APPENDIX 4: SUPPLEMENTAL MATERIAL ON SCIENTIFIC CONFERENCES, WORKSHOPS, AND MEETINGS RELEVANT TO TYPE 1 DIABETES AND ITS COMPLICATIONS

This Appendix provides information on scientific conferences, workshops, and meetings with relevance to type 1 diabetes and its complications. The input that the NIH received informed the planning process for use of the *Special Funds*.

#### RESEARCH CONFERENCES AND WORKSHOPS

### 1997 Diabetes Mellitus: Challenges and Opportunities

(September 4-5, Bethesda, MD, sponsored by the NIH Office of the Director, NIDDK, NCRR, NEI, NHGRI, NHLBI, NIA, NIAID, NICHD, and NINDS) Diabetes is a multifaceted, complex disease that directly affects many of the body's organ systems. This trans-NIH symposium brought together leading experts in diabetes and related fields to examine the state of the science and identify research gaps and opportunities that could be pursued across the NIH. Working groups convened to develop specific, in-depth recommendations on five topics of critical importance: Type 1 Diabetes—Etiology and Pathophysiology; Type 2 Diabetes—Etiology and Pathophysiology; Therapy; Microvascular Complications; and Macrovascular Complications. Cross-cutting recommendations from these groups included: expand research resources and facilities, such as tissue repositories and research databases; provide diabetes investigators necessary tools; develop new research methods and measures to foster diabetes research; pursue the development of clinical trials of potential therapies for diabetes and its complications; ensure a cadre of talented diabetes researchers by intensifying research training and career development efforts; foster translational research to enhance the timely transfer of important advances in diabetes research to the practice of medicine; develop new modes of interaction among academia, the NIH, and industry to foster diabetes research; and continue the planning process for diabetes research, for example through future workshops and conferences that could help guide program planning efforts and develop standardized research measures and assays.

#### 1998 Expert Panel on Immune Tolerance

(February, Bethesda, MD, sponsored by NIAID) Developing methods to achieve immune tolerance has the potential to halt the autoimmune destruction of beta cells in type 1 diabetes and to prevent immune-mediated rejection of transplanted

islets. Leading investigators in basic and clinical immunology convened to discuss plans for accelerating research on immune tolerance. Among the plans endorsed by this panel were recommendations for the creation of interactive, multi-institutional research programs that bring together experts in relevant basic and clinical disciplines to conduct large-scale research that cannot be accommodated within a single institution. Further, the panel advised the inclusion of mechanistic studies in conjunction with clinical trials and the establishment of immunology cooperative study groups to provide a central resource for the development of standardized assays and the identification and validation of surrogate markers of disease.

#### 1998 Working Group on Cellular and Molecular Mechanisms of Diabetic Cardiomyopathy

(July 16, Bethesda, MD, sponsored by NHLBI) Diabetes significantly increases an individual's risk of illness and death from cardiovascular disease. A panel of scientific experts reviewed the state of knowledge and research in diabetic cardiomyopathy and made recommendations for future research initiatives. The panel supported multidisciplinary, collaborative research on the cellular and molecular mechanisms of diabetic cardiomyopathy; the development of animal models that better simulate human disease; clinical research to characterize the epidemiology and pathophysiology of diabetic cardiomyopathy; and clinical trials to test novel interventions.

#### 1998 Etiology of Type 1 Diabetes

(August 31-September 1, Washington, DC, sponsored by NIAID, NIDCR, NIDDK, and the JDRF) Although there is known to be a genetic component to type 1 diabetes, genetic predisposition does not fully account for development of this disease. This workshop reviewed evidence for viral infections or other environmental factors that may trigger type 1 diabetes. Scientists with expertise in the development of

diabetes recommended that research efforts be launched to identify those at high risk for type 1 diabetes, to understand the environmental factors and natural history of the disease, and to test potential interventional agents. Participants also encouraged the development of training and career advancement mechanisms to recruit new researchers into the field of diabetes research.

#### 1999 Imaging the Pancreatic Beta Cell

(April 19-20, Washington, DC, sponsored by NIDDK, JDRF)
Type 1 diabetes is characterized by an inadequate mass of functional pancreatic islets; yet, without the ability to visualize these cells in an animal or human, many questions of the natural history of the disease remain to be answered. This meeting brought together scientific experts in the fields of beta cell biology and imaging technology for discussions on the potential impact of new imaging technologies on understanding and managing diabetes. Participants advocated funding support for exploratory, interdisciplinary research that would jump start new approaches and attract new research talent to the imaging field.

#### 1999 Advances in Neurobiology: A Key to Understanding Diabetic Neuropathy

(September 14-15, Bethesda, MD, sponsored by NIDDK, NINDS, JDRF) Despite recent advances in the management of diabetes, neuropathy remains one of the most troubling complications of diabetes and constitutes a major public health problem. A workshop was held to re-examine the pathophysiology of diabetic neuropathy in light of recent advances in neurobiology. The goal of the workshop was to bring together investigators from the diabetes and neuroscience communities to examine new insights into the molecular and cellular biology of the neuron in the setting of diabetes. Researchers discussed new advances, highlighted potential areas of research that could lead to new therapies, and encouraged collaborations between neuroscientists and diabetologists.

### 1999 Gene Therapy Approaches for Diabetes and Its Complications

(November 8-9, Rockville, MD, sponsored by NIDDK, NCRR, NHLBI, NIAID, ADA, JDRF) As technology for introducing new genes into cells has been improving, the disease targets for gene therapy have expanded beyond traditional genetic diseases to chronic diseases such as diabetes. Investigators met to discuss their results utilizing gene therapy approaches to treat diabetes in animal models and human patients. The workshop recommended support for research efforts in four key areas: insulin expression in tissues where the hormone is not normally produced; interference with the autoimmune destruction of beta cells in type 1 diabetes; creation of surrogate beta cell lines for transplantation; and treatment of macrovascular and microvascular complications of diabetes.

### 1999 Workshop on Oral Diseases and Diabetes

(December 6-7, Washington, DC, sponsored by NIDCR) Oral complications, including gum disease, salivary dysfunction, mucosal infections, and neurological problems of taste and smell, are major health problems in diabetic individuals. This workshop served as a forum for evaluation of the state-of-thescience on diabetes and oral health. Recommendations for future research that arose from this meeting included more study of the oral microbiology and immunology of diabetes.

### 2000 Stem Cells and Pancreatic Development

(April 10-11, Bethesda, MD, sponsored by NIDDK, ADA, JDRF) Stem cells, which are capable of self-renewal and differentiation into multiple cell lineages, have therapeutic potential for the treatment of diabetes. Researchers met to discuss issues in isolating and characterizing pancreatic stem cells that have the ability to reconstitute all pancreatic cell types. Among the recommendations that emerged from this workshop were the establishment of research alliances (e.g., consortia) of inves-

tigators from the stem cell biology, developmental biology, and diabetes research fields and the development of incentives to attract and train new clinical investigators in the fields of endocrinology and stem cell biology.

#### 2000 Hypoglycemia and the Brain

(September 7-8, Washington, DC, sponsored by NIDDK, NINDS, NICHD, the National Aeronautics and Space Administration [NASA], ADA, JDRF) Episodes of severe hypoglycemia are a major obstacle in the management of diabetes and prevention of long-term complications. Further, hypoglycemia confers a risk of loss of consciousness, coma, and potential brain injury. This workshop was organized to review what is known about the brain's response to metabolic changes, to set research priorities for future efforts, and to stimulate research on the molecular and cellular mechanisms by which hypoglycemia injures and kills neural cells. The participants identified several critical areas of research opportunity, including the need to develop strategies to promote glucose sensing by the brain and to restore the counter-

regulatory hormonal responses in type 1 diabetes.

#### **2000 Genetics of Diabetic Retinopathy**

(September 21-22, Bethesda, MD, sponsored by NEI) Diabetic retinopathy (eye disease) is a common, long-term complication of diabetes. A multidisciplinary group of scientists met to explore whether advances in genetic research could increase the opportunity for understanding the genetic predisposition underlying the development and/or progression of diabetic retinopathy. The group identified several high-priority recommendations for facilitating future research, including ancillary studies to identify the retinopathy phenotype in existing genetics studies; the support of interdisciplinary, collaborative research to evaluate the genetics of diabetes and its complications; the development of new research reagents and tools, such as improved animal models and microarray resources; and the recruitment of geneticists to work in vision research.

#### **2000 Genetics of Type 1 Diabetes**

(November 20, Rockville, MD, sponsored by NIDDK, JDRF)
Prior to this meeting, three genome-wide scans for type 1
diabetes genes had led to the identification of several chromosomal loci that showed evidence of harboring a diabetes susceptibility gene. Experts in the field of type 1 diabetes genetics met to explore the establishment of a collaborative effort on understanding the genetic basis of type 1 diabetes. As a result of this meeting, the Type 1 Diabetes Genetics Consortium was formed to pursue large-scale genetics research beyond the means of a single investigator study.

### 2001 Pancreatic Development, Proliferation, and Stem Cells

(October 18-19, Bethesda, MD, sponsored by NIDDK, ADA, JDRF) Replacement or regeneration of the pancreatic beta cells lost in diabetes hold promise as future therapeutic interventions for the treatment of this disease. Investigators from multiple disciplines doing cutting-edge research in developmental biology of the pancreas, islet cell biology, and stem cell biology met to discuss new insights into this rapidly developing field. Participants expressed support for the generation of essential reagents, assays, and a database of islet cell development and function, for research on the molecular mechanisms of islet cell neogenesis, proliferation, and programmed cell death, and for basic research on mouse and human stem cell biology.

### 2001 Etiology and Epidemiology of Early Autoimmune Type 1 Diabetes in Humans

(October 25-26, Alexandria, VA, sponsored by NIDDK) Large-scale epidemiological studies will be required to fully elucidate the complex interactions of genetics and environment that trigger type 1 diabetes. Researchers met to guide the NIH in the design of meaningful studies for understanding the immunologic mechanisms of diabetes. Meeting participants agreed

on the need for a large-scale, cooperative trial that can screen sufficient numbers of at-risk patients, and for standardized assays and centralized laboratory and storage resources to facilitate data collection.

#### 2001 Beta Cell Biology in the 21st Century

(November 26-28, Bethesda, MD, sponsored by NIDDK, ADA, JDRF) Loss or dysfunction of insulin-producing pancreatic beta cells is central to the development of diabetes. This workshop convened beta cell biology researchers to assess the state of the science in beta cell structure, function, and physiology and to discuss ways to advance knowledge of the complex signaling pathways that govern beta cell function. Participants identified key scientific questions that guided future research in this field, including: definition of the factors required for maintenance of differentiated beta cells; identification of signaling cascades and networks within the beta cell and among beta cells and other cells of the pancreatic islets; understanding the minimal requirements for engineering a surrogate beta cell; and the application of genomics, proteomics, and other emerging technologies to the study of the beta cell.

### 2001 Encapsulation and Immunoprotective Strategies of Islet Cells

(December 6-7, Washington, DC, sponsored by NIDDK, NCRR, NASA, JDRF) Encapsulation of transplanted islet cells holds promise as a means of preventing rejection by the body's immune system. Workshop participants met to review the current state of encapsulation technology and to develop a strategy for future research in this area. Two high-priority issues were identified as a result of this meeting: the need for successful animal studies for further evidence and ultimate validation, and standardization of capsule materials and implantation procedures.

#### 2002 Epidemiology of Diabetes Interventions and Complications (EDIC) Autonomic Neuropathy Advisory Group Meeting

(May 29, Bethesda, MD, sponsored by NIDDK) Diabetic autonomic neuropathy is a clinically significant outcome of diabetes with serious impact on quality-of-life, morbidity, and probably mortality. Yet, it is very much an uncharted discipline in diabetes research. Experts were convened to discuss the clinical importance of various forms of diabetic autonomic neuropathy, including gastroparesis, diabetic diarrhea/constipation, gall bladder dysfunction, bladder dysfunction, sexual dysfunction, orthostatic hypotension, cardiac sudden death, sweating dysfunction, and hypoglycemia unawareness. The advisory group suggested new studies to measure cardiovascular autonomic neuropathy with consideration given to using Holter monitors to measure RR intervals, perhaps with up to 24-hour blood pressure monitoring. In addition, the group recommended using the saved biologic samples of the DCCT/ EDIC participants to measure several suggested markers and predictors of neuropathy.

# 2003 Metabolic Imprinting and the Long-Term Complications of Diabetes Mellitus: Bench to Bedside and Back: 20th Anniversary of the Diabetes Control and Complications Trial (DCCT)/EDIC Study

(April 10-11, Bethesda, MD, Sponsored by NIDDK) The DCCT/EDIC study resoundingly answered its seminal question with regard to diabetes research and is widely recognized as a well-designed and implemented study. The conference goals were: to celebrate and commemorate the accomplishments of the DCCT/EDIC on its 20th anniversary; to explore the possible mechanistic basis for what has been tentatively termed "metabolic memory"; and to generate plans for the

fostering of research in developing new theories for the complications of type 1 diabetes. Although tremendous progress has been made toward improving the lives of people with type 1 diabetes, premature death from complications remains an issue of great concern. With representatives of multiple Institutes and organizations in attendance, the participants exchanged ideas on research efforts to be supported by the *Special Funding Program*.

Based on external input garnered at this meeting, the NIDDK utilized a novel "co-principal investigator" mechanism with its "Innovative Partnerships in Type 1 Diabetes Research" initiative, which is supported by the *Special Funding Program*. The standard policy at the NIH was to award a grant to only one Principal Investigator (PI), while the partner was listed as a co-investigator—an arrangement that did not recognize both partners as being equal and thus posed a barrier to collaboration. The novel solicitation was developed so that both partners were named as co-equal PIs. The co-PI mechanism is now being piloted for broader implementation by the NIH as a whole through the NIH Roadmap.

#### 2003 Imaging the Pancreatic Beta Cell

(April 21-22, Bethesda, MD, Sponsored by the NIBIB, NIDDK, JDRF) Recent advances in noninvasive imaging techniques such as magnetic resonance imaging (MRI), positron emission tomography (PET), other nuclear imaging techniques, and optical absorption or fluorescence spectroscopy and imaging, make it likely that a clinical exam to monitor beta cell number, mass, function, or lymphocyte infiltration/inflammatory activity can soon be established. This would allow at-risk individuals to be monitored prior to onset of diabetes. Patients could be monitored over the course of their disease, to follow individual responses to therapy, and to assess success of engraftment following islet transplantation. Researchers

would learn about the natural history of diabetes. The goals for this meeting were to report on ongoing work in the area of beta cell imaging using MRI, PET, ultrasound, or optical technologies; form community among those researchers who are interested in this area; and help NIH identify obstacles and opportunities toward a clinical exam for the measurement of pancreatic beta cell mass, number, function, inflammation, or engraftment.

#### 2003 Proteomics and Diabetes

(April 24-25, Bethesda, MD, Sponsored by NIDDK) Proteomic approaches have been successfully used for studying complex biological problems and for the identification of disease markers. Recent developments in proteomics indicate that the technologies available are already sufficiently advanced to approach many biological questions relevant to the NIDDK mandate. This workshop provided a venue to bring together investigators with expertise in proteomics and those interested in applying this technology to problems related to diabetes, endocrinology, and metabolic diseases. Several leaders in the field illustrated the state of the art in proteomics and their possible use to study diabetes.

#### 2003 Meeting on Cardiovascular Complications of Type 1 Diabetes: Identifying New Opportunities for Prevention and Treatment

(April 27-28, Bethesda, MD, Sponsored by NHLBI, NIDDK)
Cardiovascular disease (CVD) is the major cause of mortality and morbidity in both type 1 and type 2 diabetes patients.
Although the microvascular complications of type 1 diabetes have been studied, macrovascular CVD, its treatment, and link to diabetes have been investigated primarily in patients with type 2 diabetes. This meeting was convened to identify research strategies to improve prevention and treatment of CVD in patients with type 1 diabetes. Conference participants were asked to evaluate opportunities for studying the patho-

genesis of CVD and intervention strategies in type 1 diabetes patients. The meeting included sessions devoted to: current understanding of type 1 diabetes and CVD; opportunities to expand understanding of the pathogenesis and clinical course of CVD in type 1 diabetes; and opportunities for intervention studies to reduce cardiovascular complications.

#### 2003 Meeting on Islet Transplantation

(May 30, Bethesda, MD, Sponsored by NIDDK, NIAID, JDRF) This ad hoc advisory meeting was convened to solicit recommendations for future research directions in islet transplantation from external experts in the field. The meeting helped to inform the development of the Clinical Islet Transplantation (CIT) Consortium. Recommendations stemming from the meeting included: develop core facilities for non-human primate reagents for wide distribution and use; increase coordination; better define clinical outcomes; and continue studies on gene therapy and xenotransplantation.

### 2003 Diabetic Complications: Progress Through Animal Models

(October 20-21, Bethesda, MD, Sponsored by NIDDK, NHLBI, NINDS, NEI, JDRF) Animal models provide a vital link for translation of clinical research. This meeting addressed recent progress with animal models used to study diabetic complications. The first day was devoted to exploring the state of the art in animal models, focusing on their promise and limitations, and translation from bench to bedside. The second day was devoted to discovery, with sessions dedicated to identifying new pathways, potential targets, biomarker and surrogate identification and validation, and the development of novel therapeutic approaches.

# 2004 From Clinical Trials to Community: The Science of Translating Diabetes and Obesity Research

(January 12-13, Bethesda, MD, Sponsored by NIDDK, the NIH Office of Behavioral and Social Science Research [OBSSR], the Centers for Disease Control and Prevention [CDC]) Dramatic advances in diabetes treatment and prevention have occurred over the past decade. Unfortunately, the therapies proven to delay or prevent the complications of type 1 diabetes have not been widely operationalized. Translational research aims to determine what can improve outcomes in diverse, real-world populations and how to achieve these goals in a practical way that positively affects public health. This conference brought together investigators, health care providers, NIH representatives, and payers to discuss barriers to translation, translational research, translational interventions, community-based approaches, and public health efforts. A primary conference objective was to foster ideas to improve treatment for individuals with or at risk for diabetes through implementation of known and newly emerging prevention and treatment strategies. In addition, a "Grant Writing Workshop" was held for investigators interested in submitting translational research proposals.

### 2004 Immunobarriers for Pancreatic Islet Transplantation

(March 29-30, Washington, DC, Sponsored by NIDDK, NIBIB, JDRF) This workshop was convened to review the state-of-the-art in barrier material for tissue immunoisolation with the emphasis on pancreatic islet transplantation and other cell therapies for the treatment of diabetes. Participants were invited from academia and industry and included biomedical engineers, immunobiologists, cell biologists, diabetologists, and transplant surgeons. The meeting was organized to provide a forum for exchange of the most recent data and the latest insights and perspectives on the biomaterial components of what is commonly termed "the bioartificial pancreas." The meeting served to identify opportunities and barriers

to scientific progress. Chief among these was the need for a clearer understanding of the mechanisms of both rejection and survival of encapsulated tissue, and less emphasis upon show-and-tell survival experiments in relatively compliant rodent models. Interdisciplinary teams with strong capabilities in islet-cell biology, membrane transport, biomaterials, and immunology were identified as necessary to achieve success in this field. Finally, a need was identified for basic biology studies to uncover whether sufficient nutrients are delivered; to detail the complex nature of the host defense; and to define the mechanisms by which materials fail in the transplanted environment.

#### 2004 NIH Trans-Institute Angiogenesis Research Program (TARP) Workshop

(May 10-12, Bethesda, MD, Sponsored by NIDDK, NINDS, NHLBI, JDRF, NCI, NEI) The workshop was held: to assess the state of current knowledge about angiogenesis; to define areas of research need; and to make recommendations to expand on successes and close gaps. The workshop provided a forum to examine the state of the science in angiogenesis research as it relates to a variety of pathologic disease states; determine areas of need and overlap among the various disciplines studying angiogenesis; discuss what research could be conducted and how; and discuss novel models, systems, and core resources applicable to or needed by the community. Based on the recommendations, both NIH and JDRF announced availability of research funding for scientists to investigate angiogenesis as it relates to type 1 diabetes.

#### 2004 Food and Drug Administration (FDA)/NIH Joint Symposium on Diabetes: Targeting Safe and Effective Prevention and Treatment

(May 13-14, Bethesda, MD, Sponsored by NIH, NIDDK, FDA) The purpose of the symposium was to define the current state of the prevention and management of diabetes and to identify

and discuss therapeutic gaps and hurdles to safe and effective prevention and treatment of type 1 and type 2 diabetes. The symposium was intended to provide assistance to FDA, clinical and basic scientists, and the interested pharmaceutical industry in their efforts to reduce the burden of diabetes and improve the health of all people with diabetes. The symposium addressed important disease outcomes that should be targeted in the development of drugs and devices; issues surrounding the use of surrogate or intermediate measures of clinical effect in assessments of novel therapeutic approaches to prevention and treatment; and clinical, scientific, and regulatory issues surrounding development of new medical technologies.

### 2005 Biostatistical Issues and the Design of Type 1 Diabetes TrialNet (TrialNet) Protocols

(March 7, Bethesda, MD, Sponsored by NIDDK) The meeting was convened to address creative approaches to protocol design. Experts in the areas of biostatistics, endocrinology, and clinical trials were brought together to discuss mechanisms to ensure that multiple clinical trials can be successfully performed concurrently and rigorously within TrialNet.

### 2005 Genetics of Diabetes and Its Complications: Consortia Meeting

(July 20, Bethesda, MD, Sponsored by NIDDK) This workshop was convened in response to specific recommendations of the expert panel on the Special Statutory Funding Program for Type 1 Diabetes Research in their January 2005 meeting. The panel strongly encouraged coordination between the four major genetics consortia supported by the Special Funding Program: Family Investigation of Nephropathy and Diabetes (FIND), Genetics of Kidneys in Diabetes Study (GoKinD), EDIC, and the Type 1 Diabetes Genetics Consortium (T1DGC). Recommendations were developed for facilitating interactions among the studies and for future analytic strategies. The importance of interactions between consortia was

emphasized to enhance the value of the individual studies that aim to develop new strategies for prevention and treatment to alleviate the suffering from type 1 diabetes.

# 2005 Obstacles and Opportunities on the Road to an Artificial Pancreas: Closing the Loop

(December 19, Bethesda, MD, Sponsored by NIH, NIDDK, JDRF, FDA) The objective of the workshop was to evaluate the current state of development of the artificial pancreas and to determine the research needs to achieve a functional and safe closed-loop system. Clinical investigators discussed the optimal targets for normal glycemia and their experience with the closed-loop system. Basic research scientists addressed the technological difficulties. Participation from industry and FDA representatives provided a broad view of the current

difficulties associated with reaching the goal of an artificial pancreas.

#### 2006 Imaging the Pancreatic Beta Cell

(April 24-25, Washington, DC, Sponsored by JDRF, HHS, NIH, NIDDK, NCI, NIBIB, NIAID) The purpose of this meeting was to explore progress in the field of imaging or otherwise visualizing the pancreatic islet cell mass to assess its functionality in health and disease. The workshop showcased studies aimed at visualizing the pancreatic islet and/or beta cell *in vivo*, so as to elucidate the natural history of islet destruction underlying diabetes pathogenesis and to monitor survival during disease therapy. The goals for this workshop were to share results from promising approaches and those proven unsuccessful in this area; to learn from other applied disciplines; and to foster collaboration among scientists in the diabetes community.

## DIABETES MELLITUS INTERAGENCY COORDINATING COMMITTEE (DMICC) MEETINGS RELEVANT TO RESEARCH ON TYPE 1 DIABETES AND ITS COMPLICATIONS

This listing provides highlights of recent DMICC meetings relevant to type 1 diabetes but not specifically focused on the *Special Funding Program*. For a description of DMICC meetings focused on the *Special Funding Program*, please see Appendix 3.

# Opportunities for Research To Develop New Therapies for Vascular Complications of Diabetes (April 11, 2003)

This DMICC meeting was appended to the 20th Anniversary Symposium of the Diabetes Control and Complications Trial (DCCT) and the Epidemiology of Diabetes Interventions and Complications (EDIC) Study entitled "Metabolic Imprinting and the Long-Term Complications of Diabetes Mellitus: Bench to Bedside and Back" (described in Appendix 3). The DMICC members and guests discussed the funding of future bench-to-bedside research, highlighting the success of DCCT/ EDIC. Participants discussed: the major gaps in knowledge of the pathogenesis and therapy of vascular complications; the mechanisms to foster development of animal models; developing novel surrogate markers; identification of new therapeutic targets and agents; advancing research in therapies for complications; and translation of findings from bench to bedside. The meeting provided intriguing areas for future research, as well as identified available resources for carrying ideas to fruition. One of the recommendations emanating from this meeting was for the NIDDK to implement a novel co-PI mechanism for initiatives in which multiple scientists contribute equally to a project. This recognition was thought to be a crucial aspect of team research. In response to this recommendation, the NIDDK employed the co-PI mechanism to an "Innovative Partnerships in Type 1 Diabetes Research" initiative supported by the Special Funding Program (Goal VI). The summary minutes can be accessed on the NIDDK's website (www.niddk.nih.gov/federal/dmicc/Final-April-11-Summary.pdf).

#### Joint Meeting of the Skin Diseases Interagency Coordinating Committee and the Diabetes Mellitus Interagency Coordinating Committee (November 18, 2003)

This meeting provided an opportunity for the NIDDK and NIAMS to join with representatives of other institutes and agencies to discuss wound healing, a topic of great significance in and of itself, but particularly in relationship to diabetes. The goals of the meeting were to discuss the research efforts being done across agencies, as well as to identify opportunities and gap areas for future research directions. A complete summary of the meeting can be accessed on the NIDDK's website (www.niddk.nih.gov/federal/dmicc/FINALNov-ICC-Summary.pdf).

### Meeting on Islet Transplantation (November 23, 2004)

This meeting was held to discuss, in part, implementation of recent legislation: the Pancreatic Islet Cell Transplantation Act of 2004 (P.L. 108-362). The law included two key provisions: (1) making pancreata procured by an organ procurement organization (OPO) and used for islet cell transplantation count for purposes of certification, and (2) requiring the DMICC to include in its annual report an assessment of Federal activities related to islet transplantation. One purpose of this meeting was to discuss approaches being initiated by DMICC member agencies, either independently or through cooperative arrangements with other agencies, that could be included in the mandated report.

In addition to discussing legislative implementation, an overview of islet transplantation was provided, addressing NIH, FDA, and CMS perspectives. Furthermore, an update on the Health Resources and Services Administration (HRSA)/ Organ Procurement and Transplantation Network (OPTN) activities in pancreas and islet transplantation was provided. Several issues were discussed, including: islets as a cellular

therapy versus tissue versus organ; the development of the special organ product (cells or tissue derived from organs) category for transplantation; resolution of issues related to credit for OPOs when pancreata are used for islets (with passage of the Pancreatic Islet Cell Transplantation Act of 2004); an update on the Clinical Islet Transplantation Consortium; an update on the Medicare islet transplantation clinical investigation; and the consensus conference on pancreas allocation for whole-organ and islet transplantation sponsored by the Kidney and Pancreas Transplantation Committee of the OPTN/UNOS on January 23-24, 2005. The meeting was concluded with a discussion of the next step for the Committee, including creating a DMICC subcommittee to address the responsibilities related to promoting islet transplantation under the new legislation. The meeting summary is found at: www.niddk.nih.gov/federal/dmicc/Meeting\_112304\_final.pdf

### HbA1c, Diabetes, and Public Health (December 12, 2005)

Even though scientifically-based evidence supports current guidelines for HbA1c levels in type 1 and type 2 diabetes, national data suggest that a majority of Americans with diabetes are not meeting these guidelines. The goals of this meeting were to pool expertise and identify barriers and solutions to affect changes in the disparity between Hb1Ac guidelines and practice. Improved glycemic control will benefit individuals by helping them prevent or delay the development of complications and help reduce the public health burden of diabetes. Input from this meeting was used to inform a congressionally-mandated report on steps that the federal government could take to reduce the disparity between HbA1c guidelines and practice. The meeting summary is found at: www.niddk.nih. gov/federal/dmicc/2005/12-12-05/summary.pdf