- DRAFT

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

February 21, 2007

I. CALL TO ORDER

Dr. Griffin Rodgers, Acting Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), called to order the 173rd National Diabetes and Digestive and Kidney Diseases (NDDK) Advisory Council meeting at 8:35 a.m., Wednesday, February 21, 2007 in Conference Room 10 on the 6th Floor C Wing of Building 31, NIH, Bethesda, Maryland.

A. ATTENDANCE – COUNCIL MEMBERS PRESENT

Dr. Janis Abkowitz
Dr. Janet Brown
Dr. Roberto Coquis
Dr. Charles Elson
Dr. James Freston
Dr. William Henrich
Dr. David Klurfeld (Ex Officio)
Dr. Mitchell Lazar
Dr. Rudolph Leibel
Dr. Mark Magnuson
Dr. Juanita Merchant
Dr. William Mitch
Dr. Brian Monahan (Ex Officio)
Dr. Jerry Palmer (Ex Officio)
Dr. David Perlmutter
Ms. Margery Perry
Ms. Lisa Richardson
Dr. Anthony Schaeffer
Dr. Patrick Tso

Also present:

Dr. Griffin Rodgers, Acting Director, NIDDK, and Chairperson, NDDK Advisory Council
Dr. Brent Stanfield, Executive Secretary, NDDK Advisory Council

B. NIDDK STAFF AND GUESTS

In addition to Council members, others in attendance included NIDDK staff members, Center for Scientific Review (CSR) Scientific Review Administrators, and other members of the public. Guests were present only during the open sessions of the meeting.

Attendees included the following:

Abraham, Kristin – NIDDK
Appel, Michael - NIDDK
Arreaza-Rubin, Guillermo – NIDDK
Balen, Janice - NIDDK
Barnard, Michele – NIDDK
Beverly, Kevin – Social & Scientific Systems
Bilal, Adilah - NIDDK
Blondel, Olivier – NIDDK
Carrington, Jill - NIDDK
Chamberlain, Joan – NIDDK
Chianchiano, Dolph - NKF
Connaughton, John – NIDDK
Cowie, Catherine - NIDDK
Curry, Jennifer – NIDDK
Curtis, Leslie – NIDDK
Damirjian, Marale - NIDDK
Densmore, Christine – NIDDK
Dietz, Debbie – Social & Scientific Systems
Doa, Loretta – The Endocrine Society
Donohue, Patrick – NIDDK
Doo, Edward – NIDDK
Dove, Toni – NIDDK
Edwards, Michael – NIDDK
Eggerman, Thomas – NIDDK
Everhart, James – NIDDK
Feld, Carol – NIDDK
Ferguson, Frances - NIDDK
Fonville, Olaf – NIDDK
Gallivan, Joanne – NIDDK
Gansheroff, Lisa – NIDDK
Garfield, Sanford – NIDDK
Gladstone, Elisa – NIDDK
Graves, Reed - CSR
Greene, Elizabeth – NIDDK
Guo, Xiaodu – NIDDK
Haft, Carol - NIDDK
Hamilton, Frank - NIDDK
Hanlon, Mary – NIDDK
Harman, Joan - NIDDK
Harris, Kimberly – NIDDK
Harris, Mary – NIDDK
Hilliard, Trude - NIDDK
Hoff, Eleanor – NIDDK
Horlick, Mary - NIDDK
Hubbard, Van – NIDDK
Hunter, Christine – NIDDK
Hunter, Helen – NIDDK
Hunter, Joyce - NIDDK
Jerkins, Ann - CSR
Jones, Teresa – NIDDK
Karp, Robert - NIDDK
Ketchum, Christian – NIDDK
Kim, Sooja - CSR
Kranzfelder, Kathy – NIDDK
Kuczmarski, Robert – NIDDK
Laughlin, Maren - NIDDK
Leschek, Ellen – NIDDK
Malik, Karl – NIDDK
Malozowski, Saul – NIDDK
Manouelian, Denise – NIDDK
Margolis, Ronald – NIDDK
Maric, Christine - NIDDK
Martinez, Winnie – NIDDK
McGowan, Melissa – NIDDK
Miles, Carolyn – NIDDK
Miller, David – NIDDK
Moen, Laura – NIDDK
Moxey-Mims, Marva – NIDDK
Musto, Neal - NIDDK
Mullins, Christopher – NIDDK
O'Donovan, Diana - NIDDK
Patel, D.G. – NIDDK
Perry-Jones, Aretina – NIDDK
Pike, Robert – NIDDK
Podskalny, Judith – NIDDK
Pope, Sharon – NIDDK
Roberts, Tibor – NIDDK
Robuck, Patricia – NIDDK
Rasooly, Rebekah – NIDDK
Rodrigues, Michelle - SRI
Rushing, Paul – NIDDK
Sahai, Atul – NIDDK
Salomon, Karen – NIDDK
Sankaran, Lakshmanan – NIDDK
Sechi, Salvatore – NIDDK
Seeff, Leonard, NIDDK
Serrano, Jose – NIDDK
Sheard, Nancy - CSR

Shino, Kathleen - NIDDK
Singer, Elizabeth – NIDDK
Smith, Philip – NIDDK
Smith, Tyrone - NIDDK
Spain, Lisa – NIDDK
Tietz, Dietmar - NIDDK
Torrance, Rebecca - NIDDK
Vinson, Terra – NIDDK
Weinstein, Rachel, NIDDK
Wellner, Robert – NIDDK
Woynarowska, Barbara – NIDDK
Wright, Anne - NIDDK
Wright, Daniel – NIDDK
Wright, Elizabeth – NIDDK
Xie, Yinigh - NIDDK
Yanovski, Susan – NIDDK
Zellers, Charles - NIDDK

C. ANNOUNCEMENTS

Dr. Griffin Rodgers, Acting Director NIDDK

New Members: Dr. Rodgers began the meeting by introducing and welcoming five new Council Members. One new member joined the Diabetes, Endocrinology, and Metabolism (DEM) Subcouncil. Two new members joined the Digestive Diseases and Nutrition (DDN) Subcouncil. Two new members joined the Kidney, Urology, and Hematology (KUH) Subcouncil.

- Joining the DEM Subcouncil:
  - ***Dr. Mark Magnuson*** holds an MD degree and is presently the Earl W. Sutherland, Jr. Professor of Molecular Physiology and Biophysics, Medicine, and Cell and Developmental Biology at Vanderbilt University School of Medicine. In addition, he is currently Director of the Vanderbilt Center for Stem Cell Biology and until recently was assistant Vice Chancellor for Research at Vanderbilt University.

    Dr. Magnuson's research is focused on understanding the regulatory processes that resolve pancreatic islet and acinar cell fate, initiate islet cell differentiation, and distinguish the pancreatic beta-cell differentiation program from other islet cell differentiation programs. He has special expertise in the development of genetically-altered mice and has served in a variety of leadership and scientific advisory roles. For example, he is currently chair of the Steering Committee of the Beta Cell Biology Consortium.
- Joining the DDN Subcouncil:
  - ***Dr Charles Elson*** holds an M.D. degree and is Professor of Medicine and Microbiology at the University of Alabama at Birmingham, and is the Basil I. Hirschowitz Chair in Gastroenterology. Dr. Elson has held a number of leadership positions at UAB, including Director of the Division of Gastroenterology and Hepatology. He is currently Vice Chair for Research in the Department of Medicine.

    Dr Elson maintains an active research program in the area of mucosal immunology, focused in recent years on the immunopathogenesis of inflammatory bowel disease in experimental models. He is past president of the Society for Mucosal Immunology, of which he is a co-founder. He has also served as Chair of the National Scientific Advisory Committee of the Crohn's and

Colitis Foundation of America.

Dr Elson is an active clinician and consultant in gastroenterology, with special expertise and focus on immune mediated gastrointestinal disorders such as Celiac disease, Crohn's disease, and Ulcerative Colitis.

- ***Dr. Patrick Tso*** holds a Ph.D. degree and is Professor of Pathology and Director of the Center for Lipid and Atherosclerosis Studies at the University of Cincinnati. Dr. Tso is also Director of the Cincinnati Mouse Metabolic Phenotyping Center funded by NIDDK and Associate Director of the Cincinnati Obesity Research Center.

  Dr Tso is a very well-respected researcher in the area of lipid metabolism. He has published over 150 peer-reviewed articles and 30 book chapters and reviews. He has also served on numerous study sections including the General Medicine A2 Study Section, the Nutrition Study Section, and the NIDDK Subcommittee C. In addition, he is currently an Associate Editor for the *American Journal of Physiology, Gastrointestinal and Liver Physiology.*

  Dr. Tso has received continuous funding from NIH for the past 24 years including an NIH Career Development Award. He is currently the principal investigator of a Center grant and two R01 grants.

Joining the KUH Subcouncil:

- ***Dr. William Mitch*** holds an M.D. degree and was trained at Harvard Medical School and the Brigham and Women's Hospital. He currently holds the Gordon A. Cain Chair in Nephrology at Baylor College of Medicine in Houston. He is also the Director of the Nephrology Division at Baylor and is principally interested in protein metabolism in patients with kidney disease and other conditions causing loss of muscle mass.

  Dr. Mitch has served on several NIH Study Sections and Review Panels. He also has held a variety of leadership and advisory positions. These include being the Treasurer of the International Society of Nephrology, the President of the American Society of Nephrology, the Chair of the American Heart Association Kidney Council and Chair of the Scientific Advisory Board of the National Kidney Foundation.

- ***Dr. Anthony J. Schaeffer*** holds and M.D. degree and is the Chairman of the Department of Urology at Northwestern University's Feinberg School of Medicine where he is the endowed Herman L. Kretschmer Professor of Urology. He is a Board-certified urologist with over 30 years experience as a practitioner and educator.

  Dr. Schaeffer has published extensively on adult urinary tract infection in major urologic and primary journals including *The New England Journal of Medicine, The Journal of Urology, The Journal of Infectious Diseases,* and *Infection and Immunity.* He received the distinguished MERIT Award from the NIH/NIDDK. This grant is titled "Host Factors in Susceptibility to UTIs".

  Dr. Schaffer has developed and performed innovative approaches for incontinence in men and women, the most recent of which is the urethral sling procedure for

post prostatectomy incontinence. He is active in many national urologic groups including the Chronic Prostatitis Clinical Research Network (CPCRN), of which Northwestern is the lead member of five teams of investigators and institutions around the country. He currently serves as Chair of the Research Council for the American Urological Association.

Dr. Rodgers thanked the new members in advance for their time and efforts on Council business and suggested starting a tradition of applauding new members when they join Council.

NIDDK Leadership Change: Dr. Rodgers announced the pending retirement of NIDDK's Associate Director for Management.

- ***Ms. Barbara Merchant*** is retiring after 30 years of federal service at the National Institutes of Health, with the last 12 years of her career at NIDDK. In her first four years at NIDDK Ms. Merchant served as Chief, Administrative Management Branch, Division of Intramural Research, and in the last eight years as the Associate Director for Management (Executive Officer). In this position, she is known for supporting managers through difficult situations, and handling all of the business management operations of the institute efficiently and effectively. Throughout her career, Ms. Merchant has mentored and developed numerous administrative staff into outstanding senior professionals at NIH.

  In 1999, Ms. Merchant assisted with the establishment of the Transplant and Autoimmunity Branch at NIDDK. In this role, she coordinated with the NIH Clinical Center, the Navy Medical Center, Walter Reed Medical Center, the United Network for Organ Sharing, and various NIH Institutes and offices to establish and renovate the patient unit, provide staffing for the clinical unit and laboratory, develop an organ procurement process and address other aspects of this program. Ms. Merchant considers this one of her most rewarding experiences at NIDDK.

  Ms. Merchant worked with the Director, NIDDK, to develop a workable consolidated acquisition structure to meet the Department of Health and Human Services objectives while maintaining a responsive acquisitions program for the NIH scientists. The structure was adopted and is operating efficiently today. Most recently, she has been instrumental in succession planning for all NIH administrative positions. She championed a new NIH fellowship, "Administrative Fellows Program." This program is to attract recent masters' graduates into training positions as Administrative Officers, Grants Management Specialists, and Contract Specialist positions.

New NIDDK Staff: Dr. Rodgers recognized several new NIDDK staff members:

- ***Dr. Jill Carrington*** has joined the Division of Digestive Diseases and Nutrition and will direct a program of grants including development and inflammation of the digestive system. Dr. Carrington earned a Ph.D. in Anatomy from the University of Wisconsin at Madison and completed a post-doctoral fellowship at the National Institute of Dental and Craniofacial Research. Before joining the NIH extramural programs she served on the faculty of the Uniformed Services University in Bethesda,

Maryland. She has worked at the NIH for twelve years in both review and program positions. Most recently, she was Deputy Director for the Biology of Aging Program at the National Institute on Aging.

Dr. Mary Evans has also joined the Division of Digestive Diseases and Nutrition at NIDDK. She will lead multi-site clinical trials as Director of Special Projects in Nutrition, Obesity, and Digestive Diseases. Dr. Evans earned a Ph.D. in nutrition from the University of North Carolina at Greensboro and completed a post-doctoral fellowship at Emory University. Before joining NIDDK, she was the Associate Director of Research Projects and an Instructor in the School of Medicine and Nutrition and Health Sciences Program at Emory University where she coordinated clinical trials and was a teacher and mentor of Ph.D. students.

Dr. Andrew Narva has joined the Division of Kidney, Urologic, & Hematologic Diseases as the new Director of National Kidney Disease Education Program. Dr. Narva is a graduate of Harvard Medical School and is board certified in internal medicine and nephrology. He previously served as Chief Clinical Consultant for Nephrology for the Indian Health Service where he developed the IHS Kidney Disease Program that provided direct care in New Mexico as well as technical consultation and support to tribes throughout the country. Dr. Narva is highly-regarded. He has served on the National Kidney and Urologic Diseases Advisory Board, on the Renal Community Council of the United States Renal Data System, and as chair of the Minority Outreach Committee of the National Kidney Foundation. In addition, he is a member of the steering committee of the National Kidney Foundation's Kidney Early Evaluation Program (KEEP). Dr. Narva has also won multiple awards including the USPHS Distinguished Service Medal, the highest recognition awarded to commissioned officers.

Dr. Christine Maric has joined the Division of Kidney, Urologic and Hematologic Diseases and will serve as a program officer for the Renal Pathophysiology and Acute Kidney Injury Programs. Dr. Maric received her Ph.D. from the University of Melbourne, Australia and completed post-doctoral training at the University College London, UK and at the University of Melbourne, Australia. She is presently an assistant professor in the Division of Endocrinology and Metabolism at Georgetown University. She is also the Director of Diabetes Research at the Center for the Study of Sex Differences: in health, aging and disease at Georgetown University. Dr. Maric will split her time between her NIDDK duties and those at Georgetown University.

Mr. Robert Pike has recently joined the NIDDK's Grants Management Branch as the Chief Grants Management Officer. Mr. Pike has fifteen years of Grants Management experience at the NIH. He was a Grants Management Specialist at the National Institute on Aging, and for the past six years, he has served as the Grants Management Section Chief for the Division of Lung Diseases at the National Heart, Lung, and Blood Institute.

Mr. Cyrus Karimian has recently joined the NIDDK as the Chief Information Officer and Computer Technology Branch Manager. Mr. Karimian has nineteen years of

Information Technology experience at various government agencies. He was the Computer Services Division Manager at USDA providing enterprise services to the USDA Office of the Secretary and Under Secretaries before joining NIDDK.

II. CONSIDERATION OF SUMMARY MINUTES OF THE 171st COUNCIL MEETING

A motion was made, and unanimously passed by voice vote, to approve the summary minutes of the 172nd NDDK Advisory Council (May, 2006) as submitted.

III. FUTURE COUNCIL DATES

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

May 30-31, 2007

September 19-20, 2007

February 20-21, 2008

May 21-22, 2008

September 24-25, 2008

Dr. Rodgers then commented that NIDDK is working to streamline the Council process and make it as efficient as possible. As NIDDK does this it is expected that many if not most future Council meetings will be one-day meetings. However, Dr. Rodgers asked that as Council members develop their plans to tentatively hold both dates on their schedules. There are many changes taking place at NIH and from time to time a two day meeting may be required. Keeping a temporary hold on both dates will give NIDDK the flexibility to schedule a two-day meeting if necessary, but Dr. Rodgers stressed that NIDDK will work to make all Council meetings as efficient as possible.

IV. ANNOUNCEMENTS

Dr. Brent Stanfield, Director, Division of Extramural Activities

A. CONFIDENTIALITY AND CONFLICT OF INTEREST

Dr. Stanfield 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 only 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 ACTING DIRECTOR

Dr. Griffin Rodgers, Acting Director, NIDDK

Budget Update

Dr. Rodgers stated that he had good news to report regarding NIDDK's budget. The President's 2007 budget recommendation for NIH for fiscal year (FY) 2007 was $28.6 billion. This was ostensibly the same as FY 2006; however the budget included an increase of $110 million for the development of projects related to biodefense. To fund these projects each institute was slated to receive a cut between 0.5 and 0.8 percent. Reflecting this, the President's budget request for NIDDK was $1.694 billion dollars, representing a decrease of 0.6 percent from the FY 2006 appropriation. However, a joint Continuing Resolution (CR) passed by the House and the Senate and signed by the President negates the biodefense transfer and cut to NIDDK adding nearly $10 million dollars back to NIDDK's operating budget. Furthermore, in the CR Congress increased NIH's budget by $619.5 million dollars. While the majority of this additional money ($401 million) was focused on the NIH Director's Common fund, the outcome of this was to release all the institutes from their planned contributions to the fund. The net effect for NIDDK is a $20.4 million dollar effective increase in the institute's FY 2007 operating budget. Instructions from Congress require use of at least half of these funds to increase the number of competing awards—by 500 NIH-wide. The CR specifically focuses $91 million to help support areas defined as "vulnerable." This money is likely to be one year in length so NIH is working through the best use of the money without creating out-year commitments.

Congress established three specified goals for NIH in FY 2007 to address vulnerable populations. A key goal is NIH support for 1,500 R01 New Investigators. To meet this goal each institute has been give a target, based on the average number of New Investigators the institutes have supported over the past five years. A second goal set forth in the CR is support of New Investigators applying for their first competitive renewal. A third goal is support of those investigators, narrowly missing the payline, who have little or no other research support. To help achieve these goals non-competing research grant projects will be reduced by three percent from committed levels.

Dr. Rodgers then focused on the President's 2008 budget request. In FY 2008 the President proposes a 0.8 percent increase to the NIH budget. The top priority is an

increase of $201 million dollars for the Global Fund for HIV, AIDS, tuberculosis, and malaria. When the pass-through for this initiative is assessed the net increase to NIH would be approximately 0.1 percent. Under this budget plan NIH institutes would be slated for a varying range of small increases or decreases. NIDDK would receive an increase of about 0.2 percent in the plan.

Regarding priorities for FY 2008, the K99/R00 Pathways to Independence Award will be entering its second year and will be considered a high priority for support of new investigators. The award is a five-year program that begins with one- to two-years of mentored training supported by a K (Career) award and the remaining support is transitioned to a R (Research Project) award contingent on the awardee securing an appropriate tenure-track position at a research institution. The NIH plans to fund approximately 171 K99/R00 awards in FY 2007 and 175 additional K99/R00 awards in FY 2008 if sufficient numbers of high-quality applications are received.

Complicating the FY 2008 budget outlook are the sweeping changes resulting from the FY 2007 CR. The President's budget reflects grant numbers and dollar distributions that assumed a flat budget in FY 2007 (e.g., same as FY 2006) under a full year CR. The result is that the President's FY 2008 budget proposal figures do not accurately describe what is fundable with the amounts requested. Supplementary materials are currently being prepared to establish a new base. Under the proposal it appears likely that non-competing research project grants will once again receive a small reduction from their committed level.

Budget Hearings

Dr. Rodgers reported that the date for the House Congressional budget hearings has been set for March 6th this year. Dr. Rodgers along with five other NIH Institute Directors will accompany Dr. Zerhouni to the Congressional hearing. The Senate hearing date had not been set at the time of the Council meeting.

VI. ADVISIORY COUNCIL FORUM – PART 1

Roadmap 1.5

Dr. Betsy Wilder, Associate Director, Office of Portfolio Analysis and Strategic Initiatives (OPASI), Office of the Director, NIH

Overview

Dr. Wilder began by giving an overview of the NIH Roadmap initiative. She reported that the Roadmap is intended to be an incubator space for cross-cutting initiatives that warrant attention for the NIH as a whole. The initiatives are initially supported via a common fund intended to support development of new, highly innovative programs that will foster and enhance the research of all NIH Institutes and Centers (ICs). The first

cohort of Roadmap initiatives were funded in 2004. A central idea behind the Roadmap is that the Roadmap starts programs, nurtures them for a time and then the programs, if they continue, will be supported by other sources. In preparation for the first cadre of initiatives to transition out of the incubator space a process has begun to establish a second cohort of Roadmap initiatives.

Roadmap 1.5 Process

Dr. Wilder explained that the NIH is in the process of soliciting ideas for the next set of Roadmap initiatives that will be funded in 2008 and 2009. Criteria have been established to guide the selection of initiatives that will be considered for support.

The criteria that potential Roadmap initiatives must meet include the following:

1) The proposed initiative must be truly transforming — it must have high potential to affect dramatically how biomedical and/or behavioral research is conducted over the next decade;
2) The outcomes from the proposed initiative must synergistically promote and advance the individual missions of NIH ICs to benefit health;
3) The proposed initiative must require participation from NIH as a whole and/or address an area(s) of science that does not clearly fall within the mission of any one IC or Office of the Director program office;
4) The proposed initiative must be something that no other entity is likely or able to do, and there must be a public health benefit to having the results of the research in the public domain.

The Roadmap 1.5 process to date has been one of data gathering. During the summer and fall of 2006, NIH solicited ideas from a number of sources including NIH staff, external panels of scientific consultants, and a broad stakeholder community by virtue of a request for information (RFI). There were 342 ideas that were submitted through the idea gathering process. The Office of Portfolio Analysis and Strategic Initiatives coordinated a review of all ideas submitted that met the four criteria and then there was a preliminary assessment of the current NIH portfolio to determine which of the ideas might already be represented and where gaps in the portfolio might be. NIH Institute and Center Directors prioritized ideas and decided on broad areas to move forward. These areas are now in what is being termed as a concept development phase. Over the next few months these ideas will be refined into specific initiatives, using the four criteria as guidance.

In January the Institute and Center Directors met and selected the broad areas that will be pursued and further developed as major Roadmap initiatives. In addition, the Directors recognized a number of ideas that came out of the Roadmap 1.5 idea gathering process that already appeared to be generally well represented in the NIH portfolio, but not as well coordinated as they might be. Another outcome of the meeting was the charge to form groups to consider these areas and determine what actions NIH might take to foster better research coordination. The Directors also recognized some highly innovative ideas that are not yet ready for development as a major Roadmap initiative. These ideas were

labeled "Pilot Roadmap Areas" and will receive further consideration and perhaps testing to determine if it will be useful to pursue these further. Finally, the Roadmap process highlighted some areas where NIH is making substantial investments but concerns remain about emphasis or strategic planning. The question about these areas is what do we need to do?

Potential Major Initiative Areas

The major Roadmap 1.5 initiative areas are broad areas with many possible initiatives. Groups that develop these concepts further will focus on ideas within these broad topics that will likely have transformative effect on research.

Topics selected as potential major initiative areas include:

- Microbiome
- Inflammation as common mechanism of disease
- Phenotyping
- Proteome/ Protein capture tools
- Epigenetics

Potential Areas for Coordination

Additional information is needed for these topics especially regarding 1) the current research portfolio and 2) previous and ongoing efforts to coordinate activities in these areas. Roadmap Coordination Groups will assess current efforts in these areas and if deemed necessary, will propose activities to foster collaborations across organ systems or disease areas.

Topics identified as potential areas for coordination include:

- Regenerative Medicine
- Pharmacogenomics
- Bioinformatics

Potential Pilot Topics

These topics are potentially important concepts but not appropriate at this time for selection as major Roadmap Initiatives. Groups will form to think about what may happen regarding these topics and what may be stimulated to determine if pursuing these topics is going to be useful.

Topics identified as potential pilot topics include:

- Connectivity Map
- Transient Molecular Complexes

Roadmap Emphasis Areas

These are broad and complex areas associated with a number of issues that were highlighted through Roadmap process. The emphasis areas require more consideration and coordinated planning with existing groups.

Roadmap emphasis areas include:

- Training/Careers
  - NIH will collaborate with academic institutions and scientific societies to define:
    - What the scientific workforce should look like
    - Multiple career paths
    - Training programs to foster the development of an optimal workforce

  Health Disparities
  - NCMHD currently serves as the NIH lead for strategic planning and coordination of research funding in this area.
  - Roadmap strategic planning effort will determine whether the following would be of added value in support of current NCMHD activities
    - Further analysis of the current NIH portfolio to determine gaps in this area
    - New methods to promote coordination of activities in this area across the agency

  Science of Science Administration
  - Will be an attempt to determine the most effective administrative approaches for achieving programmatic goals
    - Will examine most effective use of multiple mechanisms
    - Will consider possible requirement for new administrative strategies for review and funding
    - Programmatic goals such as high innovation, support of junior investigators, productive research teams, etc. will be the target for new approaches

Dr. Wilder concluded by stating that in the next few months groups will meet to develop specific plans. The specific ideas that come out of that process will be reviewed by the Institute Directors in order to begin developing Roadmap funding priorities in fiscal years 2008 and 2009. These plans will receive final review and priority recommendations in the late spring—probably May. Those plans assigned the highest priority will then be forwarded to the NIH Director and the final initiatives will be selected in summer/fall 2007.

Council Questions and Discussion

What is meant by defining the workforce in the context of what training is needed? Is the question focused on bench researchers versus clinical researches? Is it a mix of M.D.s versus Ph.D.s? Is it all of the above? Dr. Wilder indicated her impression that the answer

was in the "all the above" category. Dr. Wilder continued that career tracks are a major issue. For example the standard scientific career track is graduate school to post doc to principal investigator. Is this the best and only track? Are there other career tracks that we could foster and encourage? Does everyone want to be a principal investigator? Are scientists who are not principle investigators stuck in positions they would rather not be in or are they satisfied with their situation? If there are scientists who do not wish to be a principal investigator is there a way that academic institutions can foster that career track, promote it, and recognize it as legitimate and valuable? Dr. Wilder then explained that the career development group will proceed by going through a process of gathering ideas from a number of sources including scientific groups, Deans, scientific leaders, and others including students and post docs. There will be a long period of discovery before decisions are made regarding what is needed.

What is the role of Council in helping NIDDK come up with its position on Roadmap activities? Dr. Wilder stated that NIDDK is represented on all the groups for all the ideas. Council members should speak with program staff and to NIDDK senior leadership and offer their perspectives regarding what is most transformative about the various topics. Five months ago the Roadmap process was focused on gathering ideas about the whole world of science. Now the process is restricted to a limited number of topics and the focus is on what amongst these topics should be moved forward?

Dr. Rodgers then mentioned that all information regarding the Roadmap 1.5 process is available on the OPASI website (http://opasi.nih.gov/) and encouraged Council members to visit the website to learn more about the Roadmap 1.5 and keep updated on the process. Dr. Rodgers also mentioned that he co-chairs committees for two of the potential major initiatives—the microbiome and phenotyping—and that NIDDK has staff members on all of the committees. Dr. Wilder suggested that it may be useful to give Council members a list of NIDDK staff associated with each of the topics and that if Council members wished to weigh-in on the particulars of those topics they could contact appropriate staff members directly.

Collaborations tend to be most effectively achieved when investigators are close to each other. If we really want to encourage strong cross-disciplinary collaboration to the extent possible these projects should be conducted in geographically or physically proximate research set-ups.

Among the five potential major initiative areas one of the things that seems to be falling through the cracks is developmental biology. Dr. Rodgers responded that one can envision a piece of developmental biology under the epigenetics/epigenomics Roadmap initiative. Dr. Wilder elaborated and mentioned that during the Roadmap process developmental biology per se came up mostly in the context of regenerative medicine but also in the context of the epigenetics/epigenome. Dr. Wilder continued to explain that understanding how the epigenome changes over development was a big push within that particular series of ideas and actually the developmental component of the epigenome was one of the areas within the broad topic that received considerable enthusiasm. Dr. Wilder explained that regenerative medicine also had a considerable developmental

component, in as much as regenerative medicine is largely the translational output of developmental biology. If one is going to understand how an organ or tissue repairs then you must understand how it develops in the first place.

Regarding competing resources, we are in essentially a zero sum game budget wise after the growth recognized during the NIH budget doubling period. Now, when we add new things we need to take away some things and this is a tension between the Roadmap and the individual investigator—who may be doing some very innovative research that has nothing to do with the five Roadmap domains. Dr. Rodgers indicated that what has changed in the Joint Resolution CR is that funds in the NIH Common Fund are a separate line item. Funds that would have previously been taken out of individual institute budgets to go into the Common Fund have been restored back to the institutes. In NIDDK's case, one of our overriding principles is to maintain a very vigorous investigator initiated portfolio.

Development of young scientist is a widespread concern. This is especially true for residents-in-training and particularly surgeon scientists. There seems to be a significant loss of these individuals. Dr. Wilder pointed out that new investigators in general are clearly an agency wide concern. The concern about clinical investigators was a frequent theme expressed and recognized in the idea gathering process. In recognition of this Roadmap 1.5 will specifically include consideration of what NIH can do to nurture clinical investigators.

VII. ANNUAL APPROVAL OF THE COUNCIL OPERATING PROCEDURES

Dr. Brent Stanfield, Director, Division of Extramural Activities

Dr. Stanfield explained that every year during its January/February meeting, the Council approves the Council Operating Procedures. Dr. Stanfield then reported that this year he has made some edits to the procedures to terse them up to reflect better and more succinctly the council's operation practices. He also explained that he has updated the references at the end of the document because there had been citations of several NIH Manual chapters that have now been superseded by newer ones. Finally, Dr. Stanfield reported that he has eliminated the reference to "no council action needed on items less than $50,000." The reason for this is that the NIH Reauthorization Act, which was passed in December 2006 and signed into law in January 2007, eliminates this flexibility. While it remains to be seen exactly how NIH will implement this, it appears that Council will need to approve all grants that have been peer reviewed, irrespective of their dollar value. This would include even very small competitive supplements, for example. Dr. Stanfield wanted to ensure that NIDDK Council Operating Procedures reflected whatever the implementation may be, thus the reason for the change.

With no questions forthcoming a motion was made to approve the operating procedures as changed and the motion was unanimously passed by voice vote.

VIII. SCIENTIFIC PRESENTATION

Dr. Judy Cho, Associate Professor, Departments of Medicine and Genetics, Yale School of Medicine and Director, Yale Inflammatory Bowel Disease Center

"Genetics of Inflammatory Bowel Disease(IBD): IL23R as an IBD susceptibility Gene"

Dr. Cho gave a presentation focusing genetic variation that affects susceptibility to and expression of Inflammatory Bowel Disease (see attached below).

Cho_Feb_07.pdf

IX. ADVISORY COUNCIL FORUM – PART 2

Council Oversight of Grants To Foreign Institutions
Dr. Catherine McKeon, Senior Advisor for Genetic Research, Division of Diabetes, Endocrinology and Metabolic Diseases, NIDDK

Dr. McKeon began by explaining that NIH has the authority to award grants to foreign institutions based on statute which gives the Secretary of Health and Human Services the authority to participate with other countries in cooperative endeavors in biomedical research, health care, technology and health services research. This authority has passed down to the NIH Director. To ensure any grant actions to foreign institutions meet the letter and spirit of extant law NIH has codified requirements for any such actions into policies.

Dr. McKeon explained that NIH policy requires that several criteria must be met for any NIH component to award a grant to a foreign institution. She explained that some judgment can be exercised when determining what constitutes an appropriate project but all of the following criteria must be met in order for an award to be made. The criteria include:

- The project presents special opportunities for furthering research programs through the use of unusual talents, resources, populations, or environmental conditions in other countries which are not readily available in the United States or which provide augmentation of existing United States resources;

  The project has specific relevance to the mission and objectives of the awarding Institute or Center (IC) and has the potential for significantly advancing the health sciences in the United States;

- The application must be approved by the awarding IC Council/Board;

Grants may be awarded only after assurance that the foreign institution is in compliance with human subject, animal welfare, gender and minority requirements.

Dr. McKeon then noted that there are some limitations on the types of grants that are permitted to foreign institutions. For example, small business grants and resource extensive awards such as program projects and centers may not be awarded to foreign institutions. Likewise the new Pathways to Independence awards and institutional training grants are not permitted to foreign institutions. In addition, grants may not be transferred to or between foreign institutions unless approved by Council; in contrast, transfers from foreign institutions to domestic institutions can be approved by staff.

Dr. McKeon then pointed out that foreign grants have special rules and some of these are fairly new:

All grants from foreign institutions must have a non-modular budget;

Indirect Costs for foreign Institutions may not exceed 8%;

The Study Section must provide a written justification documenting the special aspect of the research opportunity;

State Department clearance is required prior to funding.

Dr. McKeon then changed her focus to the numbers foreign awards NIDDK funds each year. Dr. McKeon pointed out that in fiscal year 2004 NIDDK funded a total of 11 competing grants to foreign institutions and in fiscal years 2005 and 2006 NIDDK funded only 10 competing grants to foreign institutions each year. Considering that NIDDK funds approximately 700 competing awards every year, this is a very small percentage of the total number of competing awards funded. As an indication of NIDDK mission relevance Dr. McKeon reported more than half of the foreign applications awarded in fiscal years 2004-2006 were in response to an RFA or PA. RFAs and PAs are issued to stimulate mission important areas where the institute has identified a need. These data suggest that the majority of NIDDK awards to foreign institutions promote research that has high mission relevance.

Council Questions and Discussion

Obviously there are some cases where we should fund grants to foreign institutions based on the criteria outlined in the presentation. We should keep in mind however that in funding these opportunities we may not be funding a new investigator or bolstering research infrastructure within the United States. Therefore, we should make sure when we fund an application from a foreign institution that it be a very good and unique opportunity, and from the data presented it is apparent that overall this is what is being done. Dr. Stanfield commented that the criteria do not include the word "unique". The criteria stipulate the opportunity needs to be special and take advantage of unusual circumstances not readily available in the United States.

Awards are granted to an institution, not an individual. How is the institution assessed? Dr. Stanfield responded that a foreign institution has to provide the same assurances that a domestic institution provides to the NIH. In this way we know that if human subjects are used they will be treated appropriately, animal subjects will be treated appropriately and so on.

Is there any consideration whether other available funds could be used by investigators at foreign institutions? Are there any reciprocal opportunities for America scientists? Dr. McKeon explained that consideration of whether or not other funds would be available to support the research is not in the criteria. Dr. Stanfield then commented that there are a variety of opportunities for American scientists from foreign institutions, especially in Europe and Japan.

It is surprising that the number of grants to foreign institutions is so small. The existing policy is excellent because it raises the bar high, but there are many opportunities such as research on unique populations that seem they would meet the requirements. The fact that NIH will fund grants to foreign institutions is something that is not well advertised. Perhaps NIDDK could be strategic in reaching out to a limited number of foreign investigators who could fill needs in its portfolio. Dr. Stanfield commented that while the number of grants to foreign institutions is small there are many grants to investigators in this country who are utilizing unique populations in other countries. Dr. McKeon elaborated that these studies are usually conducted in collaboration with scientists in other countries usually on a subcontract basis. These subcontracts to do not require Council oversight, it is the grant to a foreign institution that triggers additional requirements for oversight.

NIH Inclusion Policy of Women and Minorities in Clinical Research
Dr. Patricia Robuck, Director, Clinical Trials Program, Division of Digestive Diseases and Nutrition, NIDDK

Overview

Dr. Robuck reminded Council that NIDDK is responsible for submitting a Biennial Report on Inclusion of Women in Clinical Research. Regarding the background of this reporting obligation, Dr. Robuck recounted that the NIH Revitalization Act of 1993 (PL 103-43) reinforced existing policies requiring that NIH must:

- Ensure that women and members of minority groups and their subpopulations are included in all human subject research;
- For Phase III clinical trials, ensure that women and minorities and their subpopulations must be included such that valid analysis of differences in intervention effect can be accomplished;
- Not allow cost as an acceptable reason for excluding these groups; ***and***
- Initiate programs and support for outreach efforts to recruit these groups into clinical studies.

Dr. Robuck stressed some specific considerations regarding the NIH inclusion policy including:

- The Revitalization Act of 1993 establishes that it is the policy of the NIH that women and members of minority groups must be included in all NIH-supported biomedical and behavioral research projects involving human subjects unless a clear and compelling rationale and justification establishes that inclusion is inappropriate with respect to the health of the subject or the purpose of the research. Dr. Robuck specifically noted that:
    - It is typically acceptable to perform interventions on adults before they are performed in children.
    - The policy allows for single sex research where appropriate.
- Responsibility for complying with intention and letter of the NIH inclusion policy and the law is expansive and includes a range of individuals starting with principal investigators and NIH staff members to members of the public participating in NIH-funded clinical studies.
- The law requires that all NIH funded clinical studies collect "self-report" data on individuals participating in the studies by ethnic (Hispanic or Latino) and racial (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White) categories.
- Inclusion of Women and Minorities sections in NIH grant applications proposing human subjects research must include:
    - Targeted/planned distribution of study subjects by sex/gender and racial/ethnic groups (Targeted/Planned Enrollment Table)
    - Subject selection criteria and rationale
    - Compelling Rationale for any exclusions
    - Description of outreach programs for recruitment
- Applications with unacceptable inclusion plans cannot be funded.
    - Reviewers of NIH grant applications that propose human subjects research are instructed to consider inclusion plans as they assign a priority score to an application.
    - Applications with plans that are identified as unacceptable by reviewers must be noted in the minutes of the peer review meeting.

Dr. Robuck then commented that the "Outreach Notebook" located online at http://orwh.od.nih.gov/inclusion/outreach.pdf is an excellent resource for NIH staff and grantees for more comprehensive coverage of much of the information that she reviewed.

Report Summary

Dr. Robuck informed Council members that in fiscal year 2006 NIDDK had a total of 674 protocols (grants/studies may include more than one protocol) a slight increase from fiscal year 2004. Of these 674 protocols:

- 417 had enrollment data;
- 257 had not started to enroll subjects;
- 14 (~2%) were protocols for foreign sites;
- 12 were NIH-defined phase III[1] studies that had enrollment data (An additional 8 phase III studies had not started recruiting as of FY 2006).

Total subjects enrolled in NIDDK extramural program clinical research studies reported in fiscal year 2006 was 501,950. Of these subjects:

- Sex was unknown for 1,242;
- Of the remaining 500,708, 54% were female (46% were male);
- 139,832 (28%) of these subjects identified themselves as minorities.

Total subjects enrolled in NIH-defined phase III protocols was 6,107 and of these 57% were female and 39% indicated that they were racial or ethnic minorities. Dr. Robuck commented that representation of minorities in NIDDK clinical research overall outpaces minority representation in the general public and demonstrates exceptional effort to ensure these populations are well represented in studies.

Dr. Robuck commented that NIDDK overall deserves considerable credit for its diligence in adhering to all requirements of the inclusion policy including Review, Program and Grants Management staff. NIDDK was the first IC to report its data for fiscal year 2006 and NIDDK's report has been used as an example for many ICs to follow. Dr. Robuck concluded that based on information in the report she would give NIDDK a grade of A- in its inclusion efforts. The reason for the "minus" is the 1,242 whose sex was unknown, but otherwise the Institute's inclusion efforts have been extraordinary. She emphasized that increased effort would be made in the future to assure that sex was determined in all study participants.

With no questions forthcoming a motion was made to accept the report and the motion was unanimously passed by voice vote.

X. CONSIDERATION OF REVIEW OF GRANT APPLICTIONS

A total of 1,231 grant applications, requesting support of $280,261,536 were reviewed for consideration at the February 21, 2007 meeting. Funding for these 1,231 applications

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[1] NIH-defined phase III trials are large studies looking at comparative treatments and are different than FDA phase III studies.

was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, an additional 1,271 applications requesting $290,114,360 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 21, 2007 meeting.

XI. ADJOURNMENT

Dr. Rodgers thanked the Council members for their attendance and valuable discussion. There being no other business, the 173rd meeting of the NIDDK Advisory Council was adjourned at 4:54 p.m., February 21, 2007.

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

Griffin P. Rodgers, M.D., M.A.C.P.
Acting Director, National Institute of Diabetes and Digestive and Kidney Diseases,
Chairman, National Diabetes and Digestive and Kidney Diseases Advisory Council

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