OPPORTUNITIES FOR RESEARCH SUPPORTED BY THE SPECIAL STATUTORY FUNDING PROGRAM FOR TYPE 1 DIABETES RESEARCH: A WORKSHOP OF THE DMICC
April 8-9, 2015
6001 Executive Blvd., Room C, Rockville, MD 20852

AGENDA

April 8
8:00-8:10 am Welcome and Introduction
Griffin Rodgers, M.D., M.A.C.P., Director, NIDDK

8:10-8:30 am Overview of the Special Statutory Funding Program for Type 1 Diabetes Research
Judith Fradkin, M.D., Director, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK

TOPIC 1: DIABETES COMPLICATIONS
Primary Discussants: Matthew Breyer, M.D.; Nigel Calcutt, Ph.D.; Robert Eckel, M.D.; Mark Espeland, Ph.D.; Thomas Gardner, M.D., M.S.; James Meigs, M.D.; Robert Sherwin, M.D.; Timothy Wysocki, Ph.D.

8:30-8:40 am Current Efforts in Diabetes Complications
Judith Fradkin, M.D., Director, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK

8:40-8:55 am Presentations and Questions/Answers on:
Proposal 1: Cardiovascular Disease in Type 1 Diabetes – Biorepository and Human Tissue Research
Primary discussants: Dr. Breyer, Dr. Calcutt, Dr. Eckel

Proposal 2: Cardiovascular Disease in Type 1 Diabetes – Cohort, Registry, and Database Consortia
Primary discussants: Dr. Eckel, Dr. Espeland, Dr. Meigs

Teresa Jones, M.D., Program Director, Diabetic Complications, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK

8:55-9:15 am Panel Discussion on Proposals 1 and 2 (~10 minutes of discussion for each proposal)

9:15-9:30 am Proposal 3: Neurocognitive Effects of Glycemic Dysregulation in Type 1 Diabetes
Luke Stoeckel, Ph.D., Program Director, Cognitive & Clinical Neuroscience of Obesity & Diabetes, Division of Diabetes, Endocrinology, and Metabolic Diseases, NIDDK
Primary discussants: Dr. Calcutt, Dr. Sherwin, Dr. Wysocki

9:30-9:50 am Proposal 4: Continuation of Diabetic Complications Consortium (DiaComp)
Kristin Abraham, Ph.D., Senior Advisor, Model Systems and Resources, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK
Primary discussants: Dr. Eckel, Dr. Gardner
9:50-10:10 am Proposal 5: Continuation of Diabetic Retinopathy Clinical Research Network (DRCR.net)  
Frederick Ferris, III, M.D., Clinical Director, Division of Intramural Research, NEI  
Primary discussants: Dr. Espeland, Dr. Gardner, Dr. Meigs

10:10-10:30 am Topic 1 panel discussion led by primary discussants

10:30-10:40 am BREAK

TOPIC 2: ARTIFICIAL PANCREAS  
Primary Discussants: Richard Bergenstal, M.D.; Irl Hirsch, M.D.; Robert Sherwin, M.D.

10:40-10:50 am Current Efforts in Artificial Pancreas  
Judith Fradkin, M.D., Director, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK

10:50-11:05 am Presentations and Questions/Answers on:  
Proposal 1: Expansion of Clinical, Behavioral, and Physiological Research Testing of Current and Novel Closed-Loop Systems  
Primary discussants: Dr. Bergenstal, Dr. Hirsch, Dr. Sherwin,  
Proposal 2: Expansion of Research to Develop New or Improved Closed-Loop Automated Technologies for Type 1 Diabetes Therapy and Monitoring  
Primary discussants: Dr. Bergenstal, Dr. Hirsch, Dr. Sherwin,  
Proposal 3: Advanced Clinical Trials to Test Artificial Pancreas Device Systems in Type 1 Diabetes  
Primary discussants: Dr. Bergenstal, Dr. Hirsch, Dr. Sherwin,

Guillermo Arreaza, M.D., Program Director, Clinical Immunology of Diabetes, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK

11:05-11:25 am Panel Discussion on Proposals 1, 2, and 3 (~7 minutes of discussion for each proposal)  
Led by Drs. Bergenstal, Hirsch, and Sherwin

11:25-11:35 am Topic 2 panel discussion led by primary discussants

11:35 am-12:10 pm LUNCH

TOPIC 3: CLINICAL MANAGEMENT  
Primary Discussants: Richard Bergenstal, M.D.; Irl Hirsch, M.D.; Georgeanna Klingensmith, M.D.; Timothy Wysocki, Ph.D.

12:10-12:20 pm Current Efforts in Clinical Management  
Judith Fradkin, M.D., Director, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK
12:20-12:40 pm  
*Presentations and Questions/Answers on:*

**Proposal 1:** Improving Adherence in Young Children with Type 1 Diabetes  
*Primary discussants: Dr. Klingensmith, Dr. Wysocki*

**Proposal 2:** Improving Adherence in Pre-teens, Adolescents and Young Adults with Type 1 Diabetes  
*Primary discussants: Dr. Klingensmith, Dr. Wysocki*

**Proposal 3:** Understanding Barriers and Facilitators to Type 1 Diabetes Management in Adults  
*Primary discussants: Dr. Hirsch, Dr. Wysocki*

Christine Hunter, Ph.D., ABPP, Director of Behavioral Research, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK

12:40-1:00 pm  
*Panel Discussion on Proposals 1, 2, and 3 (~7 minutes of discussion for each proposal)*  
*Led by Drs. Hirsch, Klingensmith, and Wysocki*

1:00-1:15 pm  
**Proposal 4:** Impact of the Use of Glucose Monitoring and Control Technologies on Health Outcomes and Quality of Life in Older Adults with Type 1 Diabetes  
*Guillermo Arreaza, M.D., Program Director, Clinical Immunology of Diabetes, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK*  
*Primary discussants: Dr. Bergenstal, Dr. Hirsch, Dr. Wysocki*

1:15-1:25 pm  
*Topic 3 panel discussion led by primary discussants*

**TOPIC 4: RESOURCES**  

1:25-1:35 pm  
**Current Efforts in Resources**  
*Judith Fradkin, M.D., Director, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK*

1:35-1:50 pm  
**Proposal 1:** Human Pancreas Procurement and Analysis Program (HPPAP)  
*Olivier Blondel, Ph.D., Director, Endocrine Systems Biology Program, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK*  
*Primary discussants: Dr. German, Dr. Gill*

1:50-2:10 pm  
**Proposal 2:** Continuation of the Integrated Islet Distribution Program (IIDP)  
*Kristin Abraham, Ph.D., Senior Advisor, Model Systems and Resources, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK*  
*Primary discussants: Dr. German, Dr. Stepkowski*

2:10-2:25 pm  
**Proposal 3:** Continuation of Programs to Standardize C-peptide and HbA1c Assays  
*Beena Akolkar, Ph.D., Senior Advisor, Immunopathogenesis and Genetics of Type 1 Diabetes, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK*  
*Primary discussants: Dr. Selvin, Dr. Sherwin*
2:25-2:45 pm Proposal 4: Continuation of the Collaborative Islet Transplantation Registry (CITR)
Thomas Eggerman, M.D., Ph.D., Program Director, Clinical Islet Transplantation Trials, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK
Primary discussants: Dr. Gill, Dr. Meigs

2:45-3:00 pm Topic 4 panel discussion led by primary discussants

3:00-3:15 pm BREAK

TOPIC 5: ATTRACTING NEW TALENT TO TYPE 1 DIABETES RESEARCH
Primary Discussants: Rudolph Leibel, M.D.; James Meigs, M.D.; Maike Sander, M.D.; Robert Sherwin, M.D.

3:15-3:25 pm Current Efforts in Attracting New Talent to Type 1 Diabetes Research
Judith Fradkin, M.D., Director, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK

3:25-3:40 pm Proposal 1: Type 1 Diabetes Pathfinder Award
Carol Renfrew Haft, Ph.D., Program Director, Senior Advisor for Cell Biology and Associate Director for Grants Administration, Division of Diabetes, Endocrinology, and Metabolic Diseases, NIDDK
Primary discussants: Dr. Sander, Dr. Sherwin

3:40-3:55 pm Proposal 2: Career Development Programs in Diabetes Research for Pediatric Endocrinologists
Carol Renfrew Haft, Ph.D., Program Director, Senior Advisor for Cell Biology and Associate Director for Grants Administration, Division of Diabetes, Endocrinology, and Metabolic Diseases, NIDDK
Primary discussants: Dr. Leibel, Dr. Meigs

3:55-4:05 pm Topic 5 panel discussion led by primary discussants

TOPIC 6: SMALL BUSINESS INNOVATION RESEARCH (SBIR) AND SMALL BUSINESS TECHNOLOGY TRANSFER (STTR)

4:05-4:15 pm Current Efforts in SBIR/STTR Research
Judith Fradkin, M.D., Director, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK

4:15-4:30 pm Presentations and Questions/Answers on:
Proposal 1: Towards a Bio-artificial Pancreas: Development of New Technologies for the Advancement of Cell Replacement Research for Type 1 Diabetes
Primary discussants: Dr. Gill, Dr. Sander

Proposal 2: Towards an Artificial Pancreas: Expansion of Support for Research to Develop New Therapeutics and Monitoring Closed-Loop Automated Technologies for Type 1 Diabetes
Primary discussants: Dr. Bergenstal, Dr. Hirsch
Guillermo Arreaza, M.D., Program Director, Clinical Immunology of Diabetes, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK

4:30-4:45 pm Panel Discussion on Proposals 1, 2 (~7 minutes of discussion for each proposal)
Led by Drs. Bergenstal, Gill, Hirsch, and Sander

4:45-5:00 pm Proposal 3: New Methods and Technologies for Assessment of Risk and for Early Diagnosis and Prognosis of Type 1 Diabetes
Guillermo Arreaza, M.D., Program Director, Clinical Immunology of Diabetes, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK
Primary discussants: Dr. Diamond, Dr. Salmon

5:00-5:15 pm Topic 6 panel discussion led by primary discussants

5:15-5:45 pm Day 1 closing discussion led by Dr. Judith Fradkin, NIDDK

April 9

TOPIC 7: AUTOIMMUNE ETIOLOGY, CLINICAL TRIALS, AND EPIDEMIOLOGY

8:00-8:10 am Current Efforts in Autoimmune Etiology, Clinical Trials, and Epidemiology
Judith Fradkin, M.D., Director, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK

8:10-8:25 am Proposal 1: Mechanisms Underlying the Contribution of Type 1 Diabetes Risk-associated Variants
Beena Akolkar, Ph.D., Senior Advisor, Immunopathogenesis and Genetics of Type 1 Diabetes, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK
Primary discussants: Dr. Gregersen, Dr. Leibel

8:25-8:40 am Proposal 2: Elucidating Mechanisms Underlying Clinical Heterogeneity in Type 1 Diabetes
Andrew Bremer, M.D., Ph.D., Program Director, Clinical Research on Type 2 Diabetes Prevention and Treatment in Adults, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK
Primary discussants: Dr. Klingensmith, Dr. Sherwin

8:40-8:55 am Proposal 4: SEARCH for Diabetes in Youth
Sharon Saydah, Ph.D., CDR USPHS, Senior Scientist, Division of Diabetes Translation, Centers for Disease Control and Prevention
Primary discussants: Dr. Meigs, Dr. Selvin
8:55-9:10 am  Proposal 5: Surveillance for Type 1 Diabetes among Young Adults
Sharon Saydah, Ph.D., CDR USPHS, Senior Scientist, Division of Diabetes Translation, Centers for Disease Control and Prevention
Primary discussants: Dr. Meigs, Dr. Selvin

9:10-9:25 am  Proposal 3: Validation of Self-report Measures of Type 1 Diabetes in National Surveys
Sharon Saydah, Ph.D., CDR USPHS, Senior Scientist, Division of Diabetes Translation, Centers for Disease Control and Prevention
Primary discussants: Dr. Meigs, Dr. Selvin

9:25-9:45 am  Proposal 6: Research Using Biosamples and Subjects from Selected Type 1 Diabetes Clinical Studies
Lisa Spain, Ph.D., Program Director, Immunobiology of Type 1 Diabetes and Autoimmune Endocrine Diseases, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK
Primary discussants: Dr. Hirsch, Dr. Salmon, Dr. Selvin

9:45-10:00 am  Proposal 7: Clinical Trials in People with Established Type 1 Diabetes and Endogenous Insulin Production
Lisa Spain, Ph.D., Program Director, Immunobiology of Type 1 Diabetes and Autoimmune Endocrine Diseases, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK
Primary discussants: Dr. Bluestone, Dr. Hirsch, Dr. Sherwin

10:00-10:15 am  BREAK

10:15-10:45 am  Proposal 8: Continuation of Type 1 Diabetes TrialNet
Lisa Spain, Ph.D., Program Director, Immunobiology of Type 1 Diabetes and Autoimmune Endocrine Diseases, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK
Primary discussants: Dr. Diamond, Dr. Eckel, Dr. Salmon

10:45-11:00 am  Presentations and Questions/Answers on:
Proposal 9: Immune Tolerance Network (ITN)
Proposal 9a: Preserving Beta Cell Function with Immune Modulators in New-Onset Type 1 Diabetes
Primary discussants: Dr. Eckel, Dr. Gregersen, Dr. Salmon

Proposal 9b: A Robust Technology Platform for Assessing Islet-specific Autoimmunity in Type 1 Diabetes Clinical Trials
Primary discussants: Dr. Gregersen, Dr. Salmon

Proposal 9c: ITN NOD Preclinical Consortium
Primary discussants: Dr. Calcutt, Dr. German

James McNamara, M.D., Acting Associate Director, Clinical Research Operations Program, Division of Allergy, Immunology, and Transplantation, NIAID

11:00-11:15 am  Panel Discussion on Proposals 9a, 9b, and 9c (~7 minutes of discussion for each proposal)
11:15-11:35 am Proposal 10: Continuation of Cooperative Study Group for Autoimmune Disease Prevention (CSGADP)
Thomas Esch, Ph.D., Section Chief, Autoimmune and Primary Immunodeficiency Diseases Section, Autoimmunity and Primary Immunodeficiency Diseases Branch, Division of Allergy, Immunology, and Transplantation, NIAID
Primary discussants: Dr. Bluestone, Dr. Diamond, Dr. Salmon

11:35-12:10 pm LUNCH

12:10-12:25 pm Presentations and Questions/Answers on:
Proposal 11: The Environmental Determinants of Diabetes in the Young (TEDDY)
Proposal 11a: Continued Follow-up of TEDDY Subjects
Primary discussants: Dr. Espeland, Dr. Gregersen
Proposal 11b: Immunological Assessments of TEDDY Subjects
Primary discussants: Dr. Diamond, Dr. Gregersen
Proposal 11c: Epigenetic Modifications in TEDDY Subjects
Primary discussants: Dr. Gregersen, Dr. Leibel

12:25-12:45 pm Panel Discussion on Proposals 11a, 11b, and 11c (~7 minutes of discussion for each proposal)
Led by Drs. Diamond, Espeland, Gregersen, and Leibel

12:45-1:00 pm Presentations and Questions/Answers on:
Proposal 12: Trial to Reduce IDDM in the Genetically at Risk (TRIGR)
Proposal 12a: Completion of Follow-up of TRIGR Participants
Primary discussants: Dr. Diamond, Dr. Espeland
Proposal 12b: A Multiomics Approach to the Pathogenesis of Type 1 Diabetes: Validation of the Omics Findings in TEDDY and Other Prospective Studies
Primary discussants: Dr. Diamond, Dr. German

1:00-1:15 pm Panel Discussion on Proposals 12a and 12b (~7 minutes of discussion for each proposal)
Led by Drs. Diamond, Espeland, and German

1:15-1:45 pm Topic 7 panel discussion led by primary discussants
TOPIC 8: BETA CELL: ASSESSMENT AND THERAPIES

1:45-1:55 pm  Current Efforts in Beta Cell Research  
Judith Fradkin, M.D., Director, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK

1:55-2:10 pm  Proposal 1: Development of Tools and Techniques to Enhance the Study of Type 1 Diabetes and its Complications in Zebrafish  
Kristin Abraham, Ph.D., Senior Advisor, Model Systems and Resources, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK  
Primary discussants: Dr. Calcutt, Dr. German, Dr. Sander

2:10-2:25 pm  Proposal 2: Clinical Validation of Biomarkers for Pancreatic Beta Cell Mass and Inflammation  
Maren Laughlin, Ph.D., Senior Advisor, Integrative Metabolism, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK  
Primary discussants: Dr. German, Dr. Leibel

2:25-2:40 pm  Proposal 3: Cellular Therapies for Type 1 Diabetes Consortium  
Nancy Bridges, M.D., Chief, Transplantation Branch, Division of Allergy, Immunology, and Transplantation, NIAID  
Primary discussants: Dr. Gill, Dr. Sander, Dr. Sherwin

2:40-2:50 pm  BREAK

2:50-3:00 pm  Proposal 4: Development of New Technologies for the Advancement of Cell Replacement Research for Type 1 Diabetes  
Guillermo Arreaza, M.D., Program Director, Clinical Immunology of Diabetes, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK  
Primary discussants: Dr. Bergenstal, Dr. Gill

3:00-3:15 pm  Proposal 5: In Vivo Cell Engineering to Protect or Replenish Functional Human Beta Cell Mass  
Olivier Blondel, Ph.D., Director, Endocrine Systems Biology Program, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIDDK  
Primary discussants: Dr. German, Dr. Leibel

3:15-3:35 pm  Proposal 6: Continuation of the Nonhuman Primate Transplantation Tolerance Cooperative Study Group (NHPCSG)  
Kristy Kraemer, Ph.D., Section Chief, Transplantation Basic Sciences Section, Transplantation Branch, Division of Allergy, Immunology, and Transplantation, NIAID  
Primary discussants: Dr. Gill, Dr. Stepkowski

3:35-3:50 pm  Topic 8 panel discussion led by primary discussants

3:50-4:00 pm  Patient perspective – Ms. Ellen Leake

4:00-4:45 pm  Closing discussion led by Dr. Judith Fradkin, NIDDK