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Shared Medical Decision Making in Pediatric Diabetes

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Procedure Manual

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Shared Medical Decision Making in Pediatric Diabetes: Randomized, Controlled Trial

PROCEDURE MANUAL

Principal Investigator: Tim Wysocki, Ph.D., A.B.P.P.

Title: Co-Director, Center for Health Care Delivery Science and Principal Research Scientist

Study Sponsor: Patient-Centered Outcomes Research Institute (www.pcori.org)

Organization:
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PROJECT INFORMATION

Project Title: Shared Medical Decision Making in Pediatric Diabetes

Project Start Date: 4/1/2013

Project End Date: 3/31/2016

Awarded Amount: $1,500,000 Direct Costs; $2,092,090 Total Costs

Shared Medical Decision Making in Pediatric Diabetes: Randomized, Controlled Trial
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Abstract (modified after achievement of Aims 1 and 2):

Treatment adherence in type 1 diabetes (T1D) tends to decline among adolescents, increasing risks of acute and chronic complications, excess health care use, poorer quality of life, and T1D-related family conflict. Poor adherence is associated with psychiatric and family dysfunction and often persists into early adulthood. Therapeutic advances such as continuous subcutaneous insulin infusion (CSII or "insulin pump") and continuous glucose monitoring (CGM) could improve metabolic control and quality of life. But, teens often do not benefit fully from such advances. Many studies of adults show that patient-centered communication styles predict more favorable clinical outcomes. Shared medical decision making (SMDM) interventions have improved outcomes among adults with diabetes and other conditions. Research in pediatrics has also shown that patient-centered and family-centered communication styles predict favorable outcomes, but most of this research is in primary care and has not studied youth with chronic conditions. Since there have been no controlled trials of SMDM with chronically ill youths, we propose a randomized controlled trial of an SMDM intervention compared with Usual Clinical Practice (UCP). Qualitative interviews of youths and parents who have previously faced these decisions and reliance on expert consultants, pediatric endocrinologists and diabetes educators have preceded this trial and provided valued input for refining the planned intervention and adapting the structured SMDM format for pediatrics. Now, we will recruit and randomize 166 11-<17 year old youth with T1D who are candidates for CSII or CGM (and a parent/caregiver) at all Nemours sites. The SMDM intervention will be delivered via a web-based platform, facilitated by Diabetes Educators (DEs) at each site in a standardized, yet individually tailored format. SMDM will employ multimedia “decision aids” prepared with the award-winning Nemours Center for Children’s Health Media and the “e-city interactive” web design firm in Philadelphia in accord with pertinent international standards. SMDM will also include individualized assistance from the DE in assuring that each youth’s and parent’s preferences, values and cultural beliefs are carefully addressed and communicated to the attending endocrinologist. After a baseline evaluation and randomization to SMDM or UCP, effects on the primary outcome (treatment adherence; device utilization) and secondary outcomes (glycemic control, treatment alliance, decision conflict and regret, treatment satisfaction, diabetes-related distress and self-efficacy) will be measured over 1 year. Mixed effects modeling will be the primary analytic technique for evaluating effects on primary/secondary outcomes, examining selected variables as moderators and mediators of treatment effects, and assessing whether such effects are comparable for the two medical decisions of interest. The results will verify whether SMDM in this context enhances treatment adherence, device use and parent/patient-reported outcomes in youth with T1D.

KEY PERSONNEL

Name	E-mail	Organization	Role
Doyle, Daniel	Daniel.doyle@nemours.org	AIDHC	Physician/Co-I
Ross, Judith	judith.ross@jefferson.edu	Thomas Jefferson U	Physician/Co-I
Kummer, Mark	mkummer@nemours.org	NCC – Pensacola	Physician/Co-I
Carakushansky, Mauri	mcarakus@nemours.org	NCC-Orlando	Physician/Co-I
Wadwa, Paul	Paul.Wadwa@ucdenver.edu	Barbara Davis Ctr, Denver	Physician/Co-I
Hossain, Jobayer	jhossain@nemours.org	AIDHC	Co-I/Statistician
Brinkman, William	Bill.Brinkman@cchmc.org	Cincinnati Children's Hosp	Physician/Consultant
Lawson, Margaret	Lawson@cheo.on.ca	Children's Hosp E. Ontario	Physician/Consultant
Fiks, Alexander	FIKS@email.chop.edu	Children's Hosp Philadelphia	Physician/Consultant

BUDGET SUMMARY FOR ENTIRE PROPOSED PROJECT PERIOD

Personnel Direct Costs	Year 1	Year 2	Year 3	Totals
Salaries	$162,081	$271,919	$317,414	$751,414
Fringe Benefits	$48,624	$81,576	$95,224	$225,424
Sub Totals	$210,705	$353,495	$412,638	$976,838
Other Direct Costs				
Consultant Costs	$4,000	$4,000	$4,000	$12,000
Supplies (Kids Health & e-city interactive, inc.)	$252,193	$119,403	$43,610	$415,206
Travel	$10,000		$8,000	$18,000
Other Expenses	$5,000	$5,000	$8,000	$18,000
Consortium /Contract	$18,102	$18,102	$18,102	$54,306
Sub Totals	$289,295	$146,505	$81,712	$517,512
Indirect Costs	$200,000	$200,000	$197,740	$597,740
Sub Totals	$200,000	$200,000	$197,740	$597,740
Budget Totals	$700,000	$700,000	$692,090	$2,092,090

FIRST YEAR DETAILED BUDGET JUSTIFICATION

Personnel:

Funds were awarded to support Dr. Wysocki's salary as Principal Investigator at 3.6 calendar months (30% FTE) in Year 1, 2.4 calendar months (20%) in Year 2 and 4.2 calendar months (35%) in Year 3. Dr. Wysocki will maintain overall responsibility for implementing, monitoring, analyzing and disseminating the proposed work. He will be responsible for personnel and fiscal management, training and supervision of project staff, communication with colleagues at the participating sites, the responsible conduct of the research and protection of participants' rights, relationships with external consultants and the project statistician, and the analysis, interpretation and dissemination of the project results.

Support was awarded for Senior Research Coordinator Alex Taylor, M.A.C.P. as Project Coordinator for 6 calendar months (50% FTE) in all 3 project years. She will have overall responsibility for ensuring the appropriate collection, transmission and management of study data from the clinical sites to Nemours Children's Clinic in Jacksonville. She has performed similar roles in several of Dr. Wysocki's prior NIH grants over the past 19 years.

Support was awarded for a 50% Diabetes Educator (DE). This budgeted amount will be dedicated to supporting DEs at each site based on an estimated "extra" time commitment of 6 hours per patient and parent who are assigned to the SMDM group. The DE will see each SMDM family for two study visits: the first visit will be an orientation of the participants to the decision aids and web platform and registration of the family on the website; the second visit will consist of a consultation about the family's experience with the decision aid and the preparation of a post-SMDM assessment report. The DE will transmit the participants' electronic self-assessment generated by the decision aid and the post-SMDM assessment report to the attending endocrinologist for further consideration and discussion with the adolescent and parent.

Support was awarded for 5% FTE appointment for all 3 years of the project for Jobayer Hossain, Ph.D. who will function as the project statistician. Dr. Hossain has foundation-wide responsibility to provide statistical expertise to investigators at all Nemours sites. He is the statistician on Dr. Wysocki's study "Clinician-Patient-Parent Communication in Pediatrics" and they are collaborating on a grant in preparation regarding prevention of child obesity. Dr. Hossain an expert at such analytic techniques as individual growth modeling, mixed models, and hierarchical growth modeling which are central to the analysis plan for the proposed work.

Support was also awarded for 5%FTE appointments for four pediatric endocrinologists, who will function as co-investigators for all 3 years of this project. These are Drs. Daniel Doyle (Wilmington, DE), Judith Ross (Philadelphia, PA), Mauri Carakushansky (Orlando, FL), and Mark Kummer (Pensacola, FL). These physicians have participated in the preparation of this application and will perform several important roles. They participated in the Qualitative Interview Study and helped in engaging other health care providers to do the same, ensuring that the perspectives of expert clinicians and diabetes educators are reflected in the multimedia decision aids and the SMDM intervention. For the randomized controlled trial, they will identify and recruit eligible participants, manage the study patients clinically, coordinate the medical management of enrolled participants and participate in preparing abstracts, posters and journal articles. These physicians have fulfilled similar roles in Dr. Wysocki's ongoing NIH-funded trial of continuous glucose monitoring in adolescents with T1DM.

Funds were awarded to support a Research Coordinator/Specialist at each Nemours site throughout the project. The coordinators will probably be recruited from among research coordinators and/or specialists who are already employed at the various sites and they will each be reassigned to this study for at 40% FTE in Year 2 and 50% FTE in Year 3. All of these individuals possess degrees in relevant disciplines and several years of relevant research experience. They will recruit participants and obtain signatures on parental permission and adolescent assent forms. The Research Coordinators will manage the collection of project data and its transmission to the coordinating center. Clinic staff (MD and DE) will identify potentially eligible participants, but all of the other recruitment, informed consent, data collection and other research duties will be the responsibilities of these research staff.

Consultant Costs:
Funds were awarded to support three consultants at $1,000 per year each for all three years of the project. William Brinkman, M.D. of Cincinnati Children's Medical Center has published extensively on shared medical decision making in the context of pediatricians' management of children with attention deficit hyperactivity disorder. Alex Fiks, M.D. of the Children's Hospital of Philadelphia has also published extensively on this same topic and he is also an accomplished qualitative researcher. Margaret Lawson, M.D. is a board certified pediatric endocrinologist with extensive clinical and research experience in type 1 diabetes. She also directs a Shared Medical Decision Making Service at the Children's Hospital of Eastern Ontario. All three of these physicians has extensive familiarity with the International Patient Decision Aids Standards and they will assist the research team in ensuring that the CSII and CGM decisions developed for this study meet those standards. They are also experts in measurement methods that pertain to shared medical decision making.

Supplies:
Results HbA_{1C} tests conducted routinely at the point of care at each clinic visit for study participants will be retrieved from the EMR for use as a secondary outcome measure. Thus, there will be no laboratory costs incurred to this grant for collection of those important data.

Gathering information about the use of the CGM and insulin pump provides some of the key data for the study. We have budgeted a $5 payment to adolescents for completing the Insulin Pump Use Profile and $5 for completing the CGM Use Profile. Noting that some patients will be using two of these types of devices, these amounts total an estimated $6,640 for the entire study, which has been distributed across project years in the budget. Additional incentives are provided in the form of $25 gift cards provided to each family in exchange for completing the scheduled questionnaires and other study measures at Visits 1, 3, and 5 during the study, which are the most burdensome of the study visits. These costs total $12,450 ($25 X 166 patients X 3 visits/patient) and have been distributed equally across Years 2-3.

KidsHealth/Nemours Diabetes Decision Aids/Multimedia Project

A key category of expenses that will be incurred during the study consists of the costs associated with planning, creating and refining the multimedia decision aids for internet delivery that will be central elements of the proposed SMDM intervention. These costs were estimated in consultation with Nemours Center for Children's Health Media based on their extensive experience in budgeting recent similar projects and include the costs of developing and producing multimedia content for distribution via a web platform. Decision aids will be created for Continuous Subcutaneous Insulin Infusion (insulin pump) therapy and Continuous Glucose Monitoring. A detailed outline of the planned content for each of the decision aids appears in the Appendix. The total of $342,340 (Year 1: $247,193; Year 2: $95,147) reflect the costs estimated based on past production of similar internt educational programs. In Year 1, the requested support would be dedicated to Editorial Costs (Producer, Medical Review, Editing, Scriptwriting, Copy Editing): $14,832; Design (Art Direction, Illustration, Medical Review): $22,247; and Production/Post-Production Costs (Producer, Medical Review, Studio rental, Talent fees, Production/shoot days, Music, Audio mixing, Post-production, Web Formatting): $210,114. In Year 2, the requested support would be dedicated to Editorial Costs: $5,709; Design: $8,563; and Production/Post-Production Costs: $80,875.

KidsHealth's Responsibilities
1. Review and editing of content outlines (to determine what can and can't be incorporated into the video programs)
2. Scriptwriting
3. Pre-production (casting for host, assistance in screening and casting teens and families, shooting locations acquisition)
4. Art Creation (storyboarding and production of medical illustrations and animations upon final approval of scripts)
5. Production (hiring of crew, shooting within Nemours and at off-site locations in DE area)
6. Post-Production (video editing, facilitating review of videos, voiceover recording, music selection)
7. Delivery of a beta-test version of each decision aid for final review and editing by adolescents, parents and health care professionals.
8. Final delivery of Web application

Dr. Wysocki's Team Responsibilities
1. All content research, to be delivered to NCCHM in the form of detailed outlines
2. Assembly of core content review committee, who will review scripts and videos per schedule
3. Review and editing of scripts, medical illustrations/animations, and videos (in various stages of completion) per schedule
4. Search and screening of local teens and families to appear on camera in both speaking and nonspeaking roles

5. Recruitment of Nemours medical staff to appear on camera and as on-set advisors for all clinical scenes
6. Assistance in clearing and acquiring shooting locations within Nemours as needed (e.g. hospital rooms, exam rooms, etc.)
7. Acquisition of all needed props (e.g. various types of insulin pumps, etc.)

About KidsHealth
KidsHealth.org has separate areas for parents, kids, and teens, each with its own focus and flavor – and has a huge, constantly updated library of physician-reviewed, jargon-free content consisting of over 10,000 articles, movies, animations, and other features. In addition, the Center develops a companion site, KidsHealth in the Classroom, which provides free grade-appropriate health curricula to teachers, school nurses, coaches, and others that work with children and teens.

KidsHealth.org has received numerous juried-awards, including 4 Webbys as Best Family/Parenting Site and Best Health Site online. The National Library of Medicine, through its publically-facing Medline Plus site, links to over 1,200 KidsHealth articles. The approach of KidsHealth, which focuses on both "hard" medical issues with emotional issues, is recognized as a model of effective, engaging communication.

In addition to the KidsHealth.org website, the Center provides widely distributed education through partnerships with over 50 of the nation's children's hospitals, and well as about 200 other media, governmental, and corporate partnerships - providing them with KidsHealth content as their online education. The Center is the largest single provider of online educational content to children's hospitals in the nation.

Travel:
Support for travel is requested in Year 1 for 4 co-investigators to come to Jacksonville for a study planning meeting. The cost is estimated at $2,000 per person per trip. Support for travel is requested in Year 1 for 1 investigator to attend a relevant professional conference and in Year 3 for 4 investigators to attend relevant professional conferences. The cost is estimated at $2,000 per person per trip.

Inpatient Care Costs:
None

Outpatient Care Costs:
None

Consortium/Contractual Costs:
We have established a subcontract with Thomas Jefferson University to cover the personnel costs associated with supporting Judith L. Ross, M.D. for 0.6 calendar months per year (5% FTE) for all 3 years of the project as a Co-Investigator. Dr. Ross is a board certified pediatric endocrinologist who will serve as the co-investigator for the Nemours-Jefferson Pediatrics site in a role equivalent to that of Drs. Kummer, Carakushansky and Reeves, each of whom are Nemours employees. The TJU fringe benefit rate of 29.3% of salary, and the PCORI indirect cost rate of 40% have been applied to this subcontract. A letter of commitment from Thomas Jefferson University to enter into this subcontract accompanies this application. Note: This subcontract will be voided effective January 1, 2015 when Dr. Ross and the other research staff at Nemours-Jefferson Pediatrics will become Nemours employees.

We have established a subcontract withThe Barbara Davis Center for Childhood Diabetes, the only freestanding pediatric diabetes treatment center in the US. Affiliated with the University of Colordao College of Medicine and Children's Hospital of Colorado, BDC manages over 3,300 pediatric patients with type 1 diabetes. A subcontract with the Barbara Davis Center would commit BDC to the recruitment of 80 eligible patients/parents between June 1 and November 30, 2015 and to maintain study follow-up over the following 12 months for each participant. The subcontract would cover the personnel costs (salary plus fringe benefits) for the involvement of Paul Wadwa, M.D. as a co-investigator on this project, Sally Sullivan, RN CDE as Diabetes Nurse and Cierra Sullivan as Research Assistant.

Other Expenses:
Support was awarded for $3,000 for publication costs in Year 3 for such expenses as journal page

charges, preparation and printing of posters, graphic and medical illustration services, abstract and poster submission fees and other expenses related to the dissemination of study results.

Support was awarded for reimbursement of 10 members of the Family Advisory Council in the amount of $500 per year per member to offset their costs for travel, child care, etc. incurred due to their service on this important committee.

We were awarded $5,000 per year in Years 1 and 2 and $8,000 in Year 3 to cover the costs of participation incentives in the form of $25 gift cards per family for questionnaire completion and $5 gift cards for bringing insulin pumps or CGMs to study visits for downloads. These funds will enable us to offer reimbursement for travel costs, meals, parking and child care for low-income participants, particularly those who are members of racial and ethnic minority groups. Reduction of these practical barriers to study enrollment and retention is critical to achieve the sampling objective of enrolling 24% of the full sample of participants from racial and ethnic minority groups. In addition to its humanistic value, the achievement of sufficient minority representation is crucial from a scientific standpoint since this would permit analyses to determine if the tested intervention is equally effective with important sub-groups of the population.

Equipment:
None

Other Sources of Funding:
None

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Tim Wysocki, Ph.D., A.B.P.P.	POSITION TITLE Principal Research Scientist and Co-Director, Center for Health Care Delivery Science; Chairperson, Nemours IRB #2 and IRB #3
eRA COMMONS USER NAME Twysocki	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
U. of Texas	BS	1972	Psychology
U. of Texas	MA	1976	Psychology
Western Michigan University	PhD	1980	Psychology
Johns Hopkins School of Medicine	Post-Doc	1981	Pediatric Psychology

A. Personal Statement

My role in this project is as Principal Investigator with overall responsibility for study coordination, management of human and fiscal resources and the responsible conduct of the proposed research. I will coordinate the design and production of the two decision aids for internet delivery with our study consultants and our partners at KidsHealth and E-City Interactive. I will oversee both the qualitative interview study in the first year of the project and the randomized controlled trial of shared medical decision making in the latter two years. I will consult with the project statistician about the analysis, interpretation and dissemination of the resultant research findings.

I have earned over $20M in continuous NIH and other external funding since 1992 for my research on family adaptation to pediatric type 1 diabetes (T1D) that has been completed at Nemours Children's Health System. This work includes studies of the developmental psychology of family management of T1D, efficacy trials of behavioral interventions to promote T1D management, studies of youth and parent coping with risks of long-term diabetic complications and investigations into how families adapt to technological advances such as insulin pump therapy and continuous glucose monitoring. I was the only non-physician Principal Investigator and a member of the protocol steering and writing committees of the NIH-funded Diabetes Research in Children Network and the Juvenile Diabetes Research Foundation's (JDRF) Continuous Glucose Monitoring Research Group. My current NIH grant supports an efficacy trial of a behavioral intervention to enhance adolescents' benefits from continuous glucose monitoring. I was also recently awarded a Department of Defense grant to study variables affecting maintenance of clinical proficiency among pediatricians and to test electronic decision support systems to promote it. I received the 2006 Award for Distinguished Research from the Society of Pediatric Psychology (2006) and am incoming President of that organization. With the JDRF Continuous Glucose Monitoring Research Group, I shared in receiving the 2011 JDRF Award for Excellence in Clinical Research. I am an Associate Editor of the Journal of Pediatric Psychology and on the editorial boards of Health Psychology and Pediatric Diabetes. I have chaired two Nemours IRBs since 2001 and played a key role in the organization's acquisition of certification by the Association for Accreditation of Human Research Protection Programs. I became Co-Director of the newly created Nemours Center for Healthcare Delivery Science in August of 2012 and share that role with Anne Kazak, Ph.D., A.B.P.P. We are jointly charged with fulfilling the mission of that center to develop a premier program for family-centered comparative effectiveness research in pediatrics and to promote Nemours' contributions to translation and dissemination of health care delivery science throughout and beyond the Nemours enterprise. As this center has developed over the past year, Nemours has invested generously in infrastructure that positions the center exceptionally well to facilitate the conceptualization, planning, implementation and dissemination of research such as the work proposed in this application. Among Nemours' principal objectives in creating the Center for Health Care Delivery Science is that the center would stimulate research that evaluates approaches to patient activation such as that proposed here.

B. Positions and Honors

9/81-9/86: Assistant Professor of Pediatrics, Texas Tech University Health Sciences Center; Staff Psychologist, Lubbock General Hospital.

9/86-11/92: Assistant (9/86) to Associate Professor (8/92) of Pediatrics, Ohio State University College of Medicine. Staff Psychologist, Nationwide Children's Hospital, Columbus, OH.

11/92-1/04: Chief, Division of Psychology and Psychiatry, Nemours Children's Clinic, Jacksonville, FL;

4/01: Professor of Psychology in Psychiatry, Mayo Clinic College of Medicine, Jacksonville campus.

1/04-Present: Principal Research Scientist, Nemours Children's Clinic

11/92-Present: Director, Center for Pediatric Psychology Research, Nemours Children's Clinic; Courtesy Professor of Clinical & Health Psychology, University of Florida.

1/01-Present: Chairperson, Nemours IRB #2 (Pediatrics) and Nemours IRB #3 (Oncology).

08/12-Present: Co-Director, Nemours Center for Health Care Delivery Science

Professional Service and Honors

Editorial Boards: Diabetes Forecast, 1994-96; Diabetes Spectrum, 1995-97; Journal of Applied Behavior Analysis, 1995-97; Diabetes Care, 1998-2000; American Journal of Diabetes 2003-2006; Associate Editor, Journal of Pediatric Psychology, 2008-2015; Health Psychology, 2011-2014; Pediatric Diabetes, 2011-2014.

Society Offices: Chairperson, Council on Behavioral Medicine and Psychology, American Diabetes Association, 1990-92. Advisory Council Member, International Society for Pediatric and Adolescent Diabetes 2010-2011. Currently, candidate for President-Elect, Society of Pediatric Psychology.

Grant Reviewing: NIH Behavioral Medicine IRG 1992-1998; NIH Behavioral Medicine Interventions and Outcomes IRG 2012-2015; Numerous NIH and CDC IRG's and Special Emphasis Panels since 1998; American Diabetes Association Research Grant Review Panel, 1998-2001; Juvenile Diabetes Research Foundation Medical Research Review Committee, 2010-2011.

Licensure & Certification: Licensed Psychologist, State of Florida (#PY4811); Diploma in Clinical Health Psychology, American Board of Professional Psychology (Diploma #5125). Certified IRB Professional, Applied Research Ethics National Association, since October, 2003.

Statewide Committees: Florida Department of Health, Governor's Diabetes Advisory Panel; 2003-2007.

National Awards: 2006 Logan Wright Award for Distinguished Research, Society of Pediatric Psychology; JDRF Mary Tyler Moore & Robert Levine, MD Award for Excellence in Clinical Research in 2011.

C. Selected publications (of 271 journal articles, abstracts, invited articles, books and chapters).

1.) Wysocki, T., Harris, M.A., Greco, P., Bubb, J., Elder, C.L., Harvey, L.M., McDonell, K., Taylor, A., & White, N.H. (2000). Randomized, controlled trial of behavior therapy for families of adolescents with insulin-dependent diabetes mellitus. *Journal of Pediatric Psychology, 25*, (1) 23-33.

2.) Wysocki, T., Harris, M.A., Wilkinson, K., Sadler, M., Mauras, N., & White, N.H. (2003). Self management competence as a predictor of outcomes of intensive therapy or usual care for children with type 1 diabetes mellitus. *Diabetes Care, 26*, (7), 2043-2047.

3.) Wysocki, T., Harris, M.A.,Buckloh, L.M., Mertlich, D., Lochrie, A.S., Taylor, A., Sadler, M., Mauras, N., & White, N.H. (2006). Effects of behavioral family systems therapy for diabetes on adolescents' family relationships, treatment adherence and metabolic control. *Journal of Pediatric Psychology, 31* (9), 928-938.

4.) Diabetes Research in Children Network (DirecNet) Study Group. (2006). Psychological aspects of continuous glucose monitoring in pediatric diabetes. *Pediatric Diabetes, 7*, 32-38 (Chair of Writing Committee)

5.) Buckloh, L.M., Lochrie, A.S., Antal, H., Milkes, A., Canas, J.A., Hutchinson, S., & Wysocki, T. (2008). Diabetes complications in youth: qualitative analysis of parents' perspectives of family learning and

knowledge. *Diabetes Care, 31*, 1516-1520.

6.) JDRF Continuous Glucose Monitoring Study Group. (2008). Continuous glucose monitoring and intensive treatment of type 1 diabetes in adults and children. *New England Journal of Medicine, 359*, (14), 1464-76.

7.) Wysocki, T., Iannotti, R., Weissberg-Benchell, J., Hood, K., Laffel, L., Anderson, B.J., & Chen, R. (2008). Diabetes problem solving by youths with type 1 diabetes and their caregivers: measurement, validation and longitudinal associations with glycemic control. *Journal of Pediatric Psychology, 33*, (8), 875-884.

8.) JDRF Continuous Glucose Monitoring Study Group. (2009). Factors Predictive of Use and of Benefit from Continuous Glucose Monitoring in Type 1 Diabetes. *Diabetes Care,* 32, (11) 1947-1953

9.) Wysocki, T., Nansel, T.R., Holmbeck, G.N., Chen, R., Laffel, L., Anderson, B.J. & Weissberg-Benchell, J. (2009). Collaborative involvement of primary and secondary caregivers: Associations with youths' diabetes outcomes. *Journal of Pediatric Psychology, 34,* 869-881.

10.) JDRF Continuous Glucose Monitoring Study Group. (2010). Validation of Measures of Satisfaction With and Impact of Continuous and Conventional Glucose Monitoring. *Diabetes Technology and Therapeutics, 12*, (9), 679-684.

11.) Wysocki, T., Lochrie, A., Antal, H., & Buckloh, L. (2011). Youth and Parent Knowledge and Communication About Major Complications of Type 1 Diabetes: Associations with Diabetes Outcomes. *Diabetes Care, 34*, (8), 1701-1705.

12.) Wysocki, T., Buckloh, L., Antal, H., Lochrie, A., & Taylor, A. (2012). Evaluation of a self report version of the Diabetes Self Management Profile. *Pediatric Diabetes, 13*, 438-443; doi: 10.1111/j.1399-5448.2011.00823.x

13.) Lochrie, A.S., Wysocki, T., Hossain, J., Milkes, A., Antal, H., Buckloh, L., Canas, J.A., Bobo, E., & Lang, J. (2013). The Effects of a Family Based Intervention (FBI) for Overweight Children on Health and Psychological Functioning. *Clinical Practice in Pediatric Psychology, 1* (2), 159-170.

14.) Barnard, K.D., Wysocki, T., Allen, J.M., Elleri, D., Thabit, H., Leelarathna, L., Gulati, A., Nodale, M., Dunger, D.B., Tinati, T., and Hovorka, R. (2014). Closing the Loop Overnight at Home Setting: Psychosocial Impact for Adolescents with Type 1 Diabetes and their Parents. *British Medical Journal: Diabetes Research and Care,* 2:000025. doi:10.1136/bmjdrc-2014-000025

15.) Antal, H., Hossain, M.J., Henry, S.I., Fuzzell, L., Taylor, A., & Wysocki, T. (2014). Audio-Video Recording of Health Care Encounters for Pediatric Chronic Conditions: Observational Reactivity and its Correlates *Journal of Pediatric Psychology*.doi: 10.1093/jpepsy/jsu046

D. Research Support

Completed Research Support (Recent or pertinent to this application)

Wysocki, T. (PI) Behavior therapy for families of diabetic adolescents. NIH/NIDDK #1-RO1-DK43802. Oct., 1992 to July, 2006. This grant supported two efficacy trials evaluating the effects of the Robin and Foster Behavioral Family Systems Therapy intervention on outcomes of care for adolescents with type 1 diabetes. Primary outcomes were HbA_{1C}, treatment adherence and a variety of measures of family communication and relationships.

Wysocki, T. (PI) & White, N.H. Intensive therapy for IDDM in youth: Outcome predictions. NIH/NIDDK (1-RO1-DK50860). December, 1996 through June, 2003. This study examined possible mediators and moderators of glycemic benefit from intensified therapy regimens for children and adolescents with type 1 diabetes.

Wysocki, T. (PI) Continuous glucose sensors in youth: Biobehavioral study. NIH/NICHD/NIDDK Cooperative Clinical Research Agreement #U10-HD/DK-41918. September, 2001 through August, 2007. This grant constituted Nemours' participation in the Diabetes Research in Children Network (DirecNet), a cooperative research network that conducted Nemours studies of clinical application of continuous glucose monitoring in pediatric type 1 diabetes.

Wysocki, T. (PI) & Fox, L. Validating continuous glucose sensor technology. Nemours clinical center under Juvenile Diabetes Research Foundation Artificial Pancreas Project Grant 1/06 through 6/09. This grant constituted Nemours participation in the JDRF Continuous Glucose Monitoring Research Group that designed and conducted a 10-center randomized controlled trial of continuous glucose monitoring in adults, adolescents and children with type 1 diabetes.

Wysocki, T. (PI) Family management of childhood diabetes (Type 1): Clinical Sites. Research contract with the NICHD Prevention Research Branch (Contract # N-01-HD-4-3361). 11/03 through 10/09. This research contract yielded a substantial pilot and feasibility study followed by a randomized controlled trial of the efficacy of a clinic-integrated, family-focused behavioral intervention designed to prevent the common deterioration in diabetes management that begins in early adolescence.

Wysocki, T. (PI) Youth and parent knowledge of diabetes complications. NIH/NIDDK Mid-Career Investigator Award in Patient-Oriented Research (K24-DK61728). 9/04-8/10. This was an NIDDK Midcareer Investigator Award that supported mentoring of several early-career pediatric psychologists in the context of designing and conducting four distinct studies of knowledge of major long term complications of type 1 diabetes and how parents and youth acquire, process and cope with that knowledge.

Lochrie, A. A family based intervention to reduce the risk of type 2 diabetes in children. American Diabetes Association Junior Faculty Award. 1/06 through 12/09. This grant supported a clinical trial of the efficacy of a behavioral intervention in preventing progression to type 2 diabetes among pre-adolescent children who were at high risk in terms of family history and metabolic status.

Wysocki, T. Clinician-parent-patient communication in pediatrics. Nemours Research Cluster Grant. 09/10-12/13. This was an internally funded grant in which we collected audio-video recordings of 403 routine clinic visits for 155 children and adolescents with a variety of chronic medical conditions along with multiple measures of proximal and distal outcomes of those visits.

Active Research Support

Wysocki, T. (PI) Use of continuous glucose sensors by adolescents with inadequate diabetic control. NIH grant #1- R01-DK080831. 12/08-11/14. This ongoing efficacy trial compares standard diabetes management with conventional finger-stick glucose monitoring to the same care augmented by continuous glucose monitoring or continuous glucose monitoring plus a behavioral intervention. The behavioral intervention targets a variety of common behavioral barriers to benefit from continuous glucose monitoring.

Wysocki, T. (PI) Shared medical decision making in pediatric diabetes. Patient Centered Outcomes Research Institute. 4/1/13 through 3/31/16. This ongoing study will test the benefits of a shared medical decision making intervention for adolescents who are candidates for incorporating either insulin pumps or continuous glucose monitoring into their type 1 diabetes regimens.

Wysocki, T. (PI) Maintenance of Health Care Providers' Clinical Proficiency: Trans-disciplinary Analysis, Modeling and Intervention. U.S. Department of Defense Medical Practice Initiative Breadth of Medical Practice & Disease Frequency Exposure (MPI-BMP). U.S. Army Telemedicine and Advanced Technology Research Center # ERMS No.12362007. September, 2013 through August, 2016. This research contract is designed to determine whether, and to what extent, health care providers' frequency of exposure to certain targeted clinical problems is associated with decay in measures of their quality of care and deviation from published practice guidelines.

Blake, K. Use of Mobile Devices and the Internet to Streamline an Asthma Clinical Trial. NIH Grant Number: 1R01HL114899-01; 8/15/2012 – 5/31/2016 (Role: Co-I @ 2.5% for all 4 years)

Mayer-Davis, E. "FL3X: An Adaptive Intervention to Improve Outcomes for Youth with Type 1 Diabetes" NIH Grant # UC4DK101132-01-01 to the University of North Carolina. January 1, 2014 through June 30, 2018. Role: Consultant @ 5% FTE.

Cox, E. Family-Centered Tailoring of Pediatric Diabetes Self-Management Resources. Grant awarded to the University of Wisconsin by the Patient-Centered Outcomes Research Institute. July 1, 2013 through June 30, 2016. (Role: Co-I @ 5%FTE all 3 years).

Forrest, C. A Pediatric Learning Health System. Grant awarded to the Children's Hospital of Philadelphia from the Patient-Centered Outcomes Research Institute Clinical Data Research Network initiative. January 1, 2014 through June 30, 2015. (D. Milov, Nemours PI). T. Wysocki Co-I @ 2.5% FTE.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Brinkman, William Bernard	Assistant Professor of Pediatrics
eRA COMMONS USER NAME (credential, e.g., agency login)	
BBRINKMAN	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
St. Louis University	B.A.	05/94	Psychology/Biology
St. Louis University School of Medicine	M.D.	05/99	Medicine
Children's Memorial Hospital, Northwestern University, Feinberg School of Medicine, Chicago, IL		07/99-06/02	Pediatric Resident
Children's Memorial Hospital, Chicago, IL		07/02-06/03	Pediatric Chief Resident
NRSA Primary Care Research Fellowship, Cincinnati Children's Hospital Medical Center, Cincinnati, OH (2 T32 HP 10027-08)		07/03-06/06	Primary Care Research
University of Cincinnati Colleges of Medicine and Education	M.Ed.	08/06	Education

A. Personal Statement

The goal of the application is to improve care and health outcomes for adolescents with diabetes through the development and testing of innovative shared medical decision making decision aid interventions. My role will be to 1) participate in refinement of procedures for the qualitative study, and 2) critique, refine, and finalize the decision aids developed to ensure that they satisfy the International Patient Decision Aids Standards (IPDAS) prior to their use in a randomized controlled trial, and 3) participate in writing abstracts and manuscripts that result from this work. I am well prepared to serve in this capacity based on advanced training in the development and evaluation of decision aids that I received at: 1) The Society for Medical Decision Making's Annual Meetings in 2005 and 2006, 2) The Dartmouth Summer Institute for Informed Patient Choice in 2007 and 2009, and 3) The International Shared Decision Making Conference in 2009. In addition, I have relevant experience developing decisions aids that comply with the IPDAS standards. Moreover, I conduct research and lead national/international educational workshops on shared medical decision making and decision aids. I have also conducted and published research that employed qualitative methods. In summary, I have a demonstrated record of successful and productive research and educational projects in areas highly relevant to completion of the current project.

B. Positions and Honors

Positions and Employment

2006- Assistant Professor, Department of Pediatrics, Cincinnati Children's Hospital Medical Center, University of Cincinnati, Cincinnati, OH

Other Experience and Professional Memberships

2003-- Fellow, American Academy of Pediatrics
2003-- Member, Academic Pediatric Association
2004-- Member, American Academy on Communication in Healthcare
2005-- Member, Society for Medical Decision-Making

Honors

1994	Magna cum laude
1994	Psi Chi – Psychology National Honor Society
2001	Chicago Pediatric Society Unusual Case Competition Award
2003	Best Resident Abstract, Ambulatory Pediatric Association Region V
2004	Young Investigator Award, Ambulatory Pediatric Association
2007	Fellowship at the Summer Institute for Informed Patient Choice, "Values clarification, preference elicitation, and dealing with probabilistic uncertainty in patient decision making", June 25 – July 6, 2007, Dartmouth College, Hanover, NH
2007	Invited Lecture at the *International Collaboration Workshop: Translating Shared Decision Making into Clinical Practice* at University of Laval, Quebec
2007	Richard T. Sarkin Memorial Lecture at Women and Children's Hospital of Buffalo
2009	Fellowship at the Summer Institute for Informed Patient Choice, "Complexity in decision support/patients' decision aids", June 10-14, 2009, Boston MA
2010	Invited Lecture at the Ottawa Decision Support Framework Workshop at University of Ottawa, Ottawa Hospital Research Institute, Canada

C. Selected Peer-reviewed Publications

Most relevant to the current application

1. Brinkman WB, Sherman SN, Zmitrovich AR, Visscher MO, Crosby LE, Phelan KJ, Donovan EF. "Parental Angst Making and Revisiting ADHD Treatment Decisions." *Pediatrics* 2009 Aug; 124: 580-589.
2. W. B. Brinkman, and J. N. Epstein, 'Promoting Productive Interactions between Parents and Physicians in the Treatment of Children with Attention-Deficit/Hyperactivity Disorder', Expert Rev Neurother, 11 (2011), 579-88.

Additional recent publications of importance to the field (in chronological order)

1. Brinkman WB, Geraghty SR, Lanphear BP, Khoury JC, Gonzalez del Rey JA, DeWitt TG, Britto MT. "Effect of Multi-Source Feedback on Resident Communication Skills and Professionalism. A Randomized Controlled Trial." *Archives of Pediatrics and Adolescent Medicine* 2007 Jan; 161: 44-49.
2. Baker RC, Klein M, Samaan Z, Brinkman WB. "Exam room presentations and teaching in outpatient pediatrics: Effects on Visit Duration and Parent, Attending Physician, and Resident Perceptions." Ambulatory Pediatrics 2007 Sep-Oct; 7(5): 354-359.
3. Langberg JM, Brinkman WB, Lichtenstein PK, Epstein JN. "Interventions to Promote the Evidence-Based Care of Children with ADHD in Primary Care Settings." Expert Review of Neurotherapeutics 2009 Apr; 9(4):477-87.
4. Simmons JM and Brinkman WB. "What's New Is Old: Maximizing the Benefits of Parental Presence at Bedside Rounds through 100 Years of Insights from the Literature." J Pediatr 2009 Oct; 155(4): 466-8.
5. Epstein JN, Langberg JM, Lichtenstein PK, Altaye M, Brinkman WB, House K, Stark LJ. "Attention-Deficit/Hyperactivity Disorder (ADHD) outcomes for children treated in community-based pediatric settings." Archives of Pediatrics and Adolescent Medicine 2010 Feb, 164(2): 160-5.
6. Langberg JM, Vaughn AJ, Brinkman WB, Froehlich TE, & Epstein JN. Clinical utility of the Vanderbilt ADHD rating scale for identifying children without comorbid learning disorders. Pediatrics 2010 Nov, 126 e1039-e1044.
7. J. N. Epstein, J. M. Langberg, P. J. Rosen, A. Graham, M. E. Narad, T. N. Antonini, W. B. Brinkman, T. Froehlich, J. O. Simon, and M. Altaye, 'Evidence for Higher Reaction Time Variability for Children with Adhd on a Range of Cognitive Tasks Including Reward and Event Rate Manipulations', Neuropsychology, 25 (2011), 427-41.
8. Brinkman, W. B., Majcher, J., Poling, L. M., Shi, G., Zender, M., Sucharew, H., & ... Epstein, J.
9. N. (2013). Shared decision-making to improve attention-deficit hyperactivity disorder care. *Patient Education and Counseling*, *93*(1), 95-101. doi:10.1016/j.pec.2013.04.009
10. Lipstein, E.A., Brinkman, W.B., & Britto, M.T. (2012). What is known about parents' treatment

decisions? A narrative review of pediatric decision making. *Medical Decision Making, 32*(2) 246-258. doi: 10.1177/0272989X11421528

D. Research Support

Ongoing Research Support

1K23MH083027-01A2 Brinkman (PI) 01/01/10-11/30/14
NIMH
Medication Continuity in Children Treated for ADHD
The primary goal of this project is to develop expertise for becoming an independent investigator in the study of medication continuity in children with ADHD cared for in primary care settings.
Role: PI

No grant # Brinkman (PI) 07/01/09-12/31/10
Cincinnati Children's Hospital Medical Center Place Outcomes Research Award
Shared Decision Making to Improve Care for Children with ADHD
The primary goal of this project is to improve the education materials (visual aids) that are available to families and to test how these education materials change the way parents, children, and their doctors make decisions about treatment for ADHD.
Role: PI

Completed Research Support

R01 MH074770 Epstein (PI) 06/01/06 – 06/31/09
NIMH
Response Variability in Children with ADHD
The primary goal of this project is to examine response variability in children with ADHD using a variety of neuropsychological paradigms and advanced measurement strategies.
Role: Co-investigator and study physician

271-2007-00005-C Shanahan (PI) 09/01/07 – 02/31/08
NIMH
Families as Research and Treatment Partners: Developing Evidence Based Decision Aids for Mental Health Treatment (Topic 58)
This was a subcontract with Medispin, Inc. to develop content and pilot test a web-based software program to inform parents about treatment options for their child with ADHD and support parent partnership with their child's doctor to develop a treatment plan.
Role: Subcontract Site PI

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Mauri Carakushansky, MD	Pediatric Endocrinologist, Attending Physician
eRA COMMONS USER NAME	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Federal University of Rio de Janeiro, Brazil School of Medicine	MD	1995	Medicine
Federal University of Rio de Janeiro, Brazil	Post-Graduate	1995-1997	Medical Genetics
Jackson Memorial Hospital, Miami	Pediatric Residency	1997-2000	Pediatrics
Johns Hopkins Hospital, Baltimore	Fellowship	200-2003	Pediatric Endocrinology

A. Personal Statement:

My contribution to this project is as a Co-Investigator on Dr. Wysocki's trial of a trans-disciplinary care model for adolescents with type 1 diabetes.

I have been a pediatric endocrinologist at Nemours Children's Clinic in Orlando since 2003, achieved subspecialty board certification in 2005, and I became Chief of the Division of Endocrinology and Metabolism there in 2011. I have enrolled several of my patients in Dr. Wysocki's NIH-funded study of the clinical use of continuous glucose monitoring in adolescents who are not meeting HbA_{1C} targets. I am interested in expanding the research activities of my division and am especially interested in contributing to research that could lead to better ways to care for adolescents with type 1 diabetes. For the present study, I would assist Dr. Wysocki during the initial qualitative component of the proposed research and in the refinement of the Trans-Disciplinary model of care to be developed. When the randomized trial starts, I will assist in recruiting eligible patients from my own clinic and encourage my colleagues to do the same and I will provide medical management of any of my patients who are study participants. Our clinic manages over 1,000 patients with type 1 diabetes and there are approximately 100-120 newly diagnosed cases per year. The Division of Endocrinology employs four endocrinologists, two nurse practitioners and a part time dietitian and we have psychology, psychiatry and social work services available on a consultative basis. There will be no problem recruiting a sample of 40 patients for this study and my colleagues and I look forward to contributing to implementation of this valuable work.

B. Positions and Honors

EMPLOYMENT

November 2003 - Present — Pediatric Endocrinologist, Attending Physician
Nemours Children's Clinic-Orlando
Division of Endocrinology

February 2006 - Present — Medical Director of the Program for Type 2 Diabetes in Children and Adolescents
Nemours Children's Clinic-Orlando

April 2004- Present — Clinical Assistant Professor
Department of Pediatrics
College of Medicine, Florida State University
Tallahassee, FL

ACADEMIC APPOINTMENTS
Assistant Professor, University of Central Florida
Assistant Professor, Florida State University

ACTIVE SOCIETY MEMBERSHIPS:
Endocrine Society
American Diabetes Association
American Board of Pediatrics
Brazilian Pediatric Society

BOARD CERTIFICATION AND LICENSURE:
Educational Commission for Foreign Medical Graduates Examination (ECFMG) ECFMG No 0-551-627-3. Certificate issued December 16, 1996

Board Certified in Pediatrics -American Board of Pediatrics, 2002

Board Certified in Pediatric Endocrinology -American Board of Pediatrics, Sub Board of Pediatric Endocrinology, 2005

Licensed Physician and Surgeon, State of Florida, 2003

AWARDS:
Schwentker Award for excellence in clinical research at Johns Hopkins, 2003

C. Selected publications
Carakushansky M, O'Brien K, Levine MA: Vitamin D and Calcium: Strong Bones for Life through Better Nutrition. Cont Pediatrics. 2003 Mar; 20(3): 37-53

Carakushanky M, Whatmore AJ, Clayton PE, Shalet SM, Gleeson HK, Price DA, Levine MA, Salvatori R: A New Missense Mutation in the Growth Hormone-Releasing Hormone Receptor Gene in Familial Isolated GH Deficiency. Eur J Endocrinol. 2003 Jan; 148(1): 25-30

Carakushansky M, Levine MA, Salvatori R: Role of C-terminal Phosphorilation Sites of the GHRH Receptor in cAMP Signaling. Abstract, The Endocrine Society's Meeting (Philadelphia, 2003)

Carakushansky M, Levine MA, Salvatori R: A Quick Method for Screening Mutations in High Number of DNA Samples Using DGGE. Abstract, LWPES Meeting (Seattle, 2003)
Published in Pediatric Research Supplement 2003 Apr; 53(4): 153A

Kossoff EH, Silvia MT, Maret A, **Carakushansky M**, Vining EP: Neonatal Hypocalcemic Seizures: Case Report and Literature Review. J Child Neurol. 2002 Mar; 17(3): 263-9

Carakushansky G., Rosembaum S., **Carakushansky M**: Achondroplasia Associated with Down Syndrome. Am J Med Genet. 1998 May 1; 77(2): 168-9

Carakushansky G, Aguiar MB, Goncalves MR, Berthier CO, **Carakushansky M**: Identical Twins Discordance for the Brachmann-de Lange Syndrome Revisited. Am J Med Genet. 1996 Jun 14; 63(3): 458-60

D. Research Support
Active Support
(Tercica Study) Protocol MS301: Recombinant Human Insulin-Like Growth Factor-1 (rhIGF-1) Treatment Of Pre-pubertal Children With Growth Failure Associated With Primary IGF-1 Deficiency: Phase 3, Randomized, Open-Label, Observation-Controlled, Multicenter, Parallel-Dose Comparison Trial

Protocol 85-036: Genentech National Cooperative Growth Study (NCGS) Post Marketing Surveillance Program For Nutropin Depot® [Somatropin (Rdna Origin) For Injectable Suspension], Nutropin Aq® [Somatropin (Rdna Origin) Injection], Nutropin® [Somatropin (Rdna Origin) For Injection], And Protropin® [Somatrem For Injection]

Bone Mineral Density In Adolescent Subjects With Growth Hormone Deficiency Who Are Completing Treatment With Nutropin Aq®, Nutropin®, Or Protropin® In The National Cooperative Growth Study (NCGS) – Substudy 10

Protocol 85-036 Substudy 12: Genentech National Cooperative Growth Study (NCGS) Post Marketing Surveillance Program For Nutropin Depot® [Somatropin (rDNA Origin) For Injectable Suspension], Nutropin Aq® [Somatropin (rDNA Origin) Injection], Nutropin® [Somatropin (rDNA Origin) For Injection], And Protropin® [Somatrem For Injection

KIGS (Kabi International Growth Study)

The Genetics and Neuroendocrinology of Short Stature International Study: GeNeSIS [B9R-EW-GDFC(a)] - Core Program

The Genetics and Neuroendocrinology of Short Stature International Study (GeNeSIS), Main Study and DNA Analysis and Idiopathic Short Stature Substudies

The Genetics and Neuroendocrinology of Short Stature International Study: GeNeSIS [B9R-EW-GDFC(a)] - DNA Analysis Sub-study (Relative)

The Genetics and Neuroendocrinology of Short Stature International Study (GeNeSIS), Main Study and Growth Prediction Substudy.

The Genetics and Neuroendocrinology of Short Stature International Study: GeNeSIS - Idiopathic Short Stature Sub-study (Relative) [B9R-EW-GDFC(a) (10)]

The Genetics and Neuroendocrinology of Short Stature International Study (GeNeSIS); Main Study and SHOX Deficiency and Neoplasia Substudies.

Norditropin® National Registry Program

GH Monitor

TrialNet research program

Use of Novolog versus Humalog insulin in type 1 diabetic patients utilizing insulin pump therapy

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FOUR PAGES.

NAME	POSITION TITLE
Doyle, Daniel A. eRA COMMONS USER NAME (credential, e.g., agency login) doyled	Associate Professor of Pediatrics

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

INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
Saint Joseph's University	B.A.	05/82	English
Hahnemann University	MD	06/90	Medicine
Thomas Jefferson University	Resident	06/93	Pediatrics
Saint Christopher's Hospital for Children	Fellow	06/96	Endocrinology

A. Personal Statement

The goal of the proposed research is to investigate the process of transition for a type 1 diabetic population from our large pediatric endocrinology practice with approximately 1200 active type 1 diabetic patients to various adult diabetes providers in the state of Delaware. Our intention is to mine data from the EMR which has been in use in the outpatient area of our hospital since 2003 and look at an approximate 10 year span of patients from age 18 years to 28 years. We will track their demographics, their hemoglobin A1C levels pre and post transition as well as the frequency of outpatient visits pre and post-transition to see the impact of visit frequency on overall diabetes control. For patients who remain in the state of Delaware (which should be the majority of our patients) we will also mine data from the DHIN or Delaware Health Information Network. For patients who are not being followed in practices which utilize the DHIN a questionnaire will be provided which will focus on acquiring basic the basic information about hemoglobin A1C and length of time to first visit with and adult diabetes provider. Our intention is to publish these data in peer-reviewed journals and to use the current study as a baseline or platform from which we can perform measureable interventions to improve the transition process. The current application builds logically on previous work performed by Dr. Renwick in the transition arena and should provide additional expertise in navigating the obstacles which are often encountered during the difficult transition from being an adolescent with type 1 diabetes to being a young adult with diabetes. In summary, I have a demonstrated track record of successful and productive research projects in many areas of pediatric endocrinology and my 17 years of experience in caring for children with type 1 diabetes mellitus have prepared me to lead the proposed project.

B. Positions and Honors

Faculty Appointments:

1993-1996 Clinical Instructor, Temple University School of Medicine, Phila., PA.
1996-2000 Assistant Professor of Pediatrics, Temple University, Phila., PA.
2000- Present, Staff Endocrinologist, DuPont Hospital for Children, Wilm., DE.
2002-2008, Assistant Professor of Pediatrics, Thomas Jefferson University, Phila., PA.
2008- Present, Associate Professor of Pediatrics, Thomas Jefferson University, Phila., PA.

Hospital and Administrative Appointments

2000- Present, Director of Medical Education for the Division of Endocrinology, AI duPont Children's Hospital

Specialty Certification:
1993 American Board of Pediatrics: Pediatrics, recertified 2000 and 2007.
1997 American Board of Pediatrics: Pediatric Endocrinology, recertified 2004.

Awards, Honors and Membership in Honorary Societies:
1990 Distinguished Academic Performance in Pediatrics, Hahnemann University.
2009 Teaching Excellence Award, Awarded by the Pediatric Housestaff, Thomas Jefferson University and Al duPont Children's Hospital
2011 Faculty Educator of the Month (October) Awarded by the Pediatric Housestaff, Thomas Jefferson University and Al DuPont Children's Hospital

Memberships in Professional and Scientific Societies:
1997- Present, Lawson Wilkins Pediatric Endocrine Society
1994- Present, Endocrine Society
2001- Present, American Diabetes Association
2001-2007 American Academy of Pediatrics
2001- Present, Philadelphia Endocrine Society

C. Recent Publications

Cordrey C, Peeke K, Budd S, **Doyle D:** CF Care Team: Addition of Endocrine Specialty Nurse to CF Clinic Improves Adherence to CFRD Evaluation/Screening. Program and Abstracts of the Annual North American Cystic Fibrosis Conference, Anaheim, CA November, 2011.

Cordrey C, Peeke K, Chidekel A, **Doyle D:** Use of Continuous Glucose Monitoring System (CGMS) to Diagnose CFRD in a Pediatric CF clinic. Christiana Care Annual Research Symposium, Wilmington, DE November 2010.

Doyle D, Kirwin SM, Sol-Church K, Levine MA (2012) A novel mutation in the GCM2 gene causing severe congenital isolated hypoparathyroidism. J Pediatr Endocrinol Metab 25(7–8):741–746

Sammon MR, Doyle D, Hopkins E, Stabley D, McGready J, Schulze K, Alade Y, Hoover-Fong J, Gripp K. Normative growth charts for individuals with costello syndrome. *Am J Med Genet*. 2012;158A:2692-2699

Rauen K, Hefner E, Carrillo K, Taylor J, Messier L, Aoki Y, Gripp K, Matsubara Y, Proud V, Hammond P, Allanson J, Delrue M, Axelrad M, Lin A, **Doyle D,** Kerr B, Carey J, McCormick F, Silva A, Kieran M, Hinek A, Nguyen T, Schoyer L. Molecular aspects, clinical aspects and possible treatment modalities for Costello syndrome: Proceedings from the 1st Internationational Costello Syndrome Research Symposium 2007. Am J Med Genet 146A(9):1205-1217, May 2008.

Gripp K, Innes A, Axelrad M, Gillian T, Parboosingh J, Davies C, Leonard N, Lapointe M, **Doyle D,** Catalano S, Nicholson L, Stabley D, Sol-Church K. Costello syndrome associated with novel germline HRAS mutations: An attenuated phenotype? Am J Med Genet 146A(6):683-690, March 2008.

Edghill E, Flanagan S, et al (**Doyle D** as a member of the Neonatal Diabetes International Collaborative Group). Insulin Mutation Screening in 1,044 Patients with Diabetes. Diabetes 57:1034-1042, 2008.

Stoy J, Edghill E, et al, (**Doyle D** as a member of the Neonatal Diabetes International Collaborative Group). Insulin gene mutations as a cause of permanent neonatal diabetes. PNAS, 104(38):15040-15044, 2007.

Gripp KW, Lin AE, Stabley DL, Nicholson L, Scott CI Jr, **Doyle D**, Aoki Y, Matsubara Y, Zackai EH, Lapunzina P, Gonzalez-Meneses A, Holbrook J, Agresta CA, Gonzalez IL, Sol-Church, K. HRAS mutation analysis in Costello syndrome: Genotype and phenotype correlation. Am J Med Genet A. Jan 1;140(1):1-7, 2006.

Doyle D, Gonzalez I, Thomas B, Scavina M: Congenital Hypothyroidism, Neonatal Respiratory Distress and ataxia caused by a mutation of NKX2-1. J Pediatr 2004:145:190-3.

Reeves G, **Doyle D**: Growth Hormone Treatment and Pseudotumor Cerebri: Coincidence or Close Relationship? J of Ped Endo & Met 15, 723-730, 2002.

Liu G, Duranteau L, Carel J, Monroe J, **Doyle D,** Shenker A: Leydig-cell Tumors Caused by an Activating Mutation of the Gene Encoding the Luteinizing Hormone Receptor. NEJM, Vol. 341, No. 23, 1731-1736, Dec. 1999.

D. Research Support

Ongoing Research Support

1. TrialNet Natural History of the Development of Type 1 Diabetes. Grafton Reeves, Affiliate Principal Investigator, **Daniel Doyle,** Co-investigator.
The goal of this study is to screen the first degree relatives of known type 1 diabetics for immune markers for diabetes.

2. TrialNet Oral Insulin Study for Prevention of Diabetes in Relatives at Risk for Type 1 Diabetes. Grafton Reeves Affiliate Principal Investigator, **Daniel Doyle,** Co-investigator.
The goal of this study is to test the hypothesis that oral insulin can stop or prolong the time to onset of type 1 diabetes in at-risk first degree relatives of known type 1 diabetics.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Alexander G. Fiks	Assistant Professor of Pediatrics
eRA COMMONS USER NAME (credential, e.g., agency login) agfiks	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Harvard University, Cambridge, MA	AB	1992	Biology, *summa cum laude*
University of Salamanca, Spain	Diploma in Hispanic Studies	1993	Hispanic Studies
Harvard University, Boston, MA	MD	1997	Medicine
The Children's Hospital of Philadelphia, PA	N/A	1998	Intern in Pediatrics
The Children's Hospital of Philadelphia, PA	N/A	2000	Resident in Pediatrics
National Library of Medicine, Woods Hole, MA	N/A	2006	Fellowship in Biomedical Informatics
University of Pennsylvania, Philadelphia, PA	MSCE	2007	Epidemiology & Health Services Research

A. Personal Statement

I am a primary care pediatrician practicing in an urban setting and an Assistant Professor of Pediatrics at the University of Pennsylvania School of Medicine and The Children's Hospital of Philadelphia. My research is directed at improving outcomes for ambulatory pediatric patients through collaborative practice-based research that focuses on understanding and improving decision making. I have published multiple qualitative and quantitative studies and reviews addressing how families and clinicians understand shared decision making in the care of chronic child health problems. This year, at the national meeting of the Pediatric Academic Societies, I co-led a workshop on the use of decision aids in pediatrics with both Drs. Brinkman and Lawson who are also participating in this grant application. With support from a K23 Award (K23HD059919) from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) entitled "Shared Decision Making in ADHD," I am currently investigating optimal strategies for using health information technology to promote shared decision making. Participation in this grant represents a logical extension of my work to foster shared decision making in pediatrics in order to improve adherence and outcomes for children. As a participant in the proposed research, I will help to refine and evaluate the decision aid following international standards. I also will assist in refining methods for the qualitative interview study as well as participate in writing abstracts and manuscripts that result from this work.

B. Positions and Honors.

Employment

2000-present Assistant Physician, Division of General Pediatrics, The Children's Hospital of Philadelphia
2003-2006 Clinical Assistant Professor of Pediatrics, University of Pennsylvania School of Medicine
2006-present Assistant Professor of Pediatrics at The Children's Hospital of Philadelphia, University of Pennsylvania School of Medicine

Positions

2000-2002 Residency Selection Committee, The Children's Hospital of Philadelphia
2000-2006 Medical Student Clerkship Director, University City Primary Care Center, The Children's Hospital of Philadelphia
2002-present Physician Champion Group for Implementation of the Ambulatory Computerized Medical Record (Chairman, 2005-present), The Children's Hospital of Philadelphia

2003-present Advisory Committee of the Practice-Based Research Network, The Children's Hospital of Philadelphia
2005-2008 Clinical Decision Support Committee, The Children's Hospital of Philadelphia
2005-2010 Physician Leader, Implementation Team for the Electronic Health Record, The Children's Hospital of Philadelphia
2006-present Founding Member, The Children's Hospital of Philadelphia Center for Biomedical Informatics
2007-present Senior Fellow, Leonard Davis Institute of Health Economics, University of Pennsylvania
2008-present Associate Scholar, Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania
2009-present MyChart (Patient Portal) Working Group, The Children's Hospital of Philadelphia

Other Experience and Professional Memberships

Ambulatory Pediatric Association
American Academy of Pediatrics
American Medical Informatics Association
Society for Medical Decision Making

Honors

1992 Phi Beta Kappa, Harvard University
1992 John Harvard Scholarship, Harvard University
1992-1993 Rotary Foundation Ambassadorial Scholar, Salamanca, Spain
2004-2005 Faculty Honor Roll, The Children's Hospital of Philadelphia
2007 Jean Cortner Divisional Teaching Award, Division of General Pediatrics, The Children's Hospital of Philadelphia
2008 Best Poster, "Impact of Clinical Alerts Within an Electronic Health Record on Routine Childhood Immunization in an Urban Pediatric Population," Greater Philadelphia Informatics Symposium
2009 Academic Pediatric Association, Young Investigator Award, "Shared Decision Making in Pediatrics: A National Perspective."
2010 Nominee, Marjorie A. Bowman New Investigator Research Award for achievement in the health evaluation sciences, University of Pennsylvania School of Medicine

C. Selected peer-reviewed publications (in chronological order).

1. **Fiks, AG**, Alessandrini, EA, Luberti, AA, Ostapenko, S., Zhang, X., and Silber, JH. "Identifying Factors Predicting Immunization Delay for Children Followed in an Urban Primary Care Network Using an Electronic Medical Record," *Pediatrics*, 2006. Vol. 118: e9242-9246.
2. **Fiks, AG**, Grundmeier, RW, Biggs, LM, Localio, AR, Alessandrini, EA, "Impact of Clinical Alerts Within an Electronic Health Record on Routine Childhood Immunization in an Urban Pediatric Population," *Pediatrics*, 2007. Vol. 120: 707-714.
3. **Fiks, AG**, Hunter, KF, Localio, AR, Grundmeier, RW, Alessandrini, EA, "The Impact of Immunization at Sick Visits on Well-Child Care," *Pediatrics*, 2008. Vol. 121: 898-905.
4. Feemster, KA, Winters, SE, **Fiks, AG**, Kinsman, S, Kahn JA. "Pediatricians' Intention to Recommend Human Papillomavirus (HPV) Vaccines to 11- to 12-Year-Old Girls Post-Licensing," *Journal of Adolescent Health*, 2008; Vol. 43: 408-411.
5. Perella, D, **Fiks AG**, Jumaan, A, Robinson, D, Gargiullo, P, Pletcher, J, Forke, CM, Schmid, DS, Renwick, M, Mankodi, F, Watson, B, Spain, CV, "Validity of a Reported Varicella History as a Marker for Varicella-Zoster Virus Immunity among Children, Adolescents, and Young Adults in the Post-Vaccine Licensure Era," *Pediatrics*, 2009; Vol. 123: e820-e828.
6. **Fiks AG**, Hunter, KF, Localio, AR, Grundmeier, RW, Bryant-Stephens, T, Luberti, AA, Bell, LM, Alessandrini, EA "Impact of Electronic Health Record-Based Primary Care Clinical Alerts on Influenza Vaccination for Children and Adolescents with Asthma: A Cluster Randomized Trial," *Pediatrics*, 2009; Vol. 124: 159-169.
7. Bell LM, Grundmeier RW, Localio R, Zorc J, **Fiks AG**, Zhang X, Bryant-Stephens T, Swietlik M, Guevara JP, "Electronic Health Record Based Decision Support to Improve Outpatient Asthma Care: A Cluster Randomized Trial," Pediatrics, 2010; Vol. 125: e770-777.
8. Pati S, Feemster KA, Mohamad Z, **Fiks A**, Grundmeier RW, Cnaan A, "Maternal Health Literacy and

Late Initiation of Immunizations in an Inner-City Birth Cohort," Maternal and Child Health Journal, 2010: Feb 24 (epub ahead of print).

9. **Fiks, AG**, Leslie LL "Partnership in the Treatment of Childhood Mental Health Problems: A Pediatric Perspective," School Mental Health, 2010, Vol. 2: 93-101.
10. **Fiks AG**, Localio AR, Alessandrini EA, Asch DA, Guevara JP, "Shared Decision Making in Pediatrics: A National Perspective," Pediatrics, 2010, Vol. 126: 306-314.
11. **Fiks AG**, Gafen A, Hughes CC, Hunter KF, Barg FK, "Using Freelisting to Understand Shared Decision Making in ADHD: Parents' and Pediatricians' Perspectives," Patient Education and Counseling, DOI 10.1016/j.pec.2010.07.035 (epub ahead of print).
12. **Fiks AG**, Jimenez ME, "The Promise of Shared Decision Making in Pediatrics," Acta Paediatrica, 2010, Vol. 99: 1464-1466.
13. Fiks AG, Hughes CC, Gafen A, Guevara JP, Barg FK. Contrasting parents' and pediatricians' perspectives on shared decision-making in ADHD. *Pediatrics*. 2011;127(1):e188-e196
14. Fiks AG. Designing computerized decision support that works for clinicians and families. Curr Probl Pediatr Adolesc Health Care. 2011;41(3):60–88
15. Fiks AG, Alessandrini EA, Forrest CB, et al. *Electronic medical record use in pediatric primary care. J Am Med Inform Assoc 2011;18:38–44.*
16. **Fiks, A. G.**, Grundmeier, R. W., Mayne, S., Song, L., Feemster, K., Karavite, D., & ... Localio, A. (2013). Effectiveness of decision support for families, clinicians, or both on HPV vaccine receipt. *Pediatrics*, *131*(6), 1114-1124. doi:10.1542/peds.2012-3122
17. **Fiks, A.**, Hughes, C.C., Gafen A., Guevara, J.P., & Barg, F.K. (2011). Contrasting parents' and pediatricians' perspectives on shared decision making in ADHD. *Pediatrics, 127*,(1), e188-196. Epub 2010 Dec 20. doi: 10.1542/peds.2010-1510
18. **Fiks, A.G.**, & Jimenez, M.E. (2010). The promise of shared decision making in paediatrics. *Acta Paediatrica*, 99(10): 1464-1466. doi: 10.1111/j.1651-2227.2010.01978.x
19. **Fiks, A.G.**, Mayne, S., Localio, A.R., Alessandri, E.A., & Guevara, J.P. (2012). Shared decision-making and health care expenditures among children with special health care needs. *Pediatrics, 129*, 99-107. Epub 2011 Dec 19. doi: 10.1542/peds.2011-1352

D. Research Support

Ongoing Research Support

Eunice Kennedy Shriver National Institute of Health and Human Development Fiks (PI) 9/30/09-7/31/2014
Shared Decision Making in ADHD
This career development award (K23) supports training for Dr. Fiks in advanced statistical methods, health measurement, and medical informatics as part of a research plan evaluating the role of health information technology in supporting shared decision making for families of children with ADHD.
Role: Principal Investigator

Maternal and Child Health Bureau (MCHB 76655) Wasserman (PI) 10/1/10-9/30/13
Pediatric Primary Care Electronic Health Record Network for Comparative Effectiveness Research
This study creates and tests a subnetwork within the American Academy of Pediatrics, Pediatric Research in Office Settings (PROS) practice-based research network focused on using electronic health records for comparative effectiveness research and includes a randomized clinical trial of electronic health record-based decision support for ADHD.
Role: Other Significant Contributor

Agency for Healthcare Research and Quality (AHRQ) Bell (PI) 9/15/09-9/15/2011
Using Health Information Technology to Improve Healthcare in Primary Care Practices and in Transitions between Care Settings
This study evaluates the relative benefit of using electronic health record-based decision support targeted at clinicians, families, or both to improve rates of receipt of vaccines among adolescents.
Role: Subcontract Lead Investigator

Agency for Healthcare Research and Quality (AHRQ) Zaoutis (PI) 8/24/09-8/23/2011

Reducing Inappropriate Prescribing of Antibiotics by Primary Care Clinicians
This study evaluates the benefit of a package of supports for appropriate antibiotic prescribing on the use of antibiotics in pediatric primary care.
Role: Other Significant Contributor

Leonard Davis Institute of Health Economics Fiks (PI) 7/1/08-12/31/10
University of Pennsylvania
Shared Decision Making to Improve Adherence and Outcomes in ADHD: A Qualitative Study
This study involves semistructured interviews with clinicians and parents of children with ADHD in order to understand the determinants of treatment decisions as well as the range of treatment preferences and goals.
Role: Principal Investigator

Agency for Healthcare Research and Quality R18 (HS017042) Forrest (PI) 9/5/07-2/28/11
Improving Otitis Media Care with EHR-Based Clinical Decision Support and Feedback
This study is a trial of electronic health record-based decision support to improve the quality of otitis media care across a network of outpatient practices.
Role: Co-Investigator

Completed Research Support
Academic Pediatric Association/ Fiks (PI) 7/1/09-6/30/10
Agency for Healthcare Research and Quality (AHRQ)
Shared Decision Making in Pediatrics: A National Perspective
This study is a secondary data analysis of the Medical Expenditure Panel Survey examining factors associated with shared decision making for children. A focus of this work is on children with ADHD, asthma, and special health care needs.
Role: Principal Investigator

Institutional Development Funds Fiks (PI) 7/1/06-6/30/10
The Children's Hospital of Philadelphia
Evaluating the Effect of Electronic Health Record-Based Decision Support for Influenza Vaccine among Children and Adolescents with Asthma
This study is a randomized trial of clinical alerts for influenza vaccine designed to improve rates of immunization among children with asthma.

AHRQ R21 (HS014873-0A12) Bell (PI) 1/1/06-12/31/07
EHR Decision Support to Improve Asthma Care
This study is a trial of electronic health record-based decision support to improve the quality of care across a network of outpatient practices for children with asthma.
Role: Co-Investigator

The Commonwealth Fund Forrest (PI) 10/1/06-9/31/07
The Children's Hospital of Philadelphia
Tiered Health Supervision: Matching Preventive Services to Child and Family Needs
This study is designed to identify factors known early in life that predict early school failure in order to better meet the health needs of children at risk.
Role: Co-Investigator

Foerderer-Murray Award Alessandrini (PI) 7/1/06-6/30/07
The Children's Hospital of Philadelphia
Health Related Quality of Life after an Acute Illness: A Patient-Centered Outcome Measure
To study the use of Health Related Quality of Life in the setting of an acute illness in both the emergency department and primary care practices.
Role: Co-Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Hossain, Md Jobayer	Manager, Biostatistics Core, Nemours Biomedical Research Adjunct Assistant Professor, Univ of Delaware
eRA COMMONS USER NAME (credential, e.g., agency login) Jobayer	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Jahangir Nagar University, Dhaka, Bangladesh	B.Sc. (Hons)	1989	Statistics
Jahangir Nagar University, Dhaka, Bangladesh Ball	M.Sc.	1991	Statistics
State University, Muncie, Indiana, USA Southern	M.A	2001	Statistics
Methodist University, Dallas, Texas, USA	Ph. D.	2006	Statistics

A. Personal Statement

My contribution to this project will be to serve as the Biostatistician for the four studies.

As a biostatistician, I have been involved with a wide variety of research projects, providing statistical consultation to clinicians/researchers in the design of clinical trials, pre-clinical, epidemiological and survey studies, power and sample size calculation, randomization, data management, data analysis, and writing statistical sections of research protocols and manuscripts. I also have teaching experience in statistics courses for researchers/research medical fellows at Nemours/ AI duPont Children Hospital (N/AIDHC) and at the University of Delaware. The goals of these grant proposals are the Infrastructure Development Program in Patient-Centered Outcomes Research. In these projects I will work as the project statistician and will collaborate with investigators in designing the study, data management, data analysis and interpretation of results in clinical report/ manuscripts. to make sure facilitate the investigators' access to REDCAP and related data management resources at N/AIDHC and work with the project statistician and Dr. Hwang to assure completion of the statistical analyses proposed. My expertise, experience, and involvement in research relevant to the proposed study have prepared me to contribute and play an important role in planning and conducting the proposed studies.

B. Positions and Honors

Positions and Employment

1991-1992 Research Assistant, Irrigation Support Program for Asia and Near East
1993-1999 Assistant Director (Statistics), The Central Bank of Bangladesh
2001-2003 Graduate Assistant, Dept. of Math Sciences, Ball State University
2003-2006 Teaching Assistant, Dept. Math Sciences, University of Texas at Dallas
2003-2006 Teaching Assistant, Dept. of Statistical Sciences, Southern Methodist University
2006-2007 Biostatistician, InVentive Clinical Solutions
2007-present Biostatistician, Nemours Biomedical Research, A.I.duPont Hospital for Children
2008-present Adjunct Assistant professor, Univ of Delaware, Department of Applied Economics and Statistics
2013-present Manager, Biostatistics Core, Nemours Biomedical Research

Professional Memberships

American Statistical Association, 2004-present
American Mathematical Society, 2002-2003
Bangladesh Statistical Association, 1993-present
Micro Array Gene Expression Data Analysis Group, Statistical Science, Southern Methodist University, 2005-2006
LEO (Leadership, Experience, and Opportunity) club, Moghbazar, Dhaka, Bangladesh, Secretary, 1982-

1985

C. Selected Peer-reviewed Publications (of 52 peer-reviewed journal articles).

1. Lang JE, Mougey E, Blake K V, Lockey R, Gong Y, **Hossain J**, Killen K, Lima J J. Nutrigenetic Response to Omega-3 Fatty Acids in Obese Asthmatics: Design, Rational and Methods for the Nemours Network for Asthma Research Contemp Clin Trials. 2013 Mar;34(2):326-35.
2. Blake K, Cury JD, **Hossain J**, Tantisira K, Wang J, Mougey E, Lima J. Methacholine PC20 In African Americans And Whites With Asthma With Homozygous Genotypes at ADRB2 Codon 16; Pulmonary Pharmacology & Therapeutics, 2013 Jun;26(3):342-7.
3. Torres-Santiago L, Mericq V, Taboada M, Unanue N, Klein KO, Singh R, **Hossain J**, Santen RJ, Ross J L, Mauras N, Metabolic effects of oral versus transdermal 17β-estradiol (e2): a randomized clinical trial in girls with turner syndrome. J Clinical Endocrinol Metab. 2013 Jul;98(7):2716-24.
4. Lochrie A S, Wysocki T, **Hossain J**, Milkes A, Antal H, Buckloh L, Canas J A, Bobo, E; Lang J. The effects of a family-based intervention (FBI) for overweight/obese children on health and psychological functioning, Clinical Practice in Pediatric Psychology, Vol 1(2), Jun 2013, 159-170.
5. Yousef E, **Hossain J**, Skorpinski E, Mannan S, McGeady S. Early Intervention with High-Dose Inhaled Corticosteroids for Control of Acute Asthma Exacerbations at Home and Improved Outcomes: A Randomized Controlled Trial; Allergy and Asthma Proceedings, Volume 33, Number 6, November/December 2012, pp. 508-513(6).
6. Cies J J, Chan S, **Hossain J**, Brenn B RI, Di Pentima M C. Influence of Body Mass Index and Antibiotic Dosing on the Risk of Surgical Site Infections in Pediatric Clean Orthopedic Surgery; Surgical Infections; 2012 Dec;13(6):371-6.
7. Benson M, **Hossain J**, Caulfield M P, Damaso L, Gidding S, Mauras N. Lipoprotein Subfractions by Ion Mobility in Lean and Obese Children; Journal of Pediatrics, 2012 Jul 19.
8. Pan TL, Maresca MM, **Hossain J**, Datto GA. Does Body Mass Index accurately reflect body fat? A Comparison of Anthropometric Measures in the Longitudinal Assessment of Fat Mass. Clinical Pediatrics; Apr 18. 2012.
9. Lang JE, **Hossain J**, Smith K, Lima JJ. Asthma Severity, Exacerbation Risk and Controller Treatment Burden in Underweight and Obese Children; Journal of Asthma, Apr 25, 2012.
10. Canas J A, Damaso L, Altomare A, Killen K, **Hossain J**, Balagopal P B. Insulin resistance and adiposity in relation to serum β-carotene levels. The Journal of Pediatrics, 161(1), 58-64, 2012.
11. Mauras N, DelGiorno C, **Hossain J**, Bird K Killen K, Merinbaum D, Weltman A, Damaso L, Balagopal P. Metformin Use in Children with Obesity and Normal Glucose Tolerance – effects on 1 cardiovascular markers and intrahepatic fat; Journal of Pediatric Endocrinology and Metabolism; Volume 25, Issue 1-2, Pages 33–40, ISSN (Online) 2191-0251, ISSN (Print) 0334-018X, DOI: 10.1515/jpem-2011-0450, January 2012.
12. Lang JE, **Hossain J**, Dixon A, Shade D, Wise R; Peters S, Lima J. Does Age Impact the Obese Asthma Phenotype?: Longitudinal Asthma Control, Airway Function and Airflow Perception among Mild Persistent Asthmatics; Chest, doi: 10.1378/chest.11-0675, July 2011.
13. Kamboj S, Yousef E, McGeady S, **Hossain J.** The prevalence of antibiotic skin text reactivity in a pediatric population. Allergy and Asthma Proceedings 2011 Mar, 32(2): 99-105
14. Han JC, Damaso L, Welch S, Sweeten S, Balagopa P, **Hossain J**, Killen K, Mauras N: Effects of GH and Nutritional Therapy in Boys with Constitutional Growth Delay: A Randomized Controlled Trial. Journal of pediatrics, October 2010.
15. Simpson B A, Yousef E, **Hossain J**. Association of peanut allergy and asthma morbidity. Journal of pediatrics, volume 156, Issue 5, pages 777-781, May 2010.

D. Research Support

Active

2P20RR020173-06A1 (PI: Shaffer) 09/17/2010-06/30/2015 2.4 Calendar Months
NIH/NCCR $939,9874

Center for Pediatric Research

Goals: The goals of this proposal are to develop a Pediatric Research Center at the Alfred I duPont Hospital for Children.

Role: Biostatistician

(PI: Gidding) 08/01/2009-12/31/2013 0.6 Calendar Months
GSK Support $442,946

Fish Oil Treatment for Dyslipidemia Associated with Children and Adolescents
Goals: The aim of this study is to evaluate effectiveness of the Fish Oil Treatment for Dyslipidemia associated with children and adolescents
Role: Biostatistician

(PI: Mauras) 10/01/2010-12/31/2013 0.1 Calendar Months
Thrasher Research Fund $397,515

Effects of Simple Obesity on Markers of Inflammation and Thrombosis
Goals: The aim of this study is to investigate the role of inflammation and thrombosis as co-morbidities in the metabolic syndrome in children and adolescents and further explore the interactions of pro-inflammatory markers with markers of insulin sensitivity and pubertal hormones.
Role: Biostatistician

(PI: Mauras) 09/01/2010-12/31/2013 0.1 Calendar Months
Nemours $660,893

Statins Children with Type 1 Diabetes: Effects on Metabolism, Inflammation and endothelial Function
Goals: The aim of this study is to investigate the safety and efficacy of the use of statins in children with type 1 diabetes
Role: Biostatistician

(PI: Hassink) 07/01/2011-12/31/2013 0.2 Calendar Months
Nemours $300,000

Obesity Research Cluster (ORC): Three Projects
Goals: Assessing risk progression of T2DM/NASH in obese Patients, Determination of Risk Factors Associated with the Development of Liver Disease in Obese Children, A Novel intervention approach of N-acetyl cysteine (NAC) in obese children with suspected nonalcoholic fatty liver disease (NAFLD)
Role: Co-Investigator (Biostatistician)

(PI: Darmaun) 07/01/2011-12/30/2013 0.24 Calendar Months
Nemours $74,683

Dietary Amino Acids and Insulin Sensitivity in Children with Type 1 Diabetes
Goals: The aim of this study is to examine the effect of oral amino acids, including glutamine, enhancing insulin sensitivity in children and adolescents.
Role: Biostatistician

(PI: Wysocki) 01/01/2013-12/31/2015 1.2 Calendar Months
NIH PCORI $2,092,090

Shared Medical Decision Making (SMDM) in Pediatric Diabetes
Goals: The aim of this study is to investigate if SMDM enhances treatment adherence, device use, and parent/patient-reported outcomes in youth with T1D
Role: Co-investigator (Biostatistician)

Wysocki, T. (PI) ERMS No.12362007 09/2013- 08/2016
1.2 Calendar Months
MPI-BMP $3,979,617
Maintenance of Health Care Providers' Clinical Proficiency: Transdisciplinary Analysis, Modeling and Intervention. U.S. Department of Defense Medical Practice Initiative Breadth of Medical Practice & Disease Frequency Exposure

Binder-Macleod (PI) U54GM104941 07/1/2013 – 6/30/2018 1.2 Calendar Months
NIGMS $5,902,620
Delaware-CTR
The overall goal of the Delaware Clinical and Translational Research Program is to increase the clinical and translational research readiness of the participating institutions.

Completed Research Support

(Pilot PI: Hossain) 01/01/2011-06/30/2013 2.4 Calendar Months
COBRE (NIH) Pilot Grant $100,000
Trajectories of Change in BMI status in early Childhood
Goals: To characterize the trajectories of temporal change in age and sex adjusted BMI-z score, to explore the relationship of the pattern of trajectories with known correlates and consequences of child obesity.
Role: Pilot Principal Investigator

1R03HD-067329-01A1 (PI: Fox) 07/01/2011-06/30/2013 0.24 Calendar Months
NIH/NICHD $132,500
Real-time use of CGM in adolescents with poorly-controlled type 1 diabetes
Goals: To investigate the effect of real time CGM use in controlling T1D without increasing the frequency of hypoglycemia in adolescents with poorly-controlled T1D
Role: Biostatistician

908-M01 (PI: Mauras) 01/01/2009-03/31/2013 Consultant
Genentech Center for Clinical Research $441,708
Estrogen Dosing in Turner Syndrome: Pharmacology and Metabolism
Goals: The goals of this study are to characterize the pharmacokinetics and pharmacodynamics, assess the relative biological potency, and investigate the differential, long term metabolic effects of different oral vs. transdermal preparations of estradiol
Role: Biostatistician

PI: Robert Hered 01/01/2008-04/30/2009
Funding: National Eye Foundation and Nemours
The goals of the study are to assess the potential for success of universal screening in selected pediatric offices after training.
Preschool Vision Screening by AAP Guidelines in the Medical Home
Role: Co-Investigator/consultant

P20-RR020173-05 PI: Shaffer 09/07/2004-07/31/2010
NIH/NCCR
Center for Pediatric Research
The goals of this proposal are to develop a Pediatric Research Center at the Alfred I duPont Hospital for Children.
Role: Biostatistician

PI: Nelly Mauras
Genentech Center for Clinical Research in Endocrinology
Effects of GH and Nutritional Therapy in Boys with Constitutional Growth Delay
The aim of this study is to examine the role of nutrition supplementation and its interaction with growth hormone (GH) therapy in boys with CDGM
Role: Biostatistician (paid consultancy as needed)

PI: Wysocki 09/01/2010-12/31/2012

Nemours $890,305
Clinician-Parent-Patient Communication in Pediatrics
Goals: The aim of this study is to investigate associations between shared medical decision making and clinician- parent-patient communication with clinical outcomes in asthma, cancer, cystic fibrosis, and diabetes
Role: Biostatistician

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Mark Anthony Kummer, M.D.	Pediatric Endocrinologist
eRA COMMONS USER NAME Not applicable	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Saint Mary's University of Minnesota	B.A.	1979	Pre-Medicine
Emory University	M.D.	1984	Medicine
Dartmouth-Hitchcock Med. Center, Hanover, NH	Residency	1987	Pediatrics
University of Iowa	Fellowship	1990	Pediatric Endocrinology and Nutrition

A. Personal Statement

I have been a pediatric endocrinologist at Nemours-Pensacola since 2006 and Division Chief since 2007. I have worked with Dr. Wysocki on his NIH-funded study of behavior therapy applied to maximizing adolescents' benefits from the use of continuous glucose monitoring. I am a site PI on several industry-sponsored studies and I am collaborating with Nelly Mauras, M.D. of Nemours Children's Clinic in Jacksonville on a study of statin therapy in children with type 1 diabetes. I have participated in the preparation of this application and look forward to the possibility of contributing to the implementation and analysis of both the qualitative interview component of the proposed work and of the subsequent randomized controlled trial of Shared Medical Decision Making.

B. Positions

1989-1990: Fellow Associate, Department of Pediatrics, U of Iowa Hospitals and Clinics, Iowa City, Iowa.
1990-1995: Assistant Professor, Department of Pediatrics, U of South Dakota School of Medicine, Sioux Falls, SD.
1995-2001: Physician, Pediatric Endocrinology, Diabetes and Nutrition, PC, Portland, OR.
1997-2000: Adjunct Clinical Professor, Department of Pediatrics, Oregon Health Sciences University, Portland, OR.
2000-2002: Assistant Clinical Professor, Department of Pediatrics, Oregon Health Sciences University, Portland, OR.
2001-2005: Volunteer in Peten, Guatemala for Mission Doctors Association, Los Angeles, CA and Catholic Medical Mission Board, New York, NY.
2006- Pediatric Endocrinologist, Nemours Children's Clinic, Pensacola, FL.
2007- Chief, Division of Pediatric Endocrinology, Nemours Children's Clinic, Pensacola, FL.

C. Pertinent peer-reviewed publications

Lowe WL Jr., Kummer MA, Karpen CW, Wu XD: Regulation of insulin-like growth factor I mRNA levels by serum in cultured rat fibroblasts. Endocrinology 1990 Dec; 127(6): 2854-61.

Altherr MR, Gusella *JF*, Wasmuth JJ, Kummer MA, McKercher SW, Johnson VP: Molecular detection of a 4p deletion using PCR-based polymorphisms: A technique for the rapid detection of the Wolff-Hirschhorn Syndrome. Am J Med Gen 44(Nov): 449-54, 1992.

Mazze RS, Etzwiler DO, Strock E, Peterson K, McClave CR, Meszaros JF, Leigh C, Owens LW, Deeb LC, Peterson A, Kummer MA: Staged Diabetes Management: Toward an integrated model of diabetes care. Diabetes Care 17(June), sup 1:56-66, 1994.

Kummer MA, Ziegler EE: Lack of adverse effects of increased protein intake in term infants. FASEB J 1989; 3(3):A264.

Kummer MA, Karpen CW, Wu XD, Lowe WL Jr.: Regulation of insulin-like growth factor I mRNA levels by

serum. The Endocrine Society, June 1990.
Kummer MA: Diabetes education outreach program. American Public Health Association Nov 1992.
Kummer MA: Growth Hormone. INSPEN Nutrition Newsletter 1990;1(2):1-3. Lubbers M, Kaatz J, Kummer MA: Living with diabetes series, Sioux Falls, SD 1991
Kummer, M.A. Kids in Control, videotape
Kummer, M.A. Join Jeremy, videotape
Kummer MA, Living with Diabetes: A Manual. 1991.
Kummer MA, Living with Diabetes: A Manual, 2nd Edition. 1996.

D. Research Support
Completed grant support
Clinical Research Center (U of IA), 1989-90. $7,000-Principal Investigator. Nutrition in Cystic Fibrosis: Evaluation of Dietary Regimens by Metabolic Balance

Parsons Grant (U ofSD), 1991-2. $8,500-Principal Investigator. Nutritional Regulation of IGF-1 Production.

U.S. Department of Health and Human Services, Office of Rural Health, 1991-4. $18,456-Principal Investigator.

Diabetes Education Network. Valerie Millar Diabetes Network, 1991-4. $2,706,1 Principal Investigator. In kind contributions for the Diabetes Education Outreach Network.

Eli Lilly & Company, 1992-3. $18,000-Principal Investigator. Use of a computerized diabetes database in a rural network.

Becton-Dickinson Co., 1992-4. $15,600-Principal Investigator. Introduction of "Staged Diabetes Management" into a statewide network.

IBM, 1992. $4,000-Principal Investigator. Donation of computer hardware for the telecommunications system.

Cosmopolitan International Diabetes Foundation, 1993. $1O0,000-Medical Director. The Cosmopolitan Fund for Children.

Children's Miracle Network, 1993. $20,000-Principal Speaker. Diabetes lecture senes.

Becton-Dickinson Co., 1995. $400,000-Prinicpal Investigator. "Staged Diabetes Management: A Plan for South Dakota." Expansion of previous work to the entire state.

Active Grant Support
Use of Continuous Glucose Sensors by Adolescents with Inadequate Diabetic Control. NIH Grant #R01-DK80831. Principal Investigator: Tim Wysocki, Ph.D. 2009-2013. (Co-Investigator @ 10% FTE)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Margaret Lawson eRA COMMONS USER NAME (credential, e.g., agency login)	Pediatric Endocrinologist, Children's Hospital of Eastern Ontario, Ottawa, Canada Associate Professor, Pediatrics, University of Ottawa

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of Toronto, Toronto, Canada	BSc	06/1984	Physiology, Economics
University of Toronto, Toronto, Canada	MHSc	06/1986	Health Administration
McMaster University, Hamilton, Canada	MD	06/1989	Medicine
University of Western Ontario, London, Canada	FRCP	06/1992	Pediatrics
Hospital for Sick Children, Toronto, Canada	Fellow	06/1995	Pediatric Endocrinology
McMaster University, Hamilton, Canada	MSc	06/1998	Clinical Epidemiology
University of Ottawa, Ottawa, Canada	Sabbatical	2008-2009	Shared Decision Making

A. Personal Statement

I am a pediatric endocrinologist with 16 years' experience in treating children with diabetes and other endocrine disorders. My clinical practice and research have focused on type 1 diabetes, specifically the problem of adherence and the use of technologies such as insulin pump therapy and continuous glucose sensors. In 2008-2009, I undertook sabbatical training with Dr. Annette O'Connor at the Ottawa Hospital Research Institute to develop knowledge and skills in shared decision making, the development, evaluation and implementation of patient decision aids, and in decision support with a focus on their application to children with diabetes and other endocrine disorders. Dr. O'Connor is world-renowned for her work in the development and evaluation of patient decision aids. She was instrumental in helping me to develop the knowledge and skills required to obtain external funding from our provincial Ministry of Health to develop and implement a pediatric decision support service which will be the first hospital-based decision support program in Canada, and the first in the world dedicated to the unique decision-making needs of children and their families. Our Decision Services Team has extensive expertise in the development and evaluation of patient decision aids with the skills and experience required to advise Dr. Wysocki and his team as they develop patient decision aids for pediatric diabetes.

B. Positions and Honors

University

1995 Assistant Professor, Department of Pediatrics, University of Ottawa
2001 Associate Professor, Department of Pediatrics, University of Ottawa

Hospital

1995- present Pediatric Endocrinologist, Children's Hospital of Eastern Ontario - Active Staff
1995-1998 Head, Diabetes Service, Children's Hospital of Eastern Ontario
1998-1999 Head, Endocrine and Diabetes Service, Children's Hospital of Eastern Ontario
1999-2006 Chief, Division of Endocrinology and Metabolism, Children's Hospital of Eastern Ontario

Honours

1996 Faculty Teaching Award (chosen by Residents), Children's Hospital of Eastern Ontario
2000 Best Oral Presentation, 26th Annual Meeting of the International Society of Adolescent and Pediatric Diabetes, Los Angeles, October 2000
2004 Selected as participant in the ELAM Program (Executive Leadership in Academic Medicine), Institute for Women's Health and Leadership, Drexel University College of Medicine, Philadelphia

(nominated by our Dean and Vice-Dean; 1 of 45 participants from North America and the only Canadian)

2003 Selected as participant in the University of Ottawa Faculty of Health Sciences Leadership Program (nominated by CEO and Chief of Staff; 1 of 30 participants from the Faculty)

2004 Award of Excellence, Juvenile Diabetes Research Foundation of Canada

2010 Award of Excellence as Outstanding Clinical Researcher, Children's Hospital of Eastern Ontario Research Institute, University of Ottawa, Canada

C. Selected Peer-reviewed Publications

1. Menon K, Ward RE, **Lawson ML**, Gaboury I, Hutchison JS, Hebert PC, Canadian Critical Care Trials Group: A Prospective Multi-Center Study of Adrenal Function in Critically Ill Children. *Am J Respir Crit Care Med*, 182:246-51, 2010. PMID: 20299532
2. Sorkio S, Cuthbertson D, Barlund S, on behalf of the **TRIGR Study Group**. Breastfeeding Patterns of Mothers with Type 1 Diabetes: Results from an Infant Feeding Trial. *Diabetes Metab Res Rev*, 26:206-11, 2010. PMID: 20474068
3. Ahmet A, **Lawson ML**, Babyn P, Tricco AC. Increased Risk of Hypothyroidism in Neonates Post Iodinated Contrast Media: A Systematic Review. *Acta Paediatrica*, 98: 1568-1574, 2009. PMID: 19575766
4. Malcolm J, Keely E, Gaboury I, **Lawson ML.** Risk perception and Unrecognized Type 2 Diabetes in Women with Previous Gestational Diabetes Mellitus *Obstetric Medicine*, 2:107-110, 2009.
5. **2008 Clinical Practice Guidelines Expert Committee**. Canadian Diabetes Association 2008 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. *Can J Diabetes*, 32 (Suppl 1), S1-200, 2008. www.diabetes.ca/files/cpg2008/cpg-2008.pdf
6. **Lawson ML**, Pacaud D, Wherrett D. Type 1 Diabetes in Children and Adolescents. In: Canadian Diabetes Association 2008 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. *Can J Diabetes*, 32 (Suppl 1), S150-161, 2008. www.diabetes.ca/files/cpg2008/cpg-2008.pdf
7. Chen X-K, Lougheed J, **Lawson ML**, Gibb W, Walker RC, Wen SW, Walker MC. Effects of Repeated Courses of Antenatal Steroids on Somatic Development in Children 6 to 10 Years of Age. *Am J Perinatology*, 25:21-28, 2008. PMID: 18050037
8. Keely EJ, Malcolm JC, Hadjiyannakis S, Gaboury I, Lough G, **Lawson ML**. Prevalence of Metabolic Markers of Insulin Resistance in Offspring of Gestational Diabetes Pregnancies. *Pediatric Diabetes*. 9:53-59, 2008. PMID: 18036135
9. Hakonarson H, Grant SFA, Bradfield JP, Marchand L, Kim CE, Glessner JT, Grabs R, Casalunovo T, Taback SP, Frackelton EC, **Lawson ML**, Robinson LJ, Skraban R, Lu Y, Chiavacci RM, Stanley CA, Kirsch SE, Rappaport EF, Orange JS, Monos DS, Devoto M, Qu H-Q, Polychronakos P. A Genome-wide Association Study Identifies *KIAA0350* as a Type 1 Diabetes Gene. *Nature*, Aug 2;448(7153):591-4, 2007. PMID: 17632545
10. **The TRIGR Study Group.** Study Design of the Trial to Reduce IDDDM in the Genetically at Risk (TRIGR). *Pediatric Diabetes*, 8:117-137, 2007. PMID: 17550422
11. Phillip M, Battelino T, Rodriguez H, Danne T, Kaufman F on behalf of the participants in the **Berlin Pediatric Pump Consensus Meeting**. Consensus Statement on the Use of Insulin Pump Therapy in the Pediatric Age-Group. *Diabetes Care,* Jun;30(6):1653-62, 2007. PMID: 17372151
12. Malcolm JC, **Lawson ML**, Keely E, Gaboury I, Lough G. Glucose Tolerance of Offspring of Mothers with Gestational Diabetes Mellitus in a Low-Risk Population, *Diabetic Medicine*, 23:565-570, 2006. PMID: 16681566
13. **Lawson ML**, Pham B', Klassen TP, Moher D. Systematic reviews involving complementary and alternative medicine interventions had higher quality of reporting than conventional medicine reviews. *Journal of Clinical Epidemiology*, 58:777-784, 2005. PMID: 16018912
14. **The Canadian Growth Hormone Advisory Committee**. Impact of Growth Hormone Supplementation on Adult Height in Turner Syndrome: Results of the Canadian Randomized Controlled Trial. *Journal of Clinical Endocrinology and Metabolism*, 90: 3360–3366, 2005. PMID: 15784709

15. **Lawson ML**, Cohen N, Richardson, C, Orrbine C, Pham B'. A Randomized Controlled Trial of Regular Standardized Telephone Contact by a Diabetes Nurse Educator in Adolescents with Poor Diabetes Control. *Pediatric Diabetes*, 6:32-40, 2005. PMID: 15787899

D. Research Support

Ontario Ministry of Health Academic Health Sciences Centre AFP Innovation Fund, 2009-2011, $189,150
Development and Evaluation of a Pediatric Decision Support Service
Principal Investigator: **Lawson ML**
The goal of this project is to develop a hospital-wide decision support service for our children's hospital which will facilitate shared decision making and assist families in making difficult health-care decisions for their children through the use of patient decision aids and decision support. Dr.. Lawson is the Principal Investigator and the Medical Director of the program.

Juvenile Diabetes Research Foundation-Southern Ontario Canadian Clinical Trials Network. 2010-2013, $3,600,000
Simultaneous vs Delayed Initiation of Continuous Glucose Monitoring in Children and Adolescents with Type 1 Diabetes Starting Insulin Pump Therapy: a Multicentre RCT
Principal Investigator: **Lawson ML**; Co-investigators: Clarson C, Erhlich R, Kirsch S, Macassey K, Mahmud F.
This is a 5-site RCT which will investigate the role of timing of initiation of continuous glucose monitoring in children and adolescents who are starting insulin pump therapy. Dr. Lawson is the Principal Investigator with responsibility for all aspects of this study.

Canadian Institutes of Health Research (CIHR), 2002-2007: $10,000,000; 2009-2017: $4,100,000
TRIGR (Trial to Reduce Insulin-dependent Diabetes in the Genetically at Risk)
Principal Investigator: Dupre J, Co-Principal Investigators: Mahon J, Dosch H-M, Fraser W, **Lawson ML**
TRIGR is an international multicentre randomized controlled trial aimed at determining whether avoidance of cow's milk in infant formula can decrease the risk of developing type 1 diabetes in those genetically at risk. Dr. Lawson is responsible for the local Ottawa site (49 subjects) as well as the operation of the Canadian Coordinating Centre which is based in Ottawa and covers the 18 TRIGR Canada sites. Dr. Lawson is Deputy PI for TRIGR Canada and a member of numerous national and international TRIGR committees.

Canadian Diabetes Association Operating Grant, $36,684, 2009–2010
Youths' and Parents' Experience of Living with Continuous Glucose Monitoring and Insulin Pump Therapy
Principal Investigator: Rashotte JM, Co-Investigators: Fothergill-Bourbonnais F, Richardson C, Nakhla M, Olivier P, **Lawson ML**
This qualitative study used a phenomenologic heuristic design to examine barriers and facilitators to the use of continuous glucose monitoring in youths on insulin pump therapy. Dr. Lawson is the senior endocrinologist and serves as an advisor on this study.

Medtronic Canada, 2009-2010, $35,000 (in-kind contribution of supplies)
Use of the REAL-Time Continuous Glucose Monitor at Initiation of Insulin Pump Therapy in Children and Adolescents: A Randomized Controlled Trial
Principal Investigator: Olivier P (Fellow), Co-investigators: **Lawson ML** (Fellowship Supervisor), Nakhla M, Richardson C.
This was the pilot study for our multicentre RCT which was just funded and will begin in 2011. The purpose of the pilot study was to determine feasibility and acceptance of the protocol. Dr. Lawson was the senior endocrinologist supervising the research fellow responsible for this study.

Physicians' Services Incorporated (PSI), September 2008-August 2009, $30,000
Prevalence of Nocturnal Hypoglycemia in Children and Adolescents with Type 1 Diabetes on a Standard (TID) Insulin Regimen Using a Continuous Glucose Monitoring System (CGMS) – A Pilot Study

Principal Investigator: Ahmet A, Co-Investigators: Dagenais S, **Lawson ML**
This pilot study of 20 children examined the prevalence of nocturnal hypoglycemia using the iPro continuous glucose monitoring in children receiving an insulin regimen which included bedtime NPH. Dr. Lawson was the senior investigator, providing supervision and advice to her junior colleague who conducted the study.

CHEO Research Institute, September 2008-August 2009, $30,000
Prevalence of Markers of Insulin Resistance amongst Offspring Exposed to Gestational Diabetes: a 13 to 17 Year Follow-Up Study of a RCT Cohort
Principal Investigator: Hadjiyannakis S, Co-Investigators: Pinto T, Adama K, Malcolm J, Keely E, Goldfield G, Gaboury I, Rutherford J, **Lawson ML**
This is a follow-up to the study that Dr. Lawson conducted of the same cohort that she first examined at 7 to 11 years of age. Dr. Lawson played a key role in the writing of the grant but has minimal involvement in the operation of the study.

Canadian Institutes of Health Research (CIHR), April 2005-March 2007, $745,277
The Epidemiology of Adrenal Dysfunction in Pediatric Critical Illness
Principal Investigator: Menon K, Co-investigators: Hebert P, Hutchison JS, **Lawson ML**, Barrowman N
This multicentre study examined the definition, prevalence and risk factors for adrenal insufficiency in critically ill children in Canadian intensive care units. Dr. Lawson is the only endocrinologist in the study group and played key roles in the grant and manuscript writing as well as interpretation of the data.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

Judith L. Ross, M.D.	POSITION TITLE Professor
eRA COMMONS USER NAME: jxr003	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as*

INSTITUTION AND LOCATION	DEGREE	YEAR(s)	FIELD OF STUDY
Wellesley College, Wellesley, Mass.	B.A.	1972	Molecular Biology
U. of Chicago Pritzker School of Medicine	M.D.	1977	Medicine

A. Personal Statement: I am a pediatric endocrinologist at Nemours-Thomas Jefferson Pediatrics under an academic affiliation agreement between Nemours and Thomas Jefferson University. I have been active in pediatric endocrine research, particularly on androgen effects in Klinefelter and Turner syndromes and I have been an NIH-funded researcher on these topics. I also collaborate with Dr. Wysocki on his Nemours-funded project "Clinician-Parent Patient Communication in Pediatrics". If funded, I will participate in the Qualitative Interview Study in Year 1 and facilitate recruitment of participants and protocol implementation during the randomized trial.

B. Positions and Honors

1977-1980 Resident in Pediatrics, Children's Hospital of Philadelphia
1980-1983 Clinical Associate, National Institute of Child Health and Human Development
1983-1988 Assistant Professor, Hahnemann University
1983-1990 Associate Professor, Hahnemann University
1990-1992 Associate Professor, Professor, The Medical College of Pennsylvania
1993-present Professor with Tenure, Thomas Jefferson University
2008-present Director, Center for Clinical Pediatric Research at Nemours/DuPont Hospital for Children
2008-present Editor: PREP Pediatric Endocrinology Self-Assessment Program, American Academy of Pediatrics

Honorary Societies

Sigma Xi
Endocrine Society
Lawson Wilkins Pediatric Endocrine Society
Society for Pediatric Research
American Pediatric Society

C. Selected peer-reviewed publications (in chronological order).

1. Levine, J., Honig, P., Boyle, T. Salmonella reactive arthritis: clue diagnosis. J Ped 94:596-597, 1979.
2. Levine, J., Wolfe, L., Schiebinger, R., Loriaux, D.L., Cutler, G., Jr. Rapid regression of fetal adrenal zone and absent adrenal reticular zone in the marmoset. Endocrinol 3:1797-1802, 1982.
3. Levine, J.A., Loriaux, D.L., Cutler, G.B., Jr. Developmental changes in neuroendocrine regulation of gonadotropin secretion in Turner's syndrome. J Clin Endocrinol Metab 57:288-292, 1983.
4. Ross, J. Levine, Cassorla, F., Skerda, M., Valk, I., Loriaux, D.L., Cutler, G.B., Jr. The effect of estrogen dose on growth in Turner's syndrome. New Engl J Med. 309:1104-1106, 1983.
5. Antonakou-Chrousos, G., Ross, J. Levine, Kenigsberg, D., Cutler, G., Jr., Loriaux, D.L. Ophthalmologic findings in Turner's syndrome: a prospective study. Ophthalmology 91:926-930, 1984.

6. Ross, J. Levine, Barnes, K., et al. A comparison of two methods for detecting hormone peaks: the effect of sampling interval of gonadotropin peak frequency. J Clin Endocrinol Metab 59:1159-1163, 1984.
7. Gelato, M., Ross, J. Levine, Malozowski, S., Pescovitz, O.H., Skerda, M., Cassorla, F., Loriaux, D.L., Merriam, G. Effects of pulsatile administration of growth hormone-releasing hormone on short term growth with growth hormone deficiency. J Clin Endocrinol Metab 61:444-450, 1985.
8. Ross, J. Levine, Long, L.M., Loriaux, D.L., Cutler, G.B., Jr. Growth hormone secretory dynamics in Turner's syndrome. J Ped 106:202-206, 1985.
9. Ross, J. Levine, Long, L.M., Cassorla, F., Loriaux, D.L., Cutler, G.B., Jr. The effect of low dose estradiol on 6-month growth rates in patients with Turner syndrome. J Ped, 109:950-953, 1986.
10. Ross, J.L., Long, L.M., Skerda, M., Cassorla, F., Loriaux, D.L. Cutler, G.B., Jr. Growth esponse relationship between growth hormone dose and short term growth in patients with Turner syndrome. J Clin Endocrinol Metab, 63:1028-1030, 1986.
11. Ross, J.L., Pescovitz, O.H., Barnes, K., Loriaux, D.L., Cutler, G.B., Jr. Growth hormone secretory dynamics in children with precocious puberty. J Ped, 111:369-374, 1987.
12. Rose, S.R., Kibarian, M., Gelato, M., Ross, J.L., Muellner, J., Gay, K., Cutler, G.B., Jr., Cassorla, F. Sex steroids increase spontaneous growth hormone secretion in short children. J Ped Endocrinol, 3:1-5, 1988.
13. Rose, S.R., Ross, J.L., Uriarte, M., Barnes, K.M., Cassorla, F.G., Cutler, G.B., Jr. The advantage of measuring stimulated as compared with spontaneous growth hormone levels in the diagnosis of growth hormone deficiency. N Engl J Med, 319:201-205, 1988.
14. Ross, J.L., Cassorla, F.G., Carpenter, G., Long, L.M., Royster, M.S., Loriaux, D.L., and Cutler, G.B., Jr. The effect of short term treatment with growth hormone and ethinyl estradiol on lower leg growth rate in girls with Turner's syndrome. J Clin Endocrinol Metab 67:285-288, 1988.
15. Rose SR, Municchi G, Barnes K.M., Uriarte M, Ross JL, Cutler, GB. Spontaneous growth hormone secretion during puberty in normal boys and girls. J Clin Endocrinol Metab, 73:428-435, 1991.
16. Ross, J.L., Long, L.M., Feuillan, P.,Cassorla, F., and Cutler, G.B., Jr. Normal bone density of the wrist and spine and increased wrist fractures in girls with Turner syndrome. J Clin Endocrinol Metab, 73:355-359, 1991.
17. Ross, J.L. and Cutler, G.B., Jr. The optimal use of estrogen in the treatment of Turner syndrome. The Endocrinol 2:119-121, 1992.
18. Johnson, R., Jr., Rohrbaugh, J.W., and Ross, J.L. Altered brain development in Turner's syndrome: an event-related potential study. Neurology 43:801-808, 1993.
19. Ross, J.L., Reiss, A.L., Freund, L., Roeltgen, D., and Cutler, G.B., Jr. Neurocognitive function and brain imaging in Turner syndrome. Hormone Research 39(suppl 2):65-69, 1993.
20. McCauley, E., Ross, J.L., Kushner, H., and Cutler, G.B., Jr. Psychological adjustment in girls with Turner syndrome. Journal of Developmental and Behavioral Pediatrics, 16:82-88, 1995.
21. Ross, J.L., Stefanatos, G., Roeltgen, D., Kushner, H., and Cutler, G.B., Jr., Ullrich-Turner syndrome: Neurodevelopmental changes from childhood through adolescence. Am J Med Gen, 58;74-82, 1995.
22. Reiss, A.L., Mazzocco, M.M., Greenlaw, R., Freund, L.S., and Ross, J.L. Neurodevelopmental effects of X monosomy: a volumetric imaging study. Ann Neurol, 38:731-738,1995.
23. Ross JL, McCauley E, Roeltgen D, Kushner H, and Cutler GB Jr. Self-image in adolescent girls with Turner syndrome: potential estrogen effects. J Clin Endocrinol Metab,81:926-931, 1996.
24. Reiss AL, Abrams, MT, Singer AS, Ross JL, and Denckla MB. Brain development, gender, and IQ in children: a volumetric imaging study. Brain 119(part 5):1763-1774, 1996.
25. Ross JL, Kushner H, and Roeltgen DP. Developmental changes in motor function in girls with Turner syndrome, Pediatric Neurology 15:317-322, 1996.
26. Ross JL, Kushner H, and Zinn, AR. Discriminant analysis of the Ullrich-Turner syndrome neurocognitive profile. Am J Med Genet 72:275-280,1997.
27. Ross JL, Feuillan P, Kushner H, Roeltgen D, and Cutler, GB, Jr. Absence of growth hormone effects on cognitive function in girls with Turner syndrome. J Clin Endocrinol Metab 82:1814-1817, 1997.

28. Romans SM, Roeltgen DP, Kushner H, and Ross JL. Executive function in females with Turner syndrome. Developmental Neuropsychology 79:140-147, 1998.
29. Ross JL, Roeltgen D, Feuillan P, Kushner H, Cutler, GB Jr. Estrogen effects on nonverbal processing speed and motor function in girls with Turner syndrome. J Clin Endocrinol Metab,83:3198-3204,1998.
30. Romans SM, Stefanatos G, Roeltgen DP, Kushner H, Ross JL. The transition to young-adulthood in Ullrich-Turner syndrome: neurodevelopmental changes, Am J of Med Gen, 79:140-147, 1998.
31. Zinn AR, Tonk VS, Chen Z, Flejter WL, Gardner HA, Guerra G, Kushner H, Schwartz SL, Sybert VP, Van Dyke DL, and Ross JL. Evidence for a Turner syndrome locus or loci at Xp11.2-p22.1, Am J Hum Genet 63:1757-1766, 1998.
32. Ross JL, Roeltgen D, Feuillan P, Kushner H, and Cutler, GB, Jr. Use of estrogen in young girls with Turner syndrome: effects on memory. Neurology 54:164-170, 1999.
33. Ross, JL, Zinn, AR, McCauley, E. Neurodevelopmental and psychosocial aspects of Turner syndrome. Mental Retardation and Developmental Disabilities Research Reviews 6:135-141, 2000.
34. Ross, JL, Roeltgen, D, Kushner, H, Wei, F, Zinn, AR. The Turner syndrome-associated neurocognitive phenotype maps to distal Xp. Am J Hum Genet 67:672-681, 2000.
35. McCauley, E, Feuillan, P, Kushner, H, Ross, JL. Psychosocial development in adolescents with Turner syndrome. Journal of Developmental and Behavioral Pediatrics 22:360-365, 2001.
36. Ross JL, Scott C Jr, Marttila P, Kowal K, et al. Phenotypes associated with SHOX deficiency. J Clin Endoc Metab 86:5674-5680, 2001.
37. Ross, JL. The Adult Consequences of Pediatric Endocrine Disease: II Turner Syndrome. Growth, Genetics, and Hormones 17:1-8, 2001.
38. Zinn, AR, Ross, JL. Molecular analysis of genes on Xp controlling Turner syndrome and premature ovarian failure (POF). Seminars in Reproductive Medicine 19:141-146, 2001.
39. Ross JL, Scott C Jr, Marttila P, Kowal K, Nass A, Papenhausen P, Abboudi J, Osterman L, Kushner H, Carter P, Ezaki M, Elder F, Wei F, Chen H, Zinn AR. Phenotypes associated with SHOX deficiency. J Clin Endoc Metab 86:5674-5680, 2001.
40. Ross, JL, Stefanatos, G, Kushner, H, Zinn, AR, Bondy,C., and Roeltgen, D. Persistent cognitive deficits in adult women with Turner syndrome. Neurology 58:218-225, 2002.
41. Lesniak-Karpiak, K, Mazzocco, MM, Ross, JL. Behavioral assessment of social anxiety in females with Turner or Fragile X syndrome. Journal of Autism and Developmental Disorders 33:55-67, 2003.
42. Brown, S.R. Kesler, WE, Eliez, S, Warsofsky, MS, Haberercht, M, Patwardham, A, Ross, JL, Neely, EK, Zeng, SM, Yankowitz, J, Reiss, AL. Brain development in Turner syndrome: A magnetic imaging study. Psychiatry Research: Neuroimaging 116:187-196, 2002.
43. Ross, JL, Roeltgen, D, Stefanatos, GA, Feuillan, F, Kushner, Bondy, C, and Cutler, GB, Jr. Androgen-responsive aspects of cognition in girls with Turner syndrome. J Clin Endoc Metab 88:292-296, 2003.
44. Lesniak-Karpiak, K, Mazzocco, MM, Ross, JL. Behavioral assessment of social anxiety in females with Turner or Fragile X syndrome. Journal of Autism and Developmental Disorders 33:55-67, 2003.
45. Wilson, CA, Heinrichs, C, Larmore, KA, Craen, M, Brown-Dawson, J, Shaywitz, S, Ross, JL, Klein, KO.
Estradiol levels in girls with turner syndrome compared to normal prepubertal girls as determined
by an ultrasensitive assay. J Ped Endocr Metab 16:91-96, 2003.
46. Boycott, K.M., Parslow, M.I., Ross, J.L., Miller, I.P., Bech-Hansen, N.T., and macLeod, P.M. A familial contiguous gene deletion syndrome at Xp22.3 characterized by severe learning disabilities and ADHD. Am J Med Genet 122A:139-147, 2003.
47. Leppig, K.A., Sybert, V.P., Ross, J.L., Cunniff, C.M., Trejo, Tl, Raskind, W.H., Disteche, C.M. Phenotype and X inactivation in 45,X/46,Xr(X) cases. Am J Med Genet 128A:276-284, 2004.
48. Ross J.L., Stefanatos G.A., Kushner H., Bondy C., Nelson, L., Zinn, A., and Roeltgen, D., The

effect of genetic differences and ovarian failure: intact cognitive function in adult women with premature ovarian failure versus Turner syndrome. J Clin Endoc Metab 89:1817-1822, 2004.
49. Leschek, EW, Rose, SR, Yanovski, JA, Troendle, JF, Quigley, CA, Chipman, JJ, Crowe, BJ, Ross, JL., Cassorla, FG, Blum, WF, Cutler, GB Jr., Baron, J. Effect of growth hormone treatment on adult height in children with non-growth hormone-deficient short stature: a randomized, double-blind, placebo-controlled trial. J Clin Endoc Metab 89:3140-3148, 2004.
50. Ross, JL, Sandberg, DE, Rose, SR, Leschek, EW, Baron, J, Chipman, JJ, Cassorla, FG, Quigley, CA, Crowe BJ, Roberts, K, and Cutler, Jr., GB. Psychological adaptation in children with idiopathic short stature treated with growth hormone or placebo. J Clin Endoc Metab 89:4873-4878, 2004.
51. Ross, JL, Samango-Sprouse, C, Lahlou, N, Kowal, K, Elder, F, Zinn, AR. The phenotype of early androgen deficiency in young boys with 47,XXY Klinefelter syndrome. Horm Res 64:39-45, 2005.
52. Ross, JL, Kowal, K, Quigley, CA, Blum, WF, Cutler, GB, Jr., Crowe, B, Hovanes, K, Elder, FF, Zinn, AR. The phenotype of short stature homeobox gene (SHOX) deficiency in childhood: contrasting children with Leri Weill dyschondrosteosis and Turner syndrome, J Ped 147:499-507, 2005.
53. Quigley, CA, Gill, AM, Crowe, BJ, Roberts, K, Chipman, JJ, Rose, SR, Ross, JL, Cassorla, FG, Wolka, AM, Wit, JM, Rekers-Mombarg, LTM, Cutler, GB, Jr. Safety of growth hormone treatment in pediatric patients with idiopathic short stature. J Clin Endoc Metab 90:5188-5196, 2005.
54. Zinn, AR, Ramos, P, Elder, FF, Kowal, K, Samango-Sprouse, C, Ross, JR. Androgen receptor CAG_n repeat length influences phenotype of 47,XXY (Klinefelter) syndrome, J Clin Endoc Metab 90:5041-5046, 2005.
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56. Ross, JL, Roeltgen, D, Zinn, AR. Cognition and the sex chromosomes: studies in Turner syndrome. Horm Res 65:47-56, 2006
57. Russell, HF, Wallis, D, Mazzocco, MMM, Moshang, T, Zackai, E, Zinn, AR, Ross, JL, Muenke, M. Increased prevalence of attention-deficit/hyperactivity disorder (ADHD) in girls with Turner syndrome with no evidence of an imprinting effect for cognitive performance or ADHD, J Ped Psych 1-11, 2006.
58. Schmidt, PJ, Cardoso, GMP, Ross, JL, Haq, N, Rubinow, DR, and Bondy, CA. Shyness, social anxiety, and impaired self-esteem in Turner syndrome and premature ovarian failure. JAMA 295:1374-1376, 2006.
59. Fechner, PY, Davenport, ML, Qualy, RL, Ross, JL, Gunther , DJ, Eugster , EA, Huseman, C, Zagar AJ, Quigley, CA. Differences in FSH Secretion Between 45,X Monosomy Turner Syndrome and 45,X/46,XX Mosaicism Are Evident at an Early Age. J Clin Endoc Metab, 91:4896-4902, 2006.
60. Zinn, AR, Roeltgen, D, Stefanatos, G, Ramos, P, Elder, F, Kushner, H, Kowal, K, Ross, JL. A Turner syndrome neurocognitive phenotype maps to Xp22.3. Behavioral and Brain Functions, 3:24 doi:
10.1 186/1744-908 1-3-24, 2007.
61. Simon, TJ, Takarae, Y, DeBoer, T, McDonald-McGinn, DM, Zackai, EH, Ross, JL. Overlapping numerical cognition impairments in children with chromosome 22q11.2 deletion or Turner syndromes. Neuropsychologia 46: 82-94, 2007.
62. Zeger, MPD, Zinn, AR, Lahlou, N, Ramos, P, Kowal, K, Samango-Sprouse, C, and Ross, JL. The effect of ascertainment and genetic features on the phenotype of Klinefelter syndrome.J Ped 152:716-722, 2008.
63. Ross, JL, Roeltgen, D, Stefanatos, Benecke, R, Zeger, MPD, Kushner, H,G, Ramos, P, Elder, F, Zinn, AR. Cognitive and motor development during childhood in boys with Klinefelter syndrome. Am J Med Gen, Part A, 146A:708-719, 2008.
64. Tartaglia, N, Davis, S, Hench, A, Nimishakavi, S, Beauregard, R, Reynolds, A, Fenton, L, Albrecht, L, Ross, J, Visootsak, J, Hansen, R, Hagerman, R. A new look at XXYY syndrome:

medical and psychological features, Am J Med Gen, Part A, 146A:1509-22, 2008.
65. Ross, JL, Mazzocco, MMM, Kushner, HK, Kowal, K, Cutler, GB, Jr., Roeltgen, D. The effect of treatment with oxandrolone for 4 years on the frequency of severe arithmetic learning disability in girls with Turner syndrome. Journal of Pediatrics, 155:714-720, 2009. PMID: 19643440

D. Research Support.

Ongoing Research Support

NIH RO1 NS050597 (J.L. Ross, P.I.) Androgen effect on motor/cognitive outcome in Klinefelter syndrome, 5/1/06-4/30/2011. This grant is the ongoing clinical trial in boys with KS.

NIH RO1 NS050597S3 (J.L. Ross, P.I.) Androgen effect on brain structure/function in Klinefelter syndrome,
1/1/09-4/30/2011, This grant evaluates brain structure and function in boys with KS.

NIH RO1 NS32531-11 (J.L. Ross, P.I.). Androgen effects on cognition in Turner syndrome. 1/94-12/09. This project is designed to evaluate the effects of androgen on cognition of girls with Turner syndrome.

Nemours Research Cluster Grant. (T. Wysocki, Ph.D., P.I., J. Ross, Co-I) Clinician-Parent-Patient Communication in Pediatrics. 09/10-12/11. This longitudinal study will examine links between directly observed clinical communication behaviors and both proximal and distal outcomes of health care among pediatric patients with five different chronic medical conditions.

RESEARCH STRATEGY

Part A: Background and Significance

A.1. Specific Aims Substantial evidence affirms that the "Holy Grail" of health care delivery science, getting the right care to the right patient at the right time, is not achieved consistently in the care of teens with type 1 diabetes (T1D). Technological advances such as continuous subcutaneous insulin infusion (CSII; insulin pump) and continuous glucose monitoring (CGM) offer great potential for improved glycemic control and greater lifestyle flexibility, but adolescents, compared with adults, derive less benefit from incorporating these advances into their care.[1-20] While any diabetes clinician can readily point to instances in which CSII or CGM have markedly improved T1D outcomes in some adolescents, the research shows that adolescents in aggregate do not realize improved outcomes with these technologies. This suggests that adolescent candidates for CSII and CGM either are not selected carefully enough, are passive participants in decision making about their health care, are inadequately prepared for the practical demands of using these technologies optimally, or have not anticipated or circumvented their key personal barriers to effective incorporation of these technologies into care. The planned work will complement Dr. Wysocki's ongoing NIH-funded trial (R01-DK080831) of a behavioral intervention to enhance teens' benefit from CGM use by testing an intervention designed to facilitate the initial incorporation of CSII and CGM into adolescents' T1D care. We will determine if a Shared Medical Decision Making (SMDM) intervention can improve the quality of decision making and behavioral and metabolic outcomes among adolescents with type 1 diabetes (T1D) who are candidates for either CSII or CGM. Leading health care organizations advocate shared decision making as a central aspect of a learning health system and in support of efforts to provide reliable evidence for making informed healthcare decisions that more effectively engage patients as partners in their own care.[21-22] Specifically, the Patient Centered Outcomes Research Institute intends to provide patients with enhanced understanding of available prevention and treatment options, as well as the science that supports these options.[22] We propose a 3-year program of research with these Specific Aims:

Specific Aim 1 (Completed): In consultation with expert qualitative researchers, we have completed separate qualitative interviews of 53 Nemours adolescent patients with T1D and parents/caregivers who have previously made a decision (*pro or con*) about initiating CSII or CGM. Interviews obtained their perspectives of the decision making process, their post-decision experiences and their recommendations regarding how their decision making could have been enhanced. We have conducted similar interviews with 14 pediatric endocrinologists and certified diabetes educators from throughout Nemours.
Specific Aim 2 (Completed): With input from parents and adolescents who have previously faced one of these decisions, Nemours Center for Children's Health Media, pediatric endocrinologists, certified diabetes educators, and three expert consultants in qualitative research and shared medical decision making (Drs. Brinkman, Lawson and Fiks), we have prepared and iteratively refined for use in pediatrics multi-media "Decision Aids" on CSII and CGM for dissemination via a web platform meeting the International Patient Decision Aids Standards. After obtaining a username and password to be provided separately, IRB members, consultants and others can explore final versions of these tools at these websites: https://Nemours.MyPumpChoice.org/ and https://Nemours.MyCGMChoice.org/.
Specific Aim 3: The current study is a multi-site randomized trial of SMDM versus usual clinical practice (UCP) with 166 11-<17 year old patients with T1D who are candidates for CSII or CGM and their parents. This study will evaluate the effects of the SMDM intervention over 1 year on primary outcome measures of: quantity and quality of use of CSII or CGM if selected and measures of decision quality, CGM or Pump knowledge and satisfaction with CSII or CGM, and on secondary outcome measures of T1D treatment adherence, glycemic control and diabetes-related distress. Utilization of the decision aids will be tracked carefully. These points justify our specific aims:

A.2. Suboptimal adherence in adolescents with T1D Adherence with T1D care declines in adolescence,[23-30] increasing risks of ketoacidosis and severe hypoglycemia.[31-35] Careful behavioral interventions targeting teens' adherence have yielded weak and transient benefits.[36-42] Adolescents are prone to suboptimal or discontinued use of new technology that has been added to care,[1-20] suggesting that their perspectives were either not obtained or potential barriers were not anticipated effectively. Poor adaptation to T1D in adolescence may persist into early adulthood, raising risks of long term medical and psychiatric complications.[43-45] Nonadherence may promote acute (i.e. hypoglycemia, hyperglycemia, diabetic ketoacidosis) and chronic complications of T1D (i.e. retinopathy, nephropathy, heart disease, neuropathy).[1, 31-35, 46] Poor adherence may obfuscate the merits of the prescribed therapy and impede evaluating and adjusting the regimen. Poor adherence may yield no immediate, salient adverse health effects, while achieving tight glycemic control may

increase hypoglycemia, thus promoting suboptimal self-care. Non-adherence may aggravate parent-youth conflict, which has been associated with poor T1D outcomes.[24, 28, 33, 35] Poor or variable adherence may impede healthy parent-adolescent teamwork, [24, 28, 31-35] a key element of effective T1D care, [47-57] inducing some parents to withdraw prematurely from their youths' care. [48-56]

A.3. SMDM and related approaches in adult medicine Studies affirm the merits of patient-centered and autonomy-supportive clinical communication, especially with adults with diabetes.[58] These have included Anderson's Patient Empowerment Model, [59-60] Williams' work on Self-Determination Theory and health behaviors, [61-66] Glasgow's work applying the Chronic Care Model to office-based diabetes management [67-68] and trials of Motivational Interviewing to improve T1D care. [69-72] This work shows promising effects on objective and subjective clinical outcomes, but little of this research has concerned pediatric T1D.

Medical decisions can be dichotomized into those in which clear empirical evidence affirms the efficacy of a specific treatment or procedure and for which no good alternative exists and those in which the evidence for a treatment or procedure is equivocal, where the alternatives have similar evidence bases or where the more effective option also carries more risk. In these latter cases ("preference-sensitive" decisions), effective patient-centered communication could facilitate offering the right care to the right patient at the right time. Shared medical decision making (SMDM) is a process by which patients' needs, values and preferences are reflected, along with a careful appreciation of the evidence base, when parents, patients and health care providers (HCPs) collaborate to make health care decisions.[73-76] SMDM has been studied both as a general style of health care communication [73-78] and as a structured intervention [73, 74, 79-80] designed to fully inform people about the risks and benefits of a specific health care choice. Extensive research affirms that patient-centered and autonomy-supportive communication [58-72] and shared medical decision making [73-80] have been associated with positive objective and subjective outcomes of care, including adult diabetes care. [76-80] Formal SMDM interventions use carefully designed "Decision Aids" to assist patients in clarifying their values and preferences about specific aspects of the decision, facilitate participation in the SMDM process by others selected by the patient, and enable the patient to draw upon the experiences of others who have faced the same decision, thus activating the patient to engage in collaborative care planning with the HCP. [73-80] Decision aids are educational interventions designed to help people make specific, deliberative choices by providing information about the options and outcomes that are relevant to them, by clarifying patients' personal values and preferences, and by helping patients communicate to the HCP any remaining issues that might affect their decision-making. SMDM research has been growing rapidly, as revealed by recent systematic reviews of SMDM measurement methods, [81-82] evaluations of decision aids and their critical elements [83] and interventions for improving adoption of decision aids by health care professionals.[84]

A.4. Much less SMDM research in pediatrics Considerable research has been done on communication among clinicians, parents and patients in pediatrics, but most of it has been in primary care and few longitudinal studies of pediatric chronic conditions have been done. [85-99] Little SMDM research has occurred in pediatrics. Croom et al. [100] showed that teens who rated their HCPs as valuing their perspectives had better treatment adherence and glycemic control and better parental relations. Channon et al. [69] reported that a motivational interviewing intervention, which shares the SMDM emphasis on patient-centered communication, yielded significant improvements in teens' glycemic control compared to standard care. Williams et al. [65-66] found that teens with more autonomy support from their parents tended to make healthier life choices. Gavin et al. [101] found that adolescents who reported a strong therapeutic alliance with their HCPs had better asthma outcomes. Williams et al. [102] analyzed correlates of the extent of shared medical decision making reported by youths in their health care. Fiks and colleagues [103-107] and Brinkman and colleagues [108-109] have contributed several studies of SMDM in the context of clinical management of attention deficit hyperactivity disorder. Since this grant application was first submitted, additional pediatric SMDM papers have been published, but none of these are reports of well-controlled trials of SMDM for pediatric health care decisions.[110-117]

Our team has recently completed a pilot and feasibility study evaluating the merits of use of carefully prepared hard-copy decision aids for patients and families facing two medical care decisions for their children: allergen immunotherapy and spinal fusion surgery for patients with severe scoliosis secondary to neuromuscular diseases. That study demonstrated improved knowledge of both treatment choices and their respective benefits and disadvantages, as well as evidence of high satisfaction among all stakeholders with use of the decision aids, and low levels of decision regret. In the case of allergen immunotherapy, the study yielded evidence of improved appointment keeping compared with similar patients who did not participate in the study. No other studies have tested a structured SMDM intervention in pediatric T1D or any other pediatric chronic conditions, but this small pilot study, as well as other studies that offer supportive evidence for SMDM, [85-117] provides justification for such a trial.

A.5. Potential mechanisms of benefit from SMDM among adolescents There are many reasons why youths' involvement in health care decisions could enhance behavioral and biomedical outcomes of care. Youths with T1D have largely taken responsibility for most aspects of diabetes care by mid-adolescence and many self-management behaviors tend to occur when away from the parents. [48-56] Medical decision making that discounts the youth's perspective could ignore barriers that may emerge later, resulting in declining enthusiasm for the chosen treatment, [57] as manifest by inadequate frequency of blood glucose monitoring and inadequate use of obtained results, [2-7] missed or delayed bolus infusions, [8-13] cessation of insulin pump use, [14-15] and declining use of continuous glucose monitors. [16-20] Involving youths in medical decision making may promote their recognition of impediments to specific treatment options, such as peer reactions, fashion issues, or intrusion into school or sports. Directly addressing these barriers may permit proactive problem solving with parents or HCPs, [33, 48-57] possibly forestalling a disappointing experience with an unacceptable modality. Although many/most parents make key life decisions for adolescents, medical decision-making may be special since the adolescent's commitment is so critical to its efficacy. [23, 27, 33, 57] Providing a safe, structured opportunity for youths to take a major role in medical decision making may help parents and youths recognize and negotiate diverse perspectives, generate solutions to anticipated barriers and reach joint decisions that respect their shared interests. Participating in medical decision making may also help adolescents become better consumers of health care, skills that could be very valuable to anyone with a lifelong chronic disease.

Finally, active involvement in medical decision making may enhance youths' motivation to embrace the treatment option if that choice is more internally driven than externally imposed. [59-80] Thus, SMDM could promote incorporation of CSII and CGM into adolescents' T1D care through these mechanisms:

- Increased knowledge of CSII or CGM and the behavioral demands of their optimal use
- Enhancement of adolescents' active involvement in decision making about CSII or CGM
- Increasing adolescents' sense of autonomous self-determination regarding CSII or CGM
- Realistic appreciation of the advantages and disadvantages of CSII and CGM
- Enhanced recognition of barriers to optimal use of CSII or CGM
- Elicitation of questions to the health care team that otherwise would not have been asked
- Greater exposure to both the positive and negative CSII or CGM experiences of others
- Facilitated opportunities to anticipate and resolve personally meaningful CSII or CGM barriers
- Enhanced recognition that T1D management goals are entirely possible without adding CSII or CGM
- Realization that a decision could be deferred until identified barriers to CSII or CGM are resolved
- Cultivation of social supports by teaching significant others about CSII or CGM

A.6. Special considerations regarding SMDM in pediatrics There is empirical support for SMDM in adult health care, but there are valid reasons to question whether these findings will obtain in pediatrics. Empirical research on SMDM in pediatrics must address characteristics of clinical communication in pediatrics that differ from that with adults. 1.) Clinical communication with adults is typically dyadic, (clinician-patient) [58, 67] while that in pediatrics is triadic (clinician-patient-parent); [81, 84, 87-90, 93] 2.) Decision-making in parent-youth dyads tends to reflect a marked power differential in which parents typically dominate in reaching major life decisions affecting adolescents; [22, 33, 47, 51] 3.) Youths' cognitive and linguistic skills increase steadily throughout childhood, implying that conversations regarding medical decisions should be tailored to each child's cognitive and linguistic development; [23, 40, 42, 46-57, 65-66] and 4.) Compared with adults, teens may be less capable of anticipating the range of barriers that may impede benefit from offered medical options. [5-24] We have accommodated these nuances explicitly in designing the SMDM intervention that we propose to test.

A.7. Innovation and Potential for Improvement Through Research Poor adherence in adolescence is so common in typical health care for diabetes that a re-examination of health care delivery to these patients is warranted. Research on patient-centered communication and shared medical decision making in adult medicine shows considerable promise in improving objective and subjective clinical outcomes. Evaluation of this approach in the pediatric diabetes population could validate new approaches to health care delivery that promote adherence and improve short-term and long-term clinical outcomes. Patients with T1D may soon face other medical decisions such as the so-called "closed loop artificial pancreas" and treatment of newly diagnosed patients with monoclonal antibodies that selectively interrupt the auto-immune attack on pancreatic islet cells, thus preserving residual endogenous insulin secretion. Empirical validation of SMDM in the context of pediatric T1D could also have relevance to applications of this approach with other chronic conditions in pediatrics and other clinical domains. A demonstration of SMDM efficacy in this context could stimulate and justify more SMDM research about other pediatric health care decisions. Dr. Wysocki's extensive accomplishments in conducting clinical trials of behavioral interventions in pediatric T1D assure that the

proposed work will be completed carefully and analyzed and disseminated responsibly and productively.[118-158] Dr. Wysocki's recent T1D behavioral intervention trials [124-126, 150-151] have concerned prediction of benefit from intensified regimens and, currently, optimization of benefit from continuous glucose monitoring. Those trials have targeted improved glycemic control and treatment adherence, and a key lesson learned from this work has been that participants' initial expressed enthusiasm for improved glycemic control is a poor predictor of lasting change in T1D self management or the consistent, meticulous use of technological aids to achieving this. The present research study will test a behavioral intervention (SMDM) that is not expected to exert robust direct effects on glycemic control or overall adherence among patients for whom these have been chronic problems. Instead, the intervention is conceived as improving decision quality and enhancing the likelihood that CSII or CGM will become meaningful elements of adolescents' T1D self management. If proven effective in this regard, the SMDM intervention may be a valuable adjunct to other behavioral interventions targeting broader T1D self management objectives or as a "stand-alone" intervention to promote incorporation of CSII or CGM into care for adolescents with the requisite cognitive, affective, motivational and environmental resources to support their success in doing so.

A substantial investment in Dr. Wysocki's research cluster on clinician-parent-patient communication in pediatrics has positioned Nemours to become a major research center in this aspect of the science of health care delivery. Dr. Wysocki has a strong record of NIH funding for multicenter trials of behavioral interventions, studies of adaptation to new T1D technologies, research on family communication in T1D and investigations of parental permission and assent for research participation. Other team members have been active in pediatric endocrinology and diabetes research (Drs. Ross, Kummer, Reeves, Carukashansky and Lawson), and all have worked collaboratively with Dr. Wysocki on recent and ongoing studies. Three expert consultants, Drs. Brinkman, Fiks and Lawson, bring special expertise in shared medical decision making, communication in pediatric health care encounters and qualitative research (Fiks). Dr. Hossain is an accomplished statistician who has collaborated with Dr. Wysocki for the past 7 years in similar research.

Innovative aspects of this research are a qualitative study to guide planning the details of the randomized controlled trial, extension of SMDM research to pediatric diabetes, careful development of multimedia decision aids for dissemination via a web platform, focus on variables influencing the effective clinical incorporation of CSII and CGM in T1D care, online administration of questionnaires and development of an SMDM service that can reach families at all Nemours sites and potentially elsewhere. The current study included a qualitative interview study that preceded the randomized controlled trial to obtain the insights of parents and teens who have previously faced and made the same medical decisions being evaluated in the planned randomized trial, as well as the insights of clinicians about how the SMDM intervention should be structured, delivered and concluded. This preliminary work, refined, implemented and interpreted in consultation with expert qualitative researchers has enabled design of an SMDM intervention plan that directly addresses the expressed concerns of this clinical population regarding the structure, process and outcomes of their prior medical decision making experiences, balanced with the perspectives of experienced clinicians and external experts in SMDM. The next step is an ambitious randomized controlled trial to compare the effects of a brief affordable, innovative and disseminable SMDM intervention to that of usual clinical practices on quantity and quality of insulin pump or CGM use, decision quality, satisfaction with use of CSII or CGM, treatment adherence, glycemic control measured by central lab, T1D-related distress, and self-efficacy for T1D self-care in a large sample of youth who have not been achieving targeted HbA_{1C} levels. Follow-up over a 1-year period should be capable of detecting treatment effects on the primary and secondary outcome variables.

A.8. Impact on Health Care Practice SMDM interventions have been promoted for decades, but their penetration into routine clinical practice has been sporadic and incomplete. This weak clinical translation of SMDM principles and methods may be due in part to the absence of definitive clinical trials, the widespread variability in definitions of SMDM, deficient understanding of the mechanisms of SMDM effects, and the lack of compelling data about the cost-effectiveness and practical feasibility of delivering SMDM interventions in clinical, as opposed to research, settings. This study will reduce some of these gaps.

A.9. Relevance to Patients Dr. Wysocki has conducted a feasibility project regarding the merits of developing an SMDM service that would assist Nemours health care providers and teams from throughout the foundation's enterprise to plan, develop, implement and evaluate SMDM interventions that are pertinent to clinical problems of the greatest interest within their specific domains of health care delivery. Dr. Lawson of our team has had similar experience in developing such a service at the Children's Hospital of Eastern Ontario. The experience and lessons learned in these projects will inform the current research. With consultation from Catherine Clay, M.Ed., R.N. of The Dartmouth Institute for Informed Patient Choice, he elicited interest from the Nemours Department of Orthopedics to develop an SMDM intervention for patients with neuromuscular

diseases who are candidates for scoliosis repair and the Division of Allergy-Immunology to develop an SMDM intervention for patients who are candidates for allergen immunotherapy (allergic desensitization). Two journal articles reporting the positive results of that study have been submitted; One has been accepted for publication and we expect a similar positive decision regarding the other very soon.

Our experiences to date suggest to us that the prospect of developing an SMDM service would be of great interest to many Nemours health care providers who view this as a mechanism to facilitate the delivery of the right care to the right patient at the right time. Similarly, parents and patients also view this very favorably as a component of a health care experience that is absolutely consistent with the principles of family-centered care.

Part B: Approach-Research Design and Methods: Having completed Specific Aims 1 and 2 in the first 18 months of this grant, we now turn to implementation of a randomized controlled trial of SMDM to evaluate Specific Aim 3.

B.1. Participants:
The planned RCT sample will consist of 166 eligible patients who receive care for type 1 diabetes at any Nemours foundation entity or at the Barbara Davis Center for Childhood Diabetes in Denver, as well as a parent or other legal caregiver of each youth. Enrollment criteria for these patients include: Age, at least 11 but not yet 18 years old, T1D for ≥ 1 year or for at least 6 months and with the most recent Hemoglobin A1c of 7.5% or higher, and facing a decision about CSII or CGM. Access to technological advances in diabetes care may be limited for racial/ethnic minorities, so we will over-sample them to enroll at least 40 youth who are self-identified racial/ethnic minorities (24% of sample). See the Section on Representation of Women and Minorities for how this will be achieved. The enrollment objectives include a minimum of 30 patients facing each treatment decision to facilitate comparisons between them.

Since preparation of the Decision Aid websites has required more time than we expected, and since the funding agency (PCORI) does not now approve no-cost extensions of their funded studies, the work must end by March 31, 2016. Therefore, the duration of follow-up for each enrolled participant will depend on the date of that participant's enrollment as follows: Enrollment before 3/31/15: 12 months; Enrollment 4/1/15 through 6/30/15: 6 months. Enrollment will end on 6/30/15 and data collection will end on 12/31/15, allowing 3 months for data cleaning and verification and completion of statistical analyses. PCORI is considering allowing no-cost extensions and if that happens, the duration of follow-up for late-enrolling participants will be extended.

Enrollment criteria are:

Inclusion Criteria for Youths: Age 11 to not yet 18 years; Physician-diagnosed T1D for at least 1 year or for at least 6 months and with the most recent Hemoglobin A_{1C} of 7.5% or higher (the minimum HbA1c criterion ensures that no patients will enroll in the study who have substantial remaining endogenous insulin secretion. This will preserve the opportunity to evaluate treatment effects on HbA1c, which is an important secondary outcome of the study); Considered by treating HCP to be an appropriate candidate for CSII or CGM

Exclusion Criteria for Youths: Concurrent participation in any other research in which treatment adherence or glycemic control are study outcomes; Daily oral glucocorticoid treatment; Significant developmental delay (self-contained special education; retention in 2 or more grades); Inability to read/comprehend study questionnaires and decision aids in English; Treatment for a coincident medical condition that, in the opinion of the treating physician, represents a contraindication to study participation.

Inclusion Criteria for Parents: Primary diabetes caregiver of index child; Anticipates continued medical care for T1D at Nemours or the Barbara Davis Center for subsequent year; capable of participating in conversations during medical visits; routinely accompanies child for diabetes care at Nemours or the Barbara Davis Center.

Exclusion Criteria for Parents: Inability to read/comprehend study questionnaires and decision aids in English;Child living in a temporary placement such as foster care or juvenile detention center; Evidence of frequent changes in the adolescent's household or living arrangements.

Recruitment, Parental Permission and Adolescent Assent: The study will be approved by a Nemours IRB before recruitment begins. All Nemours health care providers who see patients for management of type 1 diabetes, and who may be in a position to evaluate and prepare candidates for incorporation of either CSII or CGM into their care plans, will receive an initial e-mail describing the study and announcing the opening of enrollment. HCPs will be provided with a link to the web-based decision aids for their inspection. A total of 13 Nemours pediatric endocrinologists and diabetes educators provided information and feedback that has been

incorporated into the decision aids as they were being developed.

Since prospective participants may be identified as possible candidates for CSII or CGM at varied times during or between clinic visits, a flexible approach to recruitment of participants is needed. There are two basic sequences of recruitment activities with a given parent/adolescent that can be identified, calling for slightly different recruitment plans. In the first case (A), a member of the research team may have identified a potentially eligible candidate through an EMR search who is scheduled in the near future for a diabetes clinic visit. In the second case (B), a parent/adolescent may become a candidate for consideration of CSII or CGM during a clinic visit. In that instance, the Nemours care provider could refer that family to the research team for more information about the study, possibly leading to their enrollment. These two pathways are articulated in greater detail below:

Recruitment Plan A: This strategy will be used in those instances in which a parent/adolescent is identified to the research team prior to an upcoming scheduled clinic appointment by a Nemours or Barbara Davis Center care provider as being eligible for participation in this study. In these instances, the family would be sent an IRB-approved letter describing the study, an IRB-approved recruitment flyer and a copy of the IRB-approved Parental Permission and Adolescent Assent forms. A member of the research team will follow up that mailing with a telephone call to the parent about 7-10 days prior to the upcoming clinic appointment. The telephone call will provide an introduction to the study, verification of eligibility, review of the content of the informed consent documents and an opportunity for parents or adolescents to have their questions about the study answered to their
satisfaction. Those who express interest in participating will then schedule a face to face conversation with the research staff member, ideally coincident with the clinic appointment. The research staff member will review the content of the consent/assent documents and obtain signatures on those documents from those who choose to participate. If convenient for them, the parent and adolescent will complete the CSII or CGM Knowledge Test, the Rapid Estimate of Adult/Adolescent Literacy in Medicine and the Diabetes Numeracy Test, since these must be administered in person, requiring about 15-20 minutes of their time. They would be instructed in how to complete the other questionnaires online and will receive an e-mailed link enabling them to do so. Once all baseline measures are completed, the family will be randomized to one of the two study conditions.

Recruitment Plan B: This strategy will be used in those instances in which a parent/adolescent dyad who has not previously been considered candidates for either CSII or CGM expresses interest in one of these options and the care provider agrees with carrying this forward. In these instances, the clinic staff should notify the member(s) of the research team at that Nemours site or the Barbara Davis Center and, if available, that person would meet the family at
the clinic to review the study flyer and consent documents as above. Should an eligible adolescent and parent consent to participate, the research staff member would offer to administer to each of them at that time the CSII or CGM Knowledge Test, the Rapid Estimate of Adult/Adolescent Literacy in Medicine and the Diabetes Numeracy Test and to instruct them in how to complete the other questionnaires online. Some participants may be willing to complete all of the baseline questionnaires at this visit, and this will be allowed. If it is not possible for participants to complete any study measures at this visit, they will be instructed in how to complete the questionnaires online and a separate appointment will be made for completing the measures that must be obtained in person. Regardless of the specific sequence of recruitment activities for a given family, randomization to one of the two study conditions will be done after all baseline measures have been obtained.

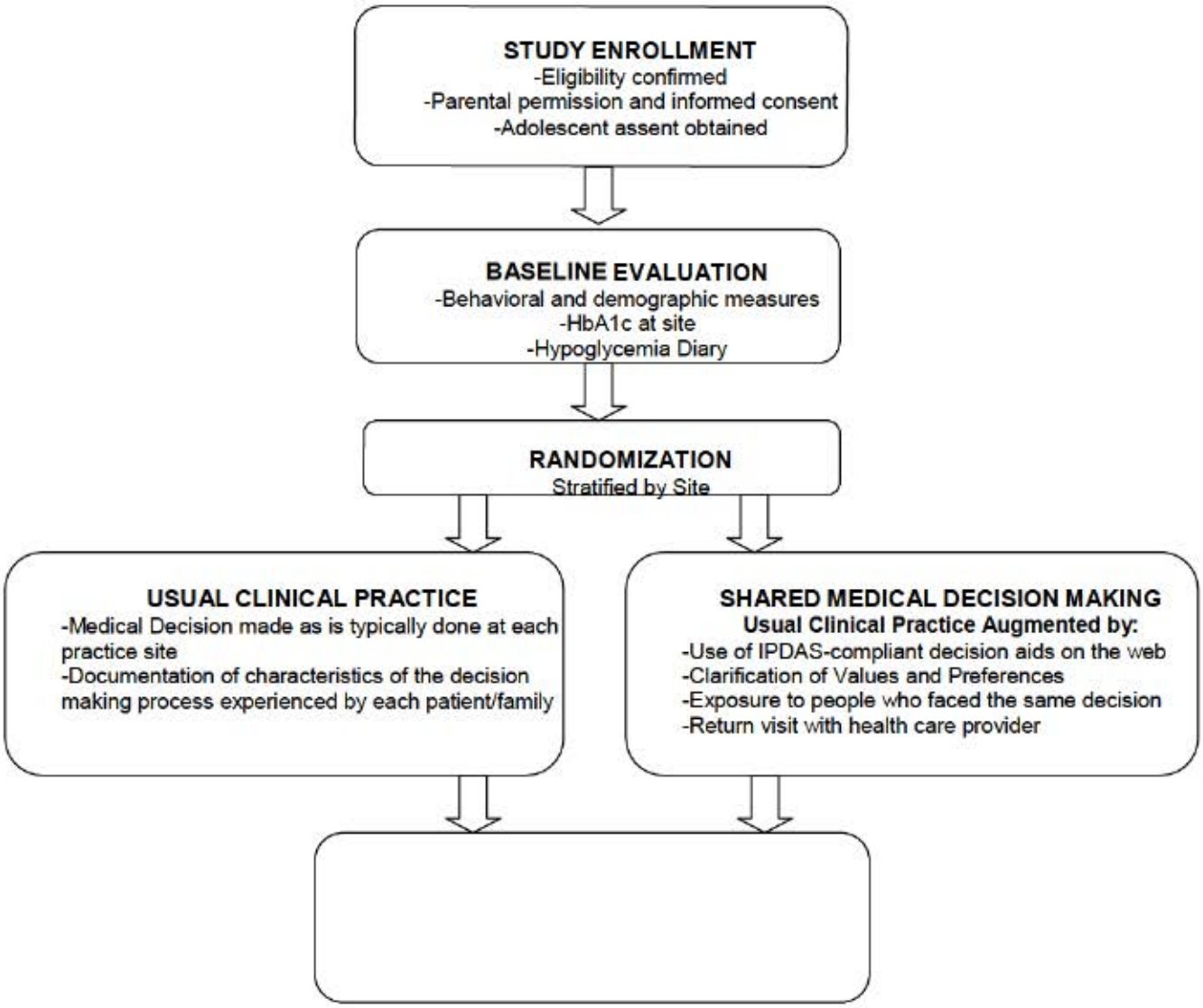
Recruitment Plan C: This strategy will be used in those instances in which a family is recruited remotely. The study will be advertised with a brief description of the study in the Childrenwithdiabetes.com website. The description will include a link for more information that will take them to a study flyer within REDCap. Then if they express interest in participating in this research, the informed consent and assent forms will pop up. Families will be offered the opportunity to speak with a representative of the research team if they wish to do so before signing the consent and assent forms. The document will conclude with an electronic signature process consisting of either signing with their mouse or if using a touchpad, signing with their finger. They will have an opportunity to print the forms prior to submitting them (families that are consented electronically will also have a copy of the signed consent forms emailed to them). Prior to submitting the signed consent and assent forms, the family will complete a few contact information questions, so that a research coordinator may contact them to get them started in the study. There will be other minor modifications to the study procedures for families enrolled remotely: study visits will not need to directly coincide with clinic visits therefore can disregard references to clinic visits; participant's diabetes physician will not play a role in the study (other than to inform him/her of the participant's enrollment and to ask for copies of A1cs); a diabetes educator nurse will

not be completing the SMDM Intervention Summary Form.
Childrenwithdiabetes.com also has a couple of international Friends for Life conferences a year, in which we will also try to recruit participants both in person and by having flyers distributed to attendees of the conferences (Church Falls conference April 8-10, 2016 and Orlando conference July 5-10, 2016).

Randomization Procedures: Once a given adolescent/parent dyad completes all baseline measures, they will be randomly assigned with equal probability to one of the two study conditions described below. Randomization will be implemented by Alex Taylor, MACP, Senior Research Coordinator in Jacksonville, using a separate randomization list for each enrolling site, to ensure that each site enrolls an approximately equal number of participants in each of the two conditions. Two or more adult caregivers for a given child may enroll in the study, in which case study questionnaires will be completed jointly by consensus of those caregivers. Some adolescents may first become a candidate for one of the devices (CSII or CGM) and thereafter become a candidate for the other. In such instances, the adolescent will remain in the same condition throughout the remainder of the study as was dictated by the initial random assignment.

B2. Study Design The study design is a 2X5 randomized treatments design with 2 groups (SMDM and UCP) and 5 measurements (5 study visits at roughly 0, 3, 6, 9, and 12 Months). A diagram of the proposed RCT design appears below. (Checklists for the tasks to be completed at each visit can be found on the shared drive at S:\PCORIgrant\Coordinator Forms; access is limited to authorized members of the research team.) A 12 month follow-up was chosen over a longer follow-up period because the planned SMDM intervention is designed to facilitate more deliberate, systematic and collaborative decision making about the adoption of T1D treatment advances, based on the presumption that successful incorporation of these treatment advances over the first year of use will facilitate continued success thereafter. Facilitating better decisions is expected to lead to more effective utilization of the available treatment option among those who accept it and prevention of unsuccessful attempts at utilizing that treatment option among those who reject it. Based on our prior trials of the adoption of intensified therapy and of continuous glucose monitoring, success or failure of that endeavor will be readily apparent for the vast majority of adolescents within 12 months and very few who initially fail to benefit will do so later. [10-13, 15-17, 19-20] A longer study could inhibit recruitment, would be more expensive and cumbersome, would not be feasible with this funding mechanism, would delay dissemination of the findings and would not add appreciably to the scientific merit. As noted above, unless PCORI allows a no-cost extension, follow-up for later-enrolling participants may be truncated at 6 months since the project currently must end by 3/31/16 and time must be allowed at the end of the project for data management and analysis.

DIAGRAM OF RCT STUDY DESIGN



REPEAT EVALUATIONS

-Measures of decision quality and CSII or CGM use
-HbA1c; Hypoglycemia Diary;
Questionnaires at appropriate intervals until
12 months after Baseline

Randomization will occur at the level of patients rather than by sites or clinicians since it is the patient's behavior that is most proximal to the primary endpoints and since randomizing at the level of site or clinician runs the risk of baseline differences between groups on key clinical practices or clinician communication style. Randomization will be stratified by enrolling site so that each site randomizes a similar number of participants to UCP and SMDM. The Senior Research Coordinator in Jacksonville will compile randomization lists for eachsite and will manage the randomization process for all sites. We considered including an "attention placebo" control group, but decided against this due to the brief, highly structured SMDM intervention (A few extra hours over 2-4 weeks), relatively long follow-up, and difficulty in defining the precise activities that would constitute a meaningful and appropriate attention control that is not seen as transparent by the participants. The extra attention to the SMDM group is in fact the independent variable, consisting of a well-defined educational intervention. Given the limited number of eligible patients, reaching recruitment objectives for a 3-group design would be more difficult and expensive than with a 2-group design. Additional discussion of this issue appears in the Limitations section.

The decision aids developed for this study have received iterative review and feedback by a diverse group of patients and parents who have previously made decisions about CSII or CGM, by multiple Nemours HCPs who care for such patients, by two general pediatricians who are SMDM experts (Drs. Brinkman and Fiks) and by two pediatric endocrinologists (Margaret Lawson, MD, one of our external consultants and Steve Dowshen, MD who is employed part time by KidsHealth). In addition, the KidsHealth production team reflects substantial expertise in development of health care communications that are designed to harmonize with the developmental characteristics and priorities of adolescents and with the typical concerns and perspectives of parents. We believe that this combined input has yielded very high quality decision aids that are exceptionally engaging, informative and interactive guides that will help adolescent patients and their parents reach better decisions about CSII and CGM that are likely to facilitate adolescents' engagement with whichever treatment alternative they ultimately select.

SMDM by definition seeks to reflect the perspectives of youths, parents, and HCPs and that is how the proposed intervention has been designed. The visits with the Diabetes Educator (DE) and use of the decision aids are designed to equip parents and youth to have more meaningful and productive discussions with HCPs about the merits of the treatment option of interest than they might achieve without the SMDM intervention. This enhanced communication, along with personal ownership of the decision, is expected to help adolescents and parents make an important treatment decision more effectively with their HCP. Hence, each SMDM patient will collaborate with their diabetes HCP and DE to reach an informed decision about CSII or CGM. We will document details of each participant's educational experiences during the decision making process as a means of verifying the integrity of the experimental manipulation (See Appendix). Each parent/adolescent dyad randomized to SMDM will have an initial orientation visit with a trained research staff member (either in person or via a scheduled phone conference), consisting of an introduction to SMDM and to the structure, content and operation of the decision aid to be used by that family. The parent and adolescent will be asked to use the decision aid over the subsequent 2-4 weeks and to come prepared to discuss with the DE at the second visit each of the discussion points that appear throughout the decision aid, as well as any other questions or comments they might wish to address. At the second visit, the DE will prepare a summary of the family's SMDM experience that will be sent to the adolescent's T1D HCP for discussion at their next clinic visit and to the research team as a process measure of each family's SMDM experience. Each HCP will be provided with a brief orientation regarding the structure of the SMDM intervention and they will be invited to inspect/use each of the two decision aids at their convenience.

UCP Intervention: The UCP intervention will consist of the education and consultation procedures currently employed at each of the participating sites for patients and families who are considered by the health care team to be suitable candidates for either CSII or CGM. There is some variability across sites and physicians in

terms of specific educational practices. All emphasize education of parents and patients so that decisions are made in an informed manner. All sites share an emphasis on activating parents and patients as active consumers of health care who participate in the planning of their treatments. Consideration of CSII or CGM may be initiated either by the parent, adolescent or HCP, and typically the candidacy moves forward only for patients deemed to have sufficient self-management skill and responsibility. In general, decisions such as CSII or CGM are made over a course of several clinic visits and rarely made at the same clinic visit at which the idea is raised initially for consideration. The experiences of each UCP participant will be carefully characterized in terms of content, duration, frequency, youth involvement, and participation of significant others so that this practice variability can be described accurately and, where possible, appropriate secondary statistical analyses performed. At the first study visit after their decisions are made, each youth-parent dyad will be asked to reconstruct precisely the types and sources of information they used, the duration of their decision-making process, the degree to which others were involved in the decision making process and the relative influence of each of these experiences in affecting their eventual decision. (See Appendix)

SMDM Intervention: All of the above features of Usual Clinical Practice will be augmented by:
- Orientation to optimal use of the decision aid web platforms by research staff
- Use of IPDAS-compliant decision aids on web platform by adolescent and parent (plus others per family preference)
- Realistic exposure to benefits and challenges associated with CSII vs. Multiple Daily Injections or with CGM (Conventional finger-stick BG checks with or without addition of CGM)
- Comprehensive understanding of the added treatment burden associated with CSII or CGM
- Exposure to the pertinent evidence base summarized for a lay audience
- Clarification of values and preferences
- Involvement of others per participants' choice
- Exposure to narrative stories of people who faced the same decision
- Preparation of an individualized summary of the patient's SMDM experience and remaining questions by the DE at a follow-up visit once the family has finished using the decision aid
- Return visit with health care provider to discuss the above summary

In addition to all components of the UCP condition, participants randomized to SMDM will receive the structured intervention described here. The intent of SMDM is to help adolescents and parents participate in making crucial health care decisions in ways that they prefer, optimizing the match between their individual preferences and life circumstances and the health care that they choose to receive. While current practices at each Nemours site already emphasize these values, the SMDM intervention is designed to supplement and extend what can realistically be achieved in a typical busy practice and to enhance the quality of decision making. SMDM is a mechanism to further enhance the probability that prudent treatment decisions will be made, thus avoiding failures and optimizing therapeutic and quality of life benefits of these decisions. The SMDM intervention is conceived as a means to enhance the initial adoption of new technologies into family management of T1D rather than as a global adherence-promoting intervention. Although adherence and glycemic control will be measured, the primary outcomes for this trial are measures of decision quality and the degree to which CSII or CGM are used optimally and become integral to management of T1D for these adolescents and their families.

SMDM participants will experience a structured consultation over ~2-4 weeks based on their use of multi-media decision aids meeting the IPDAS Standards (http://ipdas.ohri.ca/IPDAS_checklist.pdf) and a 2011 Cochrane Review (http://decisionaid.ohri.ca/docs/develop/Cochrane_Review.pdf).[83] Consistent with IPDAS, we constructed CSII and CGM decision aids that: provide accurate and detailed information about the pertinent options to enable informed decisions; present probabilities of outcomes in an understandable, unbiased manner; include methods for clarifying and expressing participants' values; and include structured guidance in deliberation and communication. A key issue in pediatrics is the extent to which decisions about treatment advances are dominated by parents versus achieved by genuine consensus between parents, adolescents and HCPs. The former could elevate the risk of eventual failure of the treatment change while the latter might be associated with more favorable longer-term outcomes. Hence, each decision aid emphasizes the merits of achieving a shared parent-youth consensus and suggestions about how this can be achieved. Pediatric endocrinologists and diabetes educators were interviewed about decision aid content and several of them subsequently critiqued and edited successive drafts of these decision aids. Draft decision aids were sent to several expert consultants (Drs. Brinkman, Fiks and Lawson) with SMDM expertise and familiarity with the IPDAS standards. Final versions of the web-based decision aids can be inspected at these websites https://Nemours.MyPumpChoice.org/ and https://Nemours.MyCGMChoice.org/ (A registered username and password must first be provided to any person who wishes to do this).

Since the medical decisions of interest are not mutually exclusive, a given patient may be a candidate for more than one of these options, either simultaneously (e.g., CGM and CSII together) or sequentially (e.g., CSII first, then CGM later). Once randomized, a patient will receive the assigned UCP or SMDM intervention for any and all of these decisions encountered during their study participation.

A Diabetes Educator (DE) at each Nemours site and the Barbara Davis Center will conduct face to face interactions with SMDM participants using the web-formatted decision aid as the framework for delivery of the SMDM intervention. Each patient, parent and any other supportive persons they wish to invite will meet with the DE after they have completed use of the decision aid (~2-4 weeks) during which the pertinent decision aid will be reviewed. Supportive persons identified by the parent or youth will be encouraged to view and use the decision aids along with the enrolled adolescent or parent. The DE will assist participants in identifying any remaining uncertainties they may have about the decision and coaching about how to bring these issues to a clinic visit with the referring HCP. A written summary of the patient's and parent's perspectives during the SMDM sessions, agreement between their perspectives and their remaining issues will be drafted by the DE and forwarded to the referring HCP (See Appendix) and to the research team as an SMDM process measure for each family. The SMDM intervention will conclude with a clinic visit with the referring HCP who will discuss the participants' remaining questions and perspectives about the information they have received and help them to arrive at a consensus decision about the medical option under consideration, including the possibility of deferring the decision to a later date. Those patients who become candidates for more than one of the options of interest during the study will repeat these interactions for each decision being considered

Practical considerations: The process of becoming a candidate for either CSII or CGM may be complicated in several ways that may make it more difficult to evaluate the specific contributions of the SMDM intervention that is planned. Below, we have listed specific complicating factors that can be anticipated and planned methods for addressing each of them:

Complicating Issue	Planned Resolution
Delay between decision to accept CSII or CGM and its actual receipt by the patient and family due to insurance denials, etc.	Questionnaire administration will occur as outlined in the measurement schedule, but collection of CSII or CGM download data will not commence until the device is received and activated.
Actual schedule of diabetes clinic visits for a given patient deviates substantially from the typical quarterly appointments.	Adolescents will not be followed for more than 12 months. If a clinic visit occurs between 9 and 12 months after the Baseline Visit, the measures designated for collection at Visit 5 will be collected at that visit, regardless of the number of previously completed study visits for that adolescent.
Indecision between adolescent and parent resulting in a period in which no clear decision is made.	Measurement plan will have slightly different measurement schedules for families who clearly decide to accept CSII or CGM, for families who clearly decide to decline CSII or CGM, and for families who either cannot reach a decision or wish to defer decision making until a later date.
Adolescent is considered to be a candidate for both CSII and CGM simultaneously.	Adolescent will be given access to both the CSII and CGM decision aids.
Adolescent already on CSII is a candidate for the so-called "low glucose-suspend" insulin pump.	Adolescent will be given access to both the CSII and CGM decision aids and especially encouraged to review the content related to the closed-loop artificial pancreas.
Adolescent and/or parent want to consider CSII or CGM, but HCP disagrees.	Adolescent is considered ineligible for the study until HCP supports the adolescent's candidacy for CSII or CGM.
Enrolled family does not have a computer for CGM or CSII downloads or for online completion of study questionnaires.	Downloads of devices and completion of questionnaires will be done in the clinic.

Adolescent initiates either CSII or CGM and then later decides to consider adding the other device to the diabetes regimen.	Device downloads will be collected for each device from the time the device is received and initialized. Measures of decision quality and device knowledge will be completed at the next study visit after receipt and initialization of the second device.

B.3. Measures: Just as the recruitment procedures have been designed to provide flexibility to prospective participants in terms of how they would enter the study, the measurement plan has also been designed to afford flexibility to participants in terms of how, where and when they will complete the various questionnaires for this project. The only measures that must be completed in person are the CSII and CGM Knowledge Tests, the Rapid Estimate of Adult/Adolescent Literacy in Medicine and the Diabetes Numeracy Test. Other study questionnaires will be available for online completion via internet access utilizing the REDCap electronic data capture software. Alex Taylor, MACP, Senior Research Coordinator, has been trained fully in developing
questionnaires in this format and she has had additional expert consultation available from Suzanne McCahan, Ph.D. of the AIDHC Bio-Informatics group. All study measures are included in a separate Appendix that is attached.

Study visits will be scheduled to be coincident with regularly scheduled diabetes clinic visits, which are expected to occur at approximately quarterly intervals for most participants. The mixed models analyses that constitute the core of the analysis plan can robustly accommodate variations in data collection schedules across participants. Adolescents and parents will each receive reminders (via e-mail, phone, text message or social media according to their preference) 2 weeks prior to the next study visit reminding them of the visit and enabling them to complete any scheduled questionnaires online. Another reminder will be sent again 5 days prior to the scheduled visit to participants who have not yet completed the questionnaires. Those who do not do so online will complete questionnaires at the clinic. In rare instances, the research team may offer the possibility of conducting home visits for collection of these measures. These procedures for online questionnaire administration were used successfully in Dr. Wysocki's recent NIH-funded trial of CGM. Total time commitment from parents and adolescents for completion of measures is ~75 min at Baseline and ~60 min at Visits 3 and 5. Visits 2 and 4 will entail little added participation burden.

Each parent/adolescent dyad will receive a $25 gift card to a discount retail chain after completing the measurement protocol at Visits 1, 3 and 5, which are the most burdensome of the visits. At each study visit in which an adolescent brings either an insulin pump or CGM to the visit for downloading, the adolescent will receive a $5 gift card for each such device that is downloaded.

Measures obtained at Baseline only

Demographic characteristics will be measured at study entry using a General Information Form as in our previous studies. This measure ascertains the child's age, diabetes duration, gender, race/ethnicity, and relevant medical history (including past CSII or CGM use) and the parents' income, educational level, occupational category, family structure, race/ethnicity, gender and age. The Hollingshead Four Factor Index of Social Status[159] will be calculated to quantify household socioeconomic status. Participants will be asked to indicate their preferred mode of contact from study staff (e.g. text, phone, e-mail, specific social media). Administration time is about 15 minutes.

Rapid Estimate of Adult/Adolescent Literacy in Medicine This brief test of health literacy will be administered in person to parents and adolescents by the research coordinator at baseline. [160]

Diabetes Numeracy Test This 14-item test of numeracy skills pertinent to T1D care will be administered in person to parents and adolescents by the research coordinator at baseline. [161]

Measures obtained at all 5 quarterly clinic visits

Glycated hemoglobin: Finger-Stick blood samples will be obtained at each quarterly visit and glycated hemoglobin (HbA_{1C}) will be determined using the point of care device currently used at each clinic (typically a DCA2000 or DCA2000plus). These devices have been found to yield results that are highly correlated with benchmark central laboratory assays and that are considered to be acceptable outcomes measures in diabetes clinical trials. HbA_{1C} reflects average glycemia over the prior 2-3 months and is considered a secondary outcome measure in this study.

Hypoglycemia Diary: Parents will record each episode of moderately severe (symptomatic and requiring

assistance from others) or severe hypoglycemia (with seizure or loss of consciousness) using a diary form developed for this purpose in Dr. Wysocki's ongoing CGM trial. Frequency of moderately severe and severe hypoglycemia is considered a secondary outcome measure in this study.

Insulin Pump and Continuous Glucose Monitor Downloads: Device downloads will be the primary outcome measures since these measures will reflect the extent to which participants demonstrate optimal use of CSII or CGM. At Visits 2 through 5, staff will download insulin pumps and CGM devices for those using them, or adolescents can e-mail data download files to the research team prior to each of those visits. For insulin pump users, the number of bolus infusions, number of times the "bolus wizard" was used and percentage of days on which fewer than 3 bolus infusions of insulin were registered will be recorded. For CGM users, the mean number of hours per day of stored CGM data will be captured from device downloads. Complete cessation of the chosen treatment will also be recorded if it occurs, which is expected to be much more common among adopters of CGM compared with adopters of CSII. Each of these scores will be transformed into z-scores relative to the full sample, permitting combined treatment of these measures in the planned analyses. Another analytic option would be to utilize an operational criterion to dichotomize patients into "Optimal" or "Suboptimal" users of CSII or CGM for the purpose of testing logistic regression models of SMDM effects. This determination will be made by Dr. Hossain, the project statistician.

Measures obtained at the first post-decision visit only

These measures will be obtained at the next study visit for those participants who have reached a decision. The Measurement schedule depicts this as Visit 2, which is expected to be the case for most participants, but some participants may take longer to reach a decision.

SMDM Satisfaction Scale: This measure, constructed for this study, will be completed only by adolescents and parents at the next study visit following their actual receipt and initialization of the chosen device (CGM or insulin pump). This scale is to be completed only by SMDM participants.

SMDM Satisfaction Scale- Clinician Form: This measure will be completed by clinicians at the first visit after each parent and adolescent in the SMDM group have reached a decision about the technology of interest (pump or CGM) to assess their level of satisfaction with how helpful the decision aid was for the patient/parent in the decision making process. The measure includes 5 items rated on a 5 point scale and space for the clinician to write additional comments. This will be completed for patients in the SMDM group only.

Description of Decision Making Process: This 10-item measure asks parents and adolescents in the UC Group only to report how often they did certain activities during the decision making process and how it affected their choice, the outcome of the decision making process and how satisfied they are with their decision. This measure was constructed for this study to enable participants randomized to the UCP group to describe the process by which they made a decision about CSII or CGM. If decision making has been actively deferred, that will be treated as a decision having been made. If decision making has simply not occurred, in the absence of a definite statement to defer decision making until some point in the future, this measure will be obtained at Visits 3 and 5. Information yielded from this measure will be used primarily for descriptive purposes to enable readers to place the UCP condition in a concrete perspective.

Measures obtained at Visit 3 and Visit 5

Decision Regret Scale (DRS): The DRS is a 5-item scale for measuring a patient's degree of regret (or satisfaction) after a specific decision. [163] Items are rated on a 5-point scale ranging from "strongly agree" to "strongly disagree", and higher scores reflect more perceived regret. Internal consistency was .81 in a prior study. The scale will be completed by parents and adolescents in both the SMDM and UCP groups. Administration time is about 2-3 minutes.

SURE Test: The SURE Test is a 4-item screening tool to measure decisional conflict in patients facing clinical decisions in primary care. If the total score is less than 4, the patient is experiencing decisional conflict. The SURE Test will be completed by parents and youth in both groups at Visit 3 and at Visit 5. Administration time is about 2-3 minutes.

Measure obtained at Baseline (Visit 1) and Visit 2

Test of CSII or CGM Knowledge: Each parent and adolescent will complete a 5-item test of CSII or CGM knowledge based on content of the respective decision aids at baseline and at Visit 2 (Or the first visit after the

family has reached a decision about CSII or CGM). Equivalent forms of this test were developed and participants will complete one form at Visit 1 and the other form at Visit 2. At each of those visits, parents and adolescents will complete different forms of the test. These measures must be completed in person to prevent interactions between parents and adolescents and to prevent use of written or online information related to the test content.

Measures obtained at Baseline (Visit 1), Visit 3 and Visit 5

Diabetes Technology Questionnaire (DTQ): This is a 30-item questionnaire that assesses satisfaction with a patient's defined "package" of diabetes technology in use (i.e. blood glucose meter, insulin pump or CGM). Parents and youth rate their satisfaction with and perceived impact of the specific cluster of technological elements that they have been using for the prior 3 months. The DTQ is an adapted version of the CGM Satisfaction Scale developed by Dr. Wysocki for the DirecNet and JDRF CGM trials,[17, 19-20, 150-151] and it is used in Dr. Wysocki's current CGM trial. Internal consistency (alpha = .91), test-retest reliability over 3 months (r = .57 to .66) and parent-youth agreement (r = .65) have been excellent. Parents and youth in both groups will complete this questionnaire at Visits 1, 3, and 5. There are separate versions for baseline and follow-up administration. Administration time is 10-15 minutes.

Diabetes Self Management Profile-Self-Report form: The DSMP-SR was derived from the previously validated DSMP structured interview.[164-165] The 24-item DSMP-SR with separate youth (age > 11) and parent forms quantifies treatment adherence and was validated recently.[165] Mean + SD DSMP total scores (maximum possible = 84) were 54.7 + 12.6 for 145 parents and 54.5 + 12.3 for 129 adolescents with mean HbA_{1C} of 8.7%. Internal consistency was .82 for youths and .80 for parents. Youth-parent scores correlated .64. Correlation with HbA_{1C} was .46 for parents and .37 for youths. Administration time is 10 minutes. Consideration will be given to forming a parent-adolescent composite score for this measure if their scores correlate > 0.70 at any measurement point Decision Aid Utilization Tracking (SMDM participants only) A benefit of developing the decision aids for delivery via a web platform relative to hard copy decision aids is that utilization tracking can be achieved automatically to record and date/time stamp virtually every keystroke made by a decision aid user. While far more data elements could be extracted from the back-end of the web platform, in consultation with E-City Interactive, we have selected these specific data elements as ones we will routinely track. E-City Interactive will prepare a monthly report format and regularly provide the research team with these statistics both in aggregate and within individual study participants:

- Total number of users
- Total number of users that logged in at least once
- Number of site visits per user with date and time
- User path through whole site
- User path through educational content only
- Amount of time each user spent on each page
- Quiz answers
- Quiz answers changed per user
- Quiz answers shared per user
- Content engagement (# of slides viewed per content page, amount of video viewed per content page)
- Decision slider location
- Decision slider movement and site page where movement took place
- Direction of decision slider movement
- Number of times the decision slider was moved per user
- Engagement with content feedback widget and corresponding content page
- Total number of times each piece of content was visited
- Number of times content was bookmarked

B.4. Measurement Schedule*

	Visits (~Months)				
	V1 (0)	**V2 (3)**	**V3 (6)**	**V4 (9)**	**V5 (12)**
General Information Form (P)	□				
Insulin Pump Use Profile/CGM Use Profile (P,C)		□	□	□	□
Hypoglycemia Diary (B)	□	□	□	□	□

HbA_{1C} (A)	□	□	□	□	□
Rapid Estimate of Adult/Adolescent Literacy in Med. (B)	□				
Diabetes Numeracy Test (B)	□				
Diabetes Self Management Profile-Self Report (B)	□		□		□
Test of CSII or CGM Knowledge (B)	□	□			
Decision Regret Scale (B)			□		□
SURE Test (B)			□		□
Diabetes Technology Questionnaire (B)	□		□		□
SMDM Satisfaction Scale (B, HCP)		□			
Description of Decision Making Process (B)		□			
Decision Aid Utilization Statistics (Monthly Reports)		□	□	□	□

*Baseline assessment (0 Months) will occur just prior to randomization to SMDM or UCP. Respondents for each measure are HCP =Adolescent's diabetes health care provider; P = Parent; A= Adolescent; B = Both. All measures are obtained from both the SMDM and UCP groups unless otherwise stated. The Decision Regret Scale, SURE Test and the Description of the Decision Making Process may be repeated at other visits if additional medical decisions (CSII, CGM) are raised for consideration. The Test of CSII or CGM Knowledge will be administered at the first post-decision visit, which is expected to be Visit 2 for most participants. As mentioned above, those who enroll after 3/31/15 are likely to be followed for only 6 months unless PCORI

decides to allow no-cost extensions.

B.5. Statistical Analyses:

Data Management and Statistical Analysis Plans The primary efficacy endpoints are indices of extent of engagement in CSII (mean number of bolus infusions/day; mean number of uses of "wizard" functions/day) or CGM use (mean number of hours of CGM use/day); and measures of decision quality (Test of CSII or CGM Knowledge; SURE Test; Decision Regret Scale; Diabetes Technology Questionnaire) at each post-decision visit. Secondary efficacy endpoints will include: HbA_{1C} measured quarterly, treatment adherence (DSMP-SR parent and youth) total scores obtained at Visits 1, 3 and 5; and Hypoglycemia Diary obtained at each quarterly clinic visit.

The Full Analysis Set will consist of all participants who provided at least one post baseline assessment record. The Completer Analysis set will include all participants who provided all post baseline primary efficacy assessment results. [166-1168] Efficacy analyses will be performed on both sets, providing both "Intention to Treat" (Full Analysis Set) and "Per-Protocol" (Completer Analysis Set) analyses. All collected data will be summarized in graphs and tables. Categorical variables will be summarized using frequencies and percentages, while quantitative variables will be described by presenting mean, median, standard deviation (or standard error of mean), minimum and maximum. Data will be summarized by group (SMDM and UCP) and type of medical decision (CSII or CGM) as well as assessment time points. Besides tabular presentation, graphical presentations of some important variables related to primary and secondary endpoints will be provided.

Assumptions for all proposed models will be checked before statistical analyses. [166-168] Appropriate transformations or non-parametric methods will be used in cases of violated model assumptions. For graphical comparison of data that are sufficiently normally distributed, group means and SE of mean will be presented via bar charts. In case of substantial deviation from normality, side by side boxplots will be used for graphical comparisons. Exploratory Subgroup analyses will be conducted as needed. All tests will be performed against a two-sided alternative at the $\alpha = 0.05$ significance level and a 95% confidence interval and/or a p-value will be provided for inferential purposes. Data from all clinics will be pooled for the analyses. All analyses will be performed using the most recent version of the SAS statistical software package.

Demographic and baseline characteristics (age, race, ethnicity, family composition, marital status, SES), primary and secondary end points, and biochemical, psychological, and behavioral variables will be summarized by intervention groups. One way analysis of variance (ANOVA) of each continuous baseline characteristic and a Fisher exact test/chi-square test/CMH test for each categorical variable will be used to compare the intervention groups at baseline. These comparisons will be used to evaluate the balance of demographic and baseline characteristics among intervention groups. Analyses of primary and secondary end points will be adjusted for significantly imbalanced baseline characteristics. For those measures completed separately by parents and youths, when parent and youth scores are correlated at $r > .70$, a combined parent-adolescent score for that variable will enter analyses. Otherwise, separate analyses will be completed on parent and adolescent scores. A mixed models (or multilevel modeling) approach will be used to test the hypotheses listed below. [169-172] The methods advocated by Holmbeck [173] will be used to evaluate baseline variables that moderate/predict SMDM-UCP treatment effects on primary study outcomes. Candidate moderator variables will include SES, youth age and gender, race/ethnicity, family structure, and health literacy and numeracy. The methods advocated by Holmbeck [173] will also be used to evaluate variables that may mediate SMDM-UCP treatment effects on primary study outcomes. In each case, these will include measures that are obtained serially and concurrently with the primary study endpoints. SAS subroutines for addressing the potential confounding influences of time- dependent covariates (e.g. youth age) will be employed as needed in these meditational analyses. With five measurement points for HbA_{1C} and hypoglycemia, the proposed mixed models approach will be capable of detecting longitudinal associations among study variables that are non-linear in form.

Hypothesis 1: Compared to UCP, the SMDM group will have significantly more favorable status in terms of indices of optimal use of CSII or CGM, scores on the CSII or CGM Knowledge Test, SURE Test, Decision Regret Scale, Diabetes Technology Questionnaire and SMDM Satisfaction Scale at each follow-up measurement point.

Hypothesis 2: Compared to UCP, the SMDM group will have significantly more favorable status in terms of scores for treatment adherence (DSMP-SR), HbA_{1C}, and frequency of moderately severe or severe hypoglycemiaat each follow-up measurement point.

Hypothesis 3: Effects of SMDM on indices of optimal use of, and satisfaction with, CSII or CGM will be mediated by changes in the measures of decision quality (Test of CSII or CGM Knowledge, Decision RegretScale, SURE Test, Decision Satisfaction Scale).

Hypothesis 4: Significant moderators of benefit from SMDM along the measured outcomes will include baseline measures of socioeconomic status, health literacy and numeracy, youth age, and family structure.

Hypothesis 5: SMDM will have indistinguishable beneficial effects on the primary study outcomes regardless of which clinical decision (CSII or CGM) was the focus of the SMDM intervention.

Statistical Power Statistical power to detect treatment effects of interest on the primary endpoints was assessed using the online DSS Research Statistical Power Calculator. [174] With enrollment of 166 eligible youth and parents and attrition of 10% over the 12-month study, and a resulting "Completer" sample size of 150, the study will have statistical power of .87 to detect a moderate treatment effect of ~0.4 SD on the measures of decision quality and CSII or CGM optimal use. Even though statistical power remains adequate for detection of somewhat smaller treatment effects, effects of less magnitude are unlikely to have sufficient clinical significance to warrant the added cost and inconvenience of implementing SMDM.

Secondary Analyses In addition to testing the above hypotheses, many secondary analyses will be possible with this rich data set. For example, utilization of the decision aid web platforms will be tracked automatically for all SMDM participants and the results of that data collection may be used to evaluate differential characteristics of high versus low users or to determine if outcomes of the trial are associated with measures of decision aid use. It would also be interesting to compare longitudinal change in certain outcomes (decision quality, treatment adherence, HbA_{1C}) among those who adopt and who do not adopt the treatment option under consideration. Other secondary analyses could include exploration of associations among changes in the various potential mediators of study outcomes. The research team will capitalize fully on the richness of the data set by pursuing many such analytic directions.

B.6. Limitations A potential limitation of the proposed work is that we have not included a comparison group that provides a control for the additional professional attention that will be afforded to the SMDM families relative to the UCP families. Our primary justification for this is that SMDM is the independent variable in this study design and thus it is legitimate that the experimental and control groups differ along this one dimension. The DE's activities in implementing the SMDM intervention are highly structured and time-limited and are based on use of very detailed decision aids supplemented by very specific interactions. The current educational and decision-making practices utilized at the various performance sites for transitions to CSII or CGM represent the most appropriate standard of comparison since these methods likely represent typical practice variations at centers that commonly offer these diabetes management alternatives. Adding a control condition that includes delivery of equal frequency and duration of professional contact as does our SMDM condition would be difficult to define or justify, would run a high risk of appearing artificial, tangential and transparent to participants and would be unlikely to mirror clinical reality anywhere. Extensive research has shown that family management of T1D is quite resistant to improvement in response to carefully designed, intensive behavioral interventions. [1, 16-22, 26, 100-103] The presumption that slight differences in the type and amount of professional attention offered to families in an attention control condition versus usual care would yield markedly different effects on diabetes outcomes is very unrealistic when viewed from this perspective. Incorporating a third condition into our study would either require a larger total sample of participants (which would be financially and logistically impractical) or impede the statistical power of the study due to smaller sample size per cell (which would be unacceptable scientifically). Finally, randomizing 67% of participants to study conditions that are expected to be less effective is less acceptable ethically than a randomization process that gives every participant a 50% chance of being assigned to the presumably more potent condition. A second limitation is that the applicability of the SMDM intervention format to situations in which youth, parents and HCPs are *collaborating* in medical decision making is unknown at this time. While SMDM interventions for adult patients have typically encouraged the involvement of the patient's significant others in decision making, it is usually clear that the final decision rests with the adult patient and HCP. This may be less clear in pediatrics, but, at a minimum, the SMDM intervention will provide youth with a safe, structured vehicle for exploring and articulating their preferences, goals, apprehensions and expectations regarding the specific medical decisions under consideration and this process should enhance the likelihood of positive outcomes regardless of the ultimate decision that is made since excellent diabetes outcomes are still possible with standard care even if the treatment option being considered is rejected or deferred.

Part C: INCLUSION OF WOMEN, MINORITIES AND CHILDREN AND HUMAN SUBJECTS PROTECTION

C.1. Representation of Women and Minorities Both studies will enroll a roughly equal proportion of maleand female youth with T1D. A substantial majority of participating parents are expected to be women. For the RCT, we will over-sample racial and ethnic minorities so that the enrolled 166 participants include at least 40 youth (24%) who are members of racial or ethnic minorities. In an effort to facilitate enrollment of minorities, we plan to make especially concerted efforts to identify all eligible minority participants through a search of the electronic medical record system, we will contact these families in person wherever we can, we will ask the treating endocrinologists to play a more active role in their recruitment, and we have budgeted funds to enable the study to pay for verifiable transportation and child care costs associated with study participation by low-SES families. In our four most recent studies of the T1D population at Nemours, enrollment of racial and ethnic minorities has averaged 28%, with most of these self-identified as either African American (77%) or Hispanic (20%). In all of the numerous T1D studies conducted by Dr. Wysocki over the past 20 years, the lowest representation of minorities in his studies has been 18%. We also expect to be able to achieve laudable representation of racial and ethnic minorities in the proposed research and we have set a target of 40 such participants (24% of the sample) as the minimum acceptable proportion.

C.2. Inclusion of Children: The RCT will enroll 166 11-<17 year old youth with type 1 diabetes as the primary research participants. At least one parent or other legal caregiver of each youth will also participate.

C.3. Human Subjects Protection

Nemours Office of Human Subjects Protection operates 3 institutional review boards: Nemours IRB 1, Nemours IRB 2 and Nemours IRB 3 (Oncology), the last two of which are chaired by Dr. Wysocki. The program is accredited by the Association for Accreditation of Human Research Protections Programs, and it is one of the few pediatric programs to have achieved this high level of recognition. The detailed policies and procedures developed and promulgated by Nemours Office of Human Subjects Protection have guided and will continue to guide every element of the design, planning and implementation of the current research, assuring that those who volunteer for this research will be treated with appropriate respect, beneficence and justice. The procedures for protection of the rights and well-being of participants are described below for the RCT.

Data and Safety Monitoring Plan

As justified below, the risks associated with the current investigations are considered to be negligible and so our assessment is that an external and independent data and safety monitoring board is unnecessary. Instead, the typical safety monitoring functions for this study will be accomplished by a Family Advisory Council, (along with Drs. Wysocki and Hossain and one of the project endocrinologists) as described in the Patient and Stakeholder Engagement Plan (See Part D of this manual). This committee will have the following charges:

- Ensure that all activities comprising this research are conducted in strict accord with the ethical principles of the American Psychological Association pertinent to the responsible conduct of research.
- Ensure that all research staff working on this project are in continuous compliance with Nemours requirements for training in human subjects protection and the responsible conduct of research.
- Serve as the liaison between the research team and Nemours Delaware IRB, Nemours Clinical Research Review Committee and Nemours Committee on Research Integrity.
- Receive and investigate reports of unanticipated problems submitted by project staff as required by Nemours Policies and Procedures governing human subjects protection.
- Receive and address complaints from participants in the study as outlined in the Nemours Office of Human Subjects Protection policy and procedure regarding this issue.
- Advise the research team regarding possible amendments to the research protocol in the interests of more effective protection of study participants' privacy, confidentiality and overall well-being.

Participants and Eligibility Criteria

Participants will be 166 patients at any participating Nemours operating entity in Florida or the Delaware Valleyand at the Barbara Davis Center for Childhood Diabetes in Denver. They will be youths ages 11-<18 years, with T1D for ≥ 1 year or for at least 6 months and with the most recent Hemoglobin A_{1C} of 7.5% or higher, facing a decision about CSII or CGM (and a parent/caregiver). Access to advances such as these may be limited for racial/ethnic minorities, so we will over-sample them to enroll at least 40 youth who are self-identified racial/ethnic minorities (24% of the sample). We have budgeted funds in Years 2 and 3 to enable us to reimburse low income participants for their justified and verifiable costs for study participation

(auto mileage, meals, child care, parking, etc.), which should also enhance recruitment and retention of minority group members. Our most recent T1D research studies utilizing these same Nemours sites have yielded 24%-31% representation of racial/ethnic minorities in the study samples. We will also enroll a minimum of 30 patients facing each of the two treatment decisions to facilitate comparisons among them. Enrollment criteria are:

Inclusion Criteria for Youths: Age 11 to <18 years; Physician-diagnosed T1D for at least 12 months or for at least 6 months and with the most recent Hemoglobin A_{1C} of 7.5% or higher; Considered by treating health care provider to be an appropriate candidate for CSII or CGM.

Exclusion Criteria for Youths: Concurrent participation in any other diabetes research in which glycemic control or treatment adherence are among the study outcomes; Daily oral glucocorticoid treatment; Significant developmental delay (self-contained special education; retention in 2 or more grades); Inability to read/comprehend study questionnaires and decision aids in English; Treatment for a coincident medical condition that, in the opinion of the treating physician, represents a contraindication to study participation.

Inclusion Criteria for Parents: Primary diabetes caregiver of index child; Anticipates continued medical care for T1D at Nemours for subsequent year; Capable of participating in conversations during medical visits; Routinely accompanies adolescent to diabetes clinic visits.

Exclusion Criteria for Parents: Inability to read/comprehend study questionnaires and decision aids in English; Open abuse/neglect case with any child protection agency over the prior 3 years; Evidence of frequent changes in the adolescent's household or living arrangements.

Sources of Research Material
Sources of research material include downloaded data from glucose meters, insulin pumps and continuous glucose monitors (primary outcome measures), questionnaires completed by youth and parents each 6 months regarding quality of life, burden of disease management, diabetes self-efficacy, decision quality, decisional conflict, health literacy, and treatment adherence, glycated hemoglobin tests performed at a central laboratory, glycated hemoglobin results obtained via point-of-care testing (DCA-2000+) at each clinic visit, and quarterly collection of hypoglycemia diaries for recording of symptomatic hypoglycemic episodes.

Methods of Recruitment
Participants will be recruited from among eligible patients treated for type 1 diabetes mellitus at any Nemours Children's Clinic location or at the Barbara Davis Center. Endocrinologists will be asked to identify patients from their clinics who are good candidates for participation in this research. Prospective participants will then be given a letter signed by Dr. Wysocki and the attending endocrinologist, either in clinic or by mail. This initial contact will be followed with a telephone call to the parents to determine eligibility and interest in study participation. Parents/caregivers and youth will sign IRB-approved consent/assent documents.

Assessment of Research-Related Risks
Even though this is a randomized trial of an intervention, we believe that this study poses no greater than minimal risk for either adolescents or parents. The primary foreseeable study risks to youth and parents are those associated with threats to privacy and confidentiality related to the measurement protocol. UCP participants will have the same medical decision making process they would experience if not enrolled in the study. SMDM participants will experience an enhanced decision making process, hopefully leading to better decisions. It is difficult to conceive of any additional risks that SMDM participants would have compared with usual medical decision making routines outside of the study.

Assessment of Research-Related Benefits
SMDM participants could experience a more effective and productive decision-making process, possibly resulting in more effective incorporation of the chosen device (Pump or CGM) into care, better treatment adherence, glycemic control, self-efficacy and quality of life after the decision. UCP participants are unlikely to derive any direct benefits from study participation.

Safeguards to Protect Against Risks
Substantial efforts are planned to protect each participant's privacy and confidentiality. All data files containing the clinical outcomes and questionnaire responses will be stored without any HIPAA-defined identifiers. All participants will be identified by a unique study ID number. A separate password-protected list will link

participants to their ID numbers. With these safeguards in place designed to minimize the risks to participating clinicians, we believe that this protocol entails minimal risks to them. Access to the list linking code numbers to individual participants will be password-protected and will be limited to Dr. Wysocki and the research specialists on his Jacksonville team. The list will not be provided to any other Nemours staff or to any non-Nemours researcher or consultant.

No individually identifiable health information about Nemours participants will be disclosed to members of the research team at the Barbara Davis Center for Childhood Diabetes in Denver.

Informed Consent and Parental Permission Process
Those who are eligible and interested will have a face to face informed consent conversation with a qualified research coordinator or research specialist. Signatures of parents will be obtained on an IRB-approved Parental Permission and Informed Consent Form and of youths on an IRB-approved assent form before they are scheduled for any research procedures, including data collection or SMDM intervention procedures. Research staff obtaining consent will be trained to use the "Teach-Back" method of verifying parents' comprehension of these key elements of the Parental Permission and Informed Consent form: What is the Purpose of the Study?; Who Can Be in the Study?; How Long Will Participation in the Study Last?; What Are the Research Procedures?; What Are the Possible Risks of being in the Study? What are the Possible Benefits of Being in the Study? Is Being in the Study Voluntary?; Will We Be Paid for Being in the Study?; and What Information About Me or My Child Will Be Used or Disclosed?. Each of these sections will be reviewed and the participant will be asked to describe the content of that section in his/her own words. The research staff member will correct instances of erroneous or absent knowledge and ensure comprehension before proceeding to the next section of the consent document. A similar but condensed procedure will be used with adolescents in reviewing the key points of the Adolescent Assent Form.

Protection of Confidentiality
As a covered entity under HIPAA, Nemours operations are all fully compliant with applicable federal and state laws and regulations regarding the protection of patients' confidentiality and the security of stored confidential data. All staff members who will interact with study participants or their research data will be trained in the HIPAA research regulations and in general human subjects protection by completing Nemours-approved online curricula on this topic. Data collection, scoring and data entry will be organized to place a priority on protecting the confidentiality and privacy of study participants. Data recording instruments, questionnaires, etc., will all be labeled with a unique study ID number rather than participants' names or other HIPAA-defined identifiers. Signed parental permission forms will be stored separately from other study data and documents since these forms will identify the participants. Raw data will be stored, without personal identifiers attached, in locked file cabinets in private offices. Data will be entered into password-protected computer files on the Nemours local area network, access to which is also password-protected.

Accessing Consent Forms from the Institutional Review Board (IRB)
Staff who are recruiting participants and/or obtaining parental permission, informed consent and adolescent assent should always be certain that they are using the current consent document by retrieving it from IRBNet. The IRB document package for the current study in IRBNet is **645658, Shared Medical Decision Making in Pediatric Diabetes: Randomized Controlled Trial**. To access this package through the IRB website, log in to https://www.irbnet.org with your IRBNet username and password. In the "My Projects" section, click on the Project Title: "Shared Medical Decision Making in Pediatric Diabetes: Randomized Controlled Trial, IRBNet ID: 645658-1". Note that there may be a more recent document package available (e.g. 645658-2, etc.). Click on "Designer" and then "Review Details" to find and download the currently approved and date-stamped consent documents,

Part D: FURTHER DETAILS OF THE RESEARCH PLAN

Consortium/Contractual Arrangements
A subcontract has been negotiated with Thomas Jefferson University that will cover the personnel costs (salary plus fringe benefits) for the involvement of Judith L. Ross, M.D. as a co-investigator on this project. Dr. Ross would be supported for 0.6 calendar months (5% FTE) during all 3 project years. Her base salary is above the PCORI cap and is budgeted at $200,000 annually. Fringe benefits and indirect costs are calculated per established Thomas Jefferson University policies and procedures in effect at the time of this application. The TJU indirect cost rate for such arrangements is below the 40% allowed by PCORI. This subcontract will end on December 31, 2014 as Dr. Ross and the research staff at TJU will become Nemours employees at that time.

We are establishing a subcontract withThe Barbara Davis Center for Childhood Diabetes, the only freestanding pediatric diabetes treatment center in the US. Affiliated with the University of Colordao College of Medicine and Children's Hospital of Colorado, BDC manages over 3,300 pediatric patients with type 1 diabetes. A subcontract with the Barbara Davis Center would commit BDC to the recruitment of 80 eligible patients/parents between June 1 and November 30, 2015 and to maintain study follow-up over the following 12 months for each participant. The subcontract would cover the personnel costs (salary plus fringe benefits) for the involvement of Paul Wadwa, M.D. as a co-investigator on this project, Sally Sullivan, RN CDE as Diabetes Nurse and Cierra Sullivan as Research Assistant.

Project Plan And Timeline

Time Frame The first 9 months of funding were dedicated to planning and implementation of the QIS study and interpreting those findings for further planning of the RCT. Development of the decision aids was finalized in month 18. Concomitantly we completed preparation of a detailed study procedure manual, preparation of a detailed SMDM intervention manual, development and pilot testing of online questionnaire administration, automated scoring and data management, and the acquisition of budgeted supplies. Project staff was hired or assigned and then trained to proficiency criteria on all aspects of protocol implementation. Recruitment ofparticipants for the RCT will begin at about month 21. If we can enrolls 16 patients per month study-wide, we would reach the 166 patient target within 10 months, or at about month 27 of the grant period. Data collection will end at month 33, December 31, 2015, regardless of the length of time the last participants are in the study. This would allow 3 months for data cleaning and verification, data analysis, preparation and submission of abstracts and papers, and preparation and submission of a renewal application. The sponsor, PCORI, may allow a one-year no-cost extension if the study aims cannot be achieved within the planned 3-year award period and it is possible that we will take advantage of that opportunity.

Patient And Stakeholder Engagement Plan

Previous research on shared medical decision making shows that consumers and health professionals often have quite divergent views regarding the value they place on different elements of the structure, process and outcomes of medical decision making. Therefore, it is particularly important to obtain and utilize the varied perspectives of key stakeholders if this line of research is to yield results that resonate with all of them. This research will place major emphasis on the appropriate engagement of patients, parents and health care providers in the planning, design, implementation, analysis and interpretation of the research and its eventual results. Our engagement plan rests on several fundamental components, each of which is described in more detail below:

- Completion of a Qualitative Interview Study in Year 1 to obtain and benefit from the perspectives of adolescents, parents and health care providers regarding the structure and content of Decision Aids that relate to consideration of incorporating either insulin pump therapy or continuous glucose monitoring into the daily management of type 1 diabetes.
- Incorporation of input at each stage of study implementation from Nemours health care providers who deliver clinical care and education to adolescents with type 1 diabetes.
- Constitution of a Family Advisory Council composed of adolescents with T1D and their parents who will be recruited to bring the perspectives of these key stakeholders to all aspects of the RCT design and management. Recruitment of 5 FAC members and their 7 adolescent offspring with T1D was completed in October, 2014 and the group has begun meeting regularly by conference call. They will be serving effectively as members of the research team in terms of giving input from a family member perspective on all aspects of study design, implementation, and dissemination project findings.
- Completion of end-of-study qualitative interviews of adolescents and parents who have been randomized to the Shared Medical Decision Making condition for the purpose of acquiring and benefitting from their perspectives of the intervention they experienced.

Family Advisory Council

Five parents and their seven adolescents with T1D were recruited to serve as members of a Family Advisory Council. They were selected to reflect diverse representation in terms of Nemours sites, socioeconomic status, race/ethnicity, gender and prior experience related to insulin pump therapy and continuous glucose monitoring. Each FAC dyad will be paid $500 annually to compensate them for expenses they incur due to their FAC participation. In constituting this group, we began by carefully examining the participants in Dr. Wysocki's ongoing NIH-funded trial of continuous glucose monitoring, from which we were able to identify adolescents who did or did not experience CGM use and who did or did not demonstrate glycemic or quality of life benefits from doing so. This group of 104 research participants consists of 67% non-Hispanic Caucasians, 21% African-Americans and 12% Hispanics, with very diverse educational attainment and household income. Similarly, we will be able to identify adolescents whose insulin delivery modalities were either insulin pumps or multiple daily insulin injections during that study.

The FAC will be convened in monthly meetings using video or telephone conferencing facilities that are in place at all Nemours operating entities. Each meeting will be audio-recorded and minutes will be taken and distributed to all members. The FAC will select its own chair, who will prepare the meeting agendas and manage the discussion of the specific agenda items. The FAC will be considered advisory to the research team, in that their recommendations will be given very serious consideration, but final decisions regarding study design, implementation or interpretation will rest with Dr. Wysocki and the Co-Investigators. The initial charge of the FAC will consist of review of, and commentary on, the study protocol, procedure manual, and human subjects protection plan. Since an external and independent Data and Safety Monitoring Board is

unnecessary for this research since it poses minimal risk to participants, the FAC (with participation by Dr. Wysocki, Dr. Hossain and one of the endocrinologists) will provide study oversight regarding the recruitment experience, and the occurrence of any data quality issues, threats to privacy or confidentiality, other unanticipated problems, participant complaints or other such issues.

Prospective FAC members have received this list of expectations regarding their involvement :

- Learn some basics about how research is planned, completed and analyzed
- Learn about the study plans and become very familiar with what other families will experience
- Try out the decision aids to become very familiar with them
- Complete study questionnaires and give feedback to us about instructions and wording
- Participate in video conferences or phone conferences with the research team about once per month
- Help us to develop a research informed consent form that is complete but also easy to understand
- Help us plan how we can best get families to join the study and to stay in it for a year
- Be a voice on the research team for families who are participating in the research
- Be a partner in writing papers or presenting research results at conferences

Input from T1D Health Care Providers

Parallel to the solicitation and incorporation of input from the FAC, Nemours health care providers (HCPs) who provide clinical care and education to patients with T1D and their families have served as key stakeholders whose feedback about the study design and implementation is fundamental to the conduct of this research. During the completed qualitative interview study, input from 13 Nemours HCPS was obtained about their perspectives of their current and ideal practices regarding the decision to start patients on insulin pumps or continuous glucose monitors, their recommendations regarding the structure, content and process of the planned SMDM intervention, methods to merge the SMDM intervention with their established clinical and educational routines and their specific comments on the successive iterations of the Decision Aids. Interviewers posed a series of structured questions and the responses were audio-recorded and subsequently transcribed verbatim for descriptive qualitative analysis. Our consultants, Drs. Hutchinson, Fiks, Brinkman and Lawson, assisted in refining the questions to be asked, training the interviewers, providing the interviewers with open-ended follow-up questions designed to probe or expand upon the initial responses, and assisting the research team in condensing and incorporating this feedback into concrete refinements to the decision aids or intervention plans. In addition, Dr. Steve Dowshen, of KidsHealth, and Margaret Lawson, our consultant, are practicing pediatric endocrinologists and each of them provided extensive input into the planning and content of the two decision aids.

Qualitative Interview Study

As described in detail in the Research Strategy, a Qualitative Interview Study (QIS) was completed during the first year of the planned research. This involved 53 parent-adolescent dyads who had previously made a decision, *pro or con*, regarding the initiation of either insulin pump therapy or continuous glucose monitoring as a component of their T1D care. The interviews were designed to achieve two purposes: 1.) To gain a thorough perspective of how these families made their decisions, their satisfaction with their decision making process and outcomes and their suggestions for how their decision making could have been improved; and 2.) Their perspectives on successive iterations of the Draft Decision Aids until the FAC, the research team and the Nemours Center for Children's Health Media staff are satisfied that these tools cannot be improved further. Interviewers posed a series of structured questions and the responses were audio-recorded and subsequently transcribed verbatim for descriptive qualitative analysis. Our consultants assisted in refining the questions to be asked, training the interviewers, providing the interviewers with open-ended follow-up questions designed to probe or expand upon the initial responses, and assisting the research team in condensing and incorporating this feedback into concrete refinements to the decision aids or intervention plans.

End-of-Study Qualitative Interviews

An important objective of this research is to take away lessons that may inform future research on shared medical decision making in pediatrics and that may guide the preparation of decision aids and SMDM interventions related to other preference-sensitive decisions that arise in pediatrics. Using the same questions employed in the qualitative interview study, each participant will be interviewed again upon exiting the randomized trial of SMDM regarding their experiences during that study and their suggestions for how the decision aids or intervention delivery could be improved to enhance their decision quality.

Governance Plan

The Family Advisory Council will meet monthly via conference call. Compensation is budgeted in the

amount of $500 per adolescent-parent dyad annually to cover their expenses for participation as FAC members. The group will select its own leadership and the elected chairperson will prepare the meeting agenda and conduct the meetings. Minutes will be distributed to all members. The FAC will serve in an advisory capacity to Dr. Wysocki and other members of the research team. The FAC will meet monthly throughout the conduct of the study and will provide input to the research team at each stage of the study, including planning, design, implementation, analysis and dissemination. They will also serve, along with Dr. Wysocki, Dr. Hossain and one of the endocrinologists as the data quality and safety review group for the study and they will process any unanticipated problems such as threats to participants' confidentiality, participant complaints, and other such issues as may arise.

REPLICATION AND REPRODUCIBILITY OF RESEARCH

Replication of Research Findings

This research is structured as a multi-site study that will recruit and randomize patients at four different Nemours pediatric care facilities. While the sites share many features in common since they are all operating entities of the Nemours Foundation, the sites differ in many important respects as well, including geography, demographic characteristics of the respective patient populations, urban versus rural population distribution, and some differences in practice patterns (e.g., proportionately fewer CSII patients in Orlando compared with the other sites; more use of private CSII educators in the Delaware Valley than at the Florida sites). This situation positions us to evaluate the extent to which results obtained from this research hold up consistently across the Nemours enterprise or if successful SMDM appears to depend on specific characteristics of individual T1D clinicians.

Our preparation of decision aids for internet delivery will also enhance the capacity of interested researchers elsewhere to conduct direct or extended replications of this research. Framing the decision aids within this familiar technological infrastructure will ensure that other researchers would have the ability to test exactly the same intervention in studies examining such issues as identification of predictor variables that appear to moderate the effectiveness of the decision aids or the specification of variables that mediate the effects of the decision aids on measures of decision quality, behavioral acceptance of CSII or CGM, and objective indices of health outcomes.

DISSEMINATION AND IMPLEMENTATION

Identification of Key Stakeholders

See the accompanying Patient and Stakeholder Engagement Plan which offers a detailed program for ensuring that adolescents with T1D, their parents and their health care providers have extensive input into all stages of this research, including planning, design, implementation, assurance of data quality, human subjects protection, analysis, interpretation of results and dissemination of the findings.

Publication Policy

Dr. Wysocki's research program is guided by a detailed publication policy that is consistent with the American Psychological Association's *Ethical Principles of Psychologists*. The policy delineates the processes by which a planned academic product (abstract, lecture, article) is proposed, how the writing team is to be constituted, and the roles, contributions of each member of the writing team and order of authorship. The policy also stipulates how secondary members of the research team can be involved in authorship and the conditions under which obtained study data can be used for the purpose of theses and dissertations. This same policy and procedure document will be used to govern the dissemination of findings from the current research.

Resource Sharing

Once IRB-approved, this study will be registered on www.clinicaltrials.gov, ensuring that information about the study will be available to interested parties and so that they will understand when archived data will be made available. Publications resulting from this study will also be shared on the pertinent website in accord with the PCORI policies and procedures regarding internet sharing of publications resulting from PCORI-supported investigations. The decision aids that are to be produced and the intervention manual will be made available to appropriately qualified diabetes programs and health care professionals. We expect to make the decision aids available to all Nemours diabetes clinicians and to the various subscribers and clients of Nemours Center for Children's Health Media. The current research will include data from 166 adolescents with type 1 diabetes and their parents recruited through multiple Nemours diabetes clinics. Data gathering will include audiotapes of qualitative interviews; however, access to these tapes will not be permitted as it would be impossible to assure anonymity of participants. The final dataset will include: self-reported demographic and behavioral data from

the participants obtained periodically during the study; laboratory data from quarterly clinic visits including, but not limited to, data on hemoglobin A1c, patterns of health care utilization, and downloaded data from the insulin pumps and continuous glucose monitors; self-report data collected at the quarterly clinic visits including information about health status and diabetes management. Identifying information will include, but not be limited to, age, age of diagnosis, gender, clinic identifier, height, weight, race/ethnicity, and socioeconomic status. Even though the final dataset will be stripped of HIPAA-defined identifiers prior to release for sharing, we believe that there remains the possibility of deductive disclosure of subjects with unusual characteristics. Thus, we will make the data and associated documentation available to users only under a data-sharing agreement that provides for: (1) a commitment to using the data only for research purposes and not to identify any individual participant; (2) a commitment to securing the data using appropriate computer technology; and (3) a commitment to destroying or returning the data after analyses are completed. The dataset will be redacted to protect subjects' identities. This project has specified research questions that address both the long-term effects of the intervention and longitudinal changes in specific variables. Datasets will be made available through a data enclave immediately following acceptance for publication of papers addressing all research questions specified in the protocol only when those data are not to be used to address subsequent specified research questions. The data will be kept for at least 3 years after the publication of the last article based on the proposed research questions.

Part E: RESEARCH PLAN: REFERENCES CITED

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Part F: APPENDICES

Appendix 1: Letters of support from Drs. Brinkman, Fiks, Lawson, Carakushansky, Reeves, Kummer, Ross, and Hossain

Appendix 2: Description of Decision making Processes for UCP and SMDM groups

Appendix 3: SMDM Intervention Summary template for return to attending endocrinologist

Appendix 4: Measures (In a separate pdf file)

Division of General and
Community Pediatrics
July 16, 2012

Tim Wysocki, Ph.D., A.B.P.P. Principal Research
Scientist
Center for Pediatric Psychology Research and Chairperson, Nemours Florida
IRB and Oncology IRB Nemours Children's Clinic
807 Children's Way
Jacksonville, FL 32207-8426

Re: Consultation on "Shared Medical Decision Making in Pediatric Diabetes"

Dear Dr. Wysocki,

I enthusiastically agree to participate as a collaborator on your PCORI application entitled, "Shared Medical Decision Making in Pediatric Diabetes." As we have discussed, my role will be to critique and refine the innovative decision aid intervention that is developed prior to use in the randomized controlled trial. I agree that 30 hours of consultation over the first 9 months of the project will be sufficient to fulfill this role.

As you know, I have an extensive background in the development and testing of decision aids to foster shared decision-making. I direct the Rapid Evidence Adoption to improve Child Health (REACH) team within the James M. Anderson Center for Health Systems Excellence at Cincinnati Children's Hospital Medical Center. Currently, our team is developing institutional infrastructure to support shared decision-making between patients, parents, and clinicians to ensure that care is evidence-based, family-centered, and of high value. In addition, I have relevant experience developing and testing decisions aids that comply with the International Patient Decision Aids Standards for a variety of pediatric conditions. I am delighted to contribute my expertise and perspective to your partnership.

I am impressed with your proposal to develop decision aids to facilitate shared medical decision making in pediatric diabetes. I look forward to the opportunity to work with you and your team on such original and important work, and I offer you my full support.

Sincerely,

William Brinkman, MD, MEd, FAAP Assistant Professor of Pediatrics
Division of General & Community Pediatrics
James M. Anderson Center for Health Systems Excellence
Cincinnati Children's Hospital Medical Center

Nemours. **Children's Hospital**

July 26, 2012

Tim Wysocki, Ph.D.
Center for Pediatric Psychology Research
Nemours Children's Clinic
807 Children's Way
Jacksonville, FL 32207-8426

Dear Dr. Wysocki:

I am writing to express my support for your PCORI grant entitled "Shared Medical Decision Making in Pediatric Diabetes". I commit to assisting you with meeting the study-wide recruitment goal of 166 adolescents with type 1 diabetes who are considered to be acceptable candidates for insulin pump therapy or continuous glucose monitoring. I accept the role of co-investigator and will work with you to refine the protocol details and will participate in co-authoring papers, abstracts and presentations that result from this work. I understand that support for my salary at 5%FTE (0.6 calendar months per year) is budgeted and that adequate time and effort is budgeted for other personnel needed to conduct the proposed study. I will look forward to the opportunity to collaborate with you.

Sincerely,

Mauri Carakushansky, M.D.
Division Chief
Division of Endocrinology

Founded 1855

The Children's Hospital of Philadelphia

34th Street and Civic Center Boulevard, Philadelphia, PA 19104-4399

July 17, 2012

RE: Shared Decision Making in Pediatric Diabetes

Dear Colleagues:

It gives me great pleasure to write in support of the grant application from Dr. Tim Wysocki entitled "Shared Medical Decision Making in Pediatric Diabetes." I am a primary care pediatrician practicing in an urban setting and an Assistant Professor of Pediatrics at the Perelman School of Medicine at the University of Pennsylvania and The Children's Hospital of Philadelphia. Dr. Wysocki initially contacted me because of my participation in multiple studies exploring distinct aspects of shared decision making in pediatrics. I view participation in this study as a logical extension of my work and believe that it will make a very meaningful contribution to both our understanding of shared decision making in children's health care and of strategies to improve adherence and outcomes in pediatric diabetes.

Overall, my research is directed at improving outcomes for ambulatory pediatric patients through collaborative practice-based research that focuses on understanding and improving decision making. I have published multiple qualitative and quantitative studies and reviews addressing how families and clinicians understand shared decision making in the care of chronic child health problems. With support from a K23 Award (K23HD059919) from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) entitled "Shared Decision Making in ADHD," I am currently investigating optimal strategies for using health information technology to promote shared decision making. Working with the team at Nemours to develop a decision aid for youth with type I diabetes who are candidates for either the insulin pump or continuous glucose monitoring builds upon multiple studies I have completed or am currently conducting. I am very familiar with the International Patient Decision Aids Standards (IPDAS) that we will use to judge the decision aids created in this study. As a member of the research team, I will also assist in refining methods for the qualitative interview study as well as participate in writing abstracts and manuscripts that result from this work. I will work as an "other significant contributor" on this project.

Once again, I very much look forward to the opportunity to participate in this project and know that the results will have important implications for improving the health of children.

Sincerely,

Alexander G. Fiks

Alexander G. Fiks, MD, MSCE Assistant
Professor of Pediatrics
Perelman School of Medicine at the University of Pennsylvania
Attending Physician in Primary Care,
The Children's Hospital of Philadelphia

Penn Medicine
Perelman School of Medicine
University of Pennsylvania Health System

Bioinformatics Core Facility
Nemours Biomedical Research
1701 Rockland Road
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Nemours.

July 24, 2012

Timothy T. Wysocki, Ph.D. , A.B.P.P.
Principal Research Scientist
Director of Center for Pediatric Psychology Research and
Chairperson, Nemours Florida IRB and Oncology IRB
Nemours Children's Clinic
Jacksonville, Florida 32207

Dear Dr. Wysocki:

I am writing to confirm my commitment to serve as biostatistician on your NIH PCORI grant entitled "Shared Medicial Decision Making in Pediatric Diabetess". I will assist you with any statistical/data issues from designing to conclusion of the study. I understand that support for my salary at 5% FTE (0.6 calendar months per year) is budgeted and that adequate time and effort is budgeted for other personnel needed to conduct the proposed study.
I look forward to a productive collaboration with you on this important research.

Thank you.

Sincerely,

Jobayer Hossain, Ph.D.
Biostatistician,
Nemours and Alfred I duPont Hospital for Children
Wilmington, DE

Nemours. Children's Clinic

July 25, 2012

Tim Wysocki, Ph.D.
Center for Pediatric Psychology Research
Nemours Children's Clinic
807 Children's Way
Jacksonville, FL 32207-8426

Dear Dr. Wysocki:

I am writing to epxress my support for your PCORI grant entitled "Shared Medicial Decision Making in Pediatric Diabetes". I commit to assisting you with meeting the study-wide recruitment goal of 166 adolescents with type 1 diabetes who are considered to be acceptable candidates for insulin pump therapy or continuous glucose monitoring. I accept the role of co-investigator and will work with you to refine the protocol details and will participate in co-authoring papers, abstracts and presentations that result from this work. I understand that support for my salary at 5% FTE (0.6 calendar months per year) is budgeted and that adequate time and effort is budgeted for other personnel needed to conduct the proposed study. I will look forward to the opportunity to collaborate with you.

Sincerely,

Mark Kummer

Mark A Kummer, MD
Division Chief Department of Pediatric Endocrinology
MAK/ew

July 23, 2012

Tim Wysocki, Ph.D., A.B.P.P.
Principal Research Scientist
Center for Pediatric Psychology Research
Nemours Children's Clinic
807 Children's Way
Jacksonville, FL 32207-8426

Dear Dr. Wysocki,

Re: Letter of Support for "Shared Medical Decision Making in Pediatric Diabetes"

I am pleased to write this very enthusiastic letter of support for your proposal entitled "Shared Medical Decision Making in Pediatric Diabetes". Your proposal is highly innovative and will address one of the most significa nt challenges in the manageme nt of pediatric diabetes, namely adherence in youth. Further, your work will be one of very few studies to examine shared decision making related to adherence in pediatric chronic illness, and the first to test the effect of a shared decision making intervention in pediatric diabetes. This will be a significant contribution both in our understanding of decision making in pediatric diabetes and in the development of a practical tool that will be of benefit to families and hea lth practitioners. The findings have the potential to be generalizable to the many other pediatric chronic illnesses in which adherence is challengi ng.

I accept w1th pleasure your offer to provide consultation during Year I and Year 2. This consultation will include refining and fmalizing your patient decision aids, evaluating them and making recommendations for revisions so they are consistent with the International Patient Decision Aids Standards (IPDAS). I look forward to participating in writing of abstracts and manuscripts resulting from this work.

I believe that I will be able to make a positive contribution to this work for the following reasons. First, I am the medical director ofCH£0 Family Decision Services, a hospital-based decision support program which we are implementing to facilitate shared decision making throughout our children 's hospital using patient decision aids and decision support. Second, I took on this role in September 2009 after completing a one-year sabbatical with Dr. Annette O'Connor, who is world-renowned for her work in the development and evaluation of patient decision aids and teaching decision support skills. Through my training with Dr. O' Connor, I developed skills in the development and evaluation of patient decision aids with particular emphasis on the unique decision making needs of children and families. These skills were further developed during my participation in the 2009 and 2011 Dartmouth Summer Institutes on Informed Patient Choice. Third, the CHEO Family Decision Services team which I lead includes individuals who are also part of the world renowned Ottawa Patient Decision Aids Resea rch Group and thus bring valuable expertise in the development and evaluation of patient decision aids which will be accessible to you through my role as consultant on this project. Finally, I am a pediatric endocrinologist. For the last 15 years, my clinical practice and research bas focused on facilitators and barriers to the use of insulin pump therapy and continuous glucose monitoring in children and youth.

1 look forward to working with you on this exciting project.

Division of Endocrinology and Metabolism
Associate Professor, Pediatrics, University of Ottawa
Medical Director, CHEO Family Decision Services – www.cheo.on.ca/en/decisionservices

Alfred I. duPont
Hospital for Children

Nemours
Children's Clinic

July 26, 2012

Tim Wysocki, PhD
Center for Pediatric Psychology Research
Nemours Children's Clinic
807 Children's Way
Jacksonville, FL 32207-8426

Dear Dr. Wysocki:

I am writing to express my support for your PCORI grant entitled "Shared Medicial Decision Making in Pediatric Diabetes". I commit to assisting you with meeting the study-wide recruitment goal of 166 adolescents with type 1 diabetes who are considered to be acceptable candidates for insulin pump therapy or continuous glucose monitoring. I accept the role of co-investigator and will work with you to refine the protocol details and will participate in co-authoring papers, abstracts and presentations that result from this work. I understand that support for my salary at 5% FTE (0.6 calendar months per year) is budgeted and that adequate time and effort is budgeted for other personnel needed to conduct the proposed study. I will look forward to the opportunity to collaborate with you.

Sincerely,

Grafton D. Reeves, MD
Division Chief
Pediatric Endocrinologist
Division of Endocrinology

Judith Ross, MD
Director
Section of Metabolism and Endocrinology
Department of Pediatrics
Founded1824

Jefferson Medical College
Jefferson College of Graduate Studies
Jefferson College of Health Professions
Jefferson University Physicians

Thomas Jefferson University | Jefferson Medical College

July 16, 2012

Tim Wysocki, Ph.D., A.B.P.P. Principal
Research Scientist
Center for Pediatric Psychology Research and
Chairperson, Nemours Florida IRB and Oncology IRB Nemours
Children's Clinic
807 Children's Way
Jacksonville, FL 32207-8426

Re: "Shared Medical Decision Making in Pediatric Diabetes"
Submitted to the Patient-Centered Outcomes Research Institute (1/1/13 -12/31/15)

Dear Dr. Wysocki,

I am writing to confirm my interest in participating in your R01 application entitled "Shared Medical Decision Making in Pediatric Diabetes." I am a board-certified pediatric endocrinologist at Nemours-Thomas Jefferson Pediatrics under an academic affiliation agreement between Nemours and Thomas Jefferson University and have extensive clinical experience taking care of children with diabetes mellitus. I have been active in pediatric endocrine research, particularly on androgen effects in Klinefelter and Turner syndromes and have been an NIH-funded researcher on these topics. I also collaborate with Dr. Wysocki on his Nemours-funded project "Clinician-Parent Patient Communication in Pediatrics". As we have discussed, my role in this study would be to get feedback from diabetes clinicians, parents and patients about the structure and content of the decision aids, and assist in identifying and recruiting eligible patients and parents for the intervention trial. I will also participate in analysis and dissemination of the results. I have relevant experience conducting pediatric clinical research on shared medical decision making and in many clinical trials.

I look forward to working with you on this innovative and important project.

If you have any questions, please do not hesitate to contact me at 2159551648 or judith.ross@jefferson.edu. Thank you for your consideration.

Yours truly,

Judith Ross, M.D.
Professor, Department of Pediatrics
Thomas Jefferson University
Chief, Pediatric Endocrinology and Metabolism

Appendix 2: Measure of Decision Making Processes for the Usual Clinical Practice and Shared Medical Decision Making Groups

Description of Decision Making Process

Usual Clinical Practice group

Decision under consideration: ___CSII ___CGM

Participants in decision making:
Patient name: _____
Parent/caregiver name: _____
Other: _____
Other: _____

For each of these activities or experiences, check the number that best describes how often you did this while you were making this decision and then check the number that matches how important that was in affecting the decision you made.

	How Often Did You Do This? 0=Never 1=Just a little 2=Quite a bit			How Much Did It Affect Your Choice? 0=Not at all 1=Just a little 2=Quite a bit		
Teaching session with diabetes educator	0	1	2	0	1	2
Chance to try out the new device or method	0	1	2	0	1	2
Seeing and touching the tools we would use	0	1	2	0	1	2
Talking with others who are using this device or method	0	1	2	0	1	2
Talking with others who decided against this device or method	0	1	2	0	1	2
Getting more information from internet, books, workshops, etc.	0	1	2	0	1	2
Talking about this with others who I trust	0	1	2	0	1	2
Learning about the amount of work and trouble it will take	0	1	2	0	1	2

Outcome of decision making:
___Reject this option, stay with current treatment
___Put off decision to a later date
___Put off decision, try harder with current treatment
___Put off decision until a recent change in treatment can be evaluated
___Get more information, then decide
___Start using this option

Parent: How satisfied are you that you made the best decision for you?
___Very Dissatisfied
___Somewhat Dissatisfied
___Neither Satisfied Nor Dissatisfied
___Somewhat Satisfied
___Very Satisfied

Adolescent: How satisfied are you that you made the best decision for you?
___Very Dissatisfied
___Somewhat Dissatisfied
___Neither Satisfied Nor Dissatisfied
___Somewhat Satisfied
___Very Satisfied

Description of Decision Making Routines
Shared Medical Decision Making group

Decision under consideration: ___CSII ___CGM

Participants in decision making:
Patient name: _____
Parent/caregiver name: _____
Other: _____
Other: _____

For each of these activities or experiences, check the number that best describes how often you did this while you were making this decision and then check the number that matches how important that was in affecting the decision you made. **Only include things that you did outside of the two video conference sessions with the Certified Diabetes Educator. This should include only the activities you would have experienced even if you weren't in this study.**

	How Often Did You Do This? 0=Never 1=Just a little 2=Quite a bit			How Much Did It Affect Your Choice? 0=Not at all 1=Just a little 2=Quite a bit		
Teaching session with diabetes educator	0	1	2	0	1	2
Chance to try out the new device or method	0	1	2	0	1	2
Seeing and touching the tools we would use	0	1	2	0	1	2
Talking with others who are using this device or method	0	1	2	0	1	2
Talking with others who decided against this device or method	0	1	2	0	1	2
Learning more from internet, books, workshops, etc.	0	1	2	0	1	2
Talking about this with others who I trust	0	1	2	0	1	2
Learning about the amount of work and trouble it will take	0	1	2	0	1	2

Outcome of decision making:
___Reject this option, stay with current treatment
___Put off decision to a later date
___Put off decision, try harder with current treatment
___Put off decision until a recent change in treatment can be evaluated
___Get more information, then decide
___Start using this option

Parent: How satisfied are you that you made the best decision for you?
___Very Dissatisfied
___Somewhat Dissatisfied
___Neither Satisfied Nor Dissatisfied
___Somewhat Satisfied
___Very Satisfied

Adolescent: How satisfied are you that you made the best decision for you?
___Very Dissatisfied
___Somewhat Dissatisfied
___Neither Satisfied Nor Dissatisfied
___Somewhat Satisfied
___Very Satisfied

Appendix 3. SMDM Intervention Summary

Shared Medical Decision Making in Pediatric Diabetes
Intervention Summary for Referring Health Care Providers

Decision under consideration: ___CSII ___CGM

Session Dates: _____

Participants in SMDM intervention:
Patient name: _____
Parent/caregiver name: _____
Other: _____
Other: _____

Parent's expressed concerns:

Adolescent's expressed concerns:

Parent's perceived benefits:

Adolescent's perceived benefits:

Areas of disagreement:

Remaining educational needs: Involvement of

other supportive persons: Utilization of

supplemental educational resources:

Interactions with others who previously faced this decision:

Competence ratings:
1=Poor 2=Marginal 3=Adequate 4=Good 5=Exceptional

	Adolescent	Parent
Effort with current regimen	1 2 3 4 5	1 2 3 4 5
Knowledge of option under discussion	1 2 3 4 5	1 2 3 4 5
Use of BG results	1 2 3 4 5	1 2 3 4 5
Organizational skills	1 2 3 4 5	1 2 3 4 5
Internal motivation to succeed	1 2 3 4 5	1 2 3 4 5
Clarity of goals	1 2 3 4 5	1 2 3 4 5
Anticipation of barriers	1 2 3 4 5	1 2 3 4 5
Realistic expectations	1 2 3 4 5	1 2 3 4 5
Communication and problem solving skills	1 2 3 4 5	1 2 3 4 5
Teamwork and collaboration	1 2 3 4 5	1 2 3 4 5
Level of SMDM engagement	1 2 3 4 5	1 2 3 4 5