Document Cover Page

Official Title of the Study:

Use of Continuous Glucose Sensors by Adolescents with Inadequate Glycemic Control

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NEMOURS
WILMINGTON, DELAWARE AND JACKSONVILLE, ORLANDO & PENSACOLA, FLORIDA
PARENTAL PERMISSION AND INFORMED CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

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. ***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?
Use of Continuous Glucose Sensors in Adolescents with Inadequate Diabetic Control

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.

Principal Investigator
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3. WHO SHOULD RESEARCH PARTICIPANTS CONTACT ABOUT THEIR RIGHTS?
If you have questions about your child's rights as a research subject, what to do if your child is 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.

Carlos Rose, M.D., Chairperson, Nemours-Delaware Institutional Review Board at (302) 651-5970.

Paul Garfinkel, MSH., Director, Nemours Office for Human Subjects Protection, at (904) 697-4023.

(Nemours Long Distance Operator) (800) SOS-KIDS (800-767-5437)
Website: http://www.nemours.org/research/nohsp.html . Email: NOHSP@nemours.org.

4. WHAT IS THE PURPOSE OF THE STUDY?

Since many adolescents with type 1 diabetes have a hard time keeping their Hemoglobin A_{1C} levels below 7.5%, new approaches are needed. Continuous glucose sensors or monitors (CGM) can measure blood sugar levels constantly through a tiny sensor placed under the skin. These devices give immediate feedback about blood sugar levels. This provides another tool to help achieve better diabetic control and avoid health problems from diabetes. Previous studies have shown that adolescents may not benefit fully from using CGM. This is mostly because they have a harder time wearing the CGM device enough to make a difference, responding quickly and correctly to CGM alarms, verifying CGM results by checking blood sugar with a home glucose meter, and working well with their parents to correct out-of-range blood sugars. The main purpose of this study is to see if having a behavioral specialist work with adolescents and parents can improve health outcomes from adding use of a CGM device to diabetes care.

5. WHO IS SPONSORING OR PAYING FOR THE STUDY?

The National Institute of Diabetes, Digestive and Kidney Diseases, a branch of the U.S. federal government, is the Sponsor of this study. This agency will pay Nemours for its costs in conducting this study.

6. WHO CAN BE IN THE STUDY?

Youths with type 1 diabetes and their parent(s) or other legal caregivers may be eligible to be in the study. This study involves answering written or spoken questions in English or Spanish. Only participants who can both read and speak either English or Spanish at a level that permits this can be in the study.

Adolescents can be in the study if they meet these requirements:

- At least 11 but not yet 18 years old when entering the study
- Have had type 1 diabetes for at least 2 years or 1 year with a blood test (c-peptide) showing little or no remaining insulin production. (Past the "honeymoon" period).
- Diabetes treatment for at least the past 6 months that has included use of either an insulin pump or at least 3 daily injections of insulin; use of a carbohydrate counting approach to eating; and use of a "correction factor" for adjusting insulin doses. If you are not sure, we can ask your doctor or diabetes educator if your child's treatment meets these criteria.
- Either the most recent glycosylated hemoglobin (HbA_{1C}) result or the average over the past 12 months of at least 7.5% but no more than 10.0%.
- No previous use of a continuous glucose monitor as part of diabetes treatment.
- Not in special education for mental retardation, autism or severe behavior disorders
- Absence of other chronic diseases or ongoing medical treatments that the adolescent's diabetes doctor feels would be barriers to safe participation in the study.
- No psychiatric hospitalizations or psychiatric day treatment in the prior 6 months.

Parents or other legal caregivers can be in the study if they meet these requirements:

- Plans to keep getting the adolescent's diabetes care at Nemours for the next year.
- Working telephone service.
- Not treated for major depression, psychosis, bipolar disorder or substance abuse disorder within the prior 6 months.
- Reliable access to the internet for downloading of blood sugar results. (The study can provide a home computer to a very limited number of families who do not have internet access).

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

There will be a total of 150 adolescents and their parents who will take part in the study at a Nemours Children's Clinic location in either Wilmington, Delaware or in Orlando, Pensacola, or Jacksonville, Florida. All study data will be sent to Dr. Wysocki and his staff at Nemours Children's Clinic in Jacksonville, Florida.

8. HOW LONG WILL PARTICIPATION IN THE STUDY LAST?

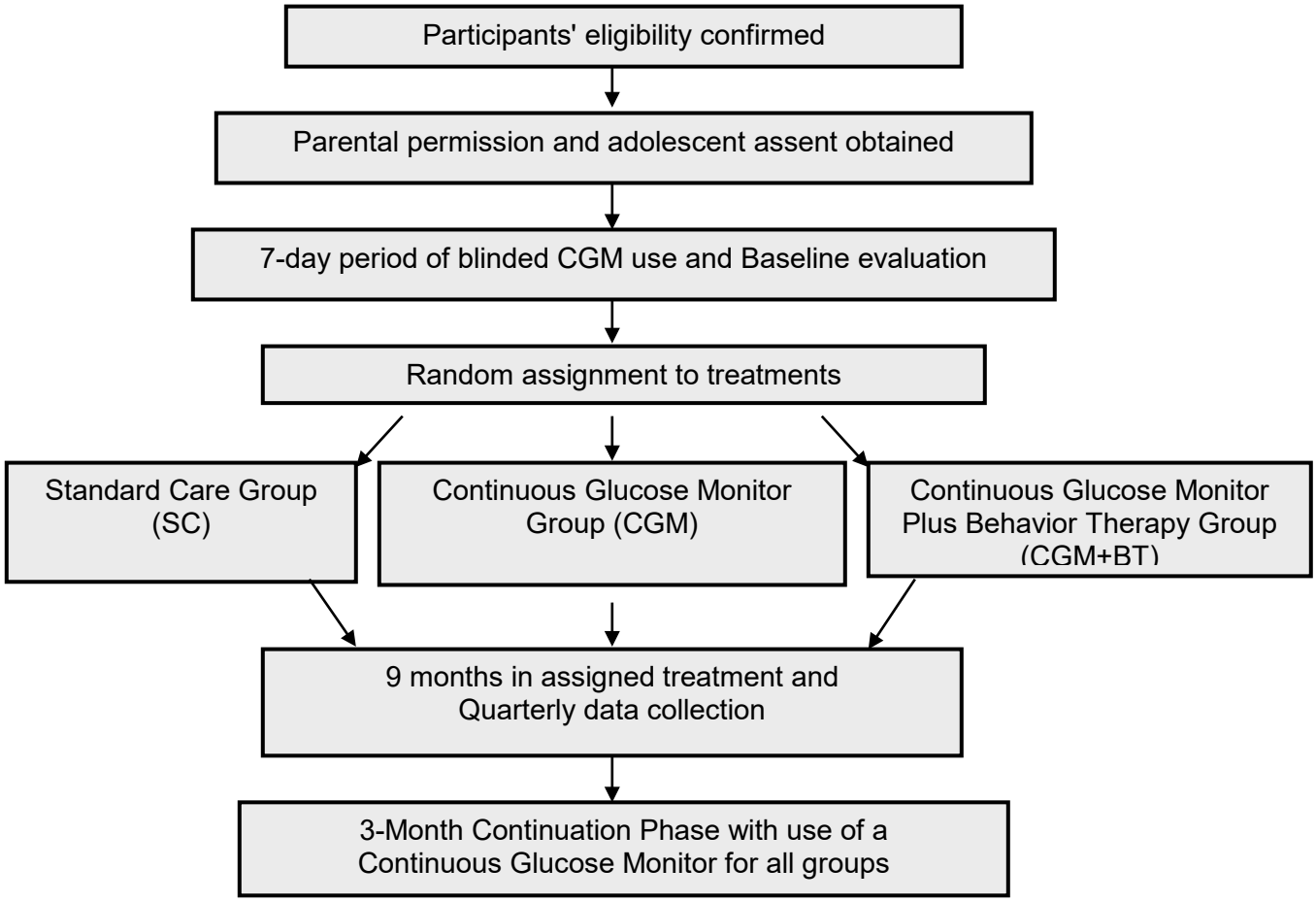
Participation in this study asks a lot of you and your child. Each adolescent and parent will be in the study for up to one year. During the first 9 months, 2 of every 3 adolescents will be randomly selected to use a CGM device as part of diabetes care. This may add about 10-15 minutes to daily diabetes care, but this may be offset by better blood sugar control. Adolescents will be asked to use a "blinded" CGM device (no blood sugar feedback) for one week at the beginning of the study. Those who are not chosen randomly to use a CGM device will be asked to do this one more time at the end of 9 months. All participants will be asked to download the results from their CGM devices once per week, requiring about 10 minutes per week. All participants will complete questionnaires that will be completed either just before or after routine diabetes visits or at other times if requested by families. This will take you between 30 to 45 minutes each time and can be done either by computer over the internet within 2 weeks before a clinic visit or at each diabetes clinic visit during waiting times. During the last 3 months of the study, all adolescents will be able to use a CGM device as part of daily diabetes treatment.

It is important that you and your child understand that use of a CGM device does not mean that your child can stop doing regular finger-stick blood sugar checks. Blood sugar checks will still be needed to calibrate or adjust the CGM device to your child's actual blood sugar and also to confirm your child's blood sugar before making any treatment decisions based on the CGM results.

9. WHAT ARE THE RESEARCH PROCEDURES?

The diagram below summarizes the study. Each adolescent will be assigned randomly (like flipping a coin) to one of three kinds of diabetes treatment. Adolescents will get that treatment approach for the next 9 months. After 9 months, all adolescents will be given a CGM device to use for the following 3 months. Adolescents and parents will complete questionnaires about diabetes management, family communication and problem solving, quality of life, and satisfaction with the method they are using for checking blood sugars (meter alone or meter plus CGM). Participants will complete questionnaires either at or just before diabetes clinic visits. At home, families will be asked to download results from CGM devices once per week, and write down details about any low blood sugar reactions that happened.

DIAGRAM OF STUDY DESIGN



9-Month Randomization Phase: Each adolescent will be randomly assigned to receive one of these diabetes treatments for the next 9 months:

- **Standard Care (SC)**: Diabetes care just like what your child is getting now based on regular finger-stick blood sugar checks and either insulin pump or multiple daily injection regimens and the use of carbohydrate counting and insulin dose correction factors.
- **Continuous Glucose Monitor (CGM):** The SC regimen above plus the use of a CGM for glucose monitoring, managed by a physician, diabetes educator and dietitian as in typical clinical practice. Parents and youths will receive very detailed training in all aspects of CGM use. Each parent and adolescent will be guided by a diabetes nurse in choosing a CGM device to use from among those that are currently available. The FDA has approved the current devices as supplements to regular blood sugar checks with a glucose meter. ***It will still be necessary for adolescents to do finger-stick blood sugar checks to calibrate the CGM device and to confirm CGM results before making any treatment decisions.*** The FDA has approved all of the CGM devices being used in this study for use by adults as a supplement to regular finger stick blood sugar monitoring. The use of the Abbott Navigator and DexCom Seven Plus devices by children and adolescents in this study is considered investigational by the FDA since these devices have been FDA-approved for use only by adults. Depending on the study's arrangements with the manufacturers of these devices, it is possible that you and your child could be offered use of a "next-generation" CGM device that does not yet have FDA approval. That possibility will be discussed with you in detail when the time comes.

- **Continuous Glucose Monitor Plus Behavior Therapy (CGM+BT):** Families assigned to this treatment will get the CGM treatment above along with a psychological intervention targeting family diabetes management behaviors that we hope will improve teens' benefits from CGM use. Trained mental health professionals, following a treatment manual and supervised carefully by Dr. Wysocki, will work with each CGM+BT family to reduce behaviors that interfere with CGM benefits and to increase behaviors that promote those benefits. Target behaviors for these sessions will include specific behaviors affecting benefit from CGM such as wearing the CGM device enough to make a difference, responding appropriately to CGM alarms, verifying CGM results by checking blood sugar with a home glucose meter, and improving parent-adolescent communication and problem-solving about out-of-range blood sugars. Each of these sessions will be audio-recorded and about 10% will be rated for compliance with the treatment manual. Each family getting this treatment will see the therapist about 5 times during the study and the therapist will follow up with you and your child by telephone or e-mail 2 weeks before and 2 weeks after each clinic visit during the study.

3-Month Continuation Phase: Each adolescent who completes the 9-Month Randomization Phase (any of the 3 treatments) will be invited to use (or continue to use) a CGM device for 3 months. Those who choose to do this will then be getting the Continuous Glucose Monitor treatment as described above.

With consultation from the diabetes team, participants will choose which of the available CGM devices they would like to use in this study. Some participants may choose the Medtronic-Minimed “Paradigm” insulin pump which includes a CGM device. These devices are being provided to study participants on a loaner basis only and must be returned to the company when you have completed the study. If you use one of the Medtronic-Minimed “loaner” pumps during the study, it may be possible for the study to provide you with a CGM device to keep after the study from one of the other companies (DexCom or Abbott). If you choose a DexCom or Abbott device for the study, when you and your child complete the study, it may be possible for you to keep the CGM device that your child used if it is an FDA-approved device. But, obtaining replaceable sensors for the device will then become your responsibility. Your diabetes team will help you in trying to get your health insurance to cover this cost, but that cannot be guaranteed. If your child uses a CGM device that does not yet have FDA approval by the time you and your child complete the study, the manufacturer will decide if you can keep the device. If so, you may have to participate in continued safety monitoring as directed by the manufacturer and the FDA.

STUDY MEASUREMENTS

The study will include collection of several kinds of information that will help the researchers answer the main study questions. Most of these will be measured several times during the study. These include:

"Blinded" CGM use for 1 week: All adolescents at the beginning of the study will be asked to use a CGM device with the blood sugar feedback disabled for a one week period. Those in the Standard Care Group will be asked to repeat this 9 months after beginning the study. This will allow the researchers to compare the blood sugar profiles of all adolescents in the study and will provide a "baseline" 24 hour glucose profile for each adolescent. These results are to be used strictly as research data and will not be used for diabetes treatment purposes.

Weekly downloads of CGM devices: Each family will be given software for downloading their CGM device so that the results can be sent to the researchers in Jacksonville. These results will allow the researchers to look at such things as average blood sugar levels, variability in blood sugar levels, proportion of blood sugar values in the normal range, and the frequency and duration of low blood sugars during sleep. Computer reports of these results will be sent regularly to your child's physician during the study.

Questionnaires: Parents and adolescents will complete a variety of questionnaires either within 2 weeks before or on the days of diabetes clinic visits. These cover basic information about your family, diabetes treatment adherence, family communication, sharing of diabetes responsibilities, quality of life and

satisfaction with the blood glucose monitoring system you are using (meter alone or meter + CGM). Parents are invited to look over all questionnaires before agreeing to be in the study. Although the researchers would prefer to get as much information as possible from you, parents and adolescents are free to skip any question if they wish to do so. These results will help the researchers evaluate whether CGM is helpful in ways other than blood sugar control and possibly to learn which adolescents may benefit from CGM.

Audio recordings of clinical encounters with the study therapist: Since this study is a test of a special behavior change method, the researchers must be able to show that the CGM+BT group received that treatment, while the other groups did not. Sometimes, the study therapist who is working with the CGM+BT group may see patients and families in the SC and CGM groups to help them with their management of diabetes. When this happens, we would like to ask your permission for the therapist to make an audio recording of that visit. Each recording will be erased as soon as it has been rated. If you do not wish to have a visit recorded, it will not be done. If a visit has been recorded and you do not wish to share it, it will be erased immediately. These recordings will be used to rate the extent to which the therapist's work with families followed the study procedure manual. This will not include any visits that are about topics other than your family's management of diabetes. The recordings will be rated by other study staff to describe the reason for the visit and the nature of the conversation and the ratings will not identify you.

Among those in the CGM+BT treatment, all sessions with the therapist will be audio-recorded. Names or other identifying information will be digitally erased from the recordings. These will be used to verify that the therapist followed the treatment manual. Some people are uncomfortable with this. Only properly authorized study staff will have access to these recordings and all will be trained to protect each participant's confidentiality. Each family's recordings will be erased once they have been rated.

Glycosylated hemoglobin (HbA_{1C}): A finger-stick blood sample will be obtained at each diabetes clinic visit and sent to Jacksonville so that all HbA_{1C} measurements can be done at a single laboratory. The researchers will try to obtain enough blood for both the local site's and Jacksonville laboratories from one finger-stick. Sometimes it may be necessary to do a second finger-stick to get enough blood.

Hypoglycemia Diary: Families will be asked to keep a logbook record of each low blood sugar reaction that is felt to be either severe or moderately severe. Parents will be taught the definitions of these events. The logbook records will be entered into the computer when you are downloading home glucose meter and CGM results each week.

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.

The risks of being in this study have to do with each of the three treatments being compared, with the tests and measurements being collected during the study and with possible threats to privacy and confidentiality.

Risks of the three treatments being compared

The three treatments being compared each have sources of risk and possible discomfort.
The Standard Care (SC) treatment carries all of the risks that you and your child are probably already aware of, including risks of low blood sugar reactions, prolonged high blood sugar that can lead to diabetic ketoacidosis and the overall burden of taking care of diabetes. Being in this study is unlikely to make these risks any better or worse.
Risks of the Continuous Glucose Monitor (CGM) treatment are those that are linked to using a CGM device. Putting a foreign object such as a CGM sensor under the skin creates risks of rash, itching, pain and possible infection where the sensor is inserted. There is a very small risk (about 2 of 10,000 sensors used) that the sensor probe or part of it could remain in the skin when the sensor is removed. This could happen due to rough play or contact sports while wearing the CGM or if the sensor is not removed carefully using

the exact methods you will be taught. If you think a sensor has broken off under your child's skin, please call the study nurse right away. No child should have an MRI (Magnetic Resonance Imaging) test for any reason while either using a CGM device normally or if there is possibly a broken sensor under the child's skin.

The CGM may give inaccurate results, possibly leading to poor treatment decisions. This is why CGM results must be confirmed with a finger-stick blood sugar check before making treatment decisions. Use of a CGM may also increase the overall burden of taking care of diabetes and it may intrude into sleep and daily activities such as school, work, or sports.

Also, the FDA has required DexCom to state in its packaging that:

- The DexCOM SEVEN PLUS CGM device is not approved for use in children or adolescents, pregnant women or persons on dialysis.
- The safety and effectiveness of the SEVEN PLUS Systems has not been evaluated for sensor probe insertion in sites other than in the skin of the abdomen.

Risks for those receiving the Continuous Glucose Monitor Plus Behavior Therapy treatment include all of those for the CGM treatment above as well as some other risks. Receiving behavior therapy can be challenging for many parents and adolescents to talk about and try to improve diabetes management, since this can often be a sensitive issue. Also, audio recordings of behavior therapy sessions will be made to assure that the treatment manual was followed. These will be digital recordings that will be stored electronically in a password-protected computer file and then erased when you complete the study.

Risks of the tests and measurements

The questionnaires ask for your opinions about many aspects of living with diabetes, including your child's treatment adherence, parent-adolescent communication and responsibility sharing, fear of hypoglycemia, quality of life and satisfaction with the glucose monitoring system you are using. These are time-consuming and some people don't like to answer questions about their private thoughts, feelings and actions. You are welcome to read all of the questionnaire questions before agreeing to being the study. You may also choose to not answer any specific questions if you wish.

Your child's diabetes doctor measures your child's glycosylated hemoglobin (HbA_{1C}) at each clinic visit using a machine called the DCA 2000. This measures your child's average blood sugar level in the prior 2-3 months. Since families will be in the study at three different clinics, and DCA 2000 results can vary between clinics, accurate analysis of these results requires that the blood samples be tested by a single "central" laboratory. For this study, a second finger-stick blood sample will be taken at diabetes clinic visits and sent to the central laboratory in Jacksonville. It is usually possible to get enough blood for the local and central HbA_{1C} tests from the same finger-stick. But this is not always true, and so a second finger-stick may sometimes be needed. If so, your child will experience the same risks of pain, bruising and possible infection that come with doing finger-sticks.

Threats to privacy and confidentiality

The different questionnaires and audio recordings all create potential threats to your privacy and confidentiality. These points are discussed in more detail in Section 19 of this form along with safeguards to protect your confidentiality.

Pregnancy

Girls deciding whether or not to be in this study may already have started having periods or may begin having periods while they are in this study. If sexually active, your child should use effective birth control to prevent pregnancy while participating in this study. As appropriate, the study doctor will discuss issues of possible sexual activity and use of effective birth control privately with your child.

There is no reason to suspect that use of a CGM device or receiving behavior therapy could cause either immediate or lasting harm to a pregnant female or a fetus. But, if there is any chance that pregnancy could

have occurred during the study, the study doctors must be told immediately. Anyone who is pregnant will be taken out of the study right away. If a girl becomes pregnant during the study, her diabetes care will be transferred to an obstetrician who specializes in managing pregnancy in women with diabetes. She will not be able to remain in this study. We encourage open honest communication between parents and their children regarding issues of sexual activity and possible pregnancy. It is also important for you to let the study doctor know if a young girl starts having periods during this study so that appropriate precautions can be taken from that point onward.

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

While the researchers cannot promise benefits to anyone in this study, there are several possible ways in which parents or adolescents could benefit from taking part.

Whether for 9 to12 months (CGM and CGM+BT treatments) or for 3 months (SC treatment), each adolescent will be able to use the CGM device chosen by you and your child's diabetes team. The CGM will give you and your child more information about how the blood sugar is changing throughout the day and night. Using this information properly could allow you and your child to achieve better blood sugar control and fewer low blood sugars. The results of your CGM downloads will also be sent regularly to your child's diabetes doctor and this could also lead to better diabetes treatment.

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

Nemours will assure that your child receives treatment, if needed, for study related injuries. Neither Nemours nor the study doctor have 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 your insurance does not pay, you understand that you will be responsible for paying for the cost of treatment.

If your insurance does not pay for study-related injury, or if you do not have insurance, you will 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.

The study staff is available Monday-Friday from 8:00am to 5:00pm. During these hours, you should call the Endocrinology Clinic at Nemours Children's Clinic for medical advice. Phone numbers for each Nemours location are given below:

Wilmington: (302) 651-5965 Orlando: (407) 650-7210 Pensacola: (850) 505-4745
Philadelphia: (215) 955-1648 Jacksonville: (904) 697-3759

During evenings, weekends, and holidays, you should call the numbers below to reach the Nemours operator. Ask the operator to page the Endocrinologist on call.

Wilmington: (302) 651-4000 Orlando: (407) 650-7000 Pensacola: (800) 767-5437
Philadelphia: (215) 955-1648 Jacksonville: (904) 697-3600

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 your child's usual medical care if you and/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 your child any differently than before your child was 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 your/your child's participation in this study, your child may continue treatment with his/her doctor, or you may seek treatment for your child from another doctor of your choice. In the event that you withdraw your child from the study, the study doctor will 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 however, ask the researcher to destroy your/your child's information or samples. Your request must be in writing. The researcher will tell you if this is possible. There may be legal reasons for keeping your child's information or samples.

If you or your child want to withdraw from the study, please tell this to a member of the study staff. If the study provided them to your child, you may keep the home glucose meter or FDA-approved CGM that you were given. If your child was given a CGM device that is not yet FDA-approved, it may have to be returned when you leave the study. Your doctor will let you know if it is possible for your child to continue using the CGM device after your child leaves the study. Also, you will be asked to return any unopened packages of CGM sensors and any unopened bottles of blood glucose test strips that were provided by the study. We would also appreciate it if you would provide your reasons for withdrawing from the study before completing it.

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

You can refuse participation in this study. There may be other research or treatment choices that could be considered. These choices include continuing to receive the same medical care for your child's diabetes that your child has been receiving, or talk with your child's doctor about the possibility of getting an FDA-approved CGM device at your expense and adding it to your child's diabetes care.

Your child's diabetes 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.

15. CAN THE RESEARCHERS REMOVE SOMEONE FROM THE STUDY?

Your participation in this study could be ended without your permission if your doctor feels that it is necessary for your child's medical safety or if the study sponsor ends the study early.

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

All of the procedures done for this study that are not part of your child's routine diabetes treatment at Nemours will be paid for by the study. This includes the costs of the CGM devices and sensors, blood glucose test strips (if you do not have insurance coverage for test strips), the extra visits with the diabetes nurse for CGM training, the central laboratory HbA_{1C} tests, and the behavior therapy sessions if your child is getting the CGM+BT treatment. Routine diabetes clinic visits and any laboratory tests ordered by your child's doctor other than those for this study will be billed to your insurance or you.

You may experience indirect costs due to being in the study. There are extra visits with a diabetes educator for training in safe and effective use of CGM devices and this could increase your expenses for travel, meals and possibly child care for other children. Completion of the study commitments takes considerable time and effort and this may interfere with work or other responsibilities. Please tell us if you feel that these costs would make it impossible for you and your child to be in the study.

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

You and your child will be able to keep the CGM device you used during the study if it is FDA-approved when you complete the study. These devices have a retail value ranging from about $800 to $2000 depending on the company. The Medtronic-Minimed company has provided the study with Model 722 and 522 Paradigm insulin pumps that can be used by study patients but must be returned to the company after patients complete the study. If the CGM device you selected is not FDA-approved when you and your child complete the study, it may be possible for you to keep it by meeting requirements imposed by the FDA and the manufacturer. During the study, your child will also be provided with sensors for the CGM device being

used, which amounts to several hundred dollars per month depending on how many sensors are used. Blood glucose test strips will be provided during the study for those who lack insurance coverage for them.

Adolescents will be paid $20 for each calendar month in which they download a CGM device or bring it to a clinic visit for downloading. This will be in the form of a check mailed to the adolescent about 3-4 weeks after the payment is earned.

Each participant will be provided with one CGM device for use during the study. Lost devices will not be replaced by the study. If a CGM device is lost, you and your child can remain in the study if you can obtain another CGM device at your expense.

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 MIGHT AFFECT MY WILLINGNESS TO PARTICPATE 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, it 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.

19. WHAT INFORMATION ABOUT MY CHILD OR MYSELF WILL BE USED OR DISCLOSED?

Identifiable health information about you or your child will be used by Nemours researchers and may be given to people outside of Nemours for this research. 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 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 Researchers

The health information that will be used within Nemours includes all data collected for this study, as described in Section 9 of this form. This includes the downloaded results from the CGM devices, glycosylated hemoglobin results, completed questionnaires, hypoglycemia diaries and necessary medical history information obtained from your child's Nemours medical record.

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.

On all study questionnaires, laboratory reports and other such documents, each participant will be identified only by a unique study ID code number. The list showing the code numbers and participants' names will be kept in password-protected computer files located on the Nemours' computer network. Only the physician and diabetes nurse at each site will be able to use this list to identify study participants at their sites. Dr. Wysocki and his authorized staff members will have access to the complete list of all study participants and their code numbers.

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

- The investigators listed on the first page of this permission form and their assigned 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

Information from this research study will also be contained in your child's Nemours' medical record along with the information about your child's regular office visits. This will help other doctors to know about the research study your child is in and give them extra information from the research that might help them take better care of your child. The same information might also be seen by anyone who can look at your child's medical records, such as your insurance company.

Identifiable health information will be given (disclosed) to the following individuals or groups:

Tim Wysocki, Ph.D. and staff at Nemours Children's Clinic in Jacksonville

The PHI that will be given (disclosed) to people or groups outside of Nemours for research purposes is checked in the table below:

Type of Identifiable Health Information:	Disclosed
Demographics (information about race, ethnicity, gender, age)	☒
Questionnaires, hypoglycemia diary, audio recordings	☒
Signed parental permission and adolescent assent forms	☒
Other: Medical record information pertinent to the study; HbA_{1C} results; Downloads of home glucose meters and CGM devices	☒

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 U.S. Food and Drug Administration
- The U.S. Department of Health and Human Services
- Other agencies of State and local government as required by law
- Governmental agencies in other countries

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 am entitled under law.

I understand that:

- I can withdraw permission for 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 / 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 withdraw permission, the use and/or disclosure of PHI described in this form will not have an expiration date.
- My / 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 form.
- If I refuse to sign this permission form, I / my child will not be allowed to be in this research study.
- I have the right to ask Nemours to tell me who has received my / my child's protected health information.
- I have the right to revoke my permission for the use and disclosure of my / child's health information at any time, which would end my / 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 / my child's individually identifiable health information, for this research study, as described in Section 19.
- As his or her parent or guardian, I give my permission for the minor child named below to participate:

Name of Minor Participant (Print)	Minor Participant Date of Birth:	
Name of Parent / Guardian (Print)	Signature of Parent / Guardian	Date

- I also consent to participate in the research study described in this form.

Name of Adult Participant (Print)	Signature of Participant	Date

Check Relation to Minor Participant: __ Parent __ Guardian: (Guardians must have documented authority to give permission for 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/legal representative signing this consent/permission form had the study fully and carefully explained and that he/she understands the nature, risks and benefits of participation in this research study.

Name of Person Obtaining permission (Investigator or Designee)	Signature of Person Obtaining permission	Date

Copy of the signed form was provided to Parent/ Guardian on [Date] _____