- DRAFT -

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

May 30, 2007

I. CALL TO ORDER

Dr. Griffin Rodgers, Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), called to order the 174th National Diabetes and Digestive and Kidney Diseases (NDDK) Advisory Council meeting at 8:30 a.m., Wednesday, May 30, 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. Janice Arnold
Dr. Janet Brown
Dr. Roberto Coquis
Dr. Charles Elson
Dr. Jeffrey Flier
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. Jerry Palmer (Ex Officio)
Dr. David Perlmutter
Ms. Margery Perry
Ms. Lisa Richardson
Dr. Anthony Schaeffer
Dr. Patrick Tso

Also present:

Dr. Griffin Rodgers, 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
Agodoa, Lawrence - NIDDK
Akolkar, Beena - NIDDK
Albert, Roberta - NIDDK
Amir, Syed - CSR
Appel, Michael - NIDDK
Balin, Janice - NIDDK
Barnard, Michele - NIDDK
Beckley, Carry - NIDDK
Begg, Lisa – NIH OD
Bishop, Terry - NIDDK
Blondel, Oliver - NIDDK
Calvo, Francisco - NIDDK
Carrington, Jill - NIDDK
Castle, Arthur – NIDDK
Chamberlain, Joan - NIDDK
Chang, Debuene - NIDDK
Chun-Lee, Angie - NIDDK
Cowie, Catherine - NIDDK
Curtis, Leslie - NIDDK
Davila-Bloom, Maria - NIDDK
Densmore, Christine - NIDDK
DeSanti, Andrea – Fisher Bio. Services
Donohue, Patrick - NIDDK
Doo, Edward - NIDDK
Douaji, Nadia - NIDDK
Edwards, Michael - NIDDK
Eggerman, Thomas - NIDDK
Eggers, Paul - NIDDK
Elder-Leak, Gayla – NIDDK
Evans, Mary - NIDDK
Everhart, James - NIDDK
Farishian, Richard - NIDDK
Feld, Carol - NIDDK
Ferguson, Frances - NIDDK
Fonville, Olaf – NIDDK
Fradkin, Judith – NIDDK
Gansheroff, Lisa - NIDDK
Garfield, Sanford - NIDDK
Gladstone, Elisa - NIDDK
Goter-Robinson, Carol - NIDDK
Greene, Lucy - NIDDK
Guo, Xiaodu - NIDDK
Hamilton, Frank - NIDDK
Hanlon, Mary - NIDDK
Harmon, Joan - MORI
Harris, Mary - NIDDK
Hilliard, Trude - NIDDK
Hoff, Eleanor - NIDDK
Horlick, Mary - NIDDK
Hubbard, Van - NIDDK
Hunter, Christine - NIDDK
Hunter, Joyce – NIDDK
James, Stephen – NIDDK
Jerkins, Ann - CSR
Karp, Robert - NIDDK
Ketchum, Christian - NIDDK
Kim, Sooja - CSR
Kranzfelder, Kathy - NIDDK
Kuczmarski, Robert - NIDDK
Laughlin, Maren - NIDDK
Leschek, Ellen - NIDDK
Malik, Karl - NIDDK
Manouelian, Denise – NIDDK
Maric, Christine - NIDDK
Margolis, Ronald - NIDDK
McGowan, Melissa - NIDDK
May, Michael - NIDDK
Miles, Caroyln - NIDDK
Miller, Megan - NIDDK
Moen, Laura - NIDDK
Morefield, Steven - Constella
Mullins, Christopher - NIDDK
Musto, Neal - NIDDK
Narva, Andrew - NIDDK
Nyberg, Leroy - NIDDK
Patel, D.G. - NIDDK
Paterson, Beth - NIDDK
Perry-Jones, Aretina - NIDDK
Pike, Robert - NIDDK
Pope, Sharon - NIDDK
Roberts, Tibor - NIDDK
Robuck, Patricia - NIDDK
Rosenberg, Mary Kay - NIDDK
Rushing, Paul - NIDDK
Sahai, Atul - NIDDK
Salomon, Karen - NIDDK
Sankaran, Lakshmanan - NIDDK
Sato, Cheryl - NIDDK
Seef, Leonard - NIDDK

Serrano, Jose – NIDDK
Sheard, Nancy - CSR
Singer, Elizabeth - NIDDK
Smith, Philip – NIDDK
Smith, Tyrone – NIDDK
Spain, Lisa – NIDDK
Star, Robert – NIDDK
Staten, Myrlene - NIDDK
Torrance, Rebecca - NIDDK
Wellner, Robert - NIDDK
Xie, Yining – RLM Communications, Inc.
Williams, Garman - NIDDK
Woynarowska, Barbara - NIDDK
Wright, Anne – NIDDK Clearing House
Wright, Daniel - NIDDK
Wright, Elizabeth - NIDDK
Yanovski, Susan – NIDDK
Zellers, Charles - NIDD

C. ANNOUNCEMENTS

Dr. Griffin Rodgers, Acting Director NIDDK

Dr. Rodgers opened his remarks by acknowledging how happy he was to address Council for the first time as Director of NIDDK. He thanked Council members for their service and support during the period he served as Acting Director and commented that he was looking forward to working with them in the future.

National Academy of Sciences Inductees: Dr. Rodgers announced that four NIDDK grantees were recently elected to the National Academy of Sciences.

- ***Dr. Mary Estes*** is Professor of Molecular Virology and Microbiology, and Medicine at Baylor College of Medicine. Dr. Estes is a leader in the field of virology and has produced ground-breaking work in the understanding and prevention of gastrointestinal viruses such as Norwalk and rotavirus. Her work has led to a new understanding of the basic biology of these viruses, including how they are controlled, interact with the organisms that host them and create disease. She and colleagues have worked to develop vaccines to protect individuals against these viruses, which are major causes of death and disability worldwide. Her research has been supported by NIDDK since 1986.

- ***Dr. Pamela Fraker*** is Distinguished Professor of Biochemistry and Professor of Food Science and Human Nutrition at Michigan State University. She is a leader in the field of nutritional immunology, particularly focusing on cellular and molecular aspects of the impact of dietary zinc on the immune response, and her research has been supported by the NIDDK for 30 years. Dr Fraker has received several research and distinguished faculty awards and has provided many years of service to the NIH and NIDDK on various review committees, including the Nutrition Study Section.

- ***Dr. Gerald Shulman*** is Professor of Medicine and Cellular & Molecular Physiology at Yale School of Medicine and a Howard Hughes Medical Institute Investigator. Dr. Shulman's primary research focus is metabolic mechanisms of insulin resistance in human subjects using noninvasive NMR imaging and spectroscopy. His work has opened a window on intracellular metabolism in man, in health and disease. Dr. Shulman has been a major force for marrying molecular, genetic, metabolic and physiologic approaches in the study of diabetes and obesity. His research has been

supported by NIDDK since 1986 when he received a K01 award

Dr. Cliff Tabin is Professor of Genetics at Harvard Medical School and Adjunct Professor of Health Sciences and Technology at MIT. Dr. Tabin's research interests center on the genetic basis by which form and structure are regulated during vertebrate development. His laboratory is especially focused on addressing the signaling pathways regulating morphogenesis of the vertebrate skeleton. Dr. Tabin has been an NIDDK grantee since 1999.

Dr. Rodgers also acknowledged a former NIDDK Intramural Program investigator who was inducted to the most recent class of the National Academy of Sciences.

- ***Dr. Angela Gronenborn*** served as Chief of the Structural Biology Section in the Laboratory of Chemical Physics here at NIDDK. Then, in 2005, Dr. Gronenborn joined the University of Pittsburgh where she is Professor of Pharmacology, and Director of the Structural Biology Program. Dr. Gronenborn's research combines NMR spectroscopy with Biophysics, Biochemistry, and Chemistry to investigate cellular processes at the molecular and atomic levels in relation to human disease. The Gronenborn group has solved solution structures of a large number of medically and biologically important proteins, including cytokines and chemokines, transcription factors and their complexes and various HIV and AIDS related proteins.

American Gastrological Association (AGA) awards: Dr. Rodgers acknowledged two individuals who recently received awards from the AGA.

- ***Dr. James Freston,*** a currently-serving NIDDK Advisory Committee member, received the AGA's Friedenwald Medal on May 21st 2007. The Julius Friedenwald Medal award was established in 1941 to recognize an individual who has made lifelong contributions to the field of gastroenterology. This is the highest honor that the AGA bestows on a member. Dr. Rodgers congratulated Dr. Freston on behalf of NIDDK for achieving this extraordinary honor.

  Dr. Daniel Podolsky was honored with the AGA's Distinguished Achievement Award. Dr. Podolsky is a former NIDDK Advisory Council member and current member of the National Commission on Digestive Diseases. The Distinguished Achievement award was established by the AGA to recognize individuals who have made a major specific accomplishment in clinical or basic research in gastroenterology. Dr. Podolsky has made many contributions to the field of gastroenterology through the study of epithelial biology and mucosal immune defense. His innovative work has advanced understanding of the mechanisms of mucosal injury, healing and repair in the context of a range of gastrointestinal disorders. This work has provided insights into pathophysiology and therapy of inflammatory bowel disease. Throughout his career, Dr. Podolsky has also supervised the training of more than 65 gastroenterology fellows and 75 post-doctoral research fellows who are now active contributors to the field.

New NIDDK Staff: Dr. Rodgers recognized one new NIDDK staff member:

Ms. Dee Doherty has recently joined the Grants Management Branch as a Senior Grants Management Specialist. Ms. Doherty worked at the NHLBI for the past five years and prior to that worked in the Sponsored Programs Office at the University of Alabama – Birmingham and Purdue University.

II. CONSIDERATION OF SUMMARY MINUTES OF THE 173rd COUNCIL MEETING

A motion was made, and unanimously passed by voice vote, to approve the summary minutes of the 173rd NDDK Advisory Council (February, 2007) as submitted.

III. FUTURE COUNCIL DATES

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

September 19, 2007

January 30, 2008

- May 23, 2008

September 24-25, 2008

- February 18-19, 2009

May 13-14, 2009

September 9-10, 2009

IV. ANNOUNCEMENTS

Dr. Brent Stanfield, Director, Division of Extramural Activities

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 for closed session discussion 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 they are in a position with no multi-campus responsibilities.

V. REPORT FROM THE NIDDK DIRECTOR

Dr. Griffin Rodgers, Director, NIDDK

House and Senate Subcommittee Hearings

Dr. Rodgers reported that he was one of a limited number of Institute Directors to accompany Dr. Zerhouni to the March 6th hearing held by the House Appropriations Subcommittee on Labor, HHS and Education. At this hearing the testimony focused on the needs of the country 10 years into the future and Dr. Zerhouni presented both a retrospective and prospective summary of NIH's role in advancing biomedicine and biomedical discovery. Among the questions from committee members Dr. Rodgers fielded specific questions about hemoglobin A1C. In addition to the March 6th hearing there were three additional collateral hearings held by the subcommittee on specific topics related to NIH including the Super Fund, the HHS Emergency Preparedness Act and research and treatment of addictions.

Regarding the 2008 Senate hearings, Dr. Rodgers reported for the first time in approximately 20 years the Senate initiated a new approach to the NIH appropriations hearing; replacing the traditional omnibus hearing with a set of theme hearings. These theme hearings included a mind-brain and behavior hearing, burden of chronic diseases hearing, and frontiers of science hearing. There were also two hearings focused on the vision of the future of health and medicine—with the first focused on predictive and preemptive research and the second emphasizing personal and participatory medicine. Dr. Rodgers reported that he had the opportunity to present at the hearing entitled "The Burden of Chronic Diseases" together with Dr. Richard Hodes of the National Institute of Aging, Dr. Steven Katz of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, and Dr. Betsy Nabel of the National Heart, Lung, and Blood Institute. The hearing was small and informal. Present for at least some part of the hearing were Senators Tom Harkin, Arlen Specter, Thad Chochran, and Larry Craig. Dr. Rodgers related that the format allowed for full discussion of subjects of interest to the senators and he had the sense that all parties were very pleased with the discussion and outcome of the meeting. Chairman Harkin made a number of statements very supportive of NIH in general and indicated that he looked for NIH funding to receive significant increases in the coming years. Dr. Rodgers indicated that Chairman Harkin was particularly interested in NIDDK's program and focused on those discoveries that have been translated to patient care, including conclusions of the Diabetes Prevention Program. He

was especially intrigued by economic analyses NIDDK is performing to indicate whether different interventions have sustained economic benefit.

Supporting Vulnerable Populations

Dr. Rodgers turned his attention to NIH's focus on supporting vulnerable populations in the biomedical research community including new investigators, newly established investigators who have projects up for their first competitive renewal, and investigators who have little or no other research support who are attempting to renew an R01.

Dr. Rodgers reported that NIH has established some specific goals for FY 2007 and one of the key goals is the support of 1,500 R01s to new investigators. NIH centrally established a goal for each Institute based on the average number of R01s supported respectively by each institute over the past five years. NIDDK's goal was set at 118 R01s to new investigators. Dr. Rodgers emphasized that he was very pleased with NIDDK staff who worked hard to prioritize enough R01 applications to meet what he felt was a rather ambitious goal. In the past NIDDK has given special attention to new investigators and more recently committed to consider all applications within a range of 10-percentile points of the general payline. In the spirit of NIH's effort to protect and encourage new applicants during especially-challenging financial times NIDDK had to reach beyond this 10-percentile point range in order to achieve its target.

Dr. Rodgers then commented that a second goal established by NIH is to support new investigators whose projects are in their first re-competition to a higher payline than the general payline. NIDDK has done this in the past by making first re-competition a criterion for special emphasis funding consideration. This year NIDDK is giving this criterion particular attention.

Next, Dr. Rodgers focused on the Director's Bridge Award. This award is associated with a third goal NIH has established for FY 2007 to help those established investigators whose competing continuation applications fall outside the nominal payline and who have insufficient means to support their research while they prepare amended applications. In the FY 2007 budget, $91 M apportioned to the NIH Office of the Director was targeted to assist Institutes in this effort using a single year R56 award which has been designated the NIH Director's Bridge Award. To date, each institute has nominated eligible and worthy applicants to the NIH Office of the Director for those awards. Final decisions on awards are made by the NIH OD and awards of up to $500,000 are provided using the R56 mechanism for up to one-year to give principal investigators additional time to reapply while maintaining their laboratory.

Dr. Rodgers also mentioned the Pathways to Independence Award—using the K99/R00 activity—as an important NIH-wide initiative that combines a research career development award with a follow-on research project award. The award provides one-to-two-year mentored postdoctoral research and then up to three years of independent research support if and when the awardee obtains an appropriate faculty position. There were 58 of these awards made in November 2006. As an institute, for 2007 NIDDK had

offered to support up to 15 awards. However, the number and quality of applications only allows NIDDK to fund 12 awards in FY2007. With this experience NIDDK has adjusted its target to 12 awards in the future. Dr. Rodgers commented that he is committed to the goals of this new program and that the benchmarks for transition form the career phase to the research project phase can be clearly communicated and are achievable. In FY 2007 NIH will make 170 of these awards and another 170 awards are planned for FY 2008.

Roadmap 1.5 Update

Dr. Rodgers reported that on May 18th the NIH Institute and Center Directors reviewed and prioritized proposals of various working groups and selected four topics to move forward as major NIH initiatives. These initiatives include:

- **Microbiome** – The goal of the proposed Human Microbiome Project is to characterize the microbial content of sites in the human body and examine the role of the microbiome in health and disease.
- **Epigenetics** – Epigenetic changes have been associated with disease, but further progress requires the development of better methods to detect the modifications and a clearer understanding of factors that drive these changes.
- **Protein Capture Tools/ Proteome Tools** – Efforts in this area would support developing and making available to the scientific community high quality probes specific to every protein in the human and in desired animal models. This would allow the ability to characterize protein function in health and disease and to monitor the markers of a disease in order to deploy early prevention efforts and to identify potential therapeutic targets.
- **Phenotyping Services and Tools** – Initiatives in this area would encourage the development of resources to systematically catalog human phenotypes in an effort to characterize complex diseases and disorders.

Dr. Rodgers explained that the Microbiome and Epigenetics programs were approved for immediate implementation as five-year programs. The Protein Capture/Proteome Tools and Phenotyping Services and Tools were approved for staged implementation with phase I programs implemented initially and further funding for phase II programs contingent on the accomplishments and outcomes of the first several years of the programs. Dr. Rodgers indicated that these initiatives remain in formative stages. Ultimately the ideas will all be presented to the NIH Advisory Committee to the Director for final decisions on the extent and magnitude of funding. Additional information about Roadmap 1.5 initiatives is available at http://nihroadmap.nih.gov/.

Core Operating Principles

Dr. Rodgers stated that while he is cautiously optimistic about NIDDK's future budget outlook, there are other needs that NIH and NIDDK are competing against and therefore there are no guarantees for the future. Given this, he presented some core principles that

he will use to help guide NIDDK and maintain a vigorous investigator-initiated research portfolio.

- *Investigator-Initiated Grants* - Innovation and problem-solving capabilities of individual investigators are crucial for progress in addressing the spectrum of diseases within the NIDDK portfolio. Maintaining funding of investigator-initiated grants at the highest levels is a key priority.
- *Cross-Cutting Science* – NIDDK will try to maximize its investments by supporting cross-cutting research, particularly through collaborations and initiatives including Roadmap activities. NIDDK will continue to seek out other opportunities as well.
- *Clinical Studies and Trials* – NIDDK will continue to support clinical studies and trials on a range of conditions within its research portfolio and mission areas and strive to obtain substantial involvement of minorities as both study participants and leaders. NIDDK will continue to develop important clinical research programs, particularly for those clinical trials that only NIH is likely to sponsor.
- *Partnerships* – NIDDK will continue to seek appropriate partnerships with industry, academia and private organizations, with special focus on private non-profit organizations where there is an intersection of activities.
- *New Investigators* – NIDDK will strive to ensure that new investigators realize their full potential as independent researchers. NIDDK will continue to foster mentorship activities, promote special consideration for funding of new investigators, and participate in NIH-wide programs and efforts to support new investigators (e.g., Pathways to Independence Awards, NIH Loan Repayment Program, workshops for new investigators, etc.).
- *Training* – Maintaining a pipeline of outstanding investigators by fostering the training and mentoring of both Ph.D. and physician scientists is critically important to the mission of NIDDK. The institute will also continue to support Research Career Development Awards, including those for mentored mid-career and minority scientists.
- *Communications and Outreach* – We must translate the results of research—particularly of pivotal clinical studies and trials—into clinical practice. Knowledge dissemination through outreach and communication is a key to getting these findings into practice. NIDDK is continuing its efforts to ensure that science-based knowledge gained from NIDDK-funded research benefits patients and their families.

Dr. Rodgers then concluded his remarks by once again thanking Council members for their work and support over the past year and asked for any questions that they might have.

Council Questions and Discussion

Could you elaborate on what you see on the budgetary horizon? Dr. Rodgers commented that NIH had expected to receive a flat budget in FY 2007. However, the full year continuing resolution that was passed in February gave an additional $600 M to

NIH. One portion of these additional funds was targeted to support vulnerable groups. Another portion was targeted to support the NIH Roadmap. The funds targeted to support NIH Roadmap allowed the Institutes and Centers, including NIDDK, to free-up funds that would otherwise have contributed to the Roadmap. This allowed NIDDK to maintain its payline at a level slightly better level. In this same spirit, staff and members on both the House and Senate side have indicated their interest in assuring that NIH's budget maintains a certain trajectory so that the investment in research that has occurred, particularly during the doubling period, is protected and capitalized upon. It was Dr. Rodgers impression that everyone leaving the House and Senate hearings was quite encouraged. However, realistically there are financial constraints and real competition for limited resources. At the Senate hearing, four NIH-funded scientists made a strong and eloquent case for the need to support NIH at a certain level. Dr. Rodgers commented that after this discussion the Senators on the committee appeared to have a better appreciation for the rationale for maintaining certain funding levels.

Regarding the marked increase in grant applications that NIH has observed over the past several years, is there any stabilization or are the numbers still continuing to climb? Dr. Rodgers remarked that there has been an expectation that with low success rates over time there would be a plateau or decline in applications. At an NIH-wide level this has not yet become apparent, although there have been some reports by some Institute Directors of what seem to be some troubling signs. It looks as if there is a trend for a decrease in the number of applications at some Institutes, especially by new investigators. Dr. Rodgers further commented that we will probably need a few more cycles before we know what the true pattern is.

Regarding the bridging grants, are the logistics worked out such that there is in fact no interruption in funding on the ground? Dr. Rodgers indicated that continuing support without interruption is certainly the intent. However, part of this depends on when applicants submit their competing renewals relative to when their funding terminates, which is something NIH can't control. If the application requires an amendment to get it within ten points of the payline an interruption is certainly possible. The program is intended to provide one additional year of support to avoid an interruption in support and help applicants collect additional data and craft a stronger application.

What are your thoughts on the reasons for not receiving enough meritorious applications to make 15 Pathways to Independence Awards? Dr. Rodgers commented that NIDDK makes strong use of a variety of career mechanisms and in particular the K mechanism. The strong training program that is in place at NIDDK may have reduced the market for the Pathways to Independence Award at NIDDK. The Pathways to Independence Award has no restriction with regard to U.S. citizenship and is therefore heavily subscribed by foreign scientists. Some NIH institutes may have been able to use this newly opened pool to a greater extent than NIDDK. Dr. Stanfield then commented that one way of looking at NIDDK having fewer meritorious applications than anticipated was that "we just didn't have a very good crystal ball." He elaborated that NIDDK was fairly ambitious compared to other institutes of similar size, hoping that 15 high-quality

applications would be received. Looking across NIH, NIDDK's goal was probably too high, rather than the number of applications being too low.

VI. ADVISORY COUNCIL FORUM – PART 1

Clinical and Translational Science Awards

Dr. Barbara Alving, Director, National Center for Research Resources (NCRR), NIH

Overview

Dr. Alving began her presentation by recognizing Dr. Robert Star, Acting Director of NIDDK's Division of Kidney, Urology and Hematology for his work as special advisor to NCRR in helping establish the Clinical and Translational Science Award (CTSA) program — a new national consortium of academic health centers that is envisioned to transform the conduct of clinical and translational research by ensuring that biomedical discoveries are rapidly translated into prevention strategies and clinical treatments for rare and common diseases.

The launch of the CTSA program culminated in the announcement of the first awards to 12 academic health centers in October 2006, along with 52 planning grants to help other Academic Health Centers prepare applications to join the consortium. When fully implemented in 2012, about 60 institutions will be linked together to energize the discipline of clinical and translational research.

The CTSA program came out of the Roadmap effort to re-engineer the clinical and translational research enterprise. Dr. Alving commented that she felt Dr. Zerhouni deserves much of the credit for his vision in stimulating this area. She explained that part of the support for the program will come from Roadmap funds, part will come from transitioning the NCRR General Clinical Research Center program—which is overseen by NCRR—to the CTSA program, and part will come from transitioning other NCRR programs into the CTSA.

The concept underpinning the CTSA program was catalyzing change—breaking silos, breaking barriers and breaking conventions—to speed translational and clinical sciences so that basic research could go from discovery into preclinical studies, into the clinic, and out into dissemination. Dr. Alving opined that the goals of the program are fairly modest. They include:

- Developing novel designs for clinical trials
- Educating the next generation
- Building diversity in leadership
- Assembling interdisciplinary teams
- Enhancing public trust
- Forging new partnerships with private and public health care organizations

- Creating a national consortium

Dr. Alving offered that this may be the first time that academic health centers have agreed to work together and there is some objective evidence indicating this spirit of cooperation is real. For example, the program's first twelve awardees posted their applications on their websites within a month of receiving their awards for all to see and share.

With the CTSA each academic health center will create a home for clinical and translational science—the home might be a center, institute, or department. The home will interact with industry, other health care organizations, and NIH and other government agencies. In addition, from the "home" a number of activities will be centrally organized including:

- Trial design
- Advanced degree-granting programs
- Participant and community involvement
- Regulatory support
- Biostatistics
- Clinical resources
- Biomedical Informatics
- Clinical research ethics

The first 12 CTSA supported academic health centers are scattered around the country. Awarded institutions include Oregon Health and Sciences University, University of California-Davis, University of California-San Francisco, The University of Texas Health Science Center at Houston, Mayo Clinic-Rochester, Duke University, Yale University, Rockefeller University, University of Rochester, University of Pittsburgh, University of Pennsylvania, and Columbia University.

Dr. Alving explained that a long-term goal for the CTSA program is to expand to 60 academic health centers by 2012. This will be accomplished using RFAs. The next cadre of applications to the program will differ somewhat in that are allowed to include multiple PIs. A special mention of pediatrics has been included in the most recent RFA to ensure compliance with the NIH's recent reauthorization. The next set of applications for CTSAs is October 24, 2007 and from this pool NCRR looks to provide up to eight awards in June 2008.

Addressing Challenges and Ongoing CTSA Activities

Dr. Alving discussed some of the challenges for the CTSA network that need to be addressed and some illustrative examples of ongoing activities at CTSA academic health centers.

Dr. Alving very quickly centered her attention on the informatics challenges that need to be addressed. She explained that:

- Standards that can structure data syntactically and semantically from devices into the electronic health record and the longitudinal record need to be adopted.
- There needs to be harmonization of clinical informatics standards with research standards.
- There needs to be work with the research community to provide interactive clinical and research records.
    - Dr. Alving commented that there are many small-scale efforts that show how accrual into clinical trials can be enhanced by having the right insertion of information about clinical trials that will "pop-up on physicians' screens as they are seeing patients."

Among the first CTSAs, 10 of the 12 have cancer centers all of which are addressing informatics issues through the Cancer Bioinformatics Grid (caBIG), which has been a large ticket initiative funded by NCI. NCRR is working diligently with the Informatics Committee, other components of NIH, and the CTSAs, to ensure that there is full exploration of all that has been developed in caBIG to see what can be expanded to areas other than cancer.

- The Mayo Clinic and the University of Pennsylvania for example, are involved in caBIG architecture, data-sharing and intellectual capital, strategic planning, tissue banks, pathology tools, and training and are working to extend some of these activities into non-cancer areas.
- The University of Pennsylvania is involved in the caBIG imaging initiative and clinical trial management system.
- The Mayo Clinic is also involved in caBIG vocabularies and common data elements.

The investigators who are involved in these activities also are very involved at a national level with the efforts that are going on at the Department of Health and Human Services.

Dr. Alving then illustrated some additional examples of current CTSA activities including:

- Duke's work to translate bench-to-bedside finding to populations using advanced informatics and health service delivery methods.
- Work at the University of California in San Francisco to pursue opportunities with the San Francisco Veteran's Administration and Kaiser-Permanente in creating new community research centers to provide better services to minority and medically-underserved populations.
- Oregon Health and Science University's development of new informatics capabilities to partner with Kaiser-Permanente, Northwest Center for Health Research Network, and the Portland VA Medical Center.

Organization

Dr. Alving commented that the focus of translational sciences is moving research from basic to pre-clinical and clinical applications and then from clinical to outreach or dissemination. In order to encourage inter-disciplinary and trans-disciplinary research the CTSA academic health centers offer competitive funding opportunities for pilot projects for investigators at their institutions.

At a national level, the CTSA program structure is somewhat of a work in progress. An important point is that because the CTSA program is a cooperative agreement, one-third of the voting membership on various committees is comprised of NIH staff—and in this way NIH has considerable leverage over the operations of the CTSA program. Overall the organization has three levels:

- The foundation "Steering" level consists of the CTSA grantees involved in coordinating/steering specific areas including 1) Informatics, 2) Community Engagement, 3) Evaluation, 4) Education and Career Development, 5) Public-Private Partnerships, and 6) Translation. At least one representative from each institution in the consortium is included on these steering committees and each of these steering committees includes an operations subgroup that takes timely action on emergent topic issues.
- The second "Oversight" level is responsible for identifying collaborative opportunities to facilitate research throughout the CTSA program, coordinating consortium-wide approaches to research, and overseeing topic-specific efforts across the consortium including a main committee and a:
    - Pediatrics Oversight Committee that ensures pediatrics is represented and ranges through all committees and collaborative opportunities involving pediatrics are ongoing.
    - Clinical Oversight Committee responsible for identifying, selecting, and coordinating collaborations and other opportunities to facilitate clinical research.
    - Operations sub-group, which is planned once the number of academic health centers in the consortium reaches approximately 20 in number. This sub-group is seen as a key to maintaining a nimble operation as the consortium grows towards membership that includes 60 academic health centers.
- The top "Advisory and Leadership" level includes the NCRR Director, the NCRR Advisory Council and an IC Directors Advisory Board composed of a select group of NIH Institute and Centers directors.

More information about the organization and leadership of the CTSA program is available at http://www.ctsaweb.org.

Dr. Alving then discussed how NCRR and the CTSA program fit together. She pointed out that in contrast to NIDDK which is "categorical" and is devoted to a range of

diseases, organ systems and patients, NCRR is focused on infrastructure and research support in general and is "non-categorical." This infrastructure and support takes a variety of forms. For example NCRR provides animal model resources including the funding of eight primate centers, aplysia and drosophila resources, and funding for the training of veterinarians. Thus, the Division of Comparative Medicine can be very active in the pre-clinical world of the CTSAs to help support the studies they want to do. The Division of Biomedical Technology funds new developments in bioimaging, informatics and other areas important for the CTSAs and the Division of Clinical Research is, in concert with the other NCRR divisions, responsible for the CTSAs. Put another way, most all components of NCRR work together to support the CTSA program. Dr. Alving also discussed NCRR's funding of research centers in minority institutions to develop investigators who can become involved in clinical and translational research. Interestingly, some minority institutions are partnering with other institutions to develop a CTSA application. For example, Meharry Medical College has had discussions with Vanderbilt, Morehouse with Emory and Drew with UCLA. Likewise, institutions in population sparse regions could band together or partner with larger institutions to create opportunities.

Dr. Alving concluded her presentation by discussing the future. She commented that the CTSA consortium offers a great opportunity to disseminate standards and best practices to guide translational and clinical research and healthcare delivery. By acting as a consortium the CTSA universities are also in excellent position to use their combined leverage with commercial firms to address needs—for example to address their needs for informatics with Microsoft, IBM, and Google who are all trying to enter the healthcare space. The success of the consortium ultimately will be measured in many ways but especially by the acceptance of its standards—including those for clinical care and informatics. Dr. Alving stressed that the CTSAs cannot create a have and have not situation. They need to form a matrix that reaches out to other matrices—especially by reaching out to geographically and ethnically diverse institutions—to broaden their impact and improve the health of populations and individuals throughout our nation and across the globe.

Assigned Discussant Questions and Comments

Dr. Henrich thanked Dr. Alving for her presentation and remarked that he enjoyed it very much. First, he commented that as a new dean he was fascinated how his institution was consumed by applying for a CTSA and how other institutions that he visited were likewise consumed. Based on this he feels that Dr. Zerhouni's idea that this initiative would spark in-depth consideration regarding integration of bench-to-bedside science has certainly been successful—because everyone wants to be counted in the group of 60 institutions that have a CTSA. Second, while originally skeptical about the CTSA program Dr. Henrich remarked that over the past several months he has come to consider that the program has already met considerable success at least at his local level. He noted that a group of no fewer than 175 people across a wide array of institutions in his region of the country have bonded together making for some strange bedfellows. For example, four-star generals from military installments around San Antonio, which is a

hotbed of military medicine, have become close friends with public health officials along the Rio Grande and officials from the four University of Texas campuses as part of the regional CTSA effort. Finally, Dr. Henrich commented that the novel idea behind the CTSA program is that there will be a single point of contact within the institution. Researchers will know where to go for help to take their questions or ideas and transform them into a research question. Dr. Henrich then asked Dr. Alving if she felt that there may be some consideration of loosening the rules barring members of one CTSA application to be a member of another CTSA group since the goal is to develop networks.

__Dr. Alving__ responded that the CTSA program is a work in progress and it is both a challenge and an opportunity to create and refine rules as the program goes along. She stated that there isn't anything that cannot be negotiated in the future.

__Dr. Perlmutter__ stated that he welcomed the CTSA program at the University of Pittsburgh Children's Hospital because he felt establishing a home in each academic health center for clinical research is appropriate. He commented that 1) academic health centers need to make a commitment to establish this home and all of the mechanisms that support it and 2) the CTSA program broadens the impact of clinical research at the academic health center by virtue of the challenge that it raises. Dr. Perlmutter also commented that he thought that having the CTSA program as part of NCRR's mission is very important because of two major challenges. The first challenge is information technology. He stated that the electronic health record is not where it should be at this time. It is technically very difficult for clinicians both to get their work done and adapt records for research. Companies putting electronic health records together are for the most part out of their realm of expertise. Having national resources focused on this problem is important. The second challenge is that clinical research is in a crisis state in this country because of the Health Insurance Portability and Accountability (HIPPA). There are huge roadblocks to clinical research that occur at the Institutional Review Board (IRB) level and having national attention to this problem through the CTSA effort should help address this issue. Regarding pediatric research specifically, Dr. Perlmutter commented that there are very few truly established clinical investigators in the area of child health research. Dr. Perlmutter also commented that he did not know how to give clinicians time to be involved in research projects. He stated that clinicians are so challenged with what they need to do clinically and financially for institutions to be successful that it is very hard, as a Department Chair, to give away their time for clinical research. This has resulted in a clinically-differentiated workforce and a research-differentiated workforce. "Where are the clinical-researchers?" he asked. While the ideal with the CTSA effort and other parts of Roadmap is that clinicians will become involved with research, Dr. Perlmutter indicted that he is not sure how this will happen.

__Dr. Lazar__ added his congratulations to Dr. Alving in launching a very exciting and ambitious project. He then commented that he has the sense that the priority for CTSA Directors has been to network with other CTSAs, but not necessarily to take stock of the resources available more locally at their own institutions. He then asked Dr. Alving is this is something that has been discussed.

__Dr. Alving__ suggested that in the first year the CTSA grantees are trying to get organized on multiple fronts. They have been especially challenged by setting up

the organization for working across and among CTSAs but getting organized within their own centers will also take some time. Like any other effort one of the keys is—rather than wait for top-down interactions it may be useful for individual investigators to alert their CTSA Director to the resources they have and ask how the pieces can interact.

Dr. Lazar indicated that this is certainly happening at his home institution at the University of Pennsylvania, but the more general point is that there is a responsibility the CTSAs need to consider. Setting up infrastructure is very important, but if you have no content, then you have nothing. One of the assumptions made in developing the CTSA program is that the rate-limiting step in progress was the infrastructure. Just as at a point not long-ago there was no World Wide Web and a network had to be created. However, at some point the focus had to shift to content to make the infrastructure useful and that content needed to be categorical. Dr. Lazar indicated that while he is eager to see CTSA structure developed, as the infrastructure becomes more mature, more emphasis needs to be focused on content and how the network can interact more productively with the infrastructural development.

Council Questions and Discussion

Key hurdles to get over when conceiving clinical and translational studies are 1) HIPAA and 2) the IRB. Not infrequently the legal constraints imposed by those institutions are extremely difficult to overcome. Has there been any thought to standardizing what should be considered in an application for HIPAA and IRB approval? Dr. Alving indicated that this is indeed a focus and priority for several CTSA oversight committees. The outcome of this committee attention is likely to be some workshops. Dr. Alving indicated that the CTSA program would like to see this issue well addressed to create some efficiency while maintaining ethical standards. One of the hurdles is that IRBs look at their roles and are risk-averse to differing degrees. Much of this has to do with institutional culture, and perhaps work as a consortium can facilitate more harmonization.

Has the CTSA organization given any thought to the growing distinction between the clinician and the clinician scientist? Are the CTSAs trying to grapple with this issue? Dr. Alving suggested that when she thought of all the NIH-funded clinical investigators who work in large clinical trials, the vast majority have some type of clinical practice. While it may be limited or highly specialized, she felt that most clinicians or clinical physician scientist would find it very difficult if they were involved in clinical research but not seeing patients. Dr. Alving continued that she felt the problem boils down to salaries. As Medicare benefits decelerate are physicians and health professionals going to work for lower salaries? Are we going to be more efficient in the business of medicine? There are many ways to tweak the system but, Dr. Alving commented, it was her impression that most clinician scientist will want to continue to see patients.

What is the vision for the informatics piece of the CTSA program? Dr. Alving indicated that there are multiple informatics pieces. One would be the ability to search patient records, another would be adverse event reporting—transmitting data directly to FDA and other organizations, and another is to mine databases including databases of clinical

information or repositories. NIH has set up a trans-NIH Biomedical Informatics Committee and there are visions on multiple fronts. There are going to be a series of workshops to establish what is needed, what we can do, and how it can be done.

Education is an important component of the CTSA program. Is there a plan to share resources? Dr. Alving indicated that education is a key component of the CTSA program and she is eager to see sharing of resources and modules so that organizations don't need to reinvent what has already been developed. Furthermore, these resources need to be shared with non-CTSA institutions and a process needs to be developed to facilitate this.

VII. SCIENTIFIC PRESENTATION

Dr. David Moore, Professor, Departments of Molecular and Cellular Biology and Molecular and Human Genetics, Baylor College of Medicine

"The Intersection of Drug Metabolism and Diabetes

moore_niddk car diab 5-07.ppt

VIII. ADVISORY COUNCIL FORUM – PART 2

NIH Reauthorization

Mr. Marc Smolonsky, Associate Director for Legislative Policy and Analysis, NIH

Background

Mr. Smolonsky reminded Council that the Congressional appropriations process is different than the authorization process. The two processes involve different members of Congress and different committees. In 2004, after the doubling of the NIH budget was completed, NIH entered into what is now in common parlance called the "post-doubling" era. During this period there was Congressional focus not on NIH appropriations, which remained flat after the doubling, but on accountability and oversight. The questions from Congress focused on the theme "what have you done with the money that we gave you?" What has the return been? Are you spending the money wisely? There were a series of investigations, most notable of which was the "Conflicts of Interest" investigation.

During this period members of Congress began discussing reauthorizing NIH—a third reauthorization of NIH, which had not been reauthorized since 1993. Some of the ideas for NIH included:

- Consolidating all NIH Institutes and Centers (ICs) into as few as 14 ICs

- Dividing NIH ICs into six budget clusters with each budget cluster having its own separate appropriation and each cluster led by a lead institute
- Dividing the ICs into mission-specific and science-enabling categories with two separate appropriations
- Establishing a "defense base closing model" for NIH where all ICs were reviewed every few years resulting in binding recommendations to close, consolidate or create new ICs

Mr. Smolonsky explained that while none of these ideas individually gained critical traction themselves the discussions fostered momentum that eventually culminated in the NIH Reform Act which was signed into law January 15th 2007. The Act passed Congress on the last day of the Congressional session on December 9, 2006 at 2 A.M—in a hectic and chaotic conclusion to a process that Mr. Smolonsky commented was based on considerable thought.

Provisions of the NIH Reform Act

Mr. Smolonsky detailed the main provisions of the NIH Reform Act.

- **NIH Director/NIH OD** – The law provides the NIH Director with new oversight and coordination responsibilities.
  - The NIH Director is responsible for program coordination across the ICs, including conducting priority-setting reviews, to ensure that NIH's research portfolio is balanced, free of unnecessary duplication, and takes advantage of collaborative cross cutting research.
  - The NIH Director is required to assemble accurate data to be used to assess research priorities, including information to evaluate better scientific opportunity, public health burdens, and progress in reducing health disparities.
  - The NIH Director is required to ensure that scientifically based strategic planning is implemented in support of research priorities as determined by the ICs and that NIH's resources are sufficiently allocated for research projects identified in strategic plans.
  - In coordination with IC Directors, the NIH Director is required to ensure that investigator-initiated research is maximized, when appropriate.
- **Reorganization**
  - The law reaffirms the authority of the Secretary of Health and Human Services (HHS) to reorganize ICs. However, to do this the Secretary must notify Congress 180-days in advance and some certain reorganizations must be conducted pursuant to a regulatory notice and comment process and with congressional review. Mr. Smolonsky commented that this stipulation is new and is designed to protect ICs from someone making a bad decision or forcing a reorganization that is not good for science.

- The NIH Director is authorized to reorganize offices within the NIH OD, but only following a series of public hearings and approval of the Secretary, HHS.
- ICs will continue to be authorized to reorganize their own divisions, centers and other administrative units, including adding, removing or transferring their functions, following a series of public hearings and the approval of the NIH Director.
    - Mr. Smolonsky commented that the requirement for a series of public hearings is significant and new. While the there is no requirement for such a process if an IC wants to, for example, close a lab, it does mean that any significant changes in an IC's mission, change in direction, or creation of a new function requires a series of public hearings. What is not clear is exactly what the requirements for a public meeting entail and this may become clearer with time.
    - Mr. Smolonsky further commented that it is important to note that these kinds of authorities have existed for 40-years in the Public Health Service Act and nobody really paid any attention to them or used them, but they are still there and now they are reaffirmed.

- **Scientific Management Review Board** – Mr. Smolonsky commented that this is a big deal and is the result of the discussion of the Base Closing Commission.
    - The law establishes for the first time a Scientific Management Review Board to conduct periodic organizational reviews within NIH.
        - While the law stipulates that the Board must be established within 60 days of enactment, it was not—it was not possible to do this, but it will be established soon.
    - Every seven years the Board, which will consist of nine IC Directors and public members, will report their review of the structure of NIH and make recommendations for changes to the NIH Director.
    - If the Board recommends an organizational change, the process to effect the change much begin within 100 days of the report and the change must be fully implemented within 3-year. These requirements do not apply if the NIH Director objects to all or part of the recommended organization change within 90-days and the objection includes a rationale.

- **Division of Program Coordination, Planning, and Strategic Initiatives**
    - NIH has already administratively created within the NIH OD the Office of Portfolio Analysis and Strategic Initiatives (OPASI), which is up and running. This unit is very similar to what as described in the legislation to form the Division of Program Coordination, Planning and Strategic Initiatives.
    - The following program offices will be moved into the new Division
        - Office of AIDS Research
        - Office of Research on Woman's Health

- Office of Behavioral and Social Sciences Research

  Office of Disease Prevention

- Office of Dietary Supplements

  Office of Rare Diseases

    - Mr. Smolonsky commented that each of these offices will maintain its existing independent authority but will be moved into the division to participate in identification of trans-NIH issues and research that need to be coordinated and funded

- The Director of NIH acting through the division will also be authorized to identify and report on research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis that would benefit from strategic coordination and planning.
- The law establishes for the first time a common fund to pay for such research. This research will be considered by a new Council of Councils comprising members of IC advisory councils, individuals nominated by OD offices, and members of the Council of Public Representatives. The Councils will be a Federal Advisory Committee, will be regulated by the Federal Advisory Committee Act and will operate with full transparency.
- Trans-NIH proposals considered by the Council of Councils and proposed to them by the new division by law must include milestones and goals for the research activities and time frames for funding the research. The law also stipulates that appropriate consideration be given to proposals for with the investigator is a first-time applicant to NIH.

- **Common Fund**
  - The mechanism for funding this trans-NIH research is the Common Fund. The Director of NIH has the authority to allocate Common Fund money to ICs to fund trans-NIH research—and the ICs will carry out research using money provided through the Common Fund. The research will not be conducted out of the NIH OD.
  - The Common Fund amounts will be reserved by the NIH Director and subject to appropriations, but the percentage constituted by the amount reserved relative to the total appropriation in any fiscal year may not be less than the percentage from the preceding fiscal year.
  - The first year that the Common Fund reaches five percent of the total NIH budget, the Director, in consultation with the Council of Councils, will be required to submit recommendations to Congress for changes regarding amounts for the Common Fund.
    - Mr. Smolonsky commented that the Common Fund now exists in the joint resolution that funded NIH for fiscal year 2007—the Common Fund received $400 M. So the appropriators immediately affirmed what the

authorizers did. The Common Fund is a reality. It has been embraced by Congress.

- **Authorization of Appropriations**
  - The NIH Reauthorization Act authorized NIH to receive up to $30.3 B in fiscal year 2007, $32.8 B in fiscal year 2008 and such sums as may be necessary in fiscal year 2009.
    - Mr. Smolonsky clarified that this does not mean that NIH will receive these amounts, but rather it means that NIH is authorized to receive up to these amounts—they are ceilings.
    - If appropriators wanted to give NIH more money than is authorized they would have to take special action on the Floor of the Senate and House to do it.
  - Report language accompanying the bill states that the elimination of other authorities of appropriations may not be construed as terminating the authority of the IC/NIH OD to carry out the program.
    - Mr. Smolonsky explained that the 1944 Public Health Services Act contains such broad and elegant authorities that NIH can fund basically anything within the NIH biomedical research mission under these broad authorities. Regardless of whether Congress creates a new authority or eliminates a specific authority, we still rely on the generic authorities from 1944.
- **Coding System**
  - NIH is already working to develop a uniform coding system that is transparent and understandable to the public and to the research community.
  - The law requires NIH to continue this work by establishing an electronic system that uniformly codes research grants and activities.
  - The system must be searchable by a variety of codes, such as the research grant, the organization managing the grant, and the public health area of interest.
  - When permissible, the Secretary of the Department of Health and Human Services acting through the Director of NIH will be required to provide information on relevant literature and patents associated with NIH research activities.
- **Reporting**
  - Rather than having a series of individual reports coming up from the ICs and going to Congress and the public, there will be a single biennial report that will be more detailed than what NIH has provided Congress in the past.
- **Review of Grants Less Than $50,000**
  - Mr. Smolonsky reported that in the past IC Advisory Councils could give a cursory look at grants less than $50,000 or not look at them at all. This

became a point of contention a few years ago when Congress looked at some behavioral research grant that they found unseemly. Some of these grants were under $50,000 and had not undergone Council review. The result of this concern is that all peer reviewed grants, regardless of their amount must be reviewed by Council.

Mr. Smolonsky concluded his presentation by stating that it will probably be two years before the NIH Reauthorization Act is fully implemented. He then asked for any question regarding the Act or anything involving NIH's interactions with Congress.

Council Questions and Discussion

There were some reports that the same committee interested in conflict of interest in the NIH Intramural program was interested in broadening their scope to include conflict of interest issues associated with NIH grantees. Does this have any traction? Mr. Smolonsky reported that this issue has substantial traction. He explained that Congress is interested in conflict of interest in the extramural community because the rules and regulations that govern Intramural scientist do not apply to extramural scientists. So, Congress is asking questions and they are likely to start looking at the extramural community. Mr. Smolonsky stated that other review organizations, in addition to Congress, are likely to pursue this matter. It is something that not only has a lot of traction but is going to occur at some level and we will se more and more of this over the next year or two.

Will the changes in coding and reporting affect the reports given to institutions regarding the total amount of NIH funding they receive? Dr. Stanfield replied that the report in question is the Departmental Rankings. He reported that the Departmental Rankings report has been eliminated and this is timely since the implementation of the multiple-PI policy would make these rankings difficult and likely inaccurate. However, there is a new tool developed and maintained by the NIH Office of Extramural Research that allows data downloads and all sorts of comparisons among institutions. This will allow institutions to do their own rankings based on criteria that they establish (see http://grants.nih.gov/grants/award/trends/FindOrg.cfm).

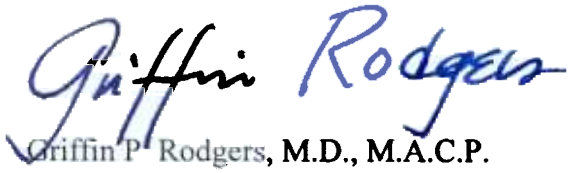
IX. CONSIDERATION OF REVIEW OF GRANT APPLICTIONS

A total of 1,638 grant applications, requesting support of $368,758,007 were reviewed for consideration at the May 30, 2007 meeting. Funding for these 1,638 applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, an additional 1,448 applications requesting $334,426,398 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 May 30, 2007 meeting.

X. ADJOURNMENT

Dr. Rodgers thanked the Council members for their attendance and valuable discussion There being no other business, the 174th meeting of the NIDDK Advisory Council was adjourned at 4:47 p.m., May 30th, 2007.

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



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