BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.

NAME: Darrell M. Wilson, M.D.

eRA COMMONS USER NAME (credential, e.g., agency login): wilson.darrell

POSITION TITLE: Professor, Pediatric Endocrinology & Diabetes

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of California, Davis CA	BS	03/1973	Electrical Engineering
University of California, San Diego CA	MD	06/1977	Medicine
Stanford University, Stanford CA		06/1980	Pediatric Residency
Stanford University, Stanford CA		06/1984	Pediatric Endocrinology Fellowship

A. Personal Statement.

I have a longstanding clinical research interest in the prevention and treatment of obesity and Type 2 diabetes in children and adolescents. I am a co-investigator on the current GOALS trial with Dr. Robinson and we have collaborated on clinical trials directed at reducing obesity for two decades and 12 publications. As in our prior and ongoing collaborations, I will provide expertise on measurement of changes in growth, body composition, and glucose and insulin metabolism. I will supervise methods and quality assurance aspects of the collection, processing and storage of biological samples for this trial, which will occur in my laboratory.

I served as the Principle Investigator of the multisite Glaser Foundation funded year-long trial of Metformin in obese adolescents, with included studies of the relationships among measures of regional fat and insulin resistance. Additionally I serve as the PI at Stanford University for the NIH funded, multi-center Type-1 Diabetes TrialNet Studies. My involvement in diabetes prevention clinical research began with the formation of TrialNet's progenitor, the Diabetes Prevention Trial (DPT-1) network. DPT-1 was initially assembled at the invitation of the NIH in 1993 to develop a protocol to determine if antigen based therapies could prevent or delay autoimmune mediated T1D. Stanford University -was one of the original ten national centers for the DPT-1, and I have served as the Stanford PI since the beginning. I have served as a center director within TrialNet for 20 years.

I am a co-investigator on the NIH funded, multi-center Diabetes Research in Children Network (DirecNet). Over the past decade, this group was initially devoted to testing how new technology such as glucose sensors can help children with diabetes, and has been extraordinarily productive. DirecNet continues now as 5 center group testing the hypothesis that dysglycemia has an adverse impact on brain development in young children.

Further, I am a co-investigator on a number of Juvenile Diabetes Research Foundation and Helmsley Foundation funded clinical investigations devoted to the development of artificial pancreas (JDRF Artificial Pancreas Project, the Continuous Glucose Sensor Human Clinical Trial, and the Artificial Pancreas Consortium).

An internationally known clinical researcher concentrating in the area of pediatric diabetes, I have published over 325 peer reviewed articles and chapters. I am a key member of Stanford University's clinical research infrastructure, serving as the Chair of one of Stanford's IRB panels, as well as a member on the NIH funded CTRU advisory committee. I am very experienced in the conduct of and analysis of clinical trials.

B. Positions and Honors.

Positions.

1984 1987 - Clinical Assistant Professor, Stanford University
1984-2015 - Director, Pediatric Diabetes Center, Packard Children's Hospital
1987-1993 - Assistant Professor, Stanford University
1988-2008 - General Clinical Research Center Advisory Committee

1994-2001 - Associate Professor, Stanford University
1998-2015 - Chief, Division of Pediatric Endocrinology and Diabetes, Stanford University
2001-2008 - General Clinical Research Center Safety Committee
2001-present - Professor, Stanford University
2004-present - Chair Panel 5 Stanford University Medical Committee for the Protection of Human Subjects
2008-present – Member, Clinical Research Translation Unit Advisory Board
2013-present – Member, CHYLD (Children with Hypoglycaemia and their Later Development) International Advisory Group and Steering Group

Honors.
1989-1993 - Editorial board: Journal of Clinical Endocrinology and Metabolism
1989-1994 - Board of Directors, Diabetes Society of Santa Clara Valley
1996-1998 - Board of Directors, American Diabetes Association, Palo Alto Chapter
2000-2008 - Board of Directors, Juvenile Diabetes Research Foundation, Silicon Valley Palo Alto Chapter
2000-present - Editorial board: Diabetes Technology and Therapeutics
2006-present - Editorial board: Journal of Diabetes Science and Technology
2008 – Honoree, Diabetes Society, Santa Clara, CA
2009 – Honoree, Juvenile Diabetes Research Foundation, San Francisco Chapter
2018 – Distinguished Medical Staff Award, Packard Children's Hospital, Stanford

C. Contribution to Science

Type 1 Diabetes Prevention: The overarching goal of NIH funded TrialNet study group is to develop and test intervention to prevent Type 1 diabetes mellitus (T1DM). Initially, the Diabetes Prevention Trial (DPT-1) network was created at the invitation of the NIH in 1993 to develop a protocol to determine if antigen based therapies could prevent or delay autoimmune mediated T1DM. As a charter member of DPT-1, I have led Stanford in this endeavor for over two decades. During these 20 plus years, Stanford has contributed extensively to all aspects of TrialNet's missions. Many promising interventions must be tested in a safe and efficient manner in order to achieve this goal. A well-organized cooperative network of capable institutes, the Type 1 Diabetes TrialNet group, has greatly facilitated the prompt completion of the many clinical trials needed to test these potential interventions. Additional details are at https://www.diabetestrialnet.org/

Stanford has taken the lead on the design and conduct of some of these studies and have enrolled subjects in essentially all TrialNet studies, both those studies directed at high risk pre-diabetes and new onset diabetes. The Stanford team is involved with the day-to-day conduct of trials, collecting and interpreting data, as well as preparing and reviewing publications.

Pescovitz MD, Greenbaum CJ, Krause-Steinrauf , Becker DJ, Gitelman SE, Goland R, Gottlieb PA, Marks JB, McGee PF, Moran AM, Raskin P, Rodriguez H, Schatz DA, Wherrett D, **Wilson DM**, Lachin JM, Skyler JS, for the Type 1 Diabetes TrialNet Anti-CD20 Study Group, Rituximab, B-Lymphocyte Depletion, and Preservation of Beta-Cell Function, New Engl J Med 361:2143-2152, 2009 PMID 19940299

Wherrett DK, Bundy B, Becker DJ, DiMeglio LA, Gitelman SE, Goland R, Gottlieb PA, Greenbaum CJ, Herold KC, Marks JB, Monzavi R, Moran A, Orban T, Palmer JP, Raskin P, Rodriguez H, Schatz D, **Wilson DM**, Krischer JP, Skyler JS, and the Type 1 Diabetes TrialNet GAD Study Group*. Antigen-based therapy with glutamic acid decarboxylase (GAD) vaccine in patients with recent-onset type 1 diabetes: a randomised double-blind trial. Lancet 2011 Jul 23;378(9788):319-27.PMID:21714999

Orban T, Bundy B, Becker DJ, DiMeglio L, Gitelman SE, Goland R, Gottlieb PA, Greenbaum CJ, Marks JB, Monzavi R, Moran AM, Raskin P, Rodriguez H, Russell WE, Schatz D, Wherrett D, **Wilson DM,** Krischer JP, Skyler JS and the Type 1 Diabetes TrialNet Abatacept Study Group. Co-Stimulation Modulation with Abatacept in Patients with Recent-Onset Type 1 Diabetes: A Randomized Double-Masked Controlled Trial. Lancet Jul 30;378(9789):412-9 2011 PMID:21719096

Moran A, Bundy B, Becker DJ, DiMeglio LA, Gitelman SE, Goland R, Greenbaum CJ, Herold KC, Marks JB, Raskin P, Sanda S, Schatz D, Wherrett DK, **Wilson DM**, Krischer JP, Skyler JS, for the Type 1 Diabetes TrialNet Canakinumab Study Group*, and Pickersgill L, de Koning E, Ziegler A, Böehm B, Badenhoop B, Schloot N, Bak JF,Pozzilli P, Mauricio D, Donath MY, Castaño L,Wägner A, Lervang HH, Perrild H, Mandrup-Poulsen T for the AIDA Study Group*, Lancet Lancet. 2013 Jun 1;381(9881):1905-15 PMID: 23562090

Haller MJ, Schatz DA, Skyler JS, Krischer JP, Bundy BN, Miller JL, Atkinson MA, Becker DJ, Baidal D, DiMeglio LA, Gitelman SE, Goland R, Gottlieb PA, Herold KC, Marks JB, Moran A, Rodriguez H, Russell W, **Wilson DM**, Greenbaum CJ and the Type 1 Diabetes TrialNet ATG-GCSF Study Group. Low-Dose Anti-Thymocyte Globulin (ATG) Preserves β-Cell Function and Improves HbA1c in New-Onset Type 1 Diabetes. Diabetes Care published ahead of print July 16, 2018, doi:10.2337/dc18-0494

Adolescent Obesity: Obesity in childhood, particularly during adolescence, is associated with significant future morbidity and mortality. Obesity greatly increases the risk for type 2 diabetes mellitus, hypertension, and cardiovascular disease. It is imperative that effective prevention and treatment modalities be identified to address the epidemic of childhood and adolescent obesity. Throughout my career, I have conducted trials of medical and lifestyle inventions designed to prevent and reverse obesity, including a large multi-site year long trial of metformin in obesity adolescents.

Robinson TN, Matheson DM, Kraemer HC, Wilson DM, Obarzanek, E, Thompson NS, Alhassan,S, Spencer, TR, Haydel KF, Fujimoto M, Varady A, Killen JD. A Randomized controlled trial of culturally-tailored dance and reducing screen time to prevent weight gain in low-Income African-American girls: Stanford GEMS. Arch Pediatr Adolesc Med. 2010;164(11):995-1004

Robinson TN, Matheson D, Desai M, Wilson DM, Weintraub DL, Haskell WL, McClain A, McClure S, Banda JA, Sanders LM, Haydel KF, Killen JD. Family, Community and Clinic Collaboration to Treat Overweight and Obese Children: Stanford GOALS -- a Randomized Controlled Trial of a Three-Year, Multi-Component, Multi-Level, Multi-Setting Intervention. Contemporary Clinical Trials Contemporary Clinical Trials 36 (2013) 421–435 PMID: 24028942

Shah S, Wilson DM, Bachrach LK. Large Doses of Vitamin D Fail to Increase 25-Hydroxyvitamin D Levels or to Alter Cardiovascular Risk Factors in Obese Adolescents: A Pilot Study. J Adolesc Health. 2015 Apr 11. S1054-139. PMID: 25873553

Evaluation of Diabetes Technology (Devices and Assays): Devices are increasingly important in the management of diabetes, particularly in children and adolescents. Glucose meters, glucose sensors, insulin infusion pumps, and integration devices such as smart phones now play a major role in diabetes management. Additionally, assays for hemoglobin A1c, C-peptide, and fructosamine are essential for monitoring and achieving good glycemic control. I conduct studies examining the accuracy and utility of these devices and assays in those with diabetes.

Wilson DM, Beck RW, Tamborlane WV, Dontchev MJ, Kollman C, Chase P, Fox LA, Ruedy KJ, Tsalikian E, Weinzimer SA. The Accuracy of the FreeStyle Navigator Continuous Glucose Monitoring System in Children With Type 1 Diabetes. Diabetes Care. 30:59-64, 2007 PMID: 17192334 .

DeSalvo DJ, Shanmugham S, Ly TT, **Wilson DM**, Buckingham BA. Accuracy evaluation of blood glucose monitoring systems in children on overnight closed-loop control. J Diabetes Sci Technol. 2014 Sep;8(5):969-73 PMID:24876427

Mazaika PK, Weinzimer SA, Mauras N, Buckingham B, White NH, Tsalikian E, Hershey T, Cato A, Aye T, Fox L, **Wilson DM**, Tansey M, Tamborlane W, Peng D, Raman M, Marzelli M, Reiss AL, for the Diabetes Research in Children Network. Variations in brain volume and growth in young children with type 1 diabetes, Diabetes 2016 Feb;65(2):476-85. doi: 10.2337/db15-1242. Epub 2015 Oct 28.PMID: 26512024

Prahalad P, Addala A, Buckingham B, **Wilson, DM**, and Maahs, DM. Sustained Continuous Glucose Monitor Use in Low-Income Youth with Type 1 Diabetes Following Insurance Coverage Supports Expansion of Continuous Glucose Monitor Coverage for All. Diabetes Technology & Therapeutics Volume 20, Number 9, 2018

Development of the Artificial Pancreas: The management of insulin dependent diabetes is particularly challenging for children, adolescents and their families. Given my undergraduate degree in Electrical Engineering, I have had a particular interest in the automatic control of insulin delivery based on glucose sensor data. I am an investigator on many studies designed to develop and test algorithms, safety features, and hardware essential for practical artificial pancreas systems.

Cameron F, **Wilson DM**, Buckingham BA, Arzumanyan H, Clinton P, Chase HP, Lum J, Maahs DM, Calhoun PM, Bequette BW. Inpatient Studies of a Kalman-Filter-Based Predictive Pump Shutoff Algorithm J Diabetes Sci Technol 2012;6(5):1142-1147 PMID:23063041

Ly TT, Breton MD, Keith-Hynes P, De Salvo D, Clinton P, Benassi K, Mize B, Chernavvsky D, Place J, **Wilson DM**, Kovatchev BP, Buckingham BA. Overnight glucose control with an automated, unified safety system in children and adolescents with type 1 diabetes at diabetes cAMP. Diabetes Care. 2014 Aug;37(8):2310-6 PMID:2487984

Wilson DM, Calhoun P, Maahs MA, Chase HP, Messer L, Buckingham BA, Aye T, Clinton P, Hramiak I, Kollman C, Beck RW for the In Home Closed Loop Study Group Factors Associated With Nocturnal Hypoglycemia in at Risk Adolescents and Young Adults with Type 1 Diabetes, Diabetes Technology and Therapeutics 2015 17(6):385-91. PMID:25761202 PMCID: PMC4432491

El-Khatib FH, Balliro C, Hillard MA, Magyar KL, Ekhlaspour L, Sinha M, Mondesir D, Esmaeili A, Hartigan C, Thompson MJ, Malkani S, Lock JP, Harlan DM, Clinton P, Frank E, **Wilson DM**, DeSalvo D, Norlander L, Ly T, Buckingham BA, Diner J, Dezube M, Young LA, Goley A, Kirkman MS, Buse JB, Zheng H, Selagamsetty RR, Damiano ER, Russell SJ. Home use of a bihormonal bionic pancreas versus insulin pump therapy in adults with type 1 diabetes: a multicentre randomised crossover trial. Lancet. 2016 Dec 20. pii: S0140-6736(16)32567-3. doi: 10.1016/S0140-6736(16)32567-3. [Epub ahead of print] PMID: 28007348

Spaic T, Driscoll M, Raghinaru D, Buckingham BA, **Wilson DM**, Clinton P, Chase HP, Maahs DM, Forlenza GP, Jost E, Hramiak I, Paul T, Bequette BW, Cameron F, Beck RW, Kollman C, Lum JW, Ly TT. Predictive Hyperglycemia and Hypoglycemia Minimization: In-Home Evaluation of Safety, Feasibility, and Efficacy in Overnight Glucose Control in Type 1 Diabetes. In-Home Closed-Loop (IHCL) Study Group. Diabetes Care. 2017 Mar;40(3):359-366. doi: 10.2337/dc16-1794. Epub 2017 Jan 18.PMID:28100606

D. Additional Information: Research Support and/or Scholastic Performance
Ongoing Research Support

5 U01 DK6104210-02 Wilson (PI) 07/01/14-06/30/19
NIH
Type 1 Diabetes TrialNet at Stanford
This is a project designed to see if Type 1 diabetes can be prevented or delayed in high risk relatives and to see if endogenous insulin secretion can be preserved in subjects with new onset T1D.

ITN058A1 Wilson (PI) 02/01/15 – 01/31/21
Immune Tolerance Network (NIH)
Preserving Beta-Cell Function with Tocilizumab in New-onset Type 1 Diabetes
To test tocilizumab in new-onset type 1 diabetes

ITN257 (SPO 132226)) Wilson (PI) 02/01/17 – 01/31/21

Immune Tolerance Network (NIH)
T1DES Follow–up of initial participants participated in T1DAL, receiving alefacept, and AbATE, receiving teplizumab
Role: PI
Major Goal: Followup for the teplizumab study
Overlap: None

(SPO 128438) Wilson (PI) 10/01/17 – 09/30/2019
Juvenile Diabetes Research Foundation
Advancing a High Through-put, Ultrasensitive and Multiplex Auto Antibody Panel
Major Goal: Prevention of autoimmune mediated Type 1 diabetes mellitus. (T1DM)
Overlap: None

3002224007 Reiss, Allan (PI) 09/10/14 – 05/31/19
Stanford (NIH)

Type 1 Diabetes and the Brain in Children: Metabolic Interventions
Role: Co-Investigator
Goal: Longitudinal evaluation of diabetes on the developing brain

Completed Research Support

U01 HL103629-01 Robinson (PI) 05/01/14 – 04/30/18
NIH Clinic, Family & Community Collaboration to Treat Overweight and Obese Children:
Role: Co-Investigator
Obesity prevention in young child

17-2013-528 Feldman (PI) 09/01/13 – 08/31/16
Juvenile Diabetes Research Foundation NCX 8/31/17
Nano-Engineered Plasmonic Chip for Monitoring of Novel T1D Biomarkers.
Role: Co-Investigator
Goal: Assay technology

17-2013-471 Buckingham (PI) 11/01/13 – 06/30/16
Juvenile Diabetes Research Foundation International
Predicting Infusion Set and CGM Failure in Artificial Pancreas Systems
Role: Co-Investigator
To predict infusion set and CGM failure in pancreas systems

5RO1 DK085591-03 Buckingham (PI) 09/30/09 – 08/31/16
NIH CFDA 93-847
In Home Closed Loop Reduction of Nocturnal Hypoglycemic and Daytime Hyperglycemia
Role: Co-Investigator
This study examines at home closed loop.

138705 Diabetes TrialNet Wilson (PI) 07/01/11 - 12/31/18
University of South Florida (NIH)
TrialNet Screening and DPT-1 Follow Up Studies
Role: PI