Cover Page:

Shared Medical Decision Making in Pediatric Diabetes

NCT02496156

Parental Permission and Informed Consent Form

Document Date: November 7, 2016

Nemours
Parental Permission and Informed Consent for Participation in a Research Study
Nemours IC / PP Template July 2016

You have been asked to be in a research study with your child. This form explains the research, your rights and your child's rights as research participants, and any responsibilities that you may have as a result of you and your child's participation. You should understand the research study before you agree to be in it and to permit your child to be in it. ***You will receive a copy of this form. Read this form carefully. You may also talk with your family or friends about it. A research team member will answer any questions you have before you make a decision.***

1. WHAT IS THE TITLE OF THE STUDY?

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

2. WHO IS IN CHARGE OF THE STUDY AT NEMOURS?

If you have a question, complaint, or problem related to the study, you can call the investigator anytime at the numbers listed below.

	Nemours–Jacksonville	Nemours-Orlando	Nemours-Pensacola	Nemours-Wilmington	Nemours-Jefferson Philadelphia	Barbara Davis Center-Denver
Principal Investigator	Tim Wysocki, Ph.D.					
Co-Investigator(s)		Mauri Carakushansky, MD	Mark Kummer, MD	Daniel Doyle, MD	Judith Ross, MD Karen Kowal, PA	Paul Wadwa, MD
Study Coordinator(s)	Alex Taylor Chelsea Kozikowski Amy Milkes Lauren James	Jessica Pierce, PhD Elizabeth Schifano	Rebecca Shackelford	Gabriela Vega	Jessica Rafalko Toni Mascaro Elif Celikors	Cierra Sullivan Sally Sullivan Isabel Weber Nhung Nguyen
Address	807 Children's Way Jacksonville, FL 32207	1353 Nemours Parkway Orlando, FL 32827	5153 North 9th Av Pensacola, FL 32504	1600 Rockland Rd Talleyville, DE 19803	833 Chestnut St. Philadelphia, PA 19107	1775 Aurora Ct Aurora, CO 80045
Daytime Phone After Hrs Phone	(904)697-3488 (904)697-3600	(407)650-7144 (407)650-7715	(850)473-4520 (850)505-4700	(302)651-5965 (302)651-4200	(215)955-1648 (302)651-4200	(303)724-9267 (303)724-2323
Long Distance	1-800-SOS-KIDS *or* 1-800-767-5437					

3. WHO SHOULD RESEARCH PARTICIPANTS CONTACT ABOUT THEIR RIGHTS?

If you have questions about your rights or your child's rights as research participants, what to do if you or your child are injured, if you would like to offer input or obtain information, or if you cannot reach the investigator or want to talk to someone else who is not involved with this research, you may contact the persons listed below.

Chairperson, Nemours IRB 1 at 302-651-5970
Director, Nemours Office of Human Subjects Protection at 302-298-7613
Email address: NOHSP@nemours.org

4. WHAT IS THE PURPOSE OF THE STUDY?

If adolescents and their parents can make really careful decisions about adding an insulin pump or continuous glucose monitor (CGM) to their diabetes treatment plans, the use of these devices might be more beneficial and satisfying. This study will test whether an approach called shared medical decision making (SMDM) can help adolescents and parents make really good choices about whether adding either device to their diabetes treatment is best for them.

5. WHO IS SPONSORING OR PAYING FOR THE STUDY?

The Patient Centered Outcomes Research Institute (www.pcori.org) is the Sponsor of this study and will pay Nemours for its costs in conducting this study.

6. WHO CAN BE IN THE STUDY?

Adolescents can be in this study if they:

- Have been diagnosed with type 1 diabetes for at least 1 year or for at least 6 months and with the most recent Hemoglobin A_{1C} of 7.5% or higher.
- Are at least 11, but not yet 18, years old when entering the study and planning to live at home for the rest of their participation in this study
- Are considered by their diabetes doctor to be a candidate for use of either the insulin pump or CGM and for being in this study
- Have a parent or other legal caregiver who also agrees to be in the study
- Have access to the internet through some method or device
- Can speak and read English well enough to complete questionnaires
- Have made normal progress in school

Parents or legal guardians of eligible adolescents can be in the study if they:

- Take part daily in the adolescent's diabetes treatment
- Can speak and read English well enough to complete questionnaires
- Plan for the adolescent to keep receiving diabetes treatment at the medical facility where child receives diabetes care until at least 1/31/17

Have access to the internet through some method or device

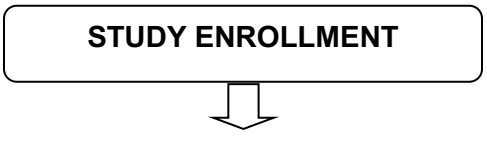
7. HOW MANY OTHER PEOPLE CAN BE IN THE STUDY?

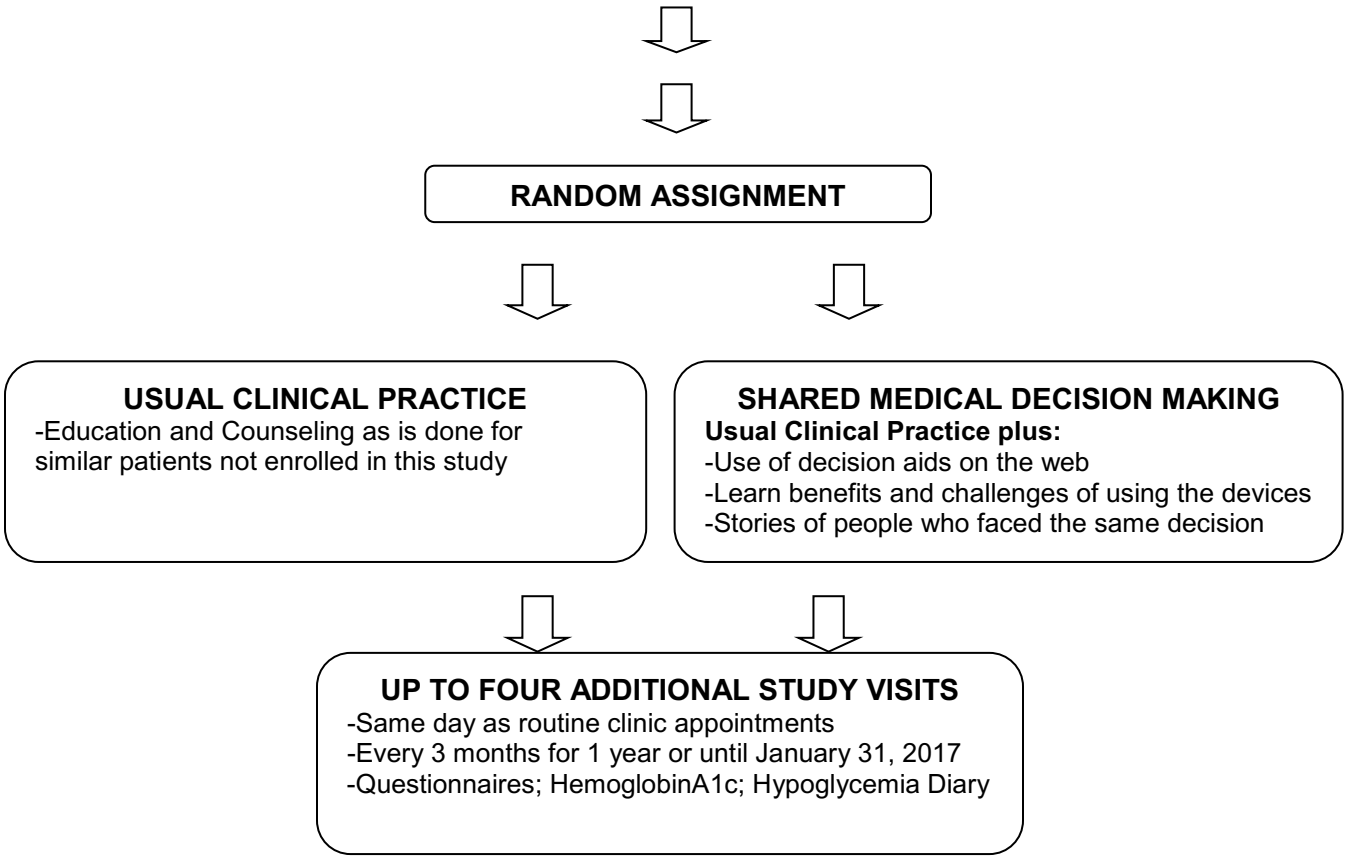
Up to 166 adolescents and their parents will be enrolled in the study at Nemours Children's Clinic locations in Florida and the Delaware Valley and at the Barbara Davis Center for Childhood Diabetes in Denver as well as through recruiting at the Friends For Life International conferences.

8. HOW LONG WILL PARTICIPATION IN THE STUDY LAST?

Each adolescent and parent will be in the study for 12 months or until January 31, 2017, whichever comes first. There will be a total of up to 5 study visits, fewer if your child enters the study after January 31, 2016, with about 3 months between visits. Ideally, these visits will take place on the same days as the adolescent's regularly scheduled diabetes clinic appointments. Research participation may add about 45-60 minutes to Visit 1, and 30-45 minutes to Visits 3 and 5, but Visits 2 and 4 shouldn't be any longer. Time spent at study visits can be reduced by completing study questionnaires online during the week before those visits. Participants entering the study after January 31, 2016 will have study follow-up visits at about 3 month intervals until the study ends on January 31, 2017.

9. WHAT ARE THE RESEARCH PROCEDURES?





Random Assignment: At the end of Visit 1 (described below) each adolescent and parent will be assigned randomly, like flipping a coin, to either of two educational approaches: **Usual Clinical Practice (UCP) or Shared Medical Decision Making (SMDM)**. Each adolescent will have an equal chance of being assigned to either approach. You don't get to choose which you will receive. These interventions are described below:

Usual Clinical Practice: All Nemours locations take very seriously the decision to start an adolescent with diabetes on the insulin pump or to add continuous glucose monitoring to their care. If you and your child agree to participate and are randomly assigned to UCP, you will receive the same counseling and education from your diabetes team that you would receive if you were not in the study.

Shared Medical Decision Making: If you and your adolescent are randomly assigned to SMDM, you will be able to use a website called a decision aid. The decision aids were planned with lots of input from parents and adolescents who have previously made these same decisions, from expert physicians and diabetes educators, from our KidsHealth partners, and from three experts on shared medical decision making. Separate decision aids have been created for those considering the insulin pump and those considering CGM. If you are randomly assigned to SMDM, a member of the research team will show you how to access the website and use the decision aid and give you a brief guided tour of what you will find within it.

The main purpose of the decision aids is to help parents and adolescents make these diabetes treatment decisions as carefully as possible by helping them to think through in detail exactly how these new technologies may or may not be the best match for them. The decision aids have been developed to be as fair and unbiased as possible, to acquaint users with both the benefits and challenges in using these devices and to help people to understand more clearly how these devices might or might not fit with their lifestyles and priorities.

Those assigned to SMDM will be asked to use the decision aid website, to explore all of the sections of the decision aid and to reply to questions within it when prompted to do so. It might be best for you and your adolescent to use the decision aid separately and then to get together to talk about the things you learned that seem most important to each of you. We hope that you can do this over a 2 to 4 week period and then let the diabetes educator know when you and your adolescent feel that you have gotten as much from it as you can. Here is a summary of what will happen at each visit:

	Visits				
Measures Obtained	**1 (Baseline)**	**2**	**3**	**4**	**5**
Questionnaires*	X	X	X	X	X
HbA1c and Medical Record Information	X	X	X	X	X
Hypoglycemia Diary	X	X	X	X	X

*Questionnaires are about your decision making process, reading ability about health care topics, knowledge about insulin pumps or CGM, satisfaction with your current diabetes technology, and diabetes treatment adherence

At the first diabetes clinic visit after you and your adolescent have finished using the decision aid, we encourage you to discuss your experience with the doctor. This can help you to get answers to any remaining questions, clear up disagreements you may have between yourselves, and provide more information about things the decision aid might not have covered completely enough for you.

Future Research Use of Data

In addition to the primary research questions that will be addressed in this study, the researchers plan to save the data from this study and to analyze that data for addressing other questions related to adolescents' benefit from the use of insulin pumps or continuous glucose monitors. Once the primary questions posed in this research have been analyzed, we will remove from the computer data file all items that can identify you or your adolescent, (such as name, date of birth, medical record number) which are known as "personal identifiers". It will then no longer be possible to guess the identity of anyone who has contributed to the stored data.

10. WHAT ARE POSSIBLE RISKS OF BEING IN THIS STUDY?

Any research has some risks (things that could make you or your child sick, feel uncomfortable, or hurt). The risks with the most chance of happening to someone in this study are listed below. Also, there is a chance of other risks that almost never happen, or unknown risks.

Usual Clinical Practice: Those who are randomly assigned to UCP would not be expected to face any added risks or discomforts beyond what they would experience in the diabetes care and education offered to similar people who are not in this study.

Shared Medical Decision Making: Those who are randomly assigned to SMDM may spend more time and effort in making a decision about the insulin pump or continuous glucose monitoring than if they were not in this study.

Completion of Questionnaires: Participants will be asked to complete questionnaires that ask questions about your private attitudes, opinions and behaviors. You are welcome to look over the questionnaires before agreeing to be in the study and you are free to not answer any questions that make you uncomfortable.

Other data collection: Other data to be collected include 1.) Collection of routine health care information from the electronic medical record such a hemoglobin A1c results, and 2.) Website usage statistics that track how you and your adolescent use the decision aid website.

Confidentiality: It is possible that an unauthorized person could see some of your questionnaire answers or other study information. Your names will not be used on any study questionnaires or paper records, all of which will be kept in locked file cabinets at the various Nemours locations. All study data will be entered electronically into a secure, password protected computer file.

Reproductive Risks: Health care for pregnant girls with type 1 diabetes who are Nemours patients are transferred to an obstetrician who specializes in that field. Anyone who stops getting diabetes care at Nemours cannot stay in the study.

11. WHAT ARE THE POSSIBLE BENEFITS OF BEING IN THIS STUDY?

If you are randomized to UCP, there are no likely direct benefits compared with what you would get if not taking part in this study. While there is no guarantee, those who are randomized to SMDM may make a better decision about adding an insulin pump or continuous glucose monitor to their care and possibly more benefit from any new device they choose to use.

12. WHAT HAPPENS IF A PROBLEM OR INJURY RESULTS FROM THE RESEARCH PROCEDURES?

Nemours will assure that you or your child will receive treatment, if needed, for study-related injuries. Neither Nemours nor the study doctor has a program to pay for medical care provided to treat the injury. If you have health insurance, it may or may not pay for the cost of treatment resulting from a study-related injury. If insurance does not pay, or if you do not have insurance, you understand that you may be responsible for paying for the cost of treatment. If you think that you or your child has been injured while in this study or has a problem related to the study, you should tell one of the study doctors as soon as possible. The study doctor or research staff will tell you what you should do. The study doctor(s)' names and phone numbers are on the first page of this form.

13. IS BEING IN THE STUDY VOLUNTARY?

Being in this study is totally voluntary. Anyone who takes part in the study can stop being in it at any time. There will be no change to you or your child's usual medical care if you or your child decide not to be in the study or decide to stop being in the study. No one will be angry with you or your child, or treat you or your child any differently than before you or your child were asked to be in the study. However, this study requires the participation of both you and your child; if you decide to stop being in the study, your child's participation will also end.

If you stop participation in this study, you and your child may continue treatment with your and / or your child's doctor**s**, or you may seek treatment from another doctor of your choice. If you and your child withdraw from the study, the study doctor may ask your permission to continue study follow-up, and all clinical data related to the study may continue to be collected from your child's medical records.

You may ask the researcher to destroy your or your child's information. Your request must be in writing. The researcher will tell you if this is possible. There may be legal reasons for keeping your and your child's information.

14. WHAT OPTIONS ARE AVAILABLE OTHER THAN BEING IN THIS STUDY?

You and your child can refuse participation in this study. There may be other research or treatment choices that could be considered. If you or your adolescent decides against being in this study, you can still get excellent counseling and education about the insulin pump or continuous glucose monitoring from your diabetes care team.

The study doctor can provide detailed information about the benefits and risks of the various treatment options available. You should feel free to discuss these alternatives with the study doctor or your and / or your child's personal physician(s).

15. CAN THE RESEARCHERS REMOVE SOMEONE FROM THE STUDY?

The researchers would only remove someone from the study who becomes pregnant or if someone asked to be removed from the study.

16. WHAT ARE THE COSTS OF BEING IN THIS STUDY?

There is no direct cost to you for being in this study. The possible added time on the days of clinic visits may lead to other costs such as child care, parking, etc., but the study has no funds to pay for such costs.

17. WILL WE BE PAID FOR BEING IN THIS STUDY?

Each family will receive a $25 gift card to a discount retailer after completing the questionnaires at Visits 1, 3, and 5. Each family who decides to begin using a new insulin pump or CGM during the study will receive a $5 gift card at each visit that they complete an Insulin Pump Use Profile and a $5 gift card at each visit that they complete a CGM Use Profile. No arrangement exists that would allow participants to share in any profit generated from this study or future research.

18. WILL I BE TOLD OF ANY NEW INFORMATION THAT MAY AFFECT MY WILLINGNESS TO STAY IN THE STUDY AND TO PERMIT MY CHILD TO STAY IN THE STUDY?

Any new information that may change your mind about participation in this study will be given to you. A committee called the Institutional Review Board (IRB) will review this study at least once per year. If the IRB finds that there is new information that you should know about while you and your child are taking part in this study, the IRB will ask the study doctor to tell you about it. You may be asked to sign a new version of this form after discussing the new information with a member of the research team.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

19. WHAT INFORMATION ABOUT ME AND / OR MY CHILD WILL BE USED OR DISCLOSED? (AUTHORIZATION TO USE AND / OR DISCLOSE PROTECTED HEALTH INFORMATION)

Identifiable health information about you and / or your child will be used by Nemours researchers. This is done to conduct the research study, to monitor the safety of research participants and for auditing. Federal law requires us to tell you about, and get your approval for, research use and disclosure of health information that includes "identifiers" that can connect the health information to you and / or your child. (Names, initials, date of birth, addresses, phone numbers, and social security numbers are examples of identifiers.) This identifiable health information is called Protected Health Information (PHI).

Use of Health Information by Nemours Staff

The health information that will be used within Nemours includes all data collected for this study, as described in Section 9 of this form.

Your identity and your child's identity will be protected as much as possible. Nemours protects your and your child's health information by storing records in files or computers that can only be used by authorized Nemours staff. All hard-copy study will be stored in locked file cabinets located at a Nemours site. These records will be labeled with a study ID code number and your name or other identifying information will not be included. Electronic data will also be stored on secure, password-protected computer servers connected to Nemours internal network. Again, these data files will identify participants by code numbers, and names or other identifying information will not be used.

The people within Nemours that may use this health information include:

- The investigators listed on the first page of this permission form and their authorized staff;
- The Nemours Institutional Review Board (IRB). (The IRB is a group of people that reviews research activities. The IRB is responsible for the safety and rights of research participants), and;
- Nemours internal audit staff.

Disclosure of Health Information to Others

No protected health information or other individually identifiable study data will be disclosed to anyone or any organization outside of Nemours. 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.

Limits on Protection of Privacy and Confidentiality

Only health care organizations have to follow laws and rules about protecting the privacy of health information. If health information containing peoples' identities is given to other kinds of companies or organizations, they are not required by law to safeguard the privacy and confidentiality of that information. Nemours expects these companies and organizations to protect the privacy and confidentiality of research participants, but it is not possible for Nemours researchers to assure that this happens.

Government agencies that may look at records for this research study, including the above health information, include:

- The Patient-Centered Outcomes Research Institute
- Other agencies of State and local government as required by law

The research results may be presented at scientific meetings or in print. Participants' identities will not be disclosed in those presentations.

20. SIGNATURES:

I am making a decision whether or not to consent to participate and to permit my child to participate in this study. I understand that my child may also have to agree to participate in the study before he / she will be allowed to be in this study. I have read, or had read to me in a language that I understand, all of the above. I have been given enough time to make this decision. I have asked questions and received answers about things I did not understand. I willingly consent to participate and give permission for my child to participate in this study. By signing this form, I am not giving up any rights to which I and my child are entitled under law.

I understand that:

- I can withdraw permission for my and my child's participation in this study and for the use and / or disclosure of PHI by contacting the person in charge of the study listed on the first page of this form.
- The use and / or disclosure of my and / or my child's PHI will stop after Nemours receives the withdrawal notice. Information that is used or disclosed before the withdrawal may still be used.
- Unless I and my child withdraw permission, the use and / or disclosure of PHI described in this form will not have an expiration date.
- My PHI and my child's PHI may be disclosed again by the person or organization (other than Nemours) that receives it. If this happens, Federal or state law may not protect the information.
- I have the right to refuse to sign this permission / consent form.
- If I refuse to sign this permission / consent form, my child and I will not be allowed to be in this research study.
- I have the right to ask Nemours to tell me who has received my and / or my child's protected health information.
- I have the right to revoke my permission for the use and disclosure of my and / or my child's health information at any time, which would end my and my child's participation in this study.
- I will receive a signed and dated copy of this form.

My signature indicates that:

- I give the researchers and Nemours permission to use and / or disclose my and / or my child's individually identifiable health information, for this research study, as described in this form.
- As his or her parent or legally authorized representative, I give my permission for the minor child named below to participate and give consent for my participation in the research study described in this form.

Name of Adult Participant (**Print**)	Signature of Adult Participant	Date

Name of Minor Participant (**Print**)	Minor Participant Date of Birth:	Date

Check Relation to Minor Participant: ☐ Parent ☐ Legally Authorized Representative

(Legally Authorized Representatives must have documented authority to give permission for a child's participation in a research study according to the laws of the State in which the treatment occurs.)

I, the undersigned, certify that to the best of my knowledge the parent(s) / legally authorized representative(s) signing this permission had the study fully and carefully explained and that the parent(s) / legally authorized representative(s) understand(s) the nature, risks and benefits of participation in this research study.

Name of Person Obtaining Permission (**Print**) (Investigator or Designee)	Date
Signature of Person Obtaining Permission (Investigator or Designee)	Date
A copy of the signed form was provided to Parent(s) / Legally Authorized Representative(s) ☐	Date