Training Program). FIC program planning involves extensive consultations with the U.S. scientific community as well as potential collaborators from abroad to identify gaps and needs in priority areas. Consultations are used by FIC as a mechanism to refine areas of investment identified in the Strategic Plan. They are also used to supplement the strategic plan by noting emerging areas of importance to FIC and NIH (e.g. Addressing the Global Burden of Trauma and Injury in Low and Middle-Income Countries. *Am. J. Public Health*; 95(1):13-17. 2005; Stigma and Global Health: Looking Forward. *The Lancet*; Vol. 367, No 9509:538-539.2006). In parallel to the consultations, FIC conducts environmental scans through literature and web reviews that take into account the global burden of disease and trends in global health. Reports from the Institute of Medicine, World Health Organization, and the National Academy of Sciences also inform program planning. Consideration of the needs of sister NIH institutes is of critical importance to FIC planning in terms of complementing their research funding with international research training. All of these actions further define and refine the unique role that FIC plays in key research areas that are not addressed by either the NIH or by other research funding agencies. The consultations and evaluations both serve to inform FIC strategic decisions about programs.

Rather than use paylines as a guide to funding, FIC makes decisions based on which programs can have the most impact and fit in with the FIC goals listed in the strategic plan. Geographic region is also important in that limited federal dollars may have more impact in a resource-poor country. Once determined that

FIC should invest in an area, this is communicated to the scientific community via RFAs and PAs.

Partners play a pivotal role in strategic planning, implementation, and evaluation of extramural programs at FIC. With Fogarty's relatively small budget and its broad global health mandate, FIC has a strong track record of developing funding partnerships both within NIH and with other USG agencies. We invite partners to participate in Strategic Planning Stakeholder conferences, to discuss FIC future directions, and in FIC consultative planning workshops to discuss implementation of the program. We expect partnership participation in annual network meetings to discuss progress and results of our programs. Partners are encouraged to help us plan and implement evaluations of our programs.

National Library of Medicine (NLM) Response to Congressional Report Language on Strategic Plan Implementation

Introduction

At its September 2004 meeting, the NLM Board of Regents charged NLM with developing a Long Range Plan for 2006-2016. This follows a very productive planning history that dates back to 1986, and which has seen the impact of new and important NLM programs that resulted from this initial Plan and its subsequent updates.

As a first step in the planning process, a Strategic Visions Working Group comprised of outstanding leaders from all sectors of NLM's diverse constituencies met in April 2005 to provide the broadest view of NLM's mission, current situation, and its potential future contributions to the health and well-being of America in the 21st Century. A vision statement identified new scientific, medical, technical, social and economic developments that may impact national and global needs for research, clinical and patient data and information. It formed the basis for the creation of four expert long range planning panels that met in 2005-6. The panelists considered, among many relevant issues and trends, exciting changes in genomic and computer science, scientific publication models, and transformational changes in health care delivery, electronic health records, and quality and safety made possible by new information technology. The promise of new research correlating genotype, phenotype and environmental data figured prominently in their deliberations, as did the challenges posed by the amount of space needed to house NLM's programs and collections; the existence of health disparities among the underserved; a lack of trust in societal institutions, including government; and the mitigation of threats to the public health from disasters and epidemics.

At its May 2006 meeting, the Board accepted with thanks the individual reports of the four planning panels, discussed the recommendations contained therein, and requested that NLM staff prepare a consolidated 10-year Plan based on these reports along with appropriate staff input.

The Board approved ***Charting the Course for the 21st Century: NLM's Long Range Plan 2006-2016*** on September 19, 2006. It includes 4 major goals and 17 recommendations:

- Goal 1. Seamless, Uninterrupted Access to Expanding Collections of Biomedical Data, Medical Knowledge, and Health Information
- Goal 2. Trusted Information Services that Promote Health Literacy and the Reduction of Health Disparities Worldwide

- Goal 3. Integrated Biomedical, Clinical, and Public Health Information Systems that Promote Scientific Discovery and Speed the Translation of Research into Practice
- Goal 4. A Strong and Diverse Workforce for Biomedical Informatics Research, Systems Development, and Innovative Service Delivery

Strategic Plan Publication and Distribution

Charting the Course will be formally published in both print and web (HTML) layouts. Copies will be sent to all participants and other interested individuals and constituent groups in the health, informatics, and library communities. Its availability will be announced on the NLM website, in the NLM Newline, and through various other electronic and print means. It is also being publicized at professional meetings, including the Medical Library Association, the American Medical Informatics Association, the Coalition for Networked Information, and the Federal Library and Information Center Committee, and in staff presentations. In the meantime, a pre-publication PDF version is available at <http://www.nlm.nih.gov/pubs/plan/lrpdocs.html>.

Additionally, presentations are made to the NLM standing study section, the Biomedical Library & Informatics Review Committee (BLIRC), by the IC director on the development and content of each plan. Copies and web link are also provided to them. A link to the Library's Plan will be incorporated into appropriate sections of the EP web site, to emphasize the relationship between grant research priorities and the Plan. Strategic plans are incorporated in the numerous speaking engagements at universities and meetings each year when EP staff are asked to describe NLM's research goals. The purpose of adding extended visibility for the plan through the Library's Extramural Division activities is to assure that grant applicants are aware of the Library's research priorities and submit applications that reflect them.

Specific Implementation Activities

With each new Long Range Plan, NLM develops and implements a functional budget structure that corresponds to the Long Range Plan and permits detailed programmatic analysis of NLM plans and expenditures in ways not previously possible. Program requests for resources each year are presented in terms of this functional budget. This has increased the yield of useful information for NLM management decision-making, congressional justification, and long range planning.

Points and Modes of Influence on Decision-making

Some of the notable recommendations of the NLM planning process in the past 20 years have been to

- pursue a national program in biotechnology information; leading to the formation of the National Center for Biotechnology Information
- to utilize advanced computer and communications technologies in medical informatics, networking and imaging
- to improve access to biomedical information for health professionals, particularly those practicing in underserved populations; leading to NLM's outreach programs
- to expand training in the use of information technologies; and to maintain and improve basic library services.

The Long Range Plan is used in the day to day management of the Library. Over the past twenty years, NLM has successfully integrated its budget and planning processes, so that the budget is "driven" by the Long Range Plan. New initiatives are presented in terms of the Plan, and progress toward achievement of recommendations is tracked. Periodic program evaluations are also undertaken, such as a major evaluation of NLM's outreach activities.

Major research themes in the Plan are identified, reviewed and discussed by extramural programs staff in terms of NLM's active programs, collaborations with other ICs and possible future RFAs. Portfolio review is done periodically, so that statements about priority research topics are adjusted to address perceived gaps, if they exist. The Plan is referenced in a program announcement, to reinforce the connection between the grant program and the plan. New grant programs and RFAs are discussed with the Board of Regents for concept review or approval. Selection of topics for RFAs is guided by the Plan and /or by solicited input from the scientific community. Funding recommendations from program staff take into account the Library's strategic priorities. Final funding decisions are made by the IC director. In payline meetings, applications beyond the payline that are of strategic interest are brought forward for discussion.

The Role of Partnerships in Strategic Plan Implementation

Partnerships and collaborations are critical in NLM's ability to implement its Plan. The primary research interests expressed in the Plan serve as the basis for partnerships with other NIH IC's (the Biomedical Information Science and Technology Initiative (BISTI) is one example) and also inter-agency agreements (support of the Protein Data Bank and the Multi-Scale Modeling initiative are two

examples). Charting the Course 2006-2016 calls upon NLM to collaborate with a wide variety of entities and organizations. For example, NLM is instructed to work in partnership with:

- The Library of Congress, the National Archives, other U.S. national and international government organizations, academia, publishers, and industry to develop workable long-term solutions to protect the full range of electronic materials, including scholarly publications, datasets, web documents, interactive publications and other formats on which 21st century research, health care, and education depend.
- Community-based and professional organizations (e.g., through “listening circles” and other consultations with American Indians, Alaska Natives and Native Hawaiians) to develop new models and strategies for promoting sustainable access to, and use of, health information in minority and underserved communities.
- Other NIH components to apply genomics to diagnosis, treatment, and prevention of disease, e.g., the flu genome project with the National Institute of Allergy and Infectious Diseases, the trans-NIH PubChem development, and whole genome association studies with the National Heart Lung and Blood Institute.

**Office of AIDS Research (OAR) Response
To Congressional Report Language on Strategic Plan Implementation**

The NIH represents the largest and most significant public investment in AIDS research in the world. Our response to the epidemic requires a unique and complex multi-institute, multi-disciplinary, global research program. Perhaps no other disease so thoroughly transcends every area of clinical medicine and basic scientific investigation, crossing the boundaries of nearly every Institute and Center (IC). This diverse research portfolio demands an unprecedented level of scientific coordination and management of research funds to identify the highest priority areas of scientific opportunity, enhance collaboration, minimize duplication, and ensure that precious research dollars are invested effectively and efficiently.

The Office of AIDS Research (OAR), located within the Office of the Director, coordinates the scientific, budgetary, legislative, and policy elements of the NIH AIDS research program. OAR develops the *Trans-NIH Plan for HIV-Related Research*, in collaboration with the ICs, and with non-government experts from academia, foundations, industry, and community representatives. The Plan and the unique processes instituted by OAR to ensure its implementation allow NIH to pursue a united research front against the global AIDS epidemic.

THE TRANS-NIH PLAN FOR HIV-RELATED RESEARCH: OAR PLANNING PROCESS

OAR develops an annual trans-NIH strategic plan for all HIV/AIDS research activities through a unique and effective model. OAR has established trans-NIH Coordinating Committees, chaired by senior OAR scientific staff, for each of the major scientific areas of the plan: Natural History and Epidemiology; Etiology and Pathogenesis; Therapeutics; Vaccines; Behavioral and Social Science; Microbicides; Racial and Ethnic Minorities; Women and Girls; and International Research. These committees, comprised of representatives of the ICs with major research portfolios in that area, provide an ongoing mechanism for collaboration, coordination, and information exchange. The Coordinating Committees prepare the first draft of the plan, reviewing and updating the previous year's plan based on their knowledge of the science and the progress made during the course of the last year. They eliminate those strategies where research is no longer necessary; add new strategies where research has uncovered new questions; and reprioritize the objectives as necessary where the science has moved or changed. In this way, the planning process serves to monitor and assess scientific progress on an annual basis.

OAR then sponsors a series of planning workshops to seek the input of non-NIH experts from academia, foundations, industry, and the community. These experts participate with the NIH Coordinating Committees to further refine and amend the plan and reach consensus on key scientific priorities. These groups also identify needs in two other areas of the Plan: Information Dissemination and Training, Infrastructure, and Capacity Building related to their area.

The resulting draft Plan is then provided to each NIH IC Director and designated IC AIDS Coordinator for additional recommendations and comments from the IC's perspective. It is also reviewed by the Office of AIDS Research Advisory Council. The Plan serves a number of critical purposes. It is used to: 1) frame the development of the NIH AIDS research budget; 2) determine the use of NIH AIDS-designated dollars; 3) define those research areas for which AIDS-designated funds may be allocated; 4) track and monitor AIDS research expenditures; and 5) inform the public, the scientific community, Congress, and the AIDS-affected communities about the NIH AIDS research agenda.

OAR ANNUAL PORTFOLIO REVIEW

OAR continues to reassess the planning process and make refinements to better capture the broadest range of scientific expertise to identify the highest scientific priorities. In FY 2006, a new element was added to the annual process -- a multi-tiered comprehensive trans-NIH review of all grants and contracts supported with AIDS-designated funds. This review: 1) establishes a new model to ensure that AIDS research dollars support the highest priority science; 2) allows OAR to direct the transfer of funds to better manage the AIDS research portfolio; 3) ensures that resources are focused on the highest scientific priorities, taking into account the ever-changing domestic and international AIDS epidemic as well as the evolving scientific opportunities; and 4) assists OAR in developing the trans-NIH AIDS research budget.

Each of the OAR staff who chairs a scientific coordinating committee initiates a grant-by-grant review of all NIH extramural projects within that scientific area supported with AIDS dollars, concentrating on those grants eligible for recompetition in the fiscal year of the strategic plan. Working with relevant IC program staff, grants are identified that are now of lower priority than when they were originally funded. This does not mean that these grants should not have been funded or were not of high priority at the time. However, as the science has evolved, and the priorities of the epidemic have shifted, these areas no longer represent the highest priorities within the current budget. For example, many grants were awarded to address basic research on then-common opportunistic infections. Over the past few years, with the advent of combination antiretroviral

therapy, these infections are no longer common among HIV-infected individuals, and thus now deemed of lower priority for AIDS-designated funding.

OAR then convenes a meeting of a small group of eminent non-government scientists to provide their expert advice, review each scientific area and all of the grants now deemed of lower priority, and to provide recommendations for redirecting funds to catalyze future initiatives and multi-disciplinary endeavors. OAR notifies each IC of those grants identified as too low a priority for support with AIDS dollars. Each IC has an opportunity to reinvest those dollars in higher priority AIDS programs in their portfolio. For those ICs who cannot identify higher priority projects, those dollars are shifted to other ICs with higher AIDS research priorities needing additional support. The ICs may renew the highly meritorious grants that fall into the low priority category with non-AIDS dollars.

OAR TRANS-NIH BUDGET DEVELOPMENT PROCESS: LINKS THE PLAN TO THE BUDGET

The OAR develops the trans-NIH AIDS research budget, which is explicitly tied to the objectives of the strategic Plan. Each year, the strategic Plan is distributed to all the ICs. The ICs must submit their AIDS-related research budget requests to OAR, presenting their proposals for all new or expanded program initiatives for each scientific area, linked/coded to specific Plan objective(s). OAR reviews the IC initiatives in relation to the Plan, its priorities, and to other IC submissions to eliminate redundancy and/or to assure cross-Institute collaboration. The NIH Director and the OAR Director together determine the total amount to be allocated for AIDS-related research within the overall NIH budget. Within that total, OAR then develops each IC's allocation for AIDS-related research starting from the Commitment Base, and based on the scientific priority of each proposed initiative. This process continues at each step of the budget development process up to the time of the final congressional appropriation. This involves consulting regularly with the IC Directors and maintaining knowledge of the ongoing scientific research programs and planned initiatives of each IC. The careful determination of the balance of the research agenda—among institutes, among areas of science, between AIDS and non-AIDS, between intramural and extramural, between basic and clinical, and between investigator-initiated and targeted—requires a finely tuned knowledge of the science and of the institute portfolios. Dollars are allocated and balanced based not on a formula, but on the priorities of the strategic Plan, scientific opportunity, and IC's capacity to absorb and expend resources for the most meritorious science.

OAR TRANS-NIH BUDGET ALLOCATION, MONITORING AND TRACKING

At the time of the appropriation, OAR informs each IC of its AIDS-related budget allocation level, specifying amounts for each approved initiative. As each IC awards AIDS-related research grants, those dollars are coded to the appropriate objective(s) of the Plan and reported to the OAR's AIDS Research Information System, a trans-NIH database of all NIH AIDS-related expenditures, including extramural, intramural, and RMS. OAR reviews the coded expenditures to ensure that they meet the criteria of high-priority AIDS research and can thus track all NIH AIDS-related expenditures by Plan objective of the key scientific areas.

DISTRIBUTION OF THE PLAN

The Plan is posted on the OAR website, distributed in CD-rom format at a wide variety of domestic and international scientific conferences and workshops, and distributed at the OAR exhibit in many venues. This allows OAR to inform investigators about NIH priorities and directions and to encourage applications and interest in these areas. The plan is also provided to CSR and IC Divisions of Extramural Activities, and is cited in the PHS 398 Grant Application Form to advise potential applicants about the scientific priorities of the Plan.

OAR STRUCTURE AND FUNCTION BASED ON PLAN

The structure of OAR is designed to provide oversight of the NIH AIDS research program, and to track and monitor the progress of the scientific agenda. The OAR Director and senior scientific staff meet with IC scientific leadership and non-government scientists throughout the year on topics of scientific importance to assure that the program and its resources are constantly adjusting to meet scientific need, relevance, and priority. OAR staff members are organized around the areas of the Plan, and are required to know the IC research portfolios, the researchers involved, as well as the cutting edge science in their scientific area of responsibility. These OAR staff members frequently facilitate or attend scientific conferences and workshops to stay abreast of the scientific area, attend Study Section meetings to hear the reviews of various grants, and attend IC Advisory Council meetings, all of which contribute to their base of knowledge and keep OAR informed and involved in this broad scientific agenda. These functions provide a mechanism for OAR to continue to measure the scientific progress and identify roadblocks.

TRANS-NIH COORDINATION TO IMPLEMENT PLAN

The strategic planning process allows OAR to play a crucial role in identifying scientific areas that require focused attention. OAR also implements the Plan by managing and facilitating multi-Institute and trans-Institute activities to address those needs. OAR fosters this research through a number of mechanisms, such as

designating funds and supplements to jump-start or pilot program areas and sponsoring reviews or evaluations of research program areas to identify research needs. OAR, alone or in collaboration with an Institute(s), also frequently convenes scientific workshops, bringing together leading scientists from around the world to review the state of the science and recommend new cutting-edge initiatives. These initiatives may be in areas that require a jump-start, or where recent information has opened a new avenue for investigation, or even where science has led to a dead-end and new directions are necessary. The result of such workshops is the issuance of new RFAs, PAs, or RFPs. The success of these initiatives is the expansion of the research portfolio in new, targeted areas as determined by peer-review to be highly meritorious. In addition, OAR utilizes meetings of the OAR Advisory Council to highlight critical scientific research areas identified in the planning process to highlight current trans-NIH efforts and seek recommendations on new avenues or mechanisms to move the science forward. For example, OAR has devoted meetings of the Advisory Council to Women and AIDS, AIDS in Minority Communities, Microbicides, New Prevention Strategies, HIV/Hepatitis C Virus coinfection, and a variety of issues around the conduct of NIH domestic and international clinical trials.

A recent example of OAR actions to implement critical priorities of the Plan is in the area of topical microbicides for HIV. The science of microbicides is moving rapidly forward, and OAR will use its authorities to improve NIH management and support for this crucial area of science. A separate section of OAR now will be dedicated to microbicide research and other issues relevant to women. The section head will chair a newly constituted NIH Microbicide Research Coordinating Committee. Coordinating Committee Members will be nominated from the institutes with significant microbicide portfolios. The Committee will assist in the development of this section of the strategic Plan, foster information-sharing and trans-NIH coordination, and help identify scientific opportunities and gaps for increased attention. The Committee will also include representatives from CDC and USAID. A Microbicide Research Working Group will be established comprised of non-government experts to advise NIAID, OAR, NIH, as well as other government and non-government entities and assist in determining which microbicide candidates should proceed to large-scale trials and other aspects related to the NIH microbicide research portfolio. OAR has informed the ICs that the highest priorities for the budget in the coming year are in the area of prevention, and microbicide research in particular.

Through its unique comprehensive trans-NIH strategic plan and budget processes, OAR is enhancing collaboration, minimizing duplication, and ensuring that

research dollars are invested in the highest priority areas of scientific opportunity that will lead to new tools in the fight against AIDS.

APPENDIX 1: LISTS OF NIH STRATEGIC PLAN

Institute and Center Strategic Plans⁶

National Cancer Institute (NCI)

NCI Strategic Plan for Leading the Nation

<http://strategicplan.nci.nih.gov/>

The Nation's Investment in Cancer Research: A Plan and Budget Proposal for Fiscal Year 2007

<http://plan2007.cancer.gov/>

The Nation's Investment in Cancer Research: A Plan and Budget Proposal for Fiscal Year 2008

<http://plan.cancer.gov/>

National Heart, Lung, and Blood Institute (NHLBI)

The NHLBI Strategic Plan is a work in progress and will not be available until the spring of 2007

National Institute of Dental and Craniofacial Research (NIDCR)

NIDCR Strategic Plan

<http://www.nidcr.nih.gov/AboutNIDCR/StrategicPlan/default.htm>

Implementation Plan for the Updated Strategic Plan 2003-2008

<http://www.nidcr.nih.gov/AboutNIDCR/StrategicPlan/ImplementationPlan.htm>

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Strategic Plans:

National Diabetes Education Program (NDEP) Strategic Plan

<http://www.ndep.nih.gov>

⁶ Because Capitol Hill staff asked that the Office of AIDS Research (OAR) respond to the report language, the OAR strategic plan is listed with institute and center plans.

Overcoming Bladder Disease—A Strategic Plan for Research
http://www.niddk.nih.gov/fund/other/archived-conferences/2001/brprg_book.pdf

Renal Disease Research Plan
<http://www.niddk.nih.gov/fund/reports/wholeRDRC.pdf>

Strategic Plan for Polycystic Kidney Disease
<http://www.niddk.nih.gov/fund/other/archived-conferences/2002/pkdmgtg-summary.pdf>

Strategic Plan of the National Kidney Disease Education Program (NKDEP)
<http://www.nkdep.nih.gov/about/reports/strategicplan.htm>

Strategic Plan for Pediatric Urology: The Strategic Plan for Pediatric Urology, NIDDK—Research Progress Report
<http://www.niddk.nih.gov/federal/planning/Pediatric-Urology/>

NIDDK Strategic Plan on Health Disparities
<http://www.niddk.nih.gov/federal/planning/mstrathealthplan.htm>

Reports from Planning Activities:

Clinical Research on Kidney Disease
<http://www.niddk.nih.gov/fund/divisions/KUH/kdcsi/>

NIDDK Annual Compendium of Recent Advances and Emerging Opportunities
http://www.niddk.nih.gov/federal/advances/2006/advances_06.htm

Progress Report on NIDDK Efforts to Promote Translational Research
http://www.niddk.nih.gov/federal/planning/DK_Translation.pdf

Research Needs in Pediatric Kidney Disease—2000 and Beyond
<http://www.niddk.nih.gov/fund/reports/nephrology/summary.pdf>

Strategic Planning for Polycystic Kidney Disease
<http://www.niddk.nih.gov/fund/other/archived-conferences/2002/pkdmgtg-summary.pdf>

Urolithiasis Research Symposium
<http://www.niddk.nih.gov/fund/other/urolithiasis2006/>

Long-Range Research Plan for Digestive Diseases (expected to be completed in 2008)

<http://www.niddk.nih.gov/federal/NCDD/>

National Institute of Neurological Disorders and Stroke (NINDS)

Neuroscience at the New Millennium

http://www.ninds.nih.gov/about_ninds/plans/strategic_plan.htm

NINDS Five-Year Strategic Plan on Minority Health Disparities

http://www.ninds.nih.gov/about_ninds/plans/disparities.htm

Report of the Brain Tumor Progress Review Group

http://www.ninds.nih.gov/find_people/groups/brain_tumor_prg/frontpage.htm

Benchmarks for Epilepsy Research

<http://www.ninds.nih.gov/funding/research/epilepsyweb/index.htm#benchmarks>

Report of the Stroke Progress Review Group

http://www.ninds.nih.gov/find_people/groups/stroke_prg/04_2002_stroke_prg_report.htm

Research Plan for Tuberous Sclerosis

http://www.ninds.nih.gov/about_ninds/plans/tscler_research_plan.htm

Muscular Dystrophy Research and Education plan for the NIH

http://www.ninds.nih.gov/find_people/groups/mdcc/MD_Plan_submitted.pdf

Action Plan for the Muscular Dystrophies

http://www.ninds.nih.gov/find_people/groups/mdcc/MDCC_Action_Plan.pdf

The SMA (spinal muscular atrophy) Project

<http://www.smaproject.org/programs.html#discovery>

Research Plan for Ataxia-Telangiectasia

http://www.ninds.nih.gov/about_ninds/plans/a-t_plan.htm

The 2006 Parkinson's Disease Research Plan

http://www.ninds.nih.gov/funding/research/parkinsonsweb/PD_Plan_2006.htm

National Institute of Allergy and Infectious Diseases (NIAID)

NIAID: Planning for the 21st Century (2000)

<http://www3.niaid.nih.gov/about/overview/planningpriorities/strategicplan/strategicplan2000.htm>

Biodefense and Emerging Infectious Diseases:

NIAID Strategic Plan for Biodefense Research (2002)

<http://www.niaid.nih.gov/biodefense/research/strategic.pdf>

Biodefense Research Agenda for CDC Category A Agents (2002)

<http://www.niaid.nih.gov/biodefense/research/biotresearchagenda.pdf>

NIAID Biodefense Research Agenda for Category B and C Priority Agents (2003)

<http://www3.niaid.nih.gov/Biodefense/Research/categorybandc.pdf>

NIAID Expert Panel on Botulinum Toxins (2002)

http://www3.niaid.nih.gov/Biodefense/PDF/bot_toxins.pdf

NIAID Expert Panel on Immunity and Biodefense (2002)

<http://www.niaid.nih.gov/publications/pdf/biodimmunpan.pdf>

NIAID Expert Panel Review of Medical Chemical Defense Research (2003)

<http://www3.niaid.nih.gov/Biodefense/PDF/chem+report.pdf>

NIAID Expert Panel on Botulinum Diagnostics (2003)

<http://www3.niaid.nih.gov/Biodefense/PDF/bot+toxins+mtg.pdf>

NIAID Expert Panel on Botulinum Neurotoxins Therapeutics (2004)

<http://www3.niaid.nih.gov/Biodefense/PDF/Report+BoNT.pdf>

NIH Strategic Plan and Research Agenda for Medical Countermeasures against Radiological and Nuclear Threats (2005)

http://www3.niaid.nih.gov/about/overview/planningpriorities/RadNuc_StrategicPlan.pdf

NIAID Research Agenda on Emerging Infectious Diseases (1997)

<http://www.niaid.nih.gov/publications/dateline/0997/edrcesup.htm>

Development of a Clinical Trial Plan for Pandemic Influenza Vaccines (2003)
<http://www.niaid.nih.gov/dmid/meetings/pansummary.htm>

HIV/AIDS:

NIAID Global Health Research Plan for HIV/AIDS, Malaria, and Tuberculosis (2001)
<http://www.niaid.nih.gov/publications/globalhealth/global.pdf>

Vaccine Research Center Strategic Plan: Research Toward Development of an Effective AIDS Vaccine (2001)
<http://www.niaid.nih.gov/vrc/pdf/vrcsp.pdf>

Infectious Diseases (non-biodefense, non-AIDS):

Blueprint for Tuberculosis Vaccine Development (1997)
<http://www.niaid.nih.gov/publications/blueprint/toc.htm>

NIAID's Research-Based Framework for Progress on Hepatitis C (1997)
<http://www.niaid.nih.gov/dmid/meetings/hepcframe.htm>

NIAID Topical Microbicide Strategic Plan (2003)
http://www.niaid.nih.gov/publications/topical_microbicide_strategic_plan.pdf

Immune-Mediated Diseases and Transplantation:

NIAID Plan for Research on Immune Tolerance (1998)
<http://www.niaid.nih.gov/Publications/immune/contents.htm>
Report of the Expert Panel on Food Allergy Research (2003)
http://www3.niaid.nih.gov/about/organization/dait/PDF/june30_2003.pdf

Report of the Expert Panel on Food Allergy Research (2006)
(in press)

Transplantation Research Action Plan (2006)
(in press)

Special Populations:

The NIAID Strategic Plan for Addressing Health Disparities Fiscal Years 2002-2006

http://www.niaid.nih.gov/healthdisparities/NIAID_HD_Plan_Final.pdf

Women's Health in the U.S.: Research on Health Issues Affecting Women (2004)

<http://www.niaid.nih.gov/publications/womenshealth/womenshealth.pdf>

National Institute of General Medical Sciences (NIGMS)

Funding Priorities and Initiatives of the National Institute of General Medical Sciences

<http://publications.nigms.nih.gov/reports/priorities.html>

National Institute of Child Health and Human Development (NICHD)

From Cells to Selves Strategic Plan for the NICHD, 2000.

<http://www.nichd.nih.gov/publications/pubs/upload/strategicplan.pdf>

Health Disparities: Bridging the Gap, 2000.

http://www.nichd.nih.gov/publications/pubs/upload/health_disparities.pdf

Reproductive Health for the 21st Century, 2001.

http://www.nichd.nih.gov/publications/pubs/upload/Reproductive_Health.pdf

Developmental Biology, 2001.

http://www.nichd.nih.gov/publications/pubs/upload/Developmenta_Biology.pdf

Genetics and Fetal Antecedents of Disease Susceptibility, 2001.

http://www.nichd.nih.gov/publications/pubs/upload/Genetics_Fetal.pdf

Biobehavioral Development, 2001.

http://www.nichd.nih.gov/publications/pubs/biobehavioral_dev.cfm

Targeting Sudden Infant Death Syndrome (SIDS): A Strategic Plan, 1995, 1998, 2001.

Demographic and Behavioral Sciences Branch Goals and Opportunities, 2002-2006. http://www.nichd.nih.gov/publications/pubs/DBSB_goals_2002.cfm

Pregnancy and Perinatology Branch Strategic Plan, 2005-2010, 2003.
http://www.nichd.nih.gov/publications/pubs/upload/ppb_strategicplan_2010_full.pdf

Research Plan for the National Center for Medical Rehabilitation Research, 1993.
http://www.nichd.nih.gov/publications/pubs/upload/NCMRR_Research_Plan_1993.pdf

Branch Reports to Council with Future Scientific Directions:

Mental Retardation and Developmental Disabilities (MRDD) Branch, Report to the NACHHD Council, June 2005
http://www.nichd.nih.gov/publications/pubs/upload/Council_MRDD_2005.pdf

National Center for Medical Rehabilitation Research (NCMRR) Report to the NACHHD Council, January 2006
http://www.nichd.nih.gov/publications/pubs/upload/ncmrr_report_online_2006.pdf

Developmental Biology, Genetics and Teratology Branch Report to the NACHHD Council, September 2006.
<http://www.nichd.nih.gov/about/org/cdbpm/dbgt/comment.cfm>

National Eye Institute (NEI)

Strategic Plans:

National Plan for Eye and Vision Research (2004)
<http://www.nei.nih.gov/strategicplanning/nationalplan1.pdf>

Vision Research--A National Plan 1999-2003: A Report of the National Eye Advisory Council
<http://www.nei.nih.gov/resources/strategicplans/plan.asp>

NEI Health Disparities Strategic Plan
http://www.nei.nih.gov/strategicplanning/disparities_draft.asp

Planning Reports:

Progress in Eye and Vision Research 1999-2006

http://www.nei.nih.gov/strategicplanning/NEI_ProgressDoc.pdf

Age-related Macular Degeneration Phenotype Consensus Meeting Report

http://www.nei.nih.gov/strategicplanning/amd_meeting.asp

*Pathophysiology of Ganglion Cell Death and Optic Nerve Degeneration
Workshop Report*

<http://www.nei.nih.gov/strategicplanning/workshop.asp>

National Institute of Environmental Health Sciences (NIEHS)

*New Frontiers in Environmental Sciences and Human Health: The 2006-2011
NIEHS Strategic Plan*

<http://www.niehs.nih.gov/external/plan2006/home.htm>

National Institute on Aging (NIA)

Action Plan for Aging Research: Strategic Plan for Fiscal Years 2001-2005

<http://www.nia.nih.gov/NR/rdonlyres/E6765778-B533-44BB-9774-1FB6821B1A14/2696/niasp.pdf>

(NIA is in the process of updating this strategic plan and expects to release the new version by May 2007.)

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

NIAMS Long-Range Plan: Fiscal Years 2006-2009

www.niams.nih.gov/an/stratplan/long_range.htm

NIAMS Strategic Plan for Reducing Health Disparities

www.niams.nih.gov/an/stratplan/strategicplanhd/strategicplanhd.htm

**National Institute on Deafness and Other Communication Disorders
(NIDCD)**

FY 2006-FY 2008 NIDCD Strategic Plan

<http://www.nidcd.nih.gov/about/plans/strategic/>

FY 2004-FY 2008 NIDCD Strategic Plan on Reducing Health Disparities

http://www.nidcd.nih.gov/about/plans/strategic/health_disp.asp

NIDCD Action Plan on Research Careers for Deaf Individuals

http://www.nidcd.nih.gov/research/training/action_plan.asp

National Institute of Mental Health (NIMH)

NIMH Strategic Plans and Priorities

<http://www.nimh.nih.gov/strategic/strategicplanmenu.cfm>

Breaking Ground, Breaking Through: The Strategic Plan for Mood Disorders Research

http://www.nimh.nih.gov/strategic/stplan_mooodisorders.cfm

Pathways to Health: Charting the Science of Brain, Mind, and Behavior

http://www.nimh.nih.gov/strategic/stplan_pathways.pdf

NIMH Five-Year Strategic Plan for Reducing Health Disparities

<http://www.nimh.nih.gov/strategic/healthdisparities.pdf>

National Institute on Drug Abuse (NIDA)

NIDA's Five-Year Strategic Plan: Bringing the Power of Science to Bear on Drug Abuse and Addiction (currently being updated):

<http://www.drugabuse.gov/StrategicPlan/Index.html>

NIDA Strategic Plan on Reducing Health Disparities, NIH Health Disparities Strategic Plan, FY 2004-2008 (Revised July 2004):

<http://www.drugabuse.gov/PDF/HealthDispPlan.pdf>

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

*National Institute on Alcohol Abuse and Alcoholism Five Year Strategic Plan
FY07-11*

[http://pubs.niaaa.nih.gov/publications/StrategicPlan/NIAAASTRATEGICPLAN.
htm](http://pubs.niaaa.nih.gov/publications/StrategicPlan/NIAAASTRATEGICPLAN.htm)

National Institute of Nursing Research (NINR)

Changing Practice, Changing Lives

<http://www.ninr.nih.gov/AboutNINR/NINRMissionandStrategicPlan/>

National Human Genome Research Institute (NHGRI)

A Vision for the Future of Genomics Research

<http://www.genome.gov/11007524>

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

NIBIB Strategic Plan I

http://www.nibib.nih.gov/nibib/File/About%20NIBIB/Strategic%20Plan/NIBIB_strategic%20plan.pdf

National Center for Research Resources (NCRR)

NCRR 2004-2008 Strategic Plan: Challenges and Critical Choices

http://www.ncrr.nih.gov/about_ncrr/StrategicPlan2004-08.pdf

National Center for Complementary and Alternative Medicine (NCCAM)

Expanding Horizons of Health Care: Strategic Plan 2005-2009

<http://nccam.nih.gov/about/plans/2005/>

National Center on Minority Health and Health Disparities (NCMHD)

See: *NIH Strategic Research Plan and Budget to Reduce and Ultimately Eliminate Health Disparities, Fiscal Years 2002-2006*, below

John E. Fogarty International Center (FIC)

Fogarty International Center Strategic Plan: Fiscal Years 2000-2003: Reducing Disparities In Global Health

<http://www.fic.nih.gov/about/plan/StrategicPlan.pdf>

National Library of Medicine (NLM)

“Charting the Course for the 21st Century: NLM's Long Range Plan 2006-2016”

<http://www.nlm.nih.gov/pubs/plan/lrpdocs.html>

Office of AIDS Research (OAR)

See: *Trans-NIH Plan for HIV-Related Research*, below

Trans-NIH Strategic Plans

(Associated Institutes, Centers, and OD Offices are listed in alphabetical order by acronym, with lead IC in bold; non-NIH participants are not listed)

NIH Strategic Research Plan and Budget to Reduce and Ultimately Eliminate Health Disparities, Fiscal Years 2002-2006

http://ncmhd.nih.gov/our_programs/strategic/volumes.asp

CC, CSR, FIC, NCCAM, NCI, **NCMHD**, NCRR, NEI, NHGRI, NHLBI, NIA, NIAAA, NIAID, NIAMS, NIBIB, NICHD, NIDA, NIDCD, NIDCR, NIDDK, NIEHS, NIGMS, NIMH, NINDS, NINR, NLM, OAR, OBSSR, OIR, ORD, ORWH

(Note: The update of this plan, which will cover Fiscal Years 2004-2008, is under review by the Department of Health and Human Services)

Trans-NIH Plan for HIV-Related Research

<http://www.oar.nih.gov/public/pubs/fy2008/FY2008Pln.pdf>

FIC, NCCAM, NCI, NCRR, NEI, NHGRI, NHLBI, NIA, NIAAA, NIAID, NIAMS, NICHD, NIDA, NIDCR, NIDDK, NIEHS, NIGMS, NIMH, NINDS, NINR, NLM, **OD (OAR)**

Action Plan for Liver Disease Research

http://www.niddk.nih.gov/fund/divisions/ddn/ldrb/ldrb_action_plan.htm

CSR, FIC, NCCAM, NCI, NCRR, NHGRI, NHLBI, NIA, NIAAA, NIAID, NIBIB, NICHD, NIDA, NIDCR, **NIDDK**, NIEHS, NIGMS, NINDS, NINR, NLM

Muscular Dystrophy Research and Education Plan for the NIH

http://www.ninds.nih.gov/find_people/groups/mdcc/MD_Plan_submitted.pdf

NIAMS, NICHD, **NINDS**

Action Plan for the Muscular Dystrophies

http://www.ninds.nih.gov/find_people/groups/mdcc/MDCC_Action_Plan.pdf

NIAMS, NICHD, **NINDS**

Parkinson's Disease Research Agenda

http://www.ninds.nih.gov/funding/research/parkinsonsweb/PD_Plan_2006.htm

NCCAM, NCRR, NHGRI, NIA, NICHD, NIDA, NIDCD, NIEHS, NIMH,
NINDS, NINR

Advances and Emerging Opportunities in Type 1 Diabetes Research: A Strategic Plan

<http://www.niddk.nih.gov/fund/diabetesspecialfunds/plan/version-1.htm>

CSR, NCCAM, NCMHD, NCRR, NEI, NHGRI, NHLBI, NIA, NIAAA, NIAID, NIBIB, NICHD, NIDA, NIDCD, NIDCR, **NIDDK**, NIEHS, NIGMS, NIMH, NINDS, NINR, NLM

Research Plan for Tuberous Sclerosis

http://www.ninds.nih.gov/about_ninds/plans/tscler_research_plan.htm

NCI, NHLBI, NIAMS, NICHD, NIDDK, NIMH, **NINDS, ORD**

NIH Plan for Social Work Research

http://obsr.od.nih.gov/Documents/Publications/SWR_Report.pdf

CC, NCI, NIA, NIAAA, NICHD, NIDA, NIMH, NINR, **OBSSR**

NIH Strategic Plan and Research Agenda for Medical Countermeasures against Radiological and Nuclear Threats

http://www3.niaid.nih.gov/about/overview/planningpriorities/RadNuc_StrategicPlan.pdf

NCI, NHLBI, **NIAID**, NIEHS

Strategic Plan for NIH Obesity Research

<http://obesityresearch.nih.gov/About/strategic-plan.htm>

CSR, DNRC, FIC, NCCAM, NCI, NCMHD, NCRR, NHGRI, **NHLBI**, NIA, NIAAA, NIAMS, NIBIB, NICHD, NIDA, NIDCR, **NIDDK**, NIEHS, NIMH, NINDS, NINR, OBSSR, ODP, ODS, ORWH, OSP

Research Plan for Ataxia-Telangiectasia

http://www.ninds.nih.gov/about_ninds/plans/a-t_plan.htm

NCI, NCRR, NEI, NHBLI, NHGRI, NIA, NIAID, NICHD, NIEHS, NIGMS, **NINDS, ORD**

*NIH Autoimmune Diseases Coordinating Committee: Autoimmune Diseases
Research Plan*

<http://www.niaid.nih.gov/publications/pdf/ADCCFinal.pdf>

CSR, FIC, NCCAM, NCI, NCCR, NEI, NHGRI, NHLBI, NIA, NIAAA, **NIAID**,
NIAMS, NIBIB, NICHD, NIDA, NIDCD, NIDCR, NIDDK, NIEHS, NIGMS,
NIMH, NINDS, NINR, ORD, ORWH

NIH Blueprint for Neuroscience Research

<http://neuroscienceblueprint.nih.gov/>

NCCAM, NCCR, NEI, NIA, NIAAA, NIBIB, NICHD, NIDA, NIDCD, NIDCR,
NIEHS, NIGMS, **NIMH**, **NINDS**, NINR, OBSSR

The NIH Roadmap for Medical Research

<http://nihroadmap.nih.gov/>

All NIH Institutes and Centers are involved in the Roadmap

APPENDIX 2: NIH PRIORITY SETTING AND AWARD PROCESSES

The NIH priority-setting and award⁷ processes described in this appendix are designed to ensure the best possible return on the Nation's investment in biomedical and behavioral research. The mission of NIH is research to generate new knowledge to improve health. NIH strives to make the most effective use of every dollar directed toward that mission.

There are several important influences on NIH's priority-setting and award-making processes. First, the scientific research enterprise encompassed by NIH is extremely broad in scope, ranging from basic molecular biology to clinical (human) testing of experimental interventions, to research on health services. Other influences pertain to the nature of science itself. Undertaking scientific research means attempting to discover what is unknown and advancement is rarely linear. Thus, scientific research is unlike most other enterprises, which can employ established means to generate planned amounts of known products. By virtue of seeking to discover what is unknown, research can lead to unexpected findings. NIH depends on the expertise and imagination of extramural and intramural scientists who plan their research using the scientific method. In these hypothesis-driven (or when the question is more technological, design-driven) plans, scientists articulate specific means to address specific questions. History shows the benefits of allowing a significant portion of our research activity to be directed by the expertise and imagination of individual scientists. Finally, as a public enterprise, NIH research aims complement those of industry. The new knowledge discovered through the aegis of NIH typically makes its impact on public health by seeding industrial development of products and processes. NIH supports product and process development on a very selective basis, i.e., only in important niches of public health need that would not otherwise be addressed adequately in the private sector.

Extramural Research

To increase knowledge fundamental to improved health, through its *extramural* program, NIH primarily supports investigator-initiated research. Competitive investigator-initiated research is the time-tested engine of innovation. Just as countries with free-market economies are better at meeting the diverse needs of their citizens, scientific enterprises that encourage investigator-initiated research and foster competition to identify the best research applications are more successful in advancing the frontiers of science and seeding the efforts of

⁷ Awards include grants, cooperative agreements, and contracts.

industry. NIH best capitalizes on the creative dynamism and ability of the free competition of ideas when it uses incentives and mechanisms that guide, without stifling innovation. This allows the Agency to zero in on unique, hypothesis-driven, scientific opportunities, with the potential to solve public health problems.

Encouraging Applications that Address NIH Priorities

NIH strategic planning is a highly consultative process involving many constituencies who generate and provide input on public health needs and research gaps, opportunities, and priorities. As such, NIH priorities both inform, and are informed by, the extramural research community. Once articulated, NIH uses a variety of means to communicate its priorities broadly to the extramural community, where these priorities can influence and complement scientists' strategic thinking and the ideas that are the basis for their research proposals. At the macro level, investigators learn about NIH priorities through the mission statements of the NIH Institutes and Centers (ICs). On a more proactive level, NIH uses several tools to stimulate new directions in science and to intensify the level of activity in a field.

NIH encourages *unsolicited* research through a variety of means, such as, convening workshops and conferences and disseminating reports of their proceedings; commissioning studies and assembling task forces or expert panels to assess the state of the science in a field; generating and disseminating strategic plans and research agendas; and issuing Program Announcements (PAs). PAs describe a broad area of research considered high priority for the NIH.

NIH also *solicits* research. To solicit research that will be conducted under a grant mechanism, ICs issue Requests for Applications (RFAs). To solicit research that will be conducted under contract, ICs issue Requests for Proposals (RFPs). RFAs generally identify a more narrowly defined area of scientific need, and/or identify an area of need with more certainty and commitment to the path, than PAs. Moreover, under an RFA the issuing IC(s) reserves a designated amount of funding and investigators apply and compete, on a one-time basis, for that specific set-aside of funds. In addition, the scientific review panels that assess the merit of the applications and determine their priority scores are convened by the issuing IC(s) specifically for the purpose of reviewing the applications submitted in response to the RFA. In contrast, the scientific review panels that assess unsolicited proposals are standing bodies with rotating memberships. Although RFAs are important tools for NIH to foster research in specific high priority areas, experience shows that unsolicited investigator-

initiated research has a great probability for advancing biomedical and behavioral research.

PAs, RFAs, and RFPs are considered “initiatives,” and the effective targeting of research initiatives involves interplay with priority setting. That is, the same priority setting and planning processes NIH uses to encourage unsolicited research—workshops, conferences, state-of-the-science reports, and strategic plans—also provide impetus and direction for developing PAs, RFAs, and RFPs. From these various inputs and sources of advice, which draw on the entire spectrum of the NIH stakeholder community, NIH staff develop initial concepts for future initiatives. Through consultation with fellow staff and IC leadership, initial concepts are further developed into formal concepts for PAs, RFAs, and RFPs and are further evaluated by IC Advisory Councils, which provide external input regarding the relevance and potential to advance the IC’s mission. IC Advisory Councils must approve all research initiatives. An initiative may be strengthened through co-sponsorship by other ICs, other federal agencies, and advocacy groups with an interest in the particular area of research to be studied.

The NIH Peer Review Process

All grant applications and contract proposals for research funding undergo evaluation by peer review—external expert panels, who determine which applications/proposals are the most scientifically and technically meritorious and should be considered for funding. The NIH grant peer review process begins with assignment. Applications relevant to the NIH mission receive two types of assignment—assignment to a Scientific Review Group (SRG) for evaluation of scientific and technical merit and assignment to an IC that has a mission encompassing the aims and objectives of the application. NIH uses established referral criteria (called Referral Guidelines) to determine the appropriate SRG to carry out review and the IC most suitable to potentially fund the project.

After an application is assigned, it is subject to the first of two sequential levels of evaluation. Both levels are required by statute. At the first level of review, peer reviewers evaluate and judge the overall scientific and technical merit of the research proposed in the application. The SRGs that carry out the first level of review are composed primarily of non-federal researchers who are actively involved in the area of the proposed research and qualified to review the applications by their research experience and training. Peer reviewers are consultants to NIH and they provide advice about the potential of the research to advance scientific knowledge and discovery. The NIH peer review process is conducted in accordance with Department of Health and Human Services policy

and established processes and criteria to ensure maximum competition, impartiality, credibility, fairness, and the highest level of ethical standards. The standardized criteria for determining the scientific and technical merit of an application are:

- 1) Significance - Does the study address an important problem?
- 2) Approach – Are the concepts and methods well thought out and appropriate to the aim?
- 3) Innovation – Does the project develop or use novel concepts?
- 4) Investigators – Are the investigators appropriately trained and well suited to carry out the work?
- 5) Environment – Will the setting for the research (facilities, resources, institutional support) contribute to probability of success?

All of these criteria are necessary factors in determining the overall scientific and technical merit of an application and the final evaluation score or “priority score” of an application. Additional review criteria may be added for applications in response to RFAs depending on the nature and scope of the initiative.

The second level of peer review is performed by the National Advisory Councils or Boards (Advisory Councils), which advise each IC, and are composed of both scientific and non-scientific public members chosen for their expertise, interest, or activity in matters related to a specific area of health and disease. The broad membership of Councils is intended to ensure that they provide diverse perspectives and advice on science, health, and the impacts of diseases within the purview of the IC. The vast majority of applications assigned to an IC go to Council⁸ and Council then recommends those that should be considered for funding. Identifying applications that further specific program priorities is a particularly important function of this second level of peer review. However, like SRGs, Advisory Councils recommend, but do not make funding decisions.

Funding Decisions

Only applications that are scientifically meritorious, based on SRG review, and favorably recommended by the Advisory Council may be considered for funding. The priority score given to an application during the peer review process is important, but not the sole factor determining an IC’s funding decisions. Other

⁸ Councils do not receive un-scored applications (these are applications deemed “not recommended for further consideration (NRFC)” at the first level of peer review. Also, until enactment of the NIH Reform Act of 2006, Councils were not obligated to review applications for less than \$50,000. Moreover, of applications sent to Council, many IC Councils evaluate only those scoring over a threshold of success at the first level of peer review.

considerations are programmatic relevance, contribution to balance in light of the existing IC portfolio, and size of the award.

Many ICs establish a “payline”—a percentile-based⁹ funding cutoff point determined at the beginning of the fiscal year by balancing the projected number of applications coming to an NIH Institute with the amount of funds determined by NIH and the ICs to be devoted to such projects. Because significance of the proposed research is a critical factor in determining the priority score, applications that score within the payline are most likely to be funded. However, Advisory Councils consider, evaluate, and make recommendations on specific applications that score both within and beyond the payline.

In addition to setting paylines, many ICs also establish procedures for granting awards for applications that scored beyond the payline. This enables ICs to closely examine the applications that fall beyond the payline, but were recommended for funding by Council, and to decide which to fund based on a variety of priorities. ICs vary in the specific procedures and processes they use to manage these reserves. Even the terminology varies by IC. Terms used include select pay, exception pools, gray zones, high program-priority proposals, special emphasis, and others. What is consistent is the use of these funds, with strong justification, to support high program priority applications that score beyond the payline. ICs introduce programmatic factors in the funding process by other means as well, and not all utilize paylines or reserve funds.

The launching of initiatives and the funding of awards is just the beginning of the story. During the life of a grant, and while an initiative is in effect, ICs monitor progress. IC staff track what is funded under each initiative and monitor scientific progress by reviewing yearly progress reports submitted by grantees. For some initiatives, there are follow-up advisory group meetings, workshops, and/or program evaluations. This type of information becomes yet another source of input for the IC as it evaluates priorities and considers mid-course programmatic corrections.

Intramural Research

To increase knowledge fundamental to improved health through its *intramural* program, NIH conducts research on its campuses in the Bethesda, Rockville Frederick, and Baltimore, Maryland areas; Research Triangle Park, North Carolina; Phoenix, Arizona; and at the Rocky Mountain Laboratories, Montana.

⁹ Percentile represents the relative position or rank of each priority score (from 1 to 100).

Most ICs have intramural research programs; the exceptions are NIGMS, CSR, FIC, and NCRR, and NCMHD.¹⁰

As with the extramural program, intramural scientists generate the research questions to be pursued. In the intramural research program, however, program directions are shaped not through grant awards, but rather through professional appointments (hiring), promotion, external reviews, and the allocation of resources to laboratories.

Each intramural research program has a promotion and tenure committee that evaluates all recommendations for professional appointment or promotion. In addition, there is a central tenure committee that reviews all candidates for tenure at the NIH. Through a competitive process, only approximately 60 percent of the individuals who enter the tenure-track at the NIH eventually become permanent tenured staff.

Although tenure guarantees a base salary, research resources are competitive. Tenured and tenure-track scientists undergo formal, annual, internal reviews. Resource allocation and promotions are determined from these reviews. In addition, at least every 4 years, an external expert Board of Scientific Counselors reviews the work of each tenured/tenure-track scientist and makes recommendations regarding continuation or modification of projects and adjustment of resources (budget, space, personnel).

Each intramural research program is led by a Scientific Director. Scientific Directors are evaluated for performance by an external committee every 5 years. The reviewing committee reports to the IC's National Advisory Council and the NIH Deputy Director for Intramural Research.

The IC Director or Scientific Director reports annually to the IC's National Advisory Council. Moreover, each IC's intramural research program is reviewed in its entirety by a blue ribbon panel approximately every 10 years. These panels review and make recommendations concerning the impact of the research program, program balance, and other significant matters that play a role in the success of the program.

Most IC intramural programs conduct research in the NIH Clinical Center. The Clinical Center, as an IC in its own right, also independently conducts research.

¹⁰ Although NCMHD does not have an intramural program, *per se*, some NCMHD funds are applied to intramural activities in partnership with other ICs.

The newly established Advisory Board for Clinical Research incorporates outside experts to consider expanded research opportunities, especially collaborations between intramural and extramural clinical researchers, and to promote careers in clinical research. The Advisory Board for Clinical Research also oversees all intramural clinical research, while also providing oversight of Clinical Center resources, planning and operations.