STUDY TITLE: Automated Insulin Delivery in Elderly with Type 1 Diabetes (AIDE T1D)

CONSENT TO TAKE PART IN A RESEARCH STUDY

STUDY DOCTOR'S INFORMATION

Doctor's Name: _____
Doctor's Contact Number: _____
Emergency (24-hour) Number: _____
Study Coordinator Name/Contact: _____
Site Name: _____
Site Address: _____

SUMMARY

This consent form will give you important information about this study. It will help you decide if you would like to take part in the study. You do not have to be in this study. You can stop the study at any time. You should read and discuss all the information in this consent form with the study doctor.

- **The study is being done to find out if low blood sugar (hypoglycemia) can be reduced in people with type 1 diabetes (T1D) with use of automated insulin delivery (AID) systems.**

- **The device systems used in this study are approved by the Food and Drug Administration (FDA) for diabetes management. We will be collecting data about how they are used, how well they work, and how safe they are. There are no experimental study procedures.**

- **You will be asked to be in the study for up to 14 months. The study includes several phases, described below. The study will involve using study devices including a continuous glucose monitor and insulin pump every day and completing questionnaires about your experience. It will also involve multiple in-clinic visits and/or virtual visits and phone contacts. At the visits you may have physical measurements, blood draws, and device training.**

- **The first phase of this study is to see if you meet the study requirements and receive training on the study devices. The study devices include an insulin pump to deliver insulin and a continuous glucose monitor (CGM) to monitor blood sugar levels. The first phase will take place over 2 to 8 weeks depending on your experience with the study devices.**

- **The second phase of the study has three periods that will last 12 weeks each for a total of about 9 months. The same type of study pump and CGM (study system) will be used but with different system features turned on during each period. The order of the system features or treatments will be randomly assigned.**
    - **During one period the study system will have a feature called "Control-IQ". This feature automatically increases or decreases insulin using a computer program based on the blood sugar levels from the CGM. You will still need to enter carbohydrate intake at meal times. The Tandem t:slim X2 Control IQ pump is approved by the Food and Drug Administration (FDA) for adults with type 1 diabetes.**

- **During one period the study system will have a feature turned on called "Basal IQ". This feature stops insulin for up to two hours when a CGM system predicts a low blood sugar. The Basal IQ feature restarts insulin delivery once the blood sugar begins to rise. The Basal IQ feature is approved by the FDA for individuals with type 1 diabetes.**

- **During one period the study system will be used without the Control IQ or Basal IQ feature. You will adjust insulin dosing based on glucose readings from the CGM as you ordinarily would.**

- **During the third phase of the study you will be given a choice on which study system feature you would like to use for an additional 3 months.**

- **The most likely risks to you are getting high or low blood glucose levels as with any individual with type 1 diabetes using an insulin pump and CGM. You may also get redness, itching or discomfort from the continuous glucose monitoring system or pump adhesive (tape). You may also feel pain or bruising from fingersticks and blood draws.**

- **The possible benefits are that you may not get as many high and low glucose values as before, but that is what the study is trying to find out. This research may help people control their glucose levels better in the future.**

- **If you do not participate, you may continue your current diabetes treatment, or talk with your doctor about other forms of diabetes management.**

WHAT IS INFORMED CONSENT?

You are being asked to take part in this research study because you have type 1 diabetes. Type 1 diabetes is a condition in which your body does not produce enough insulin to help control your blood glucose (sugar) levels. The goal of this study is to learn things that may help older adults with type 1 diabetes.

Your study doctor will be talking with you about this study and this form. You can take as much time as you need to think about whether or not you want to be in this study. You can also take a copy of this form with you to discuss with friends, family, or other doctors to help you decide. Please read this document carefully. Do not agree to be in this study unless all of your questions have been answered. After this consent form and the study procedures have been reviewed with you by study staff you will be asked to answer questions about the study and the information in this form to make sure you understand the information.

You do not have to be in this study. If you decide not to be in this study, you will not be treated differently as a person just because you didn't want to be in this study. Also, your regular care will not be impacted.

STUDY TITLE: Automated Insulin Delivery in Elderly with Type 1 Diabetes (AIDE T1D)

WHO IS DOING THE STUDY?

This study is being done by the Jaeb Center for Health Research in Tampa, Florida. It is being paid for by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) which is part of the United States National Institutes of Health (NIH). The Jaeb Center for Health Research will use the funding to organize the study. Your study doctor and clinic staff will use the funding to carry out this study. The name of the study doctor and the doctor's contact information are listed on the first page of this form. If one of the study doctors gets money or benefits from a company that makes the devices in this study, then they have to tell the Jaeb Center.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to see if features of an automated insulin delivery system (study system) can reduce low blood sugar (hypoglycemia) in older adults with type 1 diabetes. We expect up to 150 people will take part in this study at 3 to 5 sites in the United States for about 14 months.

WHAT IS BEING STUDIED?

The study system is made up of three parts: (1) a continuous glucose monitor (CGM) that measures blood sugar levels; (2) an insulin pump that delivers insulin; and (3) a computer program on the insulin pump that uses the blood sugar information from the CGM to make insulin dosing decisions when AID feature is turned on.

The CGM sensor has a thin needle that is inserted just under the skin. It measures blood sugar in the fluid under the skin and shows this information on the insulin pump every 5 minutes. The sensor needs to be changed about every 10 days. The insulin pump has a tube that is inserted under the skin. It needs to be changed about every 3 days.

The pump part of the study system is made by Tandem Diabetes Care. Both the Tandem t:slim X2 with Basal-IQ and Control-IQ features will be used for this study. The CGM is the Dexcom G6, made by Dexcom, Inc. The study system with Basal-IQ and the Control-IQ system have been approved by the FDA for commercial use.

During the study you will be asked to use the study system with the Control-IQ feature, the study system with the Basal-IQ feature and the study system without any AID features.
When the study system is used without AID features this is called sensor-augmented pump or SAP therapy.

The Basal-IQ feature has a computer program that checks the glucose readings of the CGM to determine whether a low blood sugar is likely. This feature stops insulin for up to two hours when a continuous glucose monitoring (CGM) system predicts a low blood sugar. The Basal-IQ feature restarts insulin delivery once the blood sugar begins to rise. This Basal-IQ is also called predictive low glucose suspend (PLGS).

The Control-IQ feature uses software co-developed by Tandem Diabetes Care and the University of Virginia. The pump has a computer program that automatically adjusts your insulin and delivers automatic correction boluses to keep your glucose in range. This software also has the Basal IQ feature to help prevent low blood sugar. This Control IQ feature is also called hybrid closed loop (HCL).

WHO CAN PARTICIPATE IN THIS STUDY?

In general, to take part in this study, you must:

- Have had type 1 diabetes for at least one year using an insulin pump or multiple daily injections of insulin
- Be at least 65 years old
- Have an HbA1c level of less than 10.0% (HbA1c is a test of your blood sugar control)
- Be available to download your study system data from home for virtual visits or be willing to come to the clinic for download of your study system data at visits or when needed for safety and be available when the study team reaches out to you
- Be willing to discontinue your personal CGM (including implantable CGMs) and personal pump (if you use these) and use the study devices every day
- Be willing to count carbohydrates
- Be using or willing to switch to using a rapid acting insulin approved for use in the study system
- Demonstrate understanding of the study
- Have an active prescription for glucagon and willing and able to use when necessary

Also, you must not:

- Have used insulin delivery with predictive low-glucose suspend technology or hybrid closed loop technology within the past 1 month
- Be unable to use devices due to extreme visual or hearing loss
- Have a known skin reaction to wearing CGM device
- Be using diabetes medications other than insulin and Metformin
- Be on dialysis or have severe kidney disease or any other condition where your study doctor does not recommend that you participate in this study
- Have a clinical diagnosis of dementia or lack mental capacity that would make it difficult to understand the study or study requirements

Your study doctor and staff will review more health-related requirements with you.

WHAT WILL HAPPEN IN THIS STUDY?

If you decide to take part in this study, it will take about 14 months to complete. There will be about 9-11 clinic visits or virtual visits and about 8 contacts with study staff. There is the option to complete most of the visits virtually (not including Study System Initiation or End of Extension phase visits). You can choose to have a virtual visit if you are able to upload device data at home and feel comfortable being trained on the use of the study systems over video or telephone. Some participants may need more visits and contacts. The following sections describe the procedures for each period of the study.

Screening Visit

If you decide to participate in the study and sign this consent form, you will start the screening visit. The screening visit includes questions and tests that let us know if you qualify for the study. The screening visit can take place at the clinic or over video/telephone.

There will be a fingerstick or blood draw for HbA1c if not already measured in the prior 6 months. You will be asked to complete a 5 minute assessment measuring your thinking skills and memory.

If you are already using a CGM, study staff will download the device to determine how much of the time your blood sugar was low. If you have very few low blood sugars you may not be able to continue in the study.

If you are found to be eligible for the study and you wish to continue, you will begin using the study CGM and have your first CGM training session. If you are already using a CGM you will still be given a study CGM and a brief training will be given.

If you do not qualify or if you decide not to continue, that is okay and your doctor's team will discuss your options.

Device Training (also known as the Run-In periods)

There are two device training parts of the study:

1) CGM Training Period (10 to 30 days)
   If you are using a CGM already you may skip this period.
   a. You will be trained on how to use the Dexcom G6 CGM.
   b. You will use the CGM at home for about 10 days to get used to it. You will continue to use your personal insulin pump or multiple daily injections of insulin.
   c. Then, after about 10 days you will complete the CGM training clinic visit.
   d. You will use the CGM at home again for about 10 days or longer if more time or training is needed to be comfortable with the device.

At the end of the CGM Training Period, the study team will make sure you have used the CGM enough and have enough low glucose values to be included in the study.

2) Pump with CGM (SAP) Training Period (14 to 28 days) – At the start of this period you will have an in-clinic visit.
   a. At this visit a physical exam will be done including measurement of blood pressure, height and weight
   b. You will be asked to do a short timed walk to assess how well your body functions
   c. You will have a blood draw to measure your HbA1c and C-peptide. C-peptide is a test to see how much insulin your body is still able to make
   d. We will ask you questions about yourself, your diabetes and your quality of life
   e. You will be asked to complete assessments measuring your thinking skills and memory

f. At this visit you will receive training on how to use the Tandem t:slim X2 pump along with the study CGM.
g. The study pump settings will be set to match your personal pump settings or an initial basal insulin profile will be created for you.
h. We will give you a blood ketone meter with ketone strips and instructions on when to use it.
i. You will be trained on how to upload the study device to a computer. If you do not have access to a computer or do not feel comfortable uploading the device you may need to come into the study clinic instead of having phone contacts or virtual visits during the training period.
j. You will be provided with a unique user name and password for downloading and reviewing the study device data.
k. Then, you will use both the study pump and CGM at home for about 3 weeks. You will be contacted by study staff after 1 day and after about 7 days to go over any issues or concerns you may have. You will be asked to upload the study device to review with the study team during the contact.

After you use the study system for at least 2 weeks you will have another visit to review the system data. This visit can take place in-clinic or with video/telephone. If you are not able to download the study system at home you will need to bring the device into clinic for the data to be downloaded and reviewed.

a. At this visit the study team will check if you need more training or if you are ready to start the main study. If you need more training before starting the main study you will receive additional training and repeat this period.
b. The study team will also check to see that you wore the device for enough hours. To continue in the study you will need to have worn the device for at least 10 days with 240 hours of data collected.

During the training periods you will use your personal blood glucose meter and test strips as needed. You will be trained on when to do fingerstick checks to confirm a high or low CGM reading. Your study team may have to postpone your cognitive testing and device training visits if your blood glucose is < 70 mg/dL.

After you complete any training sessions, the study doctor will see if you are eligible to continue in the study.

The table below shows what will happen during the Screening and Training periods.

	Screening/Start of Run-In	CGM Training	Study System (Pump with CGM) Training		
		CGM Training Visit	Study System Initiation/ end of CGM run-in	1 day and 7 days after study system start	Pump and CGM Evaluation
In-clinic Visit or Virtual Visit (V) or Contact (C)	**V**	**V**	**Required In-clinic Visit**	**C**	**V**
Medical history	**X**				
Physical exam, height, weight, blood pressure			**X**		
HbA1c –blood draw or fingerstick if not collected in past 6 months	**X**				
Blood draw			**X**		
10-foot timed walk			**X**		
Cognitive Assessments	**X**		**X**		
Questionnaires	**X**				
Study CGM training	**X**	**X**			
Study pump with CGM training			**X**	**X**	**X**
Hypo Assessment	**X**		**X**		
Assessment of device use					**X**
Skin Assessment		**X**	**X**		**X**
Upload device data		**X**	**X**	**X**	**X**
Review blood sugars and make insulin adjustments as needed		**X**	**X**	**X**	**X**

Main Study- Cross-over Trial

A computer program will be used to select the order you will receive each treatment. This is similar to flipping a coin to decide what treatment order you will get. Each treatment group will contain three 12-week periods of Control IQ, Basal IQ and SAP but in different orders. All treatment groups will use the Dexcom G6 CGM and Tandem t:slim X2 pump.

- **Treatment Group A** participants will use **Control IQ** in period 1, **Basal IQ** in period 2, and **SAP** in period 3.
- **Treatment Group B** participants will use **Control IQ** in period 1, **SAP** in period 2, and **Basal IQ** in period 3.
- **Treatment Group C** participants will use **Basal IQ** in period 1, **Control IQ** in period 2, and **SAP** in period 3.
- **Treatment Group D** participants will use **Basal IQ** in period 1, **SAP** in period 2, and **Control IQ** in period 3.
- **Treatment Group E** participants will use **SAP** in period 1, **Control IQ** in period 2, and **Basal IQ** in period 3.
- **Treatment Group F** participants will use **SAP** in period 1, **Basal IQ** in period 2, and **Control IQ** in period 3.

Period 1 begins after the computer selects which path you will follow during the study. You will receive additional training before you start each treatment period. You will receive all the CGM and pump supplies needed. Insulin will not be provided and will need to be obtained through your insurance as per standard care.

During the main study, you will be asked to:

- Use the Tandem t:slim X2 pump and Dexcom G6 CGM every day
- Not to change any settings on the pump without talking to the study staff first
- Try to keep the same low and high glucose alarms consistent in each study period
- Use the study ketone meter if you have high blood sugar for a specified period of time
- Contact the study staff if:
    - you are having any problems with the system
    - you have any symptoms of very high blood sugars, severe low blood sugar, or development of other medical problems
        - You may be asked to complete the same 5 minute cognitive assessment that was done at the first visit to make sure it is safe for you to continue using the study devices.
    - you want to stop participating in the trial for any reason
- Upload the study devices prior to study contacts or virtual visits and bring all devices with you to each study visit. If you are not able to upload device data from home you will need to bring all devices to the clinic so the data can be downloaded and reviewed.
- You may use available software apps from the CGM manufacturer for mobile data access or remote monitoring during the study. You may not use any software not from the manufacturer.

During the main study, you will be contacted by study staff and will be asked to complete a virtual visit or come back to the clinic for check-ups during each of the 3 periods based on the schedule below. You will be asked to upload the study device to a computer before the contact or virtual visit. If you do not have access to a computer or do not feel comfortable uploading the study device you will need to come into the study clinic so that the data on the device can be viewed by the study team.

- After about 2 weeks study staff will contact you by phone or virtual visit.
- After about 4 weeks you will have a virtual or in-clinic visit for a check-up.
- After about 8 weeks study staff will contact you by phone, or virtual visit.
- After about 12 weeks you will have a virtual or in-clinic visit to start the next study period
    - Your study data will be reviewed for any safety issues and study staff will test your HbA1c again if visit completed in clinic or you will be sent an at-home HbA1c test if visit completed over video or telephone
    - You will answer questions about your quality of life, your diabetes management, and your use and satisfaction with the devices

This schedule will be followed for all three 12-week periods of the study, for a total of about 36 weeks (about 9 months). Additional visits and contacts may occur if necessary.

The table below shows what will happen at each visit.

	Start of Main Study	Period 1 (P1)				Period 2 (P2)				Period 3 (P3)			
		2w	4w	8w	12w	2w	4w	8w	12w	2w	4w	8w	12w
In-clinic or Virtual Visit (V) or Contact (C)	**V**	**C**	**V**	**C**	**V**	**C**	**V**	**C**	**V**	**C**	**V**	**C**	**V**
Height, weight, blood pressure (for in-clinic visit only)					**X**				**X**				**X**
Blood draw or Fingerstick for HbA1c – (in clinic or at home)	**X**				**X**				**X**				**X**
Questionnaires (in clinic or at home)					**X**				**X**				**X**
Assessment of medical events		**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Upload device data		**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Review glucose patterns		**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Training on Control IQ or Basal IQ if starting next period	**X**				**X**				**X**				

Extension Phase

At the end of the last study period, you will be able to decide to use either Control IQ, Basal IQ or SAP for 3 months. You may change the technology software being used at any time during the 3 months by contacting your study team.

At the end of the 3 months, you will have an in clinic visit. The testing at this visit will be like the testing during the main study along with cognitive assessments. You may have more visits and calls if needed.

WHAT ARE THE RISKS OF THIS STUDY?

If you choose to take part in this study, you need to know that there are some side effects or risks of being in this study.

If a treatment or procedure has increased risks because it was not done according to study procedures due to error, you will be informed, and the necessary steps will be taken to care for you. We encourage you to discuss the risks with your study doctor or any other health care professional who may understand our process. The risks in this study are listed below.

Hypoglycemia (Low Blood Glucose)
As with any person who uses insulin, there is always a risk of having low blood glucose, or hypoglycemia. The frequency of low blood sugar should be no more and possibly less than it would be as part of daily living. Symptoms of low blood sugar can include sweating, jitteriness, and not feeling well. There is the possibility of fainting or seizures (convulsions). A CGM functioning poorly and significantly over-reading glucose values could lead to inappropriate insulin delivery. You should always do a blood glucose check with the meter if the sensor readings appear out of the expected range.

Hyperglycemia (High Blood Glucose)
High blood sugar could occur if insulin delivery is suspended for a long time. Prior studies have shown that an increase in mild high blood sugar may happen when the pump stops insulin for a long time. However, the risk of severe high blood sugar (which can lead to diabetic ketoacidosis or DKA) should not be more than usual. A CGM functioning poorly and significantly underestimating glucose levels could lead to a suspension of insulin delivery that was not necessary. You should always do a blood glucose check with the meter if the sensor readings appear out of the expected range.

Fingerstick Risks
It may hurt when the lancet goes into your finger but not for long. In about one in ten cases, a small amount of bleeding under the skin will cause bruising. The risk of an infection is less than one in 1,000. This should not be a significant contributor to risks in this study as fingersticks are part of the usual care for people with diabetes.

Blood Draw Risks
Possible risks from blood draws include the following: bruising, arm discomfort, clotting, excess bleeding, infection, or fainting. Please note that although these are possible risks they are unlikely.

Insulin Pump Risks
The risks of using an insulin pump may include:

- Slight discomfort during insertion of the infusion set (common);
- Slight bruising at the site of infusion set insertion (common);
- Infusion set blockages (common);
- Hyperglycemia secondary to blockage or infusion site failure (common);
- Pump malfunction and mechanical problems (common);
- Lipodystrophy/lipoatrophy (hard lumps in fatty issue) (uncommon);
- Bleeding at insertion site (rare);
- Infection at insertion site (rare);
- Allergy to the infusion set or adhesive (rare);
- Allergy to insulin (very rare).

Continuous Glucose Monitoring (CGM) Risks

The CGM sensor may cause pain when it is inserted into the skin, similar to a pump site insertion or insulin injection. Rarely, a skin infection can happen at the site of insertion of the sensor. Itchiness, redness, bleeding, and bruising at the insertion site may occur. An allergy to the tape that holds the sensor to the skin is possible. The risk of skin problems could be greater if you use a sensor for longer than it is supposed to be used. There is a chance that the sensor or needle may break under your skin. This is not expected to occur; but, if it does, you should ask your study doctor what to do.

AID System Risks

Even though the study systems have been tested extensively prior to this study, there is still a risk that parts of the system may not work right. As a result, more or less insulin than what you need could be delivered and could lead to hypoglycemia or hyperglycemia. The following are possible reasons the system may deliver too much insulin or incorrectly stop insulin delivery:

- CGM sensor reads higher or lower than your actual glucose level;
- Part of the insulin infusion system doesn't work correctly.

Risk if sensor glucose is inaccurate when Control-IQ is active:

- If a sensor glucose is much higher than a blood glucose at that time, there is a risk of hypoglycemia, because the amount of insulin delivered could be larger than if blood glucose was used.
- If you feel low (but sensor glucose value is not low), you should do a blood glucose check with the meter.

Risk if sensor glucose is inaccurate in calculating a meal bolus:

- If a sensor value is much lower than a blood glucose would be at that time, there is a risk of hyperglycemia, because the amount of insulin delivered could be smaller than if blood glucose was used.
- If a sensor glucose is much higher than a blood glucose at that time, there is a risk of hypoglycemia, because the amount of insulin delivered could be larger than if blood glucose was used.
- If you feel low (but sensor glucose value is not low), you should do a blood glucose check with the meter.

Unknown Risks

It is always possible that anyone using a device for the first time may have an allergic reaction to the adhesive used to attach the system to the body. Also, there may be additional risks from the device or the study procedures that are not known. If we find out that there are any new risks, you will be told about them.

Risks to Confidentiality

This study will be capturing some information about you that includes identifiable, personal information, like your date of birth. The study has procedures in place to protect that information. There is a chance that a loss of that protection could occur. This would be a loss of confidentiality. Please see the "How will my information be protected and kept confidential" section below for more information.

If we find out that there are any new risks, you will be told about them. You will be able to decide if you want to continue in the study based on this new information.

The study doctor and staff may use your contact information to call, text or email you during the study. They may do this to send you things like appointment reminders. They are not allowed to send you identifiable health information by text or regular email because it is unsecure. This means that there is a risk that a message may be seen by someone that is not supposed to see it, like when an email gets hacked. Your email, phone number and your name will likely be in the text or email. If you think that the study doctor's office has texted or emailed information that they should not have please contact JCHR at 813-975-8690 and ask to speak to the IRB Administrator. If you text or send a regular email the study doctor's office is unsecure and what you put in the text or email is not protected.

Questionnaires

You will be asked questions about your attitude, feelings and behavior related to diabetes and in general. You will also be asked to do some cognitive tasks. Though uncommon, it is possible that some people may find these questions to be a little bit stressful or upsetting. You can refuse to answer any questions that make you feel uncomfortable. You can decide not to answer questions, 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.

Risks may include: psychological stress and/or loss of confidentiality.

Please discuss the risks with your study doctor or any other health care provider.

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?

The possible benefits are that you may not get as many high and low glucose values (hyperglycemia and hypoglycemia) as before, but that is what the study is trying to find out. It could also be that you may not receive any direct benefit from being in the study. People who take part in this research study will add to new knowledge that may help other people with type 1 diabetes.

ARE THERE OTHER OPTIONS THAN BEING IN THIS STUDY?

If you do not take part in this study, your options include standard treatment like continuing to use your current diabetes treatment (either insulin injections on insulin pump), talking with your doctor about other forms of diabetes management, participating in other research studies, or you may choose not to do anything. Your study doctor will discuss these choices with you.

CAN I STOP BEING IN THE STUDY?

You can stop being in the study at any time. If you decide to stop being in this study, you will not be treated differently as a person. Also, your regular care will not be impacted. Please talk to your study doctor or staff so they know why you are stopping the study and can help you do so safely.

You can decide to stop getting text messages or email contacts at any time and ask that only phone calls be made. You will need to tell your study doctor if you would like to stop receiving text messages or emails. You can still be in the study if you do not want to get text messages or emails anymore.

If we find out that there is any important new information about the study, you will be told about it. You will be able to decide if you want to continue in the study based on this new information.

The study may stop or the study doctor may decide to take you out of the study at any time. You do not have to give permission for the study to stop or for the study doctor to remove you from the study. You will be told if this happens.

Some reasons why you may be removed from the study include:

- The doctors feel that it is in your best interest
- The doctors think that being in the study may cause you harm
- If you experience an injury related to the study
- If you need additional or different medication
- If you do not follow the study instructions

If you withdraw, are removed from the study, or the study is stopped, you may continue to receive care like you normally would if you were not in this study. Also, you will no longer be able to use the study devices and must return them. You will be asked to complete a final visit to see how you are doing and to collect final questionnaires and a HbA1c test.

ARE THERE COSTS RELATED TO TAKING PART IN THE STUDY?

The costs of routine treatment, office visits, and tests that are part of your regular care will be billed to you or your insurance company like they normally would if you were not in a study. The study will provide all of the devices and supplies needed for the study to you at no cost (except insulin, blood glucose meters and test strips). At the end of the study, or if you decide to withdraw from the study, you must return the study devices to your study doctor's office. You may be able to keep other study supplies.

Any additional tests and procedures will be billed to you or your insurance company like they normally would too. **Please ask to speak to someone at your study doctor's office if you want more information about what you or your insurance will be expected to pay.**

IS THERE PAYMENT FOR TAKING PART IN THIS STUDY?

If you take part in the study, you will receive $50 for each required visit that is completed in clinic or virtually (up to 9 visits) except the CGM and SAP training visits and study contacts. The form of payment is decided by your study staff. This compensation is to help you with travel and other visit-related expenses. You may be compensated if there are additional expenses related to travel. If you withdraw from the study, you will still be paid for the visits that you have completed. You will not

receive extra payments for visits that are required as part of your normal care or for visits that are for treating an illness or injury.

The use of your blood samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form.

Because payments made to you for participating in this study may be reported to the IRS as income, you may need to provide your social security number or a Form W-9 to your study doctor's office. These will not be shared outside of your doctor's office, other than as required to the IRS.

WHAT HAPPENS IF I HAVE AN ILLNESS OR INJURY FROM BEING IN THE STUDY?

If you have an illness or injury that is related to your participation in the study, then you can get care like you normally would. If you have an emergency, please seek emergency care as soon as possible. Please tell the emergency doctor that you are in a research study. Please also tell your study doctor about the emergency as soon as you can. The study does not plan to provide costs for care or other expenses relating to illnesses or injuries. The costs of care for illnesses or injuries will be billed to you or your insurance company like they normally would. Your study doctor, the study doctor's office, the Jaeb Center, and NIDDK are not planning to cover payment for lost wages, direct losses, or indirect losses. More information can be obtained by contacting the doctor's office using the information on the first page of this form.

CONTACT INFORMATION FOR QUESTIONS OR PROBLEMS

If you have questions about this study; a research illness or injury; or have concerns, suggestions or questions about the study, then contact your study doctor using the contact information on the first page of this form.

Contact the Jaeb Center for Health Research Institutional Review Board (IRB) Office at 813-975-8690 or irb@jaeb.org if you:

- Have questions about your rights as a research participant
- Wish to talk about your concerns or suggestions about the research
- Want additional information about the research, or
- Want to provide comments about the research.

HOW WILL MY INFORMATION BE PROTECTED AND KEPT CONFIDENTIAL?

As required by law, study-related records with identifying information will be kept confidential. Safety measures for the access, security, and privacy of your information have been put in place by law. Your date of birth and initials may be used in the study to help the researchers keep the right information together. This information will be protected as described below. 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.

Certificate of Confidentiality
NIDDK has given us a Certificate of Confidentiality for this study. This adds special protection for study information that identifies you and allows us, in some cases, to refuse to give out information that could identify you without your consent. This could be done when the information is requested by a federal, state, local court or public agency. If you need medical help, we may still share your identifiable information. As described in this form or in other cases, we may share identifiable information. For example, if the government inspects us, they may see your identifiable information. Your study doctor and research team will follow local laws and will tell the local or state authorities:

- if certain diseases are present;
- if they suspect neglect, abandonment, or abuse of you; and
- if your study doctor or research team learn that you plan to harm yourself or someone else

Purpose of Authorization
We have rules to protect information about you. Federal and state laws also protect your information. By signing this form you are giving your permission, called your "authorization," for the use and disclosure of information protected by the law.

You must sign this form, including the Protected Health Information Authorization statement included in the signature box at the end of this form if you want to be in the study. When you sign this form, you give permission for the use and sharing 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 study.

Using and Sharing Your PHI
Your study doctor will collect information about you. This information includes things learned from study procedures as well as your name, address, date of birth, and information from your medical records. These are examples of identifiable information. A code number with your initials and date of birth will replace your name, address, telephone number, or social security number in the results given to the Jaeb Center for Health Research in Tampa, Florida.

The following people or companies involved in this study may see your study results with things like your date of birth, initials, and date of procedures:

- Your study doctor's office
- Jaeb Center for Health Research
- Laboratories
- Pump manufacturer
- CGM manufacturer

The study doctor's office ***will not*** share study results that can identify you except as explained in this form or when required by law. The Jaeb Center and your study doctor's office will guard the privacy of your study PHI.

Who Can Receive and Use Your Study Information?
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 are providing either funding or supplies for the study, laboratories, and centers that may receive images. In most cases the information will have a code number with it instead of your name, address, telephone number, or social security number.

Your study doctor may share the results of the study assessments with your regular doctor if there is concern with your health and well-being. Before your information will be shared, you will be asked to sign a release of information form.

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). Once PHI is disclosed by your study doctor and the clinic staff, it may no longer be covered by the privacy laws. Everyone who needs to see your information will be told it is confidential, but we cannot guarantee full confidentiality once it leaves the doctor's office.

Other Considerations
The information collected in the study may be used in future studies without additional permission from you. This may include research done by other researchers. The information that may be shared will not contain any information that could identify you. There may still be a chance that someone could identify you, but this is not likely. A copy of the information collected as part of the study will be made public in a dataset. This will be done after the study ends. This dataset will not contain any PHI. The study results will also be made public. These results will not have any information that could identify you.

A limited dataset that contains some PHI may be provided to certain researchers. This PHI will not include things like your name, address, identifying pictures, or medical record numbers. Any researcher would need to sign an agreement to protect your PHI before getting this dataset as required by law.

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

At the end of the entire study, results of the study will be mailed to you. You are invited to discuss these results with the study doctor and his/her team if you would like.

Contact from the Study Doctor's Office
You may have communication with the study doctor's office by phone, text, or by video (like FaceTime or Skype). There is a chance that someone could see or hear the conversation like they could if you were speaking or texting with anyone.

Clinical Trial Reporting
A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by 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. A copy of one of the study consent form templates will also have to be posted on a federal Web site.

Can You Cancel Your Authorization?
You may cancel your permission for the collection of your study PHI at any time. You will need to contact your study doctors and give them a written notice of cancellation, or you may contact the JCHR IRB Office at 813-975-8690 or irb@jaeb.org. 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 a safety concern related to the study. If there is a safety concern, 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 that you cancel or withdraw from the study. The Jaeb Center will receive any new information about any safety concerns that may be related to the study.

When Will the Use and Sharing of Your PHI Stop?
Some of your study PHI does not have a code number with it. Your permission for the use and sharing of your PHI lasts 50 years from the date that you sign this form or until the end of the study, whichever comes first.

The rest of your study information that is not PHI does have a code number with it. When it is collected, it becomes part of a research report. Your permission for the use and sharing of this coded information will never end. This coded data does not have your name, address, telephone number, or social security number.

STUDY TITLE: Automated Insulin Delivery in Elderly with Type 1 Diabetes (AIDE T1D)

Adult Participant's Full Name (printed) _____

By signing below, you/the participant agree to take part in this study. Your signature means that:

- you have read this informed consent form
- you have been given the chance to discuss the study and to ask questions to your satisfaction
- you freely choose (or you freely choose to allow the participant) to participate and you/the participant can withdraw at any time
- you will receive a copy of this consent form
- you authorize the use and disclosure of your protected health information. This information is collected as part of participation in this study. You/the participant cannot be in this study if you do not provide this permission.

_____ _____

Participant's Signature Date

Investigator's Certification

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

_____ _____ _____

Investigator's Printed Name **Investigator's Signature** **Date**