Consent to Participate in a Research Study

*Day and night closed-loop in young people with type 1 diabetes (DAN05)*

Today, you are being asked to take part in this research study because you have type 1 diabetes and use an insulin pump. The goal of this research is to get new knowledge that may help other people, but it is not the same as treatment of type 1 diabetes. We want to find what works best for treating your and others with this condition.

Your study team will be talking with you about this research and this document. Please take your time deciding whether you want to participate in this research and please carefully read this document. To take part in the study, you will need to carefully read and sign this document.

Before you decide to take part in this research study, we encourage you to speak with friends and family members about it. If you do not understand all the information, please ask your study doctor or nurse to explain. If you are taking part in another study, please tell us right away.

**NON-PARTICIPATION STATEMENT**

Participation in this study is voluntary and you must agree to take part. If you decide to stop participation in this research, that will happen immediately. No penalty or loss of medical care will result from your decision. While the study is occurring you may continue to receive medical care not related to this study.

**WHO IS DOING THE STUDY**

Your study team will carry out this study. Their names are listed on the Cover Page of this form. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) which is part of the National Institutes of Health (NIH) is paying for this research. This funding will be used by the Jaeb Center for Health Research to organize the study and pay your study doctor(s).

**WHY ARE WE DOING THIS STUDY?**

The purpose of this study is to compare an automated insulin management system (study system) to using an insulin pump alone. The study system includes (1) a CGM that measures glucose levels, (2) a computer program on a smartphone that determines how much insulin is needed, and (3) an insulin pump that delivers the insulin. The name of this closed-loop system is FlorenceM. Half of the people taking part in the study will use the study system. The other half will continue to use their own insulin pump.
The CGM sensor has a needle that is inserted just under the skin. It measures the glucose in the fluid beneath the skin and shows this on the pump screen every 5 minutes. The sensor needs to be changed about every 7 days. The insulin pump has a tube that is inserted under the skin. It needs to be changed about every 3 days. This may be similar to the insulin pump infusion set you are already using.

The CGM and insulin pump are made by Medtronic MiniMed, Inc. The pump model name is the Medtronic 640G. The CGM sensor is called the Enlite 3 Sensor. It also is made by Medtronic Minimed, Inc.

The Enlite 3 Sensor, the Medtronic 640G insulin pump, and the overall FlorenceM system used in this study are experimental. This means they can only be used for research. Because of this, we call the entire system an investigational device. The Food and Drug Administration (FDA) and The Medicines and Healthcare Products Regulatory Agency (MHRA) have approved its use in our research study.

We have tested an earlier version of the system in more than 170 people in both the hospital and the home. We did not find any higher risk for high or low blood sugars or other problems.

**HOW MANY PEOPLE ARE WE EXPECTING TAKE PART IN THIS STUDY?**

We expect about 130 people will take part in this study at six centers in the United States and the United Kingdom.
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WHO CAN PARTICIPATE IN THIS STUDY?
To take part in this study, you will need to:

1. Be at least 6 years old and no older than 18 years old
2. Have type 1 diabetes for at least one year
3. Have an HbA1c of at least 7.5% and no higher than 10.0% (HbA1c is a measure of your blood sugar control)
4. Be using an insulin pump for at least the last three months
5. Have access to Wi-Fi in your home and a computer for uploading device data and doing online questionnaires
6. Live with a family member/guardian who is willing to be trained on use of the system
7. Avoid taking acetaminophen (Tylenol) during the study
8. Speak and understand English
9. Have a negative pregnancy test if you are a female who could become pregnant
10. Be willing to follow the procedures described in the next sections

There are some conditions that may prevent you from being part of the study. Your study doctor will check if you have these or not. Pregnant or breastfeeding women cannot participate. If you are a woman who has the potential to get pregnant we will do a urine test to be sure you are not pregnant before you enter the study.

WHAT HAPPENS IF I AGREE TO TAKE PART IN THIS STUDY?
This study will take about 14 months for you to complete. This will include up to 10 clinic visits and up to 10 telephone/email contacts.

Screening Visit
If you decide to take part in the study, you will sign this consent form. Then we will ask you some questions and you will have some blood tests done. These questions and blood tests will make sure you are eligible and it is safe for you to be in the study.

These include the following:
- Collection of information about your diabetes history and management, your medical conditions and medications, and menstrual history (females).
- Physical exam
- Blood tests for HbA1c, thyroid levels, liver function, blood counts, celiac disease screening, and blood insulin levels.
- A urine pregnancy test (if you are a female who can become pregnant)

You will be asked to complete questionnaires that ask about your and your family’s quality of life, your diabetes management, and how you feel about your current treatment for diabetes.
A CGM sensor will be placed. This CGM will record your glucose levels for up to 2 weeks, but you will not be able to see them. This is called blinded CGM. You will be taught how to care for the CGM. The blinded CGM will require little action from you. You will be asked to do at least 4 fingerstick blood glucose checks daily with your own blood glucose meter. This is part of good diabetes management.

**Treatment Group Determination and Initial Training**

You will come back to the clinic 2 weeks after screening. During this visit your use of the CGM will be checked, and your bloodwork results from screening will be reviewed. Your pump settings may be changed based on the CGM information. If you were not able to use the blinded CGM enough during the 2 weeks, you will be asked to repeat the 2 weeks. We will also recheck your HbA1c if it has been more than 4 weeks since screening. A urine pregnancy test will be done if you are a female who can become pregnant.

At this visit, a computer program will be used to select whether or not you will be given the study system or continue to use your own insulin pump. This is similar to flipping a coin. There is a 50/50 chance you will be in either group. Neither you nor your study team will have a choice in which group you will be placed.

Both groups will receive diabetes education. The education will cover key parts of diabetes management.

You will be given a blood glucose meter, a blood ketone meter, and test strips. You should check your glucose at least 4 times every day. We will give you instructions on when to use the ketone meter.

If you are in the group using the study system, you will be switched from your usual insulin pump to the study pump. This could be done on the same day or within the next few weeks. You will be taught how to use the new pump. You will need to bring your own insulin to this visit.

On either the same day as switching to the study pump or at another visit within a week of starting to use the study pump, you will start using the study CGM and be taught how to use it. You will use the study pump and study CGM until you return for another visit in about 4 weeks. During this visit, you will receive more training on the at-home study procedures.
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**At-Home Procedures**

**Pump Only Group**

You should continue to check glucose levels with the study glucose meter at least 4 times every day. You will use the ketone meter to check for ketones if your fasting glucose is 250mg/dl or higher and at other times according to instructions we give you. You will be given a phone number to call study staff if you are having any problems.

**Study System Group**

At the 4-week visit, you will receive training on how to use the study system and will be given written instructions. When you leave the clinic, you will be using the study system. You should check glucose levels with the study blood glucose meter at least 4 times each day. Two of these checks should be before breakfast and before your evening meal. When you check at these times and see that your fingerstick glucose is higher than your sensor glucose by 50mg/dL or more, you will need to enter your fingerstick glucose level into the pump. This will calibrate (readjust) the system. The study pump also may alert you for calibration glucose checks in addition to the usual times you check. You will enter all calibrations into the pump.

You will use the ketone meter to check for ketones if your fasting glucose is 250mg/dl or higher. Your study team may also give you other times to check your ketones.

You will use the Bolus Wizard calculator for all your meal bolus doses.

If you become sick during the study, you will be taught to switch out of the closed-loop function and follow your study team’s sick day guidelines.

You will be uploading the study system to a secure website at least once every week. This process takes 5-15 minutes to complete.

During the first 2 weeks of using the closed-loop system we ask that you do not travel outside the United States.

**Telephone/email contacts**

You will be contacted by email or telephone 24-48 hours after starting the study treatment. You will be contacted again in one week, and again in two weeks. After that, you will be contacted every month in between the follow up clinic visits.

The reason for these contacts is to troubleshoot any problems, and to ask you about any changes in your insulin settings and your health.
Follow-up visits
You will return to the clinic for visits after 1 week and then after 3, 6, and 9 months. At each study visit, we will review your diabetes management and may recommend changes. Data will be uploaded from the study devices.

Follow-up visits at 3, 6, and 9 months also will include the following activities:
- Finger stick to measure blood glucose level
- Body weight will be checked
- Questionnaires will be completed if not done online before the visit.
- Blood sample will be taken for HbA1c.
- A urine pregnancy test (if you are a female who can become pregnant)

At the end of each visit and again after about 12 months, you will use the blinded CGM. This CGM will be worn at home for up to 14 days and then returned to the clinic. If you are in the pump-only group, we will review the CGM data with you. We may have you make changes to your pump basal rates and insulin bolus settings.

Final Visit
The final study visit will be about 14 months after the screening visit. Procedures will be similar to those described for the 3, 6, and 9 month visits.

You and your family may be asked to join a focus group. In this group you will be asked how you feel about your current insulin delivery device, about being in a research study, and about your quality of life. These focus groups may be audio- and/or video-recorded and then transcribed.

If you are in the group using the study system, you will return all study devices. You will need to bring your own insulin to this visit. At this visit, you will be switched back to the insulin pump you were using before entering the study.

If you decide not to take part in this study and do not sign this document, you may continue receiving medical care not related to this study. You can decide to stop your participation in this study at any time. No penalty or loss of medical care will result from your decision not to take part in this study.

In the table below you will find what will happen at each visit.
Consent to Participate in a Research Study  
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<table>
<thead>
<tr>
<th>Visit(V)/Contact(C)</th>
<th>V1</th>
<th>V2</th>
<th>V3</th>
<th>V3a</th>
<th>V4</th>
<th>C1</th>
<th>V5</th>
<th>C2,3,4</th>
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</table>

1 Contact may occur via clinic visit, phone, or email.
2 Could happen on same day as V2.
3 Closed Loop System Group Only.
4 If V3 and V1 are more than 28 days apart.
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<table>
<thead>
<tr>
<th>Visit(V)/Contact(C)</th>
<th>V1</th>
<th>V2</th>
<th>V3(^2)</th>
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<th>C1</th>
<th>V5</th>
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<th>C5, 6</th>
<th>V7</th>
<th>C7, 8</th>
<th>V8</th>
<th>C9, 10</th>
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<tr>
<th>Visit(V)/Contact(C)</th>
<th>V1</th>
<th>V2</th>
<th>V3²</th>
<th>V3a³</th>
<th>V4</th>
<th>C1</th>
<th>V5</th>
<th>C2,3,4</th>
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ARE THERE RISKS IN THIS STUDY?

Taking part in research often involves some risks of physical or psychological injury or discomfort. The most likely risks of this study are described below. These deserve careful thought. We encourage you to discuss the risks with your study team or any other health care professional.

Risk of Hypoglycemia (Low Blood Sugar)

As with any person who uses insulin, there is always a risk of having low blood sugar (hypoglycemia). Symptoms of low blood sugar can include:

- sweating
- shaking
- not feeling well
- fainting
- seizures (convulsions)

In very rare cases low blood sugar can lead to brain damage or death. Even if low blood sugar does occur, it almost always goes away quickly with treatment to raise the blood sugar.

Risk of Hyperglycemia (High Blood Sugar)

Hyperglycemia usually does not cause many obvious symptoms, but you may be thirsty, or have a higher level of sugar in your urine. In severe cases of hyperglycemia, diabetic ketoacidosis (DKA) or coma may occur. DKA can lead to kidney failure, irregular heartbeat, heart attack, muscle breakdown, and even death.

Fingerstick Risks

It may hurt when the lancet goes into your finger but not for long. In about 1 in 10 cases a small amount of bleeding under the skin will produce a bruise. A small scar may persist for several weeks. The risk of an infection is less than 1 in 1000.

Blood Drawing Risks

Possible risks from blood draws include:

- Bruising (common)
- Temporary arm discomfort from the needle stick (common)
- Clotting (unlikely)
- Excessive bleeding (unlikely)
- Lightheadedness (rare)
- Infection (rare)
- Fainting (rare)

Total blood loss during this study is approximately 28 milliliters or about 5-6 teaspoons.
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Insulin Pump Therapy Risks
The risks of using an insulin pump may include:
- Discomfort during insertion of the infusion set (common)
- Bruising at the site of infusion set insertion (common)
- Bleeding at the site of insertion (rare)
- Infection at the site of insertion (rare)
- Allergy to the infusion set or adhesive (rare)
- Insulin pump malfunction and mechanical problems (rare)
- Allergy to insulin (very rare)
- Changes to your skin (very rare)

Continuous Glucose Monitoring (CGM) Sensor Risks
Potential risks from using a CGM include:
- Discomfort when the sensor is inserted into the skin (common)
- Itchiness, redness, bleeding and bruising at the insertion site (unlikely to rare)
- Tape allergies (rare)
- Infection at the site of sensor insertion (rare)

Study System Risks
Even though the study system has been tested extensively prior to this study, there is still a risk that parts of the system may not work right. As a result, you could get less or more insulin than you need and be at risk for hyper- or hypoglycemia. The following are common cases of system malfunction:
- CGM sensor reads higher or lower than your actual glucose level.
- CGM sensor stops working or cannot communicate with the system. If this occurs, the pump will start delivering its preset basal rates within 30-60 minutes.

Risk of Sharing the Continuous Glucose Monitor
We may use some of the devices with other study participants. The sensors will not be shared. The transmitter, which snaps into the sensor, will be cleaned carefully after use. The FDA approved the continuous glucose transmitter as a “single use device.” This means that they recommend that only one person use this device as there is a rare risk that a blood-borne pathogen, such as Hepatitis B, may be spread if used with multiple patients.

Risk of Sharing the Insulin Pump
Consent to Participate in a Research Study

*Day and night closed-loop in young people with type 1 diabetes (DAN05)*

The FDA approved the insulin pump for “single-patient use.” They suggest that only one person use this device as there is a rare risk that a blood-borne pathogen, such as Hepatitis B, may be spread if used with multiple patients. The insulin pump may be reused after it has been cleaned thoroughly with the appropriate cleaning solution after use.

**Questionnaires and Focus Groups**

The questions asked on the questionnaires and during the focus groups will include questions about your personal attitudes, feelings, and behaviors related to diabetes. It is possible you may find these questions to be upsetting. If any questions make you uncomfortable, you can refuse to answer.

You can take a break, or stop taking part in the study at any time. There are no physical risks present.

Many precautions will be made to keep your information confidential, but this is not a guarantee.

Similar questionnaires and interviews have been used in other studies and this reaction is uncommon, but you are not required any questions which make you uncomfortable.

**Unknown Risks**

There may be additional risks associated with the study system that are not known at this time.

If we become aware of any new risks, you will be told about them. You will be able to decide if you want to continue to take part in this study.

**Loss of Privacy**

We will be collecting your initials and date of birth. The study team will do its best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. All identifiable information about you will be replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data.

Information about your data uploaded from your study devices will be collected for the study and transmitted through a secure electronic system to the Jaeb Center for Health Research in Tampa, Florida. This center is coordinating the study. It reviews all of the study information that is collected. The Jaeb Center for Health Research will be reviewing the data, but will not have your personal information.

There is a team at Stanford University in Stanford, California, who will have your personal email address. It will be used to contact you with reminders to complete the online questionnaires. They will not use your email address for any other purpose. Your email address will not be sold, shared, or given to any third parties.

**WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?**
There may be a possible medical benefit to you if you decide to take part in the study, but it is not a guarantee. For instance, it is possible that your blood sugar control will improve during the study using the study system or using just your insulin pump. If you are just using the insulin pump, the blood sugar information from the CGM along with the instructions given for management changes will be useful for your diabetes control.

You may receive no direct benefit from being in the study. People who take part in this research study will add new knowledge that may help other people with type 1 diabetes.

WHAT ALTERNATIVE PROCEDURES OR TREATMENT ARE AVAILABLE IF I DO NOT TAKE PART IN THIS STUDY?

If you do not take part in this study, you could continue using your current insulin pump. You could also talk with your doctor about other ways to take insulin. If you do not participate, your medical care will not be affected.

We encourage you to discuss these options with your study team, your general primary care physician, or another health care professional who has knowledge of type 1 diabetes.

WHAT IF I WANT TO WITHDRAW FROM THE STUDY, OR I AM ASKED TO WITHDRAW FROM THE STUDY?

You can stop participating in this study at any time. You may continue to receive medical care not related to this study. However, we encourage you to talk to a member of the study team so they know why you are stopping the study.

If you withdraw from the study, the study team would like to collect a blood sample for HbA1c 13 months after your study treatment determination visit.

If there are any new findings during the study that may affect your participation, you will be told about them so you can decide if you want to continue.

No penalty or loss of medical care will result from your decision. You may continue to receive medical care not related to this study.

The investigators, physicians or funding source may stop the study or take you out of the study at any time. They may remove you from the study for various administrative and/or medical reasons. They can do this without your consent.

Some reasons why you may be removed from include:

- The doctors judge that it is in your best interest
Consent to Participate in a Research Study

Day and night closed-loop in young people with type 1 diabetes (DAN05)

The doctors think that being in the study may cause you harm, especially if you have a severe low blood sugar or DKA. If you experience a study-related injury, if you need additional or different medication, or if you do not follow the study plan.

If you are removed from the study or the study is stopped, you may continue to receive medical care not related to this study.

Are there costs related to taking part in the study?

Testing that is specifically for this study will be paid for by the study. The costs of treatment, office visits, and tests that are part of your type 1 diabetes will be your or your insurance company’s responsibility. The study will pay for:

- CGM-pump System, system supplies, and smartphone (Study System Group)
- Blood Glucose Meter, Test Strips, and Control Solution (Both groups)
- Blood Ketone Meter, Test Strips, and Control Solution (Both groups)
- Blinded CGM (Both groups)

At the end of the study, or if you decide to remove yourself from the study, you must return the study system and the blinded CGM to the study team listed on the Cover Page.

All other tests and procedures, including your own insulin, the screening bloodwork, and other medical problems that would happen even if you were not in this study are your or your insurance company’s responsibility.

Is there compensation for taking part in this study?

If you take part in the study, you will be paid as described below for each completed visit required for the study to cover travel and other visit-related expenses at the completion of the study.

- Visit 1 and 2: $100 for visit/$25 for baseline survey completion for total of $125
- Visit 3: $100 (training visit)
- Visit 4: $25 (treatment initiation and blinded CGM insertion)
- Visit 5: $25 (follow-up 1-week following treatment initiation)
- Visit 6: $100 for visit/ $25 if questionnaires completed during visit/$50 if questionnaires completed at home for maximum total of $150
- Visit 7: $100 for visit/ $25 if questionnaires completed during visit/$50 if questionnaires completed at home for maximum total of $150
- Visit 8: $100 for visit/ $25 if questionnaires completed during visit/$50 if questionnaires completed at home for maximum total of $150
Consent to Participate in a Research Study

*Day and night closed-loop in young people with type 1 diabetes (DAN05)*

- Visit 9: $25 (blinded CGM insertion)
- Final visit: $100 for visit/ $25 if questionnaires completed during visit/$50 if questionnaires completed at home for maximum total of $150

If you remove yourself from the study, you will be paid for the number of visits you have completed. Additional expenses will be paid in select cases for participants with higher travel expenses.

You will not receive any additional compensation for extra visits your doctor believes are needed for your usual care.

WHAT HAPPENS IF I EXPERIENCE A RESEARCH RELATED INJURY?

Medical care is available if you have a research-related injury. If you have an emergency, you can get emergency care. If possible, you should tell the emergency care medical staff that you are in a research study. You should also tell your study team about the emergency as soon as possible.

The study will not provide costs for medical expenses or any other costs for research-related injuries. The costs of care are your or your insurance company’s responsibility. Money for lost wages and/or direct or indirect losses is not available.

CONTACT INFORMATION FOR QUESTIONS OR PROBLEMS

If you have questions about this study, a research-related injury, have concerns, suggestions, or questions about the study, contact your study team using the provided contact information on the Cover Page.

If you have unanswered questions about your rights as a research participant, wish to talk about your concerns or suggestions linked to the research study, want additional information about the research, or want to provide comments about the research, contact the Jaeb Center for Health Research Institutional Review (IRB) Office at 813-975-8690 or irb@jaeb.org

HOW WILL MY INFORMATION BE PROTECTED AND KEPT CONFIDENTIAL?

As required by law, study related records with identifying information will be kept confidential. Safeguards for authorized access, security, and privacy of your information have been put in place by the Federal Privacy Regulations. Unless the law requires it, your name, address, social security number, telephone number, or any other direct identifying information will not be used to identify you.

A. Purpose of Authorization
Consent to Participate in a Research Study

_Day and night closed-loop in young people with type 1 diabetes (DAN05)_

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your information. By signing this form you provide your permission, called your “authorization,” for the use and disclosure of information protected by the Privacy Rule.

You must sign the **Protected Health Information Authorization** at the end of this form if you want to be in the study. When you sign the form, you give permission for the use and disclosure of your Protected Health Information (PHI) for the study. PHI is health information that identifies you. Your authorization is beneficial and important for the study. Without your authorization, you will not be able to be in this research study.

**B. Use and Disclosure of the PHI**

Your study doctor will collect information about you. This information includes things learned from procedures listed and described in this form as well as your name, address, date of birth, and information from your medical records. Your name, address, telephone number, and social security number are examples of identifiable information.

A code number will replace your name, address, telephone number, or social security number in the results given to the study coordinating center which is the Jaeb Center for Health Research in Tampa, Florida.

The study doctor’s office will not disclose study results that have your identifiable information except as explained in Section C. or when required by law. The Jaeb Center and this doctor’s office will guard the privacy of your study PHI.

Study results without the protected information may be shared in medical journals and at scientific meetings. Your records will be confidential. No one will disclose your identity in a medical journal or at a scientific meeting.

**C. Authorized Recipients and Users**

It is possible that people outside of this doctor’s office and the Jaeb Center may need to see or receive your information from this study. Some examples include: government agencies (such as the Food and Drug Administration), committees that monitor safety, other sites in the study, and companies that sponsor the study.

In most cases the information will have a code number with it instead of your name, address, telephone number, or social security number.
Consent to Participate in a Research Study
Day and night closed-loop in young people with type 1 diabetes (DAN05)

There are some situations where the information will not have a code number but may include your name, address, telephone number, or social security number (PHI). If so, people outside this doctor’s office who assist in your care may see your study PHI. They may not be covered by the federal Privacy Rule. Everyone who needs to see your information will be told it is confidential – but we cannot guarantee fully confidentiality.

Other Considerations

The data collected in the study may be provided to other researchers to use; however, the data that are provided will not contain any information that could identify you.

When the results are made public, all of the study data collected may also be made public. However, there will be no identifying information included.

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.

D. Cancellation of HIPAA Authorization

You may cancel your permission for the use and disclosure of your study PHI at any time. You need to contact your study doctor and give him/her a notice of cancellation in writing. When you cancel your permission or when you withdraw from the study directly, you are no longer part of the study. No new information about you will be gathered for the study except when there is an adverse (unfavorable) event that is related or potentially related to the study. If an adverse event happens, your entire medical record may need to be reviewed.

The Jaeb Center will receive all the information that was collected for the study up to the time of cancellation or withdrawal. The Jaeb Center will receive any new information about any adverse (unfavorable) event that is related or potentially related to the study.

E. 50 Year Expiration Date and Indefinite Expiration Date

Some of your study PHI does not have a code number with it. Your permission for the use and disclosure of this PHI lasts 50 years from the date of your signature or until the end of the study, whichever is sooner.
Consent to Participate in a Research Study

*Day and night closed-loop in young people with type 1 diabetes (DAN05)*

The rest of your study PHI does have a code number with it. When it is collected, it becomes a research report. Your permission for the use and disclosure of these coded data will never end.

These coded data do not have your name, address, telephone number, or social security number.

The above supports the HIPAA Privacy Rule – 45 CFR 164.508
Consent to Participate in a Research Study

Day and night closed-loop in young people with type 1 diabetes (DAN05)

STANFORD UNIVERSITY LOCAL REQUIRED LANGUAGE

Research-related Injury

This portion is complementary to the section WHAT HAPPENS IF I EXPERIENCE A RESEARCH RELATED INJURY?

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. You will be responsible for any associated co-payments or deductibles as required by your insurance.

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

CA Bill of Rights

As a research participant, you have the following rights. These rights include but are not limited to the participant’s right to:

• be informed of the nature and purpose of the experiment;
• be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
• be given a description of any attendant discomforts and risks reasonably to be expected;
• be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
• be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
• be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
• be given an opportunity to ask questions concerning the experiment or the procedures involved;
• be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
• be given a copy of the signed and dated consent form; and
Consent to Participate in a Research Study

Day and night closed-loop in young people with type 1 diabetes (DAN05)

- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

**Stanford University HIPAA Authorization**

In order to participate in this study, you must also sign the Stanford University HIPAA Authorization Form.
Consent to Participate in a Research Study
Day and night closed-loop in young people with type 1 diabetes (DAN05)

Your Full Name (printed) ______________________________

Description of Representative’s Authority to Act for the Subject
_________________________________________________________ (if applicable)

Protected Health Information Authorization

By signing, you authorize the use and disclosure of your protected health information. This information is collected as part of your participation in this study.

______________________________________________  __________________
Signature                                           Date

Study Enrollment

By signing, you agree to take part in this study. Your signature means that:
• you have read this informed consent form about the study named below;
• you have been given the chance to discuss the study and to ask questions;
• you have verbally summarized your understanding of the study to the person who is explaining it to you; and
• you freely choose to participate.

Name of Study: Day and night closed-loop in young people with type 1 diabetes (DAN05)

______________________________________________  __________________
Signature                                           Date

I certify that to the best of my knowledge the participant understands the nature, demands, risks, and benefits involved in his/her participation in this study.

______________________________________________  _________________  _________________
Investigator’s Printed Name         Investigator’s Signature         Date

You will be given a signed copy of this document in case you want to read it again.