DRAFT

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

February 23-24, 2005

I. CALL TO ORDER

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Director, Dr. Allen M. Spiegel, called to order the 167th National Diabetes and Digestive and Kidney Diseases (NDDK) Advisory Council meeting on February 23, 2005, at 8:30 a.m. in Conference Room 10, C Wing, 6th Floor, Building 31, National Institutes of Health (NIH), Bethesda, MD.

A. ATTENDANCE – COUNCIL MEMBERS PRESENT

Dr. Janis Abkowitz
Dr. Robert Alpern
Dr. Janice Arnold
Ms. Janet Brown
Ms. Mary Clark
Dr. Roberto Coquis
Dr. Raymond DuBois
Dr. Robert Eckel
Dr. Jeffrey Flier
Dr. Richard Goodman
Dr. Earl Harrison (*Ex officio*)
Dr. William Henrich
Dr. Sum Lee
Dr. Rudolph Leibel
Dr. Brian Monahan *(Ex-officio)*
Ms. Nancy Norton
Dr. Daniel Porte (*Ex-officio*)
Dr. Ronald Ruecker
Dr. Linda Sherman
Dr. E. Darracott Vaughan
Dr. W. Allan Walker

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
Lawrence Agodoa, NIDDK
Beena Akolkar, NIDDK
Sara Arnold, Health & Medicine Counsel of Washington
Nicole Belager, NIDDK
Olivier Blondel, NIDDK
Sharon Bourque, NIDDK
Josephine Briggs, NIDDK
Francisco Calvo, NIDDK
Arthur Castle, NIDDK
Dolph Chianchiano, Nat'l Kidney Foundation
Michelle Cissell, Juvenile Diabetes Research Found.
John Connaughton, NIDDK
Catherine Cowie, NIDDK
Florence Danshes, NIDDK
Patrice Davis, NIDDK
Christine Densmore, NIDDK
Edward Doo, NIDDK
Michael Edwards, NIDDK
Gayla Elder-Leak, NIDDK
William Etti, NIDDK
Jody Evans, NIDDK
Pat Evans, MaxiMax Resources
Richard Farishian, NIDDK
Ned Feder, NIDDK
Carol Feld, NIDDK
Olaf L. Fonville, NIDDK
Judith Fradkin, NIDDK
Joanne Gallivan, NIDDK
Sanford Garfield, NIDDK
Christine Gill, NIDDK
Shefa Gordon, NIDDK
Carol Goter-Robinson, NIDDK
Reed Graves, CSR
Janet Gregory, NIDDK
Carol Haft, NIDDK
Mary Hanlon, NIDDK
Robert Harris, MaxiMax Resources
Barbara Harrison, NIDDK
Andrew Hawkins, Blue Sheet
Trude Hilliard, NIDDK
Jay Hoofnagle, NIDDK
Thomas Hostetter, NIDDK
Van Hubbard, NIDDK
Donna Huggins, NIDDK
Joyce Hunter, NIDDK
James Hyde, NIDDK
Donna James, NIDDK
Stephen James, NIDDK
Ann Jerkins, CSR
Wendy Johnston-Taylor, NIDDK
Teresa Jones, NIDDK
Robert Karp, NIDDK
Christian Ketchum, NIDDK
Sooja Kim, CSR
Robert Kuczmarski, NIDDK
Kim Law, NIDDK
Phong Le, Juvenile Diabetes Research Found.
Todd Le, NIDDK
Melissa Lee, NIDDK
Ellen Leschek, NIDDK
Maxine Lesniak, NIDDK
Dan Lesom, OD/NIH
Monica Liebert, Amer. Urological Assoc.
Barbara Linder, NIDDK
Helen Ling, NIDDK
Saul Malozowski, NIDDK
Denise Manouelian, NIDDK
Ronald Margolis, NIDDK
Winnie Martinez, NIDDK
Dan Matsumoto, NIDDK
Michael K. May, NIDDK
Alexa McCarron, RTI Int'l
Crystal McDade-Ngutter, NIDDK
Julie McDermott, NIDDK
Melissa McGowan, NIDDK
Catherine McKeon, NIDDK
Carolyn Miles, NIDDK
David Miller, NIDDK
Megan Miller, NIDDK
David Mineo, NIDDK
Marva Moxey-Mims, NIDDK
Christopher Mullins, NIDDK
Neal Musto, NIDDK
Mastan Narne, NIDDK
Leroy Nyberg, NIDDK
Diana O'Donovan, NIDDK
Teri Pailen, NIDDK
D.G. Patel, NIDDK
Aretina Perry-Jones, NIDDK
Rebekah Rasooly, NIDDK
Eileen Resnick, Soc. for Women Health Research
Patricia Robuck, NIDDK
Mary K. Rosenberg, NIDDK
Paul Rushing, NIDDK
Karen Salomon, NIDDK
Lakshmanan Sankaran, NIDDK
Salvatore Sechi, NIDDK
Leonard Seeff, NIDDK
Jose Serrano, NIDDK
Elizabeth Singer, NIDDK
Philip Smith, NIDDK
Lisa Spain, NIDDK
Robert Star, NIDDK
Pamela Starke-Reed, NIDDK
Myrlene Staten, NIDDK
Karen Teff, NIDDK
Dietmar Tietz, NIDDK
Rebecca Torrance, NIDDK
Marcia Vital, NIDDK
Pam Wood, NIDDK
Barbara Woynarowska, NIDDK
Dorothy West, NIDDK
Elizabeth Wilder, NIDDK
Gina Wrench, NIDDK
Susan Yanovski, NIDDK

II. CONSIDERATION OF SUMMARY MINUTES OF THE 166th COUNCIL MEETING

A motion was made, and unanimously passed by voice vote, to approve the summary minutes of the 166th NDDK Advisory Council (September 2004) as submitted.

III. FUTURE COUNCIL DATES

Future Council meeting dates are listed below. Council members were asked to note that the next Council meeting will be only one day in duration.

May 19, 2005
September 14 and 15, 2005
February 15 and 16, 2006
May 31 and June 1, 2006
September 20 and 21, 2006
February 21 and 22, 2007
May 30 and 31, 2007
September 19 and 20, 2007

IV. ANNOUNCEMENTS

A. APPOINTMENTS, AWARDS, AND ACKNOWLEDGEMENTS
Dr. Allen Spiegel, Director

Joining the Diabetes, Endocrinology, and Metabolic Diseases Subcommittee of Council are.

Ms. Janet Brown: A clinical trials manager at the Diabetes Research Center at the Albert Einstein College of Medicine in Bronx, New York.

Dr. Jeffrey Flier: The George C. Reisman Professor of Medicine and Chief Medical Officer at Harvard Medical School at the Beth Israel Deaconess Medical Center in Boston.

Joining the Kidney, Urologic and Hematologic Diseases Subcommittee of Council are:

Dr. Janice Arnold: A physician in Reston, Virginia, and a Diplomate of the American Board of Urology.

Dr. William Henrich: The Theodore E. Woodward Professor of Medicine and Chairman of the Department of Medicine at the University of Maryland School of Medicine in Baltimore.

- Captain Brian Monahan: Director of the Hematology Training Program in the Hematology/Oncology Department at the National Naval Medical Center.

Retiring from the NDDK Advisory Council as an ex-officio member is.

Dr. Daniel Porte: An *ex-officio* Council member since 1999, Dr. Porte has represented the Department of Veterans Affairs. The expertise he has brought to the Council reflects his long-standing leadership in the diabetes research community and his commitment to mentoring the next generation of clinically oriented investigators. As a result of Dr. Porte's contributions to the Council, a number of specific initiatives have been undertaken, including initiatives to increase attention to diabetic neuropathy and foot disease, strengthen the research centers program, and standardize the insulin assay. Dr. Spiegel presented Dr. Porte with a certificate of gratitude for his wisdom and insight, which have been invaluable to the NIDDK and the NIH.

Joining the Division of Diabetes, Endocrinology and Metabolic Diseases as new staff members are:

Dr. Michael Appel: Formerly Associate Professor in the Departments of Pathology and Medicine at the University of Massachusetts Medical School, Dr. Appel received his Ph.D. at the University of Minnesota, where he trained in cell biology and anatomy. He completed his postdoctoral training with Arthur Like at the University of Massachusetts Medical School. Dr. Appel has an extensive research background in characterizing autoimmune animal models of type 1 diabetes, the susceptibility of beta cells to injury, and islet cell transplantation. As a program director at the NIDDK, he will manage grant activities related to preclinical islet transplantation, islet cell biology, and new drug and device development. He will also be the program official for related consortia and registries.

Dr. Arthur Castle: A former fellow in the Pharmacology Research Associates Training Program within NIDDK's Intramural Research Program, Dr. Castle studied glucose transport in muscle and fat cells with Dr. Sam Cushman. He received his Ph.D. from the University of Texas and has extensive experience in the genomics field with respect to supervising analysis of large microarray data sets. In addition to his diabetes research training, Dr. Castle has a background in computer science, which is vital considering the volume of data and the types of analyses now important to biomedical research. Dr. Castle's role at the NIDDK will include serving as a program director with responsibilities for the NIH Roadmap initiative on Metabolomics Technology Development, one of the new NIDDK-led initiatives, and for assisting with the Institute's informatics-related programs.

Joining the NIDDK Review Branch as Scientific Review Administrators are:

Dr. Xiaodu Guo: Dr. Guo received an M.D. from Capital Medical College in Beijing, China, and a Ph.D. from the University of Illinois in 1990. She did her postdoctoral work at the University of Illinois on the molecular biology of cardiac thin filament protein and also worked on three-dimensional (3-D) models of angiogenesis. She came to the NIH initially as an anatomy/pathology resident, then joined the Medicine Branch of the National Cancer Institute, where she was involved in Phase I/Phase II clinical trials

for gastrointestinal cancer chemotherapy. Beginning in 2003, she worked in the Center for Scientific Review as a Scientific Review Administrator intern.

Dr. Barbara Woynarowska: At the University of Texas Health Science Center in San Antonio, Dr. Woynarowska was Associate Professor in the Department of Radiation Oncology. She received a Ph.D. in biochemistry from the Technical University in Gdansk, Poland, and completed postdoctoral training in molecular pharmacology at Roswell Park Cancer Institute in Buffalo. Dr. Woynarowska has performed basic research funded by the American Cancer Society and the National Cancer Institute, on cell biology and antitumor agents in prostate cancer.

Recognizing the contributions of NIDDK grantees.

Dr. Albert Stunkard: An NIDDK grantee and Professor Emeritus of Psychiatry at the University of Pennsylvania in Philadelphia, Dr. Stunkard was awarded the 2004 Rhoda and Bernard Sarnat International Prize in Mental Health by the Institute of Medicine (IOM) for his contribution to psychiatry and mental health, particularly his research on eating disorders. As a pioneer in the field of psychosomatic medicine, Dr. Stunkard has conducted research that has altered the public perception of eating disorders and has led to improvements in how these disorders are treated. He was the first to describe binge eating disorder and night eating syndrome, and for more than 50 years, he has conducted clinical research on these disorders, as well as more general forms of obesity. He was one of the first researchers to show the strong relationship between socioeconomic factors and obesity. He developed behavioral therapy for obesity and anorexia nervosa, and his studies of twins and adoptees provided some of the strongest evidence for the genetic influences on human obesity.

Remembering a Distinguished Investigator and Research Pioneer:

- Dr. Paul Lacey: With sadness, the NIDDK reports that Dr. Paul Lacey, who was a member of the NDDK Advisory Council for many years, died at age 81. Dr. Lacey, Chair of Pathology at Washington University of St. Louis, was a distinguished investigator and pioneer in the field of pancreatic islet transplantation. He was on the original National Diabetes Commission and was one of the principal architects of what became the Juvenile Diabetes Research Foundation. This outstanding scientist and human being will be greatly missed.

B. CONFIDENTIALITY AND CONFLICT OF INTEREST
Dr. Robert Hammond, Director, Division of Extramural Activities

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 only for the purpose of review and discussion during the closed portions of the meeting. 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 in order to avoid an actual or perceived conflict of interest. This is unnecessary with *en bloc* votes, for which all members may be present and may participate. Council members from multi-campus institutions of higher education may participate in discussions of any particular matter affecting one campus of that multi-campus institution if their disqualifying financial interest is employment at a separate campus of the same multi-campus institution and is in a position with no multi-campus responsibilities.

V. REPORT FROM THE NIDDK DIRECTOR
Dr. Allen Spiegel, Director

A. TRANS-NIH ISSUES

Institute Directorships

Dr. Elizabeth Nabel: Recently appointed Director of the National Heart, Lung and Blood Institute (NHLBI), Dr. Nabel was formerly the Scientific Director of the intramural Clinical Research Program at the NHLBI. Previously, she led the Division of Cardiology at the University of Michigan. She will co-chair with Dr. Spiegel the NIH Obesity Research Task Force. Dr. Nabel is a pioneer in the application of gene therapy and genomics techniques to aspects of vascular biology.

Dr. David Schwartz: Selected for the position of Director, National Institute of Environmental Health Sciences (NIEHS), Research Triangle, North Carolina, Dr. Schwartz is currently Director of the Division of Pulmonary and Critical Care Medicine at Duke University.

Update on NIH Policy on Public Access to Literature

As of May 2, 2005, the new NIH policy on public access to literature will be in effect. The policy requests that investigators provide the NIH with electronic copies of final manuscripts that are accepted for publication if the research has been supported in whole or in part by NIH funding. Manuscripts will be archived in PubMed Central (PMC), the NIH's digital repository for biomedical research. The policy is intended to not only increase public access to the results of NIH-funded research, but also help to ensure the permanent preservation of this vital research and assist the NIH in documenting the scientific productivity of the scientists whose work is funded by the Agency.

The NIH will conduct outreach activities and convene regional meetings to increase awareness and understanding of the new policy, the implementation of which will be evaluated by the National Library of Medicine. The final public access policy, background information, and answers to commonly asked questions are available online at:
http://www.nih.gov/about/publicaccess/index.htm

Update on NIH Conflict-of-Interest Policies

In February 2005, the NIH released new supplemental ethics regulations that address concerns raised about NIH's conflict-of-interest (COI) policies.

Under the new interim final regulations, all NIH employees would be prohibited from engaging in certain outside employment with: (1) substantially affected organizations, including pharmaceutical and biotechnology companies; (2) supported research institutions, including NIH grantees; (3) healthcare providers and insurers; and (4) related trade, professional, or similar associations. Investments in organizations substantially affected by the NIH, such as the biotechnology and pharmaceutical industries, would also not permitted for those employees who are required to file public and confidential financial disclosure reports, and would be restricted for other staff. (See http://ethics.od.nih.gov/) April 4, 2005 is the closing date for the public comment period on the new interim final regulations.

Debate about the new regulations has been reflected in the media, including an editorial in *The Washington Post* entitled "Too Strict at NIH" (February 23, 2005), which states that "the new rules, particularly a broad prohibition on owning stock in drug companies and other firms potentially affected by NIH, go too far." Specifically, the editorial expresses concern about possible negative effects on recruitment and retention. As noted in the new regulations, Department of Health and Human Services (DHHS) will evaluate provisions in the rule, including those regarding outside activities and financial holdings. It is possible that modifications may be made based on this iterative process.

Meeting of New Clinical Research Task Force Convened by the American Association of Medical Colleges

On February 22, 2005, a second clinical research task force met to discuss concerns about an apparent decrease in the number of investigators pursuing clinical research and the perceived lack of support for NIH R01 grants for clinical investigation. Discussion focused on five areas:

> How are we going to train clinical researchers of the future?
> What infrastructure do schools need to support clinical research, and can the Government contribute?
> How do institutional review board (IRB) and regulatory issues affect, and in some cases impede, clinical research?
> Is there a bias in the review process against clinical research?
> What role does the university play in forming community-based clinical research networks?

Members of the task force include NIDDK Director Dr. Allen Spiegel, who serves as the NIH liaison; former Council member Dr. Ed Holmes; and current Council member Dr. Robert Alpern. In response to a request from Dr. Spiegel, Dr. Alpern commented on the task force meeting. He noted that many issues were discussed including: (1) the appropriate timing for intersecting clinical research training with an individual's career path; (2) approaches to faculty development; (3) infrastructural needs of academic research centers for support of clinical researchers,

including support for biostatistics, genomics and proteomics; development of electronic clinical records; issues facing institutional review boards; regulatory barriers; advantages and disadvantages of community-based clinical research networks; and ways to enhance the peer review and funding of clinical research. He also noted that NIDDK is well-recognized for its strong support of clinical research.

Dr. Spiegel commented that two other important issues are: (1) finding ways to ensure that appropriate credit is given to teams of researchers instead of individual principal investigators, and (2) increasing participation of surgically intensive specialties in NIH research training and career development programs.

The Council underscored the bidirectional flow of research. New knowledge flows not only from bench-to-bedside, but also from observations in the clinic that can provide insights into basic models of diseases in the laboratory.

B. NIDDK-SPECIFIC ISSUES

New NIDDK Publications

The following three publications were produced by the NIDDK Office of Scientific Program and Policy Analysis (OSPPA) and made available to the Council members and meeting attendees:

NIDDK: Recent Advances and Emerging Opportunities: This document provides a snapshot of the NIDDK's contributions to national biomedical research during the last fiscal year. It includes patient profiles, synopses of scientific advances and program initiatives, and stories of discovery.
(http://www.niddk.nih.gov/federal/advances/2005/advances_05.htm)

Action Plan for Liver Disease Research: This ambitious trans-NIH plan assesses the landscape in liver diseases research and identifies opportunities in 16 areas, including cross-cutting areas such as hepatitis C and autoimmune liver disease. Dr. Spiegel shared the *Action Plan* with Dr. Zerhouni at a meeting of NIH Institute and Center Directors in December 2004.
(http://liverplan.niddk.nih.gov)

A Progress Report on NIDDK Efforts To Promote Translational Research: This progress report documents NIDDK's efforts to promote translational research, as discussed at all three Council meetings in 2004, and outlines seven newly developed initiatives developed in consultation with the Council and with input from scientific meetings.
(http://www.niddk.nih.gov/federal/planning/DK_Translation.pdf)

Upcoming Budget Retreat

An NIH Directors' retreat is scheduled for March 1, 2005 on the topic: "Setting Priorities and Managing Resources in Challenging Times." Questions to be considered include:

How should the NIH balance corporate (NIH-wide) priorities, including those identified in the NIH Roadmap, with mission-specific, Institute-specific priorities?

- How should infrastructure priorities be established and funding decisions made?
- What long-term strategies should be established to enhance trans-NIH cost efficiencies, specifically as related to clinical trial support and training/education programs?
- What should be the role of the intramural research program in view of the resources likely to be available over the long term?
  Do any NIH-wide funding policies need to be changed to maximize the NIH's ability to fund high-priority programs in these challenging times?

Dr. Spiegel will provide feedback on some of these topics at the Council meeting scheduled for May 19, 2005.

VI. REPORT FROM THE NIDDK DEPUTY DIRECTOR
Dr. Griffin Rodgers, Deputy Director

NIDDK and NIH Appropriations for FY05

FY05 appropriations for the NIH have been provided through a consolidated appropriations act that covers several Departments. The NIDDK appropriation is approximately $1.713 billion (up from about $1,665 billion in FY04)--excluding a special funding program for type 1 diabetes research, which the NIDDK manages on behalf of the Department. *(The comparable FY05 funding level for the entire NIH is approximately $28.6 billion.)* Total FY 05 NIH Roadmap funding is expected to be $235 million ($130 million in FY04). The NIDDK's FY 05 contribution to Roadmap activities will be an estimated $10.8 million ($5.7 million in FY04). Importantly, the NIH will meet existing commitment levels for research project grants, but the average growth rate will be left to the discretion of the individual Institutes and Centers. NIDDK remains committed to supporting as many competing meritorious research project grant (RPG) applications as possible while participating in new initiatives and meeting our program priorities.

In terms of percentage change among budget categories, the following mechanisms are expected to receive above average increases in FY05 for the reasons noted:

- "Research Centers" – Funds were set aside so that funding levels for recompeting Centers could rise to newly established caps in order to standardize caps across Centers programs. FY05 completes the standardization process with a final, one-year adjustment. In addition, a mandate in the President's FY05 amended budget provided for awards to three Centers of Excellence in Translational Human Stem Cell Research, and the NIDDK was given $1.5 million to provide one of the three awards.

  "Research Careers" – There has been an increase in the average size of awards for non-competing commitments.

  "Other Research" – Continuing support for R18 grants for translational research for the prevention and control of diabetes will inflate this budget mechanism through the life of these grants. This is somewhat of a budget artifact, in that the nature of these grants is similar to

regular research grants; however, for accounting purposes, they must be displayed under the "Other Research" budget category.

"Contract Support" – Increased funds in this mechanism reflect: (1) a tap from HHS for about $3.3 million for program evaluation, (2) NIDDK's contribution to an NHLBI clinical study on the risk of cardiovascular and lung diseases among Hispanics, and (3) NIDDK's increase in the number of continuing activities using contract support.

Dr. Spiegel emphasized that projections about FY05 are very likely to change as the year progresses, due to scientific demand on the system and other factors. He noted, for example, that the Institute will closely monitor its budget, and make adjustments. Among the NIDDK's management flexibilities is the ability to reprogram funds--which is typically done, as needed, to bolster research project grants. He requested the continuing input and advice of the Council on funding strategies as the fiscal year moves forward.

NIH/NIDDK President's Budget Request for FY06

The FY06 President's Budget request proposes an average increase of about 0.5 percent in funding across the NIH. This translates into approximately $28.7 billion for the NIH, and $1.872 billion for the NIDDK (including funds for the special statutory program for type 1 diabetes, which the NIDDK manages for the Department). In absolute terms, the NIDDK would receive about $9 million more than its FY05 funding level.

Major scientific emphases in the NIH budget request are an initiative to develop a "neuroscience blueprint," biodefense efforts, and development of an AIDS vaccine. Regarding the NIH Roadmap, requested funding for all NIH Roadmap initiatives would be $333 in FY06 (up from $235 million in FY05)--with the comparable NIDDK contribution on the order of $15.5 million (increasing from $10.8 million in FY05). The President's Budget request does not provide any inflationary increases for non-competing research grants, nor any increase in average grant size for competing grants.

For the NIDDK, some influences on budget mechanisms in FY06 include:

- Research Project Grants (RPGs) – Will need to accommodate inflationary increases (i.e., biomedical research inflator) of 3.5 percent, and Roadmap increase that will consume 0.4 percent of available funds.
- National Research Service Awards -- Increases in stipends and coverage of health costs can be expected to lower the number of trainees by about one percent.
- Intramural Program -- Inflationary increase of 2.4 percent on salaries and purchases will need to be absorbed. Note that this inflationary increase is more constrained than that for extramural research project grants. It also reflects a new obesity initiative for which the NIDDK intramural program received additional funding in FY05 as part of a $22 million obesity initiative included in the FY05 President's Budget.

Dr. Spiegel noted that the Congress has yet to act on the President's Budget request. House and Senate appropriations hearings for the NIH are scheduled, respectively, for March 9 and April 6, 2005 and budget scenarios could change as a result of this process.

Questions Regarding NIH/NIDDK Budget

In response to questions from the Council, Drs. Spiegel and Hammond provided the following clarifications regarding NIH/NIDDK funding:

Funding for Obesity Research: No reduction in NIH funding for obesity research is anticipated. On the other hand, while the President allocated an additional $22 million for obesity research in FY05, there is no such increase in the President's budget for FY06.

Funding for NIH Roadmap Activities: The percent of each Institute's budget earmarked for NIH Roadmap activities is proportional to the Institute's overall budget. While these are difficult budget times, it is important to remember that all of the NIH Institute and Center Directors have agreed that the Roadmap initiatives represent valuable investments vital to moving NIH research forward.

Providing Input to the Congress: While the NIH cannot lobby Congress, it can provide input through a variety of other mechanisms—during development of the President's budget request by the Administration and during congressional action on the budget. These mechanisms include: participating in NIH budget retreats and the HHS Secretary's Budget Council, which are part of the Administration's budget formulation process; providing research examples to the Department to use in defending or appealing budget levels to the OMB; preparing for annual appropriations hearings; participating in *ad hoc* hearings and briefings requested by the Congress throughout the fiscal year; and responding to various requests for technical scientific advice and assistance from Members of the Congress and their staffs.

VII. ANNUAL APPROVAL OF THE COUNCIL OPERATING PROCEDURES
Dr. Robert D. Hammond, Director, Division of Extramural Activities

General Operating Procedures

The NDDK Advisory Council's general operating procedures address three major areas: Council recommendations, delegated authority, and provisions for exceptional situations, each of which is discussed below.

Council Recommendations: In general, the Council makes three types of recommendations relating to second-level review of the actions of the initial Scientific Review Groups: Council can: (1) concur with the SRG critique, (2) recommend changes to the budget and/or the duration of the project period, and (3) advise deferral of an application for re-review.

Delegated Authority: Delegated authorities to the NIDDK Director permit staff to negotiate adjustments in dollars and/or terms of grant and cooperative agreement awards recommended by the Council. This authority enables NIDDK staff to conduct day-to-day business without having to return to the Council for guidance during the fiscal year.

Exceptional Situations: This provision allows the NIDDK Director to make exceptions to the above-noted guidelines as circumstances require, based on programmatic considerations and after consultation with the Council. These circumstances include actions on individual applications that are normally within the authority of the Council. The NIDDK would report back to the Council if it were to take actions of this nature.

Implementation of Expedited Concurrence of *En Bloc* Actions

The early concurrence policy permits the expedited concurrence of *en bloc* actions of all grant and cooperative agreement mechanisms. For applications that have no bars to their award, this policy enables NIDDK staff to move high-priority applications from the time of receipt to the time of award as rapidly as possible. Six Council members, two from each Subcommittee, act on behalf of the overall Council for the *en bloc* concurrence committee: Drs. Abkowitz, Lee, Leibel, Sherman, Vaughan, and Walker.

The NDDK Advisory Council unanimously approved the general operating procedures and the expedited concurrence procedures.

VIII. 2005 BIENNIAL ADVISORY REPORT CERTIFYING COMPLIANCE WITH INCLUSION GUIDELINES

Dr. Patricia R. Robuck, Director, Clinical Trials Program, Division of Digestive Diseases and Nutrition

The Council is tasked with preparing and certifying a biennial report describing the manner in which the NIDDK has complied with Public Law 103-43, which requires the inclusion of women and minorities in all clinical research funded by the NIH (unless the research meets specific exclusionary criteria, which do not include considerations of cost). In compliance with this mandate, NIH policy requires all investigators who conduct clinical research to provide target data and yearly cumulative data describing the gender, race, and ethnicity of participants in each clinical study. In 2000, the General Accounting Office suggested that NIH-defined Phase III clinical trials be designed and carried out to include a sufficient number of subjects in each study to conduct valid subcomparisons between women and men, and to improve the accuracy of the data that are reported. This suggestion became the population tracking system that is in use at the NIH.

The NIH policy and guidelines regarding the inclusion of women and minorities as research subjects are available on the NIH Web site. The policy now stipulates that, for studies funded as of January 10, 2002, race and ethnicity should be considered as distinct categories. Other significant changes, such as definitions for determining human subject involvement in research, are reflected in the newly revised Application for a DHHS Public Health Service Grant (PHS 398), which is now available and will be accepted for submission/receipt dates on or after December 1, 2004. There is a transition period through May 10, 2005, during which applications using the previous version of the PHS 398 form will be accepted. After that date, applications using instructions and forms other than the revised PHS 398 form will be returned to the applicant without review.

Instructions for a PHS 398 grant application state that the inclusion plan must provide subject selection criteria and rationale, rationale for any exclusions, beginning and end enrollment dates, outreach plans for recruitment, and the proposed composition of the study. Reviewers are now specifically instructed to evaluate the inclusion plans and reflect unacceptable plans in the priority score. Applications with unacceptable plans cannot be funded, and the plans must be revised. All NIH staff members are expected to comply with the NIH inclusion policy.

Overall, the data show that the NIDDK has been compliant with the NIH requirements. A formal report, due in the Office of Women's Health (ORWH) by March 15, 2005, will address the NIDDK's particular strategies. The ORWH will prepare a summary report for the NIH Director on inclusion data, tracking policies, and Advisory Council/Board reports for all Institutes and Centers. This report will be published and made available to the public.

IX. SCIENTIFIC PRESENTATION
Fat Metabolism and Obesity

Dr. Samuel Klein
William H. Davenport Professor of Medicine
Director of the Center for Human Nutrition
Director of the Weight Management Center
Associate Program Director, General Clinical Research Center
Washington University School of Medicine, St. Louis, Missouri

Dr. Klein discussed the role of fat metabolism in obesity-related health problems, with a focus on differences in the ways normal and overweight individuals metabolize and release free fatty acids and glycerol. Dr. Klein also discussed the role of diet composition and exercise on weight loss and maintenance, as well as the metabolic impact of weight loss resulting from liposuction or gastric bypass surgery.

X. ADJOURN FOR LUNCH

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

XI. 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, February 24, 2005, from 8:00 to 9:30 a.m.

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

XIII. ADVISORY COUNCIL FORUM
National Institute on Aging Research Initiatives Involving Industry
Dr. Richard J. Hodes, Director, National Institute on Aging

Due to inclement weather, this presentation was cancelled.

XIV. CONSIDERATION OF REVIEW OF GRANT APPLICATIONS

A total of 679 grant applications, requesting support of $165,236,221 were reviewed for consideration at the February 23-24, 2005 meeting. Funding for these 679 applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, an additional 784 applications requesting $174,425,131 received second-level review through expedited concurrence. All of the expedited concurrence applications were recommended for funding at the Scientific Review Group recommended level. The expedited concurrence actions were reported to the full Advisory Council at the February 24 meeting.

XIV. ADJOURNMENT

Dr. Spiegel thanked the Council members for their attendance and efforts. There being no other business, the 167th meeting of the NDDK Advisory Council was adjourned at 9:30 a.m., February 24, 2005.

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