Meeting Minutes
Department of Health and Human Services
Public Health Services
National Diabetes and Digestive and Kidney Diseases
Advisory Council

September 24–25, 2003

I. CALL TO ORDER

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Director, Dr. Allen M. Spiegel, called to order the 163rd National Diabetes and Digestive and Kidney Diseases Advisory Council meeting on September 24, 2003, at 8:30 a.m. in Conference Room E1/E2, Building 45, National Institutes of Health (NIH), Bethesda, MD. Dr. Spiegel opened the meeting with the following general announcements:

< Four Council members are departing: The Honorable Levan Gordon, Dr. Edward Holmes, Dr. Sandra Puczynski, and Dr. Edward Benz.

< The nomination slate for 2003 appointments to the National Diabetes and Digestive and Kidney Diseases Advisory Council has been approved. Dr. Rudolph Leibel, Head, Division of Molecular Genetics and the Co-Director of the Naomi Berrie Diabetes Center at Columbia University, will join the Diabetes, Endocrinology, and Metabolic Diseases Subcommittee; Dr. Ronald Ruecker, who is in private practice and is the Medical Director and a consultant in gastroenterology at the Wabash Memorial Association, Decatur, Illinois, will join the Digestive Diseases and Nutrition Subcommittee; and Dr. Janis Abkowitz, Section Head, Division of Hematology, University of Washington Medical Center, and Director, Hematology Clinic at the Seattle Cancer Care Alliance and University of Washington Medical Center; and Dr. Roberto Coquis, a private practice physician and President, Nephrology Consultants of South Florida in Ft. Lauderdale, Florida, will join the Kidney, Urologic, and Hematologic Subcommittee.

< At the NIH level, Dr. Jeremy Berg will replace Dr. Marvin Cassman as Director of the National Institute of General Medical Sciences; Dr. Story Landis will serve as Director of the National Institute of Neurological Disorders and Stroke (NINDS); and Dr. Audrey Penn has been appointed as the NINDS representative to the Diabetes Mellitus Interagency Coordinating Committee.

< Dr. Claude Lenfant has retired from his position as Director of the National Heart, Lung, and Blood Institute (NHLBI); Dr. Barbara Alving will serve as Acting Director until the position is filled. Dr. Ellie Ehrenfeld has resigned from her position as Director of the Center for Scientific Review, and Dr. Brent Stanfield is serving as Acting Director. Also, Dr. Kenneth Olden, Director of the National Institute of Environmental Health Sciences and Director of the National Toxicology Program, is resigning from both positions. Council members are encouraged to submit suggestions of able candidates for these positions.

< Within NIDDK staff, Dr. Myrlene Staten, formerly Vice President of Cardiovascular/Metabolic Diseases Research at Pharmacia/Upjohn, and Dr. Teresa Jones, formerly of the NIDDK Intramural Research Program, have joined the Division of Diabetes, Endocrinology, and Metabolic Diseases; and Dr. Christine Densmore, formerly at the National Institute of Arthritis and Musculoskeletal and Skin Diseases, has joined the Division of Digestive Diseases and Nutrition.

A. ATTENDANCE – COUNCIL MEMBERS PRESENT

Dr. Robert Alpern
Mr. David Baldridge
Dr. Jose Caro
Ms. Mary Clark
Dr. Raymond DuBois
Dr. Robert Eckel
Dr. Richard Goodman
Hon. Levan Gordon
Dr. Earl Harrison (*Ex officio*)
Dr. Edward Holmes
Dr. Carolyn Kelly
Dr. James W. Kikendall (*Ex officio*)
Dr. Sum Lee
Dr. Daniel Porte (*Ex-officio*)
Dr. Sandra Puczynski
Dr. Vicki Ratner
Dr. Linda Sherman
Dr. E. Darracott Vaughan
Dr. W. Allan Walker

Absent Council Members:
Dr. Edward Benz
Ms. Nancy Norton

Also present:
Dr. Allen Spiegel, Director, NIDDK and Chairperson, NDDK Advisory Council
Dr. Griffin Rodgers, Deputy Director, NIDDK
Dr. Robert Hammond, Executive Secretary, NDDK Advisory Council

B. NIDDK STAFF AND GUESTS

In addition to Council members, others in attendance included NIDDK staff members, representatives of the NIH Office of the Director (OD), Center for Scientific Review (CSR) Scientific Review Administrators, and other NIH staff members. Some NIDDK staff listed below attended via videocast from 2 Democracy Plaza, Room 701. Guests were present during the open sessions of the meeting. Attendees included the following:

Kristen Abraham, NIDDK
Linda Addison-Hardy, NIDDK
Lawrence Agodoa, NIDDK
Beena Akolkar, NIDDK
Roberta Albert, NIDDK
Carolyn Benson, NIDDK
Terry Bishop, NIDDK
Sharon Bourque, NIDDK
Josephine Briggs, NIDDK
Carlos Caban, OER
Francisco Calvo, NIDDK
Joan Chamberlain, NIDDK
Dolph Chianchiano, Nat. Kid. Fd.
Michelle Cissell, JDRF
John Connaughton, NIDDK
Catherine Cowie, NIDDK
Leslie Curtis, NIDDK
Florence Danshes, NIDDK
Maria Davila-Bloom, NIDDK
Jane DeMouy, NIDDK
Christine Densmore, NIDDK
Devon Drew, NIDDK
Linda Edgeman, NIDDK
Michael Edwards, NIDDK
Thomas Eggerman, NIDDK
Paul Eggers, NIDDK
Gayla Elder-Leak, NIDDK
Donald Ellis, NIDDK
Jody Evans, NIDDK
James Everhart, NIDDK
Richard Farishian, NIDDK
Ned Feder, NIDDK
Carol Feld, NIDDK

Teresa Fitzpatrick, NIDDK
Olaf L. Fonville, NIDDK
Judith Fradkin, NIDDK
Randi Freundlich, NIDDK
Joanne Gallivan, NIDDK
M. Galvin, NIOSH
Lisa Gansheroff, NIDDK
Derek Gault, NIDDK
Robert Goldstein, JDRF
Maria Gonzalez, Constella Grp
Janet Gregory, NIDDK
Carol Haft, NIDDK
Frank Hamilton, NIDDK
Mary Hanlon, NIDDK
Dana Harris, NIDDK
Mary Harris, NIDDK
Kim Hetkowski, NIDDK
Trude Hilliard, NIDDK
Gladys Hirschman, NIDDK
Eleanor Hoff, NIDDK
Jay Hoofnagle, NIDDK
Ann Karen Howard, NIDDK
Van Hubbard, NIDDK
Donna Huggins, NIDDK
Joyce Hunter, NIDDK
James Hyde, NIDDK
Donna James, NIDDK
Stephen James, NIDDK
Ann Jerkins, CSR
Desiree Johnson, NIDDK
Teresa Jones, NIDDK
Robert Karp, NIDDK
Melissa Keefe, Am. Urol. Assoc.
Charlette Kenley, NIDDK
Christian Ketchum, NIDDK
Sooja Kim, CSR
Carolyn Kofa, NIDDK
Kathy Kranzfelder, NIDDK
Krish Krishnan, CSR
Robert Kuczmarski, NIDDK
John Kusek, NIDDK
Todd Le, NIDDK
Melissa Lee, NIDDK
Susan Lehman, NIDDK
Ellen Leschek, NIDDK
Maxine Lesniak, NIDDK
Monica Liebert, Am. Urol. Assoc.
Barbara Linder, NIDDK
Helen Ling, NIDDK
Billie Mackey, NIDDK
Denise Manouelian, NIDDK
Ronald Margolis, NIDDK
Teresa Marquette, NIDDK
Dan Matsumoto, NIDDK
Michael K. May, NIDDK
Julie McDermott, NIDDK
Barbara Merchant, NIDDK
Catherine Meyers, NIDDK
Carolyn Miles, NIDDK
David Miller, NIDDK
Megan Miller, NIDDK
David Mineo, NIDDK
Marva Moxey-Mims, NIDDK
Christopher Mullins, NIDDK
Neal Musto, NIDDK
Leroy Nyberg, NIDDK
Diana O'Donovan, NIDDK
Denise Payne, NIDDK
Aretina Perry-Jones, NIDDK
Bobbie Peterson, MBS
Judith Podskalny, NIDDK
Sharon Pope, NIDDK
Jeanie Robinson, NIDDK
Patricia Robuck, NIDDK
Mary K. Rosenberg, NIDDK
Betsy Roy, Soc.&Scient. System
Paul Rushing, NIDDK
Lakshmanan Sankaran, NIDDK
Salvatore Sechi, NIDDK
Leonard Seeff, NIDDK
Jose Serrano, NIDDK
S. Shack, NIOSH
Kathleen Shino, NIDDK
Elizabeth Singer, NIDDK
Jay Skyler, Univ. of Miami
Philip Smith, NIDDK
Jennifer Soloman, Constella Grp
Rosa Sorrell, NIDDK
Delia Tang, CSR
Mehrdad Tondravi, NIDDK
George Tucker, NIDDK
Renetta Washington, NIDDK
B. Wedding, NIOSH
Dorothy West, NIDDK
Elizabeth Wilder, NIDDK
Gina Wrench, NIDDK
Susan Yanovski, NIDDK

II. CONSIDERATION OF SUMMARY MINUTES OF THE 162nd COUNCIL MEETING

The summary minutes of the 162nd Council meeting were approved unanimously.

III. FUTURE COUNCIL DATES

Dr. Spiegel asked Council members to take note of future Council meeting dates as follows:

February 4–5, 2004
May 26–27, 2004
September 22–23, 2004
February 23–24, 2005
May 19–20, 2005

IV. ANNOUNCEMENTS: CONFIDENTIALITY AND CONFLICT OF INTEREST

Dr. Robert Hammond

Dr. Hammond outlined the procedures to guarantee confidentiality and avoid conflicts of interest, discussed the scope and applicability of these procedures, and requested Council compliance. Members were asked to sign and return a conflict-of-interest statement, and were reminded that materials furnished are considered privileged information and are to be used for the purpose of review and discussion during the closed portions of the meeting only. The outcome of the closed-session discussions may be disclosed only by staff and only under appropriate circumstances; all communications from investigators to Council members regarding actions on applications must be referred to NIDDK staff.

Furthermore, Council members should recuse themselves when individual applications from their institutions are discussed to avoid an actual or perceived conflict of interest. However, this is unnecessary with *en bloc* votes, for which all members may be present and participate. Council members from multi-campus institutions of higher education may participate in discussion of applications from sites that are within the same institution, but are separate from the campus to which they are appointed, if the employee's disqualifying financial interest is employment in a position with no responsibilities at a separate campus of the same multi-campus institution. Thus, individuals may act upon other campus actions regarding second-level review.

V. REPORT FROM THE NIDDK DIRECTOR

Dr. Allen Spiegel

On the topic of the NIH Roadmap, Dr. Spiegel highlighted reasons for its creation, outlined its chronology, and addressed issues regarding its implementation.

Why a Roadmap?

The purpose for creating the Roadmap is to identify major opportunities and gaps in broad areas of biomedical research that need to be addressed by the NIH as a whole. These cross-cutting areas will benefit from planning that transcends the single-Institute level to enable prioritizing across Institutes. Acceleration is needed in the pace of discoveries in the life sciences, formulation of more effective approaches, and development of more rapid translational processes, which must be a national priority.

Roadmap Chronology

Shortly after his appointment as Director of the NIH in May 2002, Dr. Elias Zerhouni, having recognized the need for new approaches, called together representatives from all of the NIH Institutes and Centers (IC) and many outside groups for a series of meetings. The purpose of these meetings was to identify areas in need of enhancement and new opportunities for biomedical research. In September 2002, at the annual IC Directors' Leadership Forum, participants evaluated the feedback from the Roadmap meetings and identified several major areas for pursuit.

In the Spring of 2003, 15 Roadmap Working Groups, involving 300 experts and chaired by IC Directors, were formed. The groups were asked to develop specific initiative concepts, with each group assigned detailed topics to integrate in a more comprehensive way. At the NIH Budget Retreat in June 2003, representatives from each Working Group presented their material to the NIH Director and the IC Directors, who determined which initiative concepts should go forward based on the following considerations:

< Is the initiative truly transforming—will it dramatically change how or what biomedical research is conducted in the next decade?
< Can the NIH afford not to do it?
< Will the initiative be compelling to our stakeholders, especially the public?
< Does the initiative position the NIH as unique—doing something that no other entity can or will do?
< Will the outcomes from the initiative be used by and synergize the work of many ICs?

Roadmap Implementation Groups

Three themes emerged: (1) New Pathways to Discovery, (2) Research Teams of the Future, and (3) Reengineering the Clinical Research Enterprise. Within these areas, the initiatives of the Working Groups were aggregated into nine implementation groups:

- Building Blocks, Biological Pathways, and Networks
- Structural Biology
- Bioinformatics and Computational Biology
- Molecular Libraries and Molecular Imaging
- Nanomedicine
- Interdisciplinary Teams
- Private-Public Partnerships
- High-Risk Research
- Reengineering the Clinical Research Enterprise

Of the nine implementation groups, the last is particularly important. Clinical research is viewed as being in crisis in this country. On the one hand, researchers must protect the rights and safety of the public and the scientific integrity of research projects; on the other hand, it is important to avoid the creation of barriers that discourage clinical protocols.

The Role of the NIDDK

The NIDDK has been engaged proactively in this process and is taking the lead role on three new initiatives: (1) a metabolomics initiative that will look at the development of more powerful technology for analyzing small molecules of every sort; and (2) two interdisciplinary research training initiatives; (3) Translational research core resources.

Roadmap Implementation

A common pool of resources will be used for current and future investment in the Roadmap initiatives. Totaling approximately $125 million in fiscal year (FY) 2004, the resources devoted to the Roadmap initiatives are expected to increase to approximately $500 million per year. The Roadmap is not intended to be a rigid outline; if a project is launched and is not working or meeting the criteria that have been set, it will be terminated and the funds rerouted.

Discussion

Responding to a comment about linking basic science and clinical science, Dr. Spiegel stressed the objective of developing an ethical and appropriate way to use current technology to assess human genotypic and phenotypic variation. Attaining this objective is possible technologically, but there is a need to resolve ethical issues in order to establish a national clinical research core to create a real-time, online laboratory for phenotypic variation. Dr. Spiegel also agreed that the Roadmap may present an ideal opportunity for basic and clinical scientists to focus their attention on a common "model organism," humans.

In response to a question about the recruitment of young scientists, Dr. Spiegel stated that major initiatives are planned for clinical research training, specifically the implementation of a new "M.D.-plus" kind of training program that would focus on clinical and translational research. The goal should be to create training mechanisms that will permit truly new disciplines to emerge at the interface of existing disciplines. Council members supported the idea of including curricula related to clinical investigation.

Regarding budgetary resources in FY 2004, Dr. Spiegel explained that the common pool of resources fueling the Roadmap is no longer identified with any one IC. The grants that will be awarded, irrespective of which IC awards them, will come out of this common pool. In addition, Institutes may decide to fund disease-specific research within their missions that relates to the non-disease-specific Roadmap themes.

REPORT FROM THE NIDDK DEPUTY DIRECTOR

Dr. Griffin Rodgers

Dr. Rodgers explained budget expectations for FY 2004. The House of Representatives has accepted the President's proposal as it is, and the Senate has proposed an additional 1.2 percent to the overall NIH budget. If approved, this NIH funding scenario could result in a 5-percent increase in the NIDDK budget over FY 2003. However, Congress has implemented a continuing resolution for now that may lead to an indefinite continuation of funding at last year's level.

Development of the Institute of Medicine (IOM) Report on Organizational Change at NIH

The IOM Report largely stemmed from an article by the former NIH Director, Dr. Harold Varmus, in a March 2001 publication (*Science*) on the proliferation of the organization components at the NIH. He noted the increase from six Institutes in 1960 to 27 NIH components in 2001, and predicted that the NIH will include 50 ICs by 2050 if growth were to continue at this rate.

Concerned about organizational proliferation, the Congress called together a panel of individuals from the IOM of the National Academy of Sciences to examine the state of the NIH. Dr. Harold Shapiro, a Princeton economist, chaired the Committee on the Organizational Structure of the NIH, which identified specific concerns and recommended solutions.

Summary of Recommendations

The panel proposed the following: (1) assure that centralizing management will not undermine the NIH's ability to identify, fund, and manage the best of research and training; (2) create a public process for considering proposed changes in the number of ICs; (3) strengthen the overall NIH clinical research effort through consolidation of programs and creation of a new leadership position; (4) enhance and increase trans-NIH strategic planning and funding; (5) strengthen the Office of the Director at the NIH; (6) establish a process for creating new offices and programs for the Office of the Director; (7) devote up to $1 billion to a new Director's Special Projects Program to support high-risk, high-potential-payoff research; (8) promote innovation and risk-taking in intramural research; (9) standardize level-of-investment data and information management systems; (10) set term limits for IC Director appointments and improve the IC Director review process; (11) set term limits for the NIH Director appointment; (12) reconsider the special status of the NCI; (13) retain integrity in appointments to advisory councils and reform advisory council activity and membership criteria; and (14) increase funding for research management support. (Note: the full IOM report can be accessed at the following URL: http://www.nap.edu/books/0309089670/html/.)

Discussion

The recommendation to reform advisory council membership criteria includes a suggestion that to achieve sufficient independence and avoid conflicts of interest, a substantial proportion of a council's scientific membership should consist of persons whose primary source of research support is derived from a different institute or center or from outside NIH. Many members questioned the proposal, citing relevant experience in the Institute's area of focus as an important factor for Council appointment.

Regarding the recommendation that the intramural program exclusively conduct studies that cannot be done extramurally, Dr. Spiegel pointed out the potential benefit from high-impact/high-risk intramural work. However, such research also carries a high risk of failure, which can be a disincentive to scientists who are seeking tenure largely based on positive research achievements.

Dr. Spiegel also discussed reorganization, explaining that issues of organizational structuring were not included in the Roadmap creation process and clarifying the role of Congress in approving certain major re-organizational efforts.

Dr. Rodgers encouraged further discussion of the IOM recommendations within the Subcommittees, for continued discussion in combined session on day 2 of the Council meeting.

The NIH Extramural Loan Repayment Programs

Dr. Hammond

Background

The purpose of the NIH Extramural Loan Repayment Programs is to recruit and retain highly qualified professionals as clinical investigators and pediatric researchers. Individuals may apply for educational loan repayment of up to $35,000 per year plus a tax offset for 2 years while engaged in clinical or pediatric research. Two major program changes occurred in 2003. First, the budget nearly doubled; with increased NIH funding across the board, the NIDDK targeted approximately $4 million for the two loan repayment programs combined. Second, clinical and pediatric research activity can now be supported through any NIH research grant mechanism, nonprofit source, or both.

In 2003, the NIDDK received 93 clinical and 78 pediatric research applications for a total of 171 applications—almost triple the number received in 2002. For the clinical research program, the NIDDK funded 36 applications, and other ICs supported an additional 12 NIDDK awards to yield a 52-percent overall success rate. In pediatric research, the NIDDK supported 34 awards, and other ICs funded 8 more NIDDK awards for a 54-percent overall success rate for the Institute.

Review Process

The NIDDK review included the participation of a panel of external scientists through an Internet-assisted review process followed by a teleconference. Applications were assigned to one of six categories: diabetes, endocrinology, and metabolism; kidney; urology; hematology; digestive diseases; or nutrition and obesity. The review group focused primarily on the applicant's research plan for the next 2 years. Retention of individuals in research careers is a foremost goal of these programs.

Discussion

Dr. Hammond explained that an NIH evaluation committee is in place to assess the long-term effects of the loan repayment programs on recipients' careers, in addition to short-term quarterly reports already in place to measure progress.

Asked when the NIH may broaden the loan repayment program to include areas other than clinical and pediatric research, Dr. Spiegel pointed out that such a change must be legislated by Congress. The evaluation model will assess the success and cost-effectiveness of the current programs to determine the advisability of expanding the program.

NIDDK-Supported Centers—Opening Remarks

Dr. Hammond

The NIDDK is consulting with the public and the Advisory Council to explore potential approaches to enhancing the vitality of existing and future Centers. With their shared resources,

NIDDK Centers may be highly appropriate mechanisms to develop clinical, translational, and high-impact research. Areas identified for enhancement are the structural components of Center grants, including cores and pilot-and-feasibility programs, and programmatic activities such as clinical and translational research, multi-institutional collaborations, and interactions with research training and career development programs. The goal is to develop vision statements for each of these areas, which can be tailored in RFAs for specific Center programs.

Dr. Hammond encouraged the Advisory Council members to continue discussion of this topic within the Subcommittee meetings. A summary discussion on the NIDDK-supported Centers is slated for day 2 of the Council meeting.

VI. SCIENTIFIC PRESENTATION

"Human Genome Variation and the Genetics of Common Disease"

Dr. David Altshuler
Director of the Program on Medical and Population Genetics,
Whitehead Genome Center
Assistant Professor of Genetics, Harvard Medical School
Endocrinologist, Massachusetts General Hospital

Genetic variation plays an important role in disease. Identifying genetic risk factors provides the following: (1) A direct connection between the underlying biology and the disease in the population; (2) validation of the pathway as an "Achilles' heel"; and (3) the possibility of presymptomatic risk assessment and improved prevention.

Approaches

The traditional approach to identifying genes that underlie diseases is linkage analysis, a method designed to find mutations that are rare in the population but have a significant effect. Genetic diseases have turned out to be more heterogeneous than expected; therefore, while this approach may be successful for single-gene disorders, it is problematic for complex traits for which strong correlations are more difficult to discern. Complex common diseases are caused by interactions of the environment, behavior, and genetic factors.

The more recent approach of association studies compares the frequencies of exposures (genetic and environmental) between cases and controls. This approach is designed to find mutations with a higher frequency in the population but that have a weaker effect.

Common Variation

Humans have limited heterozygosity, genetic variability among individuals, which is largely attributable to common genetic variation. The more common a variation is across genomes, the older the mutation. Haplotypes look at genetic variations over whole segments of chromosomes. They can thus provide a comprehensive view of genome sequence variation, indicating shared ancestry across genetic regions.

Scientific Opportunities

Increasingly powerful tools and informational resources are available for capturing common genetic variation in the human population. Presently, 10 to 15 common genetic variants have been reproducibly associated with common diseases. The impact on clinical practice will occur with the design and execution of careful, relevant trials, particularly those based on partnerships between clinicians and genomic scientists.

VII. ADJOURN FOR LUNCH

Dr. Spiegel thanked all of the presenters and adjourned the open session of the full Council.

VIII. SUBCOMMITTEE MEETINGS

From approximately 1:00 to 5:30 p.m., separate meetings were convened by the Subcommittees for Diabetes, Endocrinology, and Metabolic Diseases; Digestive Diseases and Nutrition; and Kidney, Urologic, and Hematologic Diseases. The Subcommittees met again on Thursday, September 25, 2003, from approximately 8:00 to 9:30 a.m.

IX. REPORTS OF SUBCOMMITTEES: CONSIDERATION OF APPLICATIONS (CLOSED SESSION)

X. ADVISORY COUNCIL FORUM

Dr. Spiegel reconvened the open session of the full Council at approximately 10:00 a.m. on Thursday, September 25, 2003.

NIDDK-Supported Centers

Dr. Hammond

Dr. Hammond identified the goal of developing "principles" statements in the five areas identified for Centers enhancement.

Shared Resources

The NIDDK Working Group on Centers Enhancement identified three major categories of shared resources: national, institutional, and project cores. The Working Group proposed that some P50s be considered for conversion to P30s and that Requests for Applications should encourage investigative communities to develop ideas for resources that could be broadly useful. Dr. Spiegel raised the possibility that the NIDDK could take a more proactive role in identifying national shared resources.

Pilot-and-Feasibility (P&F) Programs

These programs should encourage innovation, clinical and translational projects, and high impact/high-risk research. Because high-risk endeavors have a higher failure rate, they are often outliers that lower the merit rating of the overall Center's success; segregating funds for high-risk research would result in a more accurate program assessment.

One point for further consideration is the type of investigators to target for high-impact, high-risk research. Clearly, junior investigators have more to lose professionally if the project fails.

Clinical and Translational Research

The NIDDK should consider: (1) whether to target guidelines for Centers that exclusively or predominantly suggest either basic or clinical research; (2) whether to have a separate budget cap for Centers with cores that enhance both clinical and basic research; and (3) where to target pilot-and-feasibility funds. Also important is the most effective use of special supplements and the fostering of collaborations with General Clinical Research Centers (GCRCs). Dr. Spiegel remarked on the underutilization of GCRCs, which spurred a discussion on the barriers to their effective use and the possible marriage between existing NIDDK Centers and GCRCs.

Multi-institutional Collaborations

Priority areas for collaborations include developing review criteria for multi-institutional components (in both the program guidelines for the Centers and the RFAs) as guidance for applicants; defining the research base (with an "extended base" for regional or national resources); and assessing mechanisms other than Centers that are available to support multi-institutional collaborations (e.g., "Glue" Grants, consortia, and R24 research support grants).

Interactions with Research Training and Career Development Programs

The research training and career development programs interact with Centers, and the cores and enrichment programs within Centers are heavily used. Some restrictions exist for the pilot-and-feasibility programs, but the NIDDK offers special programs, such as the Medical Student Research Training Program, which require utilization of and interaction with an NIDDK-supported Center.

NIH Roadmap

Dr. Spiegel

Citing the extensive discussion of the NIH Roadmap during Wednesday's open session, Dr. Spiegel encouraged further questions and comments.

Discussion

A concern was raised that NIDDK investigators may not have sufficient technical expertise to take advantage of opportunities offered by the Roadmap implementation groups. Dr. Spiegel replied that, although not every aspect of the Roadmap will be accessible to every investigator, the results of the initiatives may spur and propel NIDDK-relevant research endeavors. If investigators have the appropriate expertise to collect information, then technical needs can be met through other means, such as partnering with a small biotechnology company or accessing a specialized facility.

Bench-to-bedside translation is a particularly challenging issue for which Council members are encouraged to identify focus areas and roadblocks to progress. Council is urged to reexamine the relevance of informatics, looking beyond the clinical research dimension to the functional applications of the science.

NIH manpower issues surrounding Roadmap implementation may be addressed through the temporary assignment of IC staff to implementation teams or by following the National Science Foundation model, which engages university employees.

IOM Report on Organizational Change at the NIH

Dr. Rodgers

Dr. Rodgers revisited the IOM Report, following the Subcommittee discussions of the issue. The Council members were reminded of an upcoming combined House and Senate hearing at which Dr. Harold Shapiro will present the IOM report recommendations. Dr. Rodgers then requested input on the recommendations applicable to the NIDDK.

Discussion

Dr. Spiegel explained that, because the IOM study was congressionally mandated, the Senate and House authorizing committees will accept or reject the recommendations.

In order to increase translational clinical research substantially, a goal envisioned in both the NIH Roadmap and the 14 IOM recommendations, it was suggested that Institutional Review Boards (IRBs) should be standardized and consolidated.

Dr. Rodgers welcomed continued input from the Council members on the IOM Report.

XI. CONSIDERATION OF REVIEW OF GRANT APPLICATIONS

A total of 1,404 grant applications, requesting support of $303,960,735 were reviewed for consideration at the September 24-25, 2003 meeting. Funding for these 1,404 applications was recommended at a level of $298,544,806. Prior to the Advisory Council meeting, an additional 250 applications requesting $70,912,990 received second-level review through expedited concurrence. All of the expedited concurrence applications were recommended for funding at the requested levels. The expedited concurrence actions were reported to the full Advisory Council at the September 25, 2003 meeting.

XII. ADJOURNMENT

Dr. Spiegel thanked the Council members for their attendance and advice. There being no other business, the 163rd meeting of the NIDDK Advisory Council was adjourned at 12 Noon, September 25, 2003.

I hereby certify that to the best of my knowledge, the foregoing summary minutes are accurate and complete.

Allen M. Spiegel, M.D.
Director, National Institute of Diabetes and Digestive and Kidney Diseases
Chairman, National Diabetes and Digestive and Kidney Diseases Advisory Council