

Special Statutory Funding Program for Type 1 Diabetes Research
Potential Initiative Concepts Should the Program Be Extended to Fiscal Year 2018

Purpose: This document describes concepts for new initiatives that could be pursued through the [Special Statutory Funding Program for Type 1 Diabetes Research](#) (Special Diabetes Program), should the Program be extended to fiscal year 2018 (FY18). If that occurs, the NIH plans to develop new Funding Opportunity Announcements (FOAs) to solicit grant applications from the scientific community to pursue these concepts. It should be noted that if there is an extension of the Special Diabetes Program, the timing of the extension may require a shorter-than-usual period between the issuance of any attendant FOAs and associated application receipt dates.

Background: On April 26-27, 2017, a panel of scientific and lay experts met in Rockville, Maryland, to provide input on draft concepts, put forth by the NIH and CDC, for initiatives that could be pursued with funds from the Special Diabetes Program in FY18-19, should the Program be extended. The Program's current authorization expires September 30, 2017. Based in part on input from the panel, and with consideration of research opportunities outlined in the current [Diabetes Research Strategic Plan](#), the NIH may pursue the initiatives described below, pending availability of future Program funds. To enhance competition for these funds and to allow investigators to develop proposals and collect preliminary data, the NIH wishes to apprise the broader scientific community of the anticipated funding opportunities, should the Special Diabetes Program be extended. The initiative concepts are organized around six broad topics related to research on type 1 diabetes.

This initiative concepts document is not a solicitation for grant applications. If the Special Diabetes Program is extended to FY18, applications for new and competing research associated with those funds will be solicited through FOAs that will be announced in the NIH Guide for Grants and Contracts (<https://grants.nih.gov/funding/about-nih-guide-to-grants-and-contracts.htm>) and posted on the Special Diabetes Program website (www.T1Diabetes.nih.gov). It is important to note that plans may change from what is described in this document based on factors such as availability of funds, additional scientific input from workshops and conferences, and emerging scientific opportunities.

Scientific Topic Area: Autoimmune Etiology, Clinical Trials, and Epidemiology

Immune System Engineering for Targeted Tolerance in Type 1 Diabetes: New research applications will be solicited to encourage research on type 1 diabetes-specific deactivation of immune responses through the development of tolerizing vaccines and/or inhibitory compounds. Research also would be encouraged to explore the prospects for engineering immune regulation during autoimmune attack through the direct manipulation of regulatory and other cell types for applications in cell therapy. A scientific [workshop](#) will be held on November 1-2, 2017, to explore research on this topic.

The Characterization and Discovery of Novel Autoantigens in Type 1 Diabetes: New research applications will be solicited to encourage discovery of new autoantigens and to

characterize the T-cell and humoral response to both new and previously identified autoantigens in type 1 diabetes. A scientific [workshop](#) will be held on October 31-November 1, 2017, to explore research on this topic.

Mass Spectrometric Assays for the Reliable and Reproducible Detection of Proteins/Peptides of Importance in Type 1 Diabetes Research: New research applications will be solicited to encourage development of mass spectrometric assays for some of the most commonly quantified proteins/peptides in type 1 diabetes research (*e.g.*, glucagon).

Research Using Subjects from Selected Type 1 Diabetes Clinical Studies [(Reissue) Living Biobank]: New research applications will be solicited to encourage ancillary studies using subjects from participating type 1 diabetes clinical trials and studies (*e.g.*, the Type 1 Diabetes TrialNet, clinical trials network). Ancillary studies are expected to generate scientific discoveries on the pathogenesis of type 1 diabetes, on biomarkers of disease progression, or on clinical responses to interventions.

Scientific Topic Area: Beta Cells – Assessment and Therapies

Development of New Technologies and Bioengineering Solutions for the Advancement of Cell Replacement Therapies for Type 1 Diabetes: New research applications will be solicited to encourage development of technologies to improve cell replacement interventions for type 1 diabetes treatment. Such technologies could include device, platform, and encapsulation technologies for engineering a bio-artificial pancreas; optimization of islet handling and preservation methods to enhance islet cell replacement/transplantation interventions; and techniques to maintain and expand human insulin-producing cells derived from stem/progenitor cells.

High-Resolution Exploration of the Human Islet Tissue Environment: New research applications will be solicited to encourage study of the human islet tissue environment by investigating the cellular and molecular identity and function of important islet architecture components (endocrine, immune, vascular, and neuronal), exploring the interactions and communication methods used by the islet environment's cell types and subtypes, and assessing the contribution of adjacent and neighboring tissues to islet cell function and dysfunction.

Discovery of Early Type 1 Diabetes Disease Biomarkers in the Human Pancreas (HIRN Consortium on Beta Cell Death and Survival [CBDS] [<https://hirnetwork.org/>]): New research applications will be solicited to encourage exploration of human pancreatic tissues toward discovery of early biomarkers of human type 1 diabetes pathogenesis, the development of clinical diagnostic tools for the detection and staging of early type 1 diabetes in at-risk or recently-diagnosed individuals, the description of specific signaling or processing pathways that may contribute to pathogenesis during the asymptomatic phase of type 1 diabetes, or the identification of therapeutic targets for the development of preventative or early treatment strategies.

Scientific Topic Area: Diabetes Complications

Research Using Subjects and Biosamples from Selected Type 1 Diabetes Clinical Studies-Complications: New research applications will be solicited to encourage ancillary studies using subjects and biosamples from participating type 1 diabetes clinical trials and studies (*e.g.*, the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications). Ancillary studies are expected to generate scientific discoveries on the complications of type 1 diabetes, toward developing biomarkers for the evaluation of new therapeutics for diabetes complications.

Scientific Topic Area: Clinical Management

Impact of the Use of Glucose Monitoring and Control Technologies on Health Outcomes and Quality of Life in Older Adults with Type 1 Diabetes (Reissue): New research applications will be solicited for clinical studies investigating the use of current and emerging blood glucose monitoring and insulin administration technologies (*e.g.*, novel self-monitoring and decision support systems, continuous glucose monitors and/or combinations of sensing and pancreatic hormone delivery devices in open- or closed-loop systems, or other adjuvant technologies), by older adults with type 1 diabetes, to determine if such interventions can improve their clinical and psychosocial outcomes.

Patient Reported Outcomes (PRO) in Type 1 Diabetes Research and Practice: New research applications will be solicited to encourage research to develop and accelerate the use of validated, generalizable, and standardized PRO measures in type 1 diabetes research and practice. A scientific [workshop](#) co-sponsored by NIDDK and the American Diabetes Association will be held November 6-7, 2017, to explore research on this topic.

Understanding Needs and Identifying Research Opportunities to Improve Treatment and Self-Management for Adults Living with Type 1 Diabetes: New research applications will be solicited to encourage investigation of the treatment needs, as well as the barriers to facilitators of good self-management, in adults with type 1 diabetes, specifically to understand how specific life issues (*e.g.*, building and caring for a family, establishing and maintaining a career) affect diabetes care and self-management, and to understand how to optimally manage diabetes in the context of age- and diabetes-related changes in health or living situation.

Scientific Topic Area: Artificial Pancreas

Clinical, Behavioral, and Physiological Studies of Closed-loop Systems: New research applications will be solicited to build on current technology and ongoing clinical research to address clinical, behavioral, and physiological barriers that limit progress toward development of a fully automated pancreatic hormone replacement closed-loop system. This includes research to test and improve the safety, reliability, and clinical efficacy of these technologies in humans; address behavioral/psychosocial factors that play a role in the usability and acceptability of these systems and validation of outcomes measures to demonstrate efficacy and benefit; test these technologies in subpopulations not usually included in clinical trials of these technologies but that may benefit most from their use; and use these technologies as tools to advance understanding of glucose regulation in people with type 1 diabetes.

Development and Integration of Novel Components for Open- and Closed-loop Hormone Delivery for Type 1 Diabetes Therapy: New research applications will be solicited to encourage development of new technologies to tackle the most important obstacles at the levels of sensing, hormone formulations and delivery, automated controllers, self-management decision support systems, and controllers/algorithms to manage an integrated platform (adaptable to remote monitoring and telemedicine when needed) for more physiological and personalized glucose control in individuals with type 1 diabetes.

Support for Small Business Innovation Research to Develop New Therapeutics and Monitoring Closed-Loop Automated Technologies for Type 1 Diabetes: New research applications will be solicited from small businesses to encourage development of novel and current technologies that may lead to the development or optimization of a clinically viable, portable, personalized, automated closed-loop/artificial pancreas system with commercial potential and high usability and acceptability to people with type 1 diabetes. Such technologies could include more effective fault-tolerant control systems algorithms, more durable and reliable hormone infusion systems, next-generation sensors (including non-invasive and long-term implantable devices), improved hormone replacement formulations, glucose-responsive biomaterials, and remote monitoring systems.

Scientific Topic Area: Resources

Career Development Programs for Diabetes Research for Adult Endocrinologists (K12 Program): New applications will be solicited to encourage research training and career development, with the goal of developing a highly trained workforce of adult endocrinologists to assume future leadership roles in type 1 diabetes research.