NCT07212179

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Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Parents' or Guardians' Permission for Your Child to Be in a Research Study

Agreement of a Child to Be in a Research Study (15-18 years old)

In this form "you" means the child in the study *and* the parent or guardian.

- ✓ If you are the parent or guardian, you are being asked to give permission for your child to be in this study.
- ✓ If you are a child, you are being asked if you agree to be in this study.

In this form "we" means the researchers and staff involved in running this study at the University of Virginia.

In this form "you" means the person (your child) who is being asked to be in this study. As the parent or guardian, you are being asked to give permission for your child to be in this study.

Participant's Name_____ **Medical Record #** _____

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a copy of this form.

Who is funding this study?

This study is being funded by the Lormar Foundation. Funds received from the Launchpad Program will be used to pay for hotel rooms, hotel meals, insulin pump supplies, continuous glucose monitoring (CGM) supplies, glucometer, ketone meter testing kit, and other study supplies.

Note: You will need to provide your own insulin.

Key Information About This Research Study

Principal Investigator:	Melissa Schoelwer, MD Division of Pediatric Endocrinology University of Virginia School of Medicine Box 800386, Charlottesville, VA 22903 434-326-2069

Funding Source:	Lormar Foundation Breakthrough Type 1 Diabetes (BT1D) / formerly JDRF

You are being asked to take part in a research study. You do not have to take part in this study.

You should only agree to take part in this study after reading this consent form and discussing it with the study team. You may also discuss this with your family, friends, health care providers or others before you make a decision.

What is the purpose of this study?

The purpose of this study is to find out if an Automated Insulin Delivery (AID) system and the InsuLearn bolus calculator algorithm (complex mathematical formula) with simplified meal announcement (SMA) are safe and can help better control your blood sugar when you eat a meal. The algorithm will review up to 2 weeks of your meal information (e.g., bolus treatments, CGM readings, and insulin delivery) and will attempt to identify non-obvious patterns so it can improve your insulin doses at mealtime.

InsuLearn-SMA algorithm is still being tested and has not been approved by the U.S. Food and Drug Administration (FDA). So far, we don't know if it's safe or helpful. We are currently testing the algorithm in another clinical trial with people using multiple daily injections (MDI) to treat their diabetes. The system has been tested using computer programs with data from thousands of people with Type 1 Diabetes. This is called **computer simulation.**

This study uses the following equipment:

- A special research phone call Diabetes Assistant (DiAs) which will contain the bolus calculator algorithm called InsuLearn-SMA
- A special research insulin pump called the Tandem t:ap
- A Dexcom continuous glucose monitor (CGM)

The goal is to improve your blood glucose levels after you eat a meal.

You are being asked to take part in this study because you have been diagnosed with type 1 diabetes and are between the ages of 14-21 years old.

Why would you want to take part in this study?

You might like to take part in this study because this study may improve your understanding of your diabetes or may improve your ability to manage your diabetes after you eat. The information gained by doing this study may help others in the future.

Why would you NOT want to take part in this study?

You might not want to take part in this study because of the following reasons:

- This study uses an algorithm called 'InsuLearn SMA' which is not approved by the FDA.
- You will attend an in-person training session to learn how to use the study equipment unless the study doctor says you can complete the training at home.
- You will need to stay at a local hotel with other study participants for 3 days and 2 nights. If you are less than 18 years old, your parent/legal guardian will be required to stay with you. IF you

are 18 years old and older, you can choose to have your parent/legal guardian/companion stay with you at the hotel. The study team will determine the Hotel Admission dates when the hotel has availability. You will be asked if you can participate during those dates. If you are unable to participate during that time, you will not be able to participate in the study.

- You may need to share up to 6 months of your data from your personal insulin pump, CGM, and/or glucometer if the study doctor wants to look at how you usually manage your diabetes care.
- You will have the option of using your personal smartphone or receive a study smartphone to use in order to collect the data from the devices. Using your personal phone may result in data and text charges.
- Your participation in this study will last about 3 weeks. Your participation in the study could last a total of 5 weeks, if you agree to share 2 weeks of your usual care CGM data after the study ends.
- It is preferred that you don't change your insulin parameters during the study. If necessary, you are asked to speak with the study physician before making any changes.

What will I have to do if I take part in this study?

Full details of all the procedures are found later in this form. If you agree to take part in this study, you will:

- Wear a study issued insulin pump and use a study issued research phone (DiAs) that will contain the study algorithm.
- Wear a study issued or your personal, Dexcom G6 CGM during the study. You will be provided with these supplies at no cost.
- Need to use your personal insulin during the study. This insulin will need to be an FDA approved insulin in the study insulin pump (e.g., lispro or aspart, or a biosimilar FDA-approved insulin) as determined by the study doctor.
- Need to verify that you have a personal glucometer and ketone meter; otherwise, a glucose & ketone meter testing kit with test strips will be provided to you at no cost. This meter requires you to use the manufacturer's app. The study team may ask that this equipment be downloaded to review any event in more depth (e.g., low blood glucose values, high blood glucose values, etc.).
- The equipment training visit will likely be in person at the clinic.
- Need to verify that you have glucagon at home.
- Stay about 48 hours at a local Charlottesville hotel with other study participants on the dates that the study team chooses. If you are not able to attend those dates, you will not be able to participate in the study.
- Your parent/legal guardian will need to stay at the hotel with you if you less than 18 years of age. Your parent/legal guardian will also need to complete the various check-visits during the study with the study team.
- Select three meals from the menu to be eaten during the hotel admission (1 breakfast, 1 lunch, 1 dinner). You will be asked to identify each meal as either low, medium, or high in carbohydrates as compared to the meals that you usually eat. This information is for simplified carbohydrate counting. You will eat the same meal each day of the hotel admission.
- The hotel admission and the study meals will be provided at no cost to you.

- Need to share your personal insulin data with the study team. You may be asked to upload data from study or personal devices. Study staff will be available to assist you as needed.
- Be asked to complete questionnaires to tell the study team about your expectations with the study equipment and then your experience with the study equipment.
- Not be able to participate in another clinical trial during this study.
- You will need to be able to read and write English.

What is the difference between being in this study and getting usual care?

If you take part in this study, the following things will be done differently than if you do not take part in this study.

- Your study visits will occur remotely (e.g., video chat, phone call, text message and/or email) and in-person at the clinic and hotel. You will have to give permission later in this consent form to be contacted via email or text message as it is optional. The study team will ship you supplies if your visits are completed remotely.
- You will need to have access to internet and to be willing to upload data during the study.
- You will use study equipment during the study (e.g., insulin pump, CGM, study phone, and study app).
- You will have regular check-in visits with the study team to see how you are feeling.

What other treatments may I receive if I decide to not take part in this study?

The following alternative treatments are available to you if you decide not to take part in this study:

- You may continue your personal care for management of your diabetes developed by your doctor.

How many people will take part in this study?

Up to 6 people will complete this study at UVA.

When a person or an organization has a financial or other interest large enough to seem as if it could affect their judgment, it is called a conflict of interest. While members of this study team are owners of the intellectual property rights of the InsuLearn+SMA algorithm, the study team members will not make money from this study. As owner of the intellectual property rights in this algorithm, the University of Virginia and some members of this research team may make money in the future if this study has good results.

How long will this study take?

Your participation in this study will require 11 study visits in about 3 weeks. Check-in visits will take about 15-30 minutes each and may be completed in the clinic, by telephone, video chat, email, and/or text messaging.

- The Screening Visit (visit 1) will take about 1-2 hours and may be completed by video, phone call, and/or in-person clinic visit.
- You will be asked to share 2 weeks of your usual care CGM data before you begin wearing the study equipment (visit 10). This is an optional visit.
- The Study Equipment Training Visit (visit 2) will take about 6-8 hours.
- You will learn how to use the study equipment during visit 3, which will last about 4-8 hours.

- You will participate in a Check-In Visit (visit 4) about one day after going home with the study equipment to see how you are feeling and how you are doing with the equipment. This Check-In Visit will take about 15-30 minutes each to complete and may also be completed by email or text messaging as well as video chat, phone call, and/or in-person clinic visit.
- There will be a Check-In Visit (visit 5) prior to the start of the Hotel Admission.
- The Hotel Admission (visit 6 and visit 7) will last 3 days and 2 nights. You will be asked to bring quiet activities to do during the day.
- You will use study equipment at home for 7 days (visit 8).
- You will participate in a Check-In Visit (visit 9) about one day after going home with the study equipment to see how you are feeling and how you are doing with the equipment. This check-in visit will take about 15-30 minutes each to complete and may also be completed by email or text messaging as well as video chat, phone call, and/or in-person clinic visit.
- You will participate in an End of Study Visit (visit 10) to assist you in transiting back to your personal diabetes equipment. This visit will take about 15-30 minutes.
- You will participate in a Follow-Up Check-In Visit (visit 11) to see how you are feeling now that the study is over and to talk about any issues you may have experienced when returning to using your personal equipment. This visit will take about 15-30 minutes.
- At visit 12, you will be asked to share 2 weeks of your usual care CGM data after you are done wearing the study equipment (visit 10). This is an optional visit.

NOTE: All procedures/assessments and tests described in this consent are completed for research purposes only.

What will happen if you are in the study?

Visit 1: Screening Visit

(Day 1) This visit will be completed with a clinic visit, phone, email, text, or video call and will take about 1-2 hours.

If you agree to participate, you will sign this consent form before any study-related procedures take place. Before you can start, there will be a screening period. You will have tests and procedures during this time to make sure you are eligible, and it is safe for you to participate. These include the following:

- Demographics (date of birth, gender, race, and ethnicity).
- Contact information (name, phone number, e-mail address, mailing address, emergency contact).
- A review of your medical and surgical history, allergies, and current medications.
- A physical examination and vital signs (height, weight, blood pressure, heart rate, temperature) if your visit is completed in the clinic. A physical history from your endocrinologist or another doctor dated within the last 6 months may be substituted.
- Blood may be taken from your finger to obtain a hemoglobin A1c test. This is the same test that you have done at your endocrinologist's office every 3 months to measure your blood glucose level over the last 3 months. A hemoglobin A1c value that was obtained within the last 3 months prior to the screening visit may be used for this test. If the study doctor recommends having additional laboratory testing drawn at a local laboratory, this A1c test can be completed from a blood draw from your arm.

- If needed based on your medical history, the study doctor may request a thyroid function or kidney/electrolyte blood test for laboratory testing. Changes in these lab results may help show changes in your insulin resistance (when cells in your muscles, fat, and liver don't respond well to insulin). Lab results within 3 months of your screening appointment may be used.
- If you can become pregnant, a urine pregnancy test will be performed and must be negative for you to participate in the study. A blood test may be collected if other lab tests are necessary.
- The results of the pregnancy test will be provided to you. Also, Virginia law requires release of the test results to your parent(s)/legal guardian if they request the results or request a copy of your medical records.

Note: Potential eligibility may be assessed during a routine-care physical examination. Any labs required may be obtained at a local laboratory (e.g., UVA, LabCorp) that is convenient to you.

If you are eligible to participate in the study, you will be asked to complete a Demographic Data Survey (date of birth, gender, race, ethnicity, where you live, your education level, etc.), and the INSPIRE survey (quality of life questions relating to using the AID system). You will complete this survey through a secure study website using your personal tablet or phone. If you do not have a personal tablet or phone, you may complete the survey on a phone provided by the study. Answering these questions is optional but important to our research. It will take about 15 minutes to complete these surveys.

If these tests show you are eligible, you will return within 30 days to complete visit 2. The goal is to complete Visit 1 within 30 days from signing the consent form.

Optional: CGM Data Collection

You are also asked to share a 2-week CGM download of your usual care CGM data before you begin wearing the study equipment. This data is to look at how people's habits around mealtime are different.

RANDOMIZATION

Once the study physician says that it is safe for you to participate in the study, you will be randomly assigned (like the flip of a coin) to 1 of 2 study interventions (device) groups. You have an equal chance of being assigned to any one of the groups. Neither you nor your doctor can choose which intervention you are assigned. These randomizations will be used only during the Hotel Admission.

AID+CC→AID+InsuLearn-SMA

You will first use AID with the usual carbohydrate counting (CC) bolus calculator for 18 hours before switching to AID with the InsuLearn simplified meal announcement bolus calculator (AID+InsuLearn-SMA) for 18 hours.

AID+InsuLearn-SMA→AID+CC

You will first use AID with the InsuLearn simplified meal announcement bolus calculator (AID+InsuLearn-SMA) for 18 hours before switching to AID with the usual carbohydrate counting (CC) bolus calculator for 18 hours.

Visit 2: Study Equipment Training

(Day 2) The study physician will determine if this visit will be completed at the clinic or by video (approximately 2-8 hours).

Visit 1 and Visit 2 may be completed on the same day per the discretion of the study doctor

You will receive following equipment at the training visit:

- insulin pump, infusion sets, and infusion cartridges
- the diabetes assistant (DiAs) smart phone
- CGM transmitter and sensors
- a study glucometer/ketone meter and test strips if you don't have this equipment at home

You will confirm that they have rescue glucagon available to use at home.

At this Equipment Training Visit, the study team will discuss the use of the study issued diabetes equipment with you and your parent/legal guardian, if you less than 18 years of age. You will remove your personal insulin pump and begin wearing the study insulin pump to treat your diabetes. If you have one, you may use your personal Dexcom CGM during the study. Your training will depend on how familiar you are with using the Dexcom CGM. You will share your CGM download data with the study team at the completion of the AID+CC data collection.

You and your parent/legal guardian will be trained on how to use the Glycemic Treatment Guidelines. These guidelines will tell you how to manage your low and high blood glucose levels during the home portion of the study. You may obtain fingerstick blood glucose measurements if you experience low or high blood glucose values. You may obtain fingerstick blood ketone measurements if you experience high blood glucose values.

The t:AP pump will be programmed with your back-up insulin parameters as determined by the study doctor in case the insulin pump and study phone become disconnected. Once the system is started, you will have your diabetes care managed using this system for the rest of the study.

Your weight will be measured at Training Visit if completed in the clinic.

Your CGM value must read between 80-250 mg/dL prior to leaving the clinic. A meal or snack may be provided by the study team.

You will be asked to download your personal data from your diabetes equipment before the start of this visit and after this visit. Staff will be available to assist you as needed.

It is preferred that you don't change your insulin parameters during the study. If necessary, you are asked to speak with the study physician before making any changes.

Visit 3: AID+CC At-Home Period

(Day 3-9) Data collection will occur at home and will last about 1 week.

This data collection phase is to gather information on your normal insulin doses and amount of carbohydrates that you typically use each day. You are asked to follow your normal routine involving diet, exercise, and insulin administration.

During the At-Home Period, you or your parent/legal guardian will manage your diabetes using the study t:ap insulin pump and the CGM which will be connected to the study phone (DiAs platform). It is important to wear your CGM continuously during this phase of the study. If you are using your personal Dexcom CGM, you will be asked to share your CGM download data with the study team at the completion of this week if the data is not available through a commercial portal (a cloud account). The use of the Dexcom Apps on a personal phone may result in data and text charges.

Study staff will be monitoring your blood glucose levels remotely during the At-Home Periods of the study.

During this At-Home Period, it is important that you count your carbohydrates, using your carbohydrate ratio, and correction factors consistently on the insulin pump and then using this information to bolus for your meals or corrections.

If you complete this data collection phase before you start your hotel admission, you will be permitted to continue using this equipment so you won't have interruptions with your care. This data will not be collected from you.

Visit 4: AID+CC Check-In Visit

(Day 4) This visit will be completed in clinic, by phone, email, text, or video call and will take about 15-30 minutes.

If you are less than 18 years of age, all Check-In Visits will be completed with parental supervision.

You can come to the clinic if you prefer to do this visit in person.

A study team member will contact you or your parent by phone, email, text, or video call to:

- Ask if you have any questions about using the study equipment.
- Ask you about any changes to your medical history and medication.
- Review your CGM data.
- Review any hypoglycemic events that are less than 60 mg/dL that you may have experienced.
- Review any hyperglycemic events that are more than 300 mg/dL that you may have experienced.

Visit 5: Pre-Hotel Admission Check-in Visit

(Day 9) This visit will be completed by clinic, phone, email, text, or video call and will take about 15-30 minutes.

You can come to the clinic if you prefer to do this visit in person.

A study team member will contact you by phone, email, text, or video call to:

- Ask you about any changes to your medical history and medication.
- Verify that a new CGM sensor was placed approximately 24-72 hours prior to the Hotel Admission for proper warm-up.
- Remind you that the CGM reading should be less than 200 mg/dL at the start of the study at the hotel. The study physician may call you if you are experiencing low or high blood glucose levels prior to the Hotel Admission.
- Remind you to bring your insulin and other medications that you will need during the study.
- You will be reminded to bring quiet activities to enjoy during the Hotel Admission.
- You will be asked to complete the INSPIRE Questionnaire any time prior to the start of the Hotel Admission. These questions will take about 15 minutes to complete. You will complete this survey through a secure study website.
- Should any concerns regarding your health or unforeseen issues arise, the Hotel Admission may be canceled at the discretion of the study physician.

Visit 6 & 7: Hotel Admission

(Day 10-12) This visit will be completed in-person and will last about 3 days and 2 nights.

After arrival at the hotel, you will be trained on InsuLearn+SMA, the new simple meal announcement bolus calculator prior to the start of dinner.

You will be supervised at all times by research staff. There will be research staff present in the hotel overnight to perform overnight glucose testing as needed.

The Hotel Admission will be the same for each group regardless of which group you are randomly assigned.

There will be about 6 participants during the Hotel Admission at the same time.

Hotel Admission Arrival:

- You will come to a hotel with your parent or legal guardian if you are less than 18 years old. Your parent will stay with you in your room during this hotel admission.
- The study team will confirm that you brought your insulin and regular medications to the Hotel Admission.
- You will have vital signs (e.g., blood pressure, pulse, heart rate) completed.
- Your CGM reading and ketone values will be recorded. The study physician may recommend treatment if your CGM is not reading between 80-250 mg/dL.
- At least two study team members (e.g., technician, nurse, physician, nurse practitioner, or physician assistant) will be present during the day and overnight hours of the Hotel Admission.

Hotel Admission:

- You will eat the same three meals per day during the Hotel Admission. You will bolus (give yourself insulin) two different ways during the admission. You will use your usual insulin:carbohydrate ratio (ICR) for one day. You will bolus using the InsuLearn+SMA for the

other day. The study team will record the time of these meals so they can evaluate the performance of the InsuLearn+SMA algorithm.
- When using the InsuLearn bolus calculator, you will simply announce an upcoming meal rather than enter the exact carbohydrate count.
- Snacks with carbohydrates will not be allowed unless for the treatment of low blood sugars. Non-carbohydrate snacks may be allowed throughout the Hotel Admission per investigator discretion. Snacks will be provided by the study team. Your parent/legal guardian/companion will be provided meals during the hotel study.
- You are free to do low-intensity activities, like walking, during the Hotel Admission. You must be accompanied by staff if you want to leave the hotel. You will not be permitted to use the hotel pool during the hotel admission.
- Any adjustments to your current insulin parameters during the Hotel Admission will be done with the assistance of the study doctor.
- Any CGM reading below 70 mg/dL or any potential low blood glucose symptoms will be confirmed with a fingerstick blood glucose using the study glucometer.

Hotel Discharge:
- Your CGM value will need to be stable and between 80-250 mg/dL. Your ketone levels need to be stable (less than or equal to 0.6 mmol/L.). The study physician will talk with you about any treatment that you may need before you are discharged.

Visit 8: InsuLearn-SMA At-Home Period

(Day 13-17) Data collection will occur at home and will last about 1 week

During the At-Home Period, you or your parent/legal guardian will manage your diabetes using the study t:ap insulin pump and the CGM which will be connected to the study phone (DiAs platform). This is the same equipment that you used during the Hotel Admission. When using the InsuLearn bolus calculator, you will press a button to simply announce an upcoming meal rather than enter the exact carbohydrate count.

This data collection phase is to gather information on your normal insulin doses and amount of carbohydrates that you typically use each day. You are asked to follow your normal routine involving diet, exercise, and insulin administration.

It is important to wear your CGM continuously during this phase of the study. If you are using your personal Dexcom CGM, you will be asked to share your CGM download data with the study team at the completion of this week if the data is not available through a commercial portal (a cloud account). The use of the Dexcom Apps on a personal phone may result in data and text charges.

Visit 9: InsuLearn-SMA Check-In Visit

(Day 14) Clinic, Telephone, Email, Text, or Video (approximately 15-30 minutes)
You can come to the clinic if you prefer to do this visit in person.

A study team member will contact you or your parent/legal guardian by phone, email, text, or video call to:

- Ask you about any changes to your medical history and medication.
- Review your CGM data.
- Review any hypoglycemic events that are less than 60 mg/dL that you may have experienced.
- Review any hyperglycemic events that are more than 300 mg/dL that you may have experienced.
- Request download of data from the glucometer and ketone meter at the End of Study visit (visit 10).

Visit 10: End of Study Visit

(Day 17) Clinic, Telephone, Email, Text, or Video (approximately 15-30 minutes)

You can come to the clinic if you prefer to do this visit in person.

You will return to using your personal equipment and using your usual insulin parameters. A qualified clinical study team member (e.g., MD, NP, PA, CDE) will be available to discuss the transition back to your usual care if you have questions. Transitioning back to your usual care may result in low and high blood glucose values.

A study team member will contact you or your parent/legal guardian by phone, email, text, or video call to:

- Ask if you have any questions related to transitioning back to your personal equipment.
- Ask if you have any questions about using the study equipment.
- Ask you about any changes to your medical history and medication.
- Review your CGM data.
- Instruct you on the risk of low glucose and high glucose levels as you return to using your personal equipment.
- Review any hypoglycemic events that are less than 60 mg/dL that you may have experienced.
- Review any hyperglycemic events that are more than 300 mg/dL that you may have experienced.
- Request download of data from the CGM and pump devices when you complete an intervention if needed

If your visit doesn't happen in the clinic, you will be provided with a pre-paid shipment label to promptly return all study equipment (e.g., study phone, insulin pump, and remaining CGM supplies).

Visit 11: Follow-Up Check-In Visit

(Day 18) Clinic, Telephone, Email, Text, or Video (approximately 15-30 minutes)

You can come to the clinic if you prefer to do this visit in person.

A study team member will contact you or your parent/legal guardian by phone, email, text, or video call about 24-48 hours after taking off the study equipment to:

- Ask you about any changes to your medical history and medication.
- Review any hypoglycemic events that are less than 70 mg/dL that you may have experienced.
- Review any hyperglycemic events that are more than 300 mg/dL that you may have experienced.
- Review the range of your ketone values (e.g., are they in the moderate or large range?).

- Ask if you have any questions regarding the study. You can talk with the study doctor or the physician's assistant if you have questions related to adjusting back to your usual insulin parameters.

A member of the study data team may contact you if there are questions related to your data collection or equipment.

You will be asked to complete this visit and sign the Leaving the Study Early (last page of this consent form) if you choose to end the study early.

Visit 12: CGM Data Collection (optional)

(Day 18-31) Clinic, Telephone, or Video (14 days)

The study team will ask you to share 14 days of your usual care CGM data after you have finished the study. This data is to look at how people's habits around mealtime are different.

END OF STUDY PARTICIPATION:

After the Follow-Up Check-In Visit (Visit 11), your participation in the study is complete. You will be referred to your primary care provider/or specialist for standard-of-care treatment. The study team may contact you after you have completed the study if they have questions related to data collection and equipment issues

Study Schedule

	Study Screening	Equipment Training	AID+CC At-Home Period	AID+CC Check-In Visit	Pre-Hotel Admission Check-In Visit	Hotel Admission (Day 1)	Hotel Admission (Day 2)	InsuLearn-SMA At-Home Period **InsuLearn-SMA At-Home Period**	At-Home Check-In	End of Study Visit	Follow-Up Check-In Visit	CGM Data
Location	CV/R/Ph	CV	Home	CV/R/Ph	CV/R/Ph	Hotel	Hotel	Home	CV/R/Ph	CV/R/Ph	CV/R/Ph	CV/R/Ph
Visit #	1	2	3	4	5	6-7		8	9	10	11	12
Day (approximate)	1	2	3-9	4	9	10-12		13-17	14	17	18	18-31
Visit variation	(+/- 30 days)	(+/- 30 days)	(+/- 1 day)	(+/- 1 day)	(+/- 1 day)	(+/- 1 day)	(+/- 1 day)	(+/- 1 day)	(+/- 1 day)	(+/- 1 day)	(+/- 2 days)	(+/- 7 days)
Informed consent	X											
Eligibility assessment	X											
Medical History	X											
HbA1c	X											
Pregnancy test (if applicable)	X											
Physical exam	X											
Concomitant Medication Review	X			X		X			X	X	X	
Vital signs (height/weight)	X					Weight only						
Demographic Data Survey (if eligibility is met)	X											

Randomization (if eligibility is met)	X											
Data download	X		X	X	X	X	X	X	X	X	X	X
Study Equipment Training		X				X	X					
Glycemic Treatment Guidelines Training		X				X	X					
Device and supplies dispensed		X					X					
AID+CC with remote monitoring		X			X							
AID+CC or AID+InsuLearn-SMA						X	X					
AID+InsuLearn-SMA with remote monitoring									X			
Inspire Questionnaires					X					X		
Glucose monitoring			X	X	X	X	X	X	X			
Study device and supplies returned										X		
Review diabetes management and AEs					X	X	X		X	X	X	
2 weeks of Usual Care data Pre/Post study (Optional)	X											X

What are your/and your parent/legal guardian's responsibilities in the study?

You and your parent/legal guardian have certain responsibilities to help ensure your safety.

These responsibilities are listed below:

- You, or your parent/legal guardian must bring you to each study visit.
- You and your parent/legal guardian must be completely truthful about your health history.
- Follow all instructions given.
- You or your parent/legal guardian should tell the study doctor or study staff about any changes in your health or the way you feel.
- Inform the study doctor or study staff as soon as possible if you have to take any new medications, including anything prescribed by a doctor or those that you can buy without a prescription (over-the-counter), including herbal supplements and vitamins. The study doctor will let you know if you can take these medications.

Blood Testing

We will take (or "draw") up to 1 teaspoon of blood for screening. The blood we take will be tested to measure your hemoglobin A1c, a blood test used to monitor how well you're managing your diabetes. The total amount of blood we will take is less than 1 teaspoon of blood if tested at a laboratory and a droplet of blood if tested in the clinic.

If you are a female of child-bearing potential and having a blood serum pregnancy test done instead of a urine pregnancy test, you will have an additional ½ teaspoon of blood taken for each blood serum pregnancy test.

If the study doctor asks for additional labs (for example: hematocrit, liver function tests, and thyroid stimulating hormone) at your screening appointment, we will take less than 1 teaspoon of blood. The study doctor may request these blood tests as these results may help show changes in your insulin resistance (when cells in your muscles, fat, and liver don't respond well to insulin).

When these tests are done any leftover sample will be thrown away. This means there is no information that could be used by anyone to determine who the sample came from.

If you want to know about the results before the study is done:

During the study you are having an investigational test done. The purpose of the test is NOT to diagnose any disease or abnormality you may have. Because the test is investigational there is no way for the study leader to understand if the results are "normal" or "abnormal". However, if any test results are concerning, your study leader will let you know. In addition, as the research moves forward, your study leader will keep you informed of any new findings about the research itself that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time, you may ask for more information about the study results.

What are the risks of being in this study?

Loss of Privacy:

The risk of allowing us to collect information about you is a potential loss of privacy. The University of Virginia will do its best to protect your records so that facts about you and your health will be kept private. The chance that information identifying you will be given to someone else is very small. However, we cannot guarantee it will be safe.

- The study team will do their 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 of 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.
- We encourage you to discuss the risks with your study doctor or any other health care professional who may understand our process.
- The Hotel Admission will have other study participants also in attendance.
- The study team is not able to restrict other participants from sharing photographs that include you (e.g., social media) which could lead to a loss of confidentiality.

Risks and side effects related to treating type 1 diabetes (with or without using study equipment):

Likely:

- Risks of possible mild to moderate low blood sugar and possible symptoms of low blood sugar, such as sweating, trembling, difficulty thinking, dizziness, and feeling uncoordinated.
- Risk of possible mild to moderate high blood sugars and symptoms of high blood sugars such as thirst and frequent urination. You may have a higher level of sugar in your urine.

Rare but serious:

- Risk of severe temporary low blood sugar (hypoglycemia) that can lead to unconsciousness, hypoglycemic seizure, hospitalization or even death. One of the ways this could happen is if the system delivers too much insulin when a meal was not eaten but the system detected what looked like a meal based on the CGM increasing.
- Risk of prolonged high blood sugar leading to Diabetic Ketoacidosis (DKA), hospitalization, and coma. DKA can lead to renal failure (kidney failure), cardiac arrhythmia (irregular heartbeat), myocardial infarction (heart attack), rhabdomyolysis (muscle breakdown), and even death.

Risks related to use of an Insulin Pump:

Likely:

- Risk of pump site failure and need to re-establish a functional pump site for insulin delivery.

Rare but serious:

- Risk of symptoms related to the inserting of an infusion set: sensitivities to adhesives resulting in skin irritation, bruising, and bleeding. Risk of the tissues in your body not absorbing the insulin properly.
- Risk of low blood sugar (hypoglycemia): One of the ways this could happen is if the system delivers too much insulin when a meal was not eaten, but the system detected what looked like a meal based on the CGM increasing.

- Risk of high blood sugar (hyperglycemia): One of the ways this could happen is if the insulin pump tubing gets bent and is unable to dispense insulin properly.

Risks and side effects related to the algorithm:

Even though the study algorithm has been tested in a computer simulation or in another clinical study, there is still a risk that parts of the system may malfunction. As a result, you could receive less or more insulin than you need and be at risk for hyper- or hypoglycemia.

The following are common cases of system malfunction:

Rare but serious:

- CGM sensor reads higher or lower than your actual blood glucose level.
- CGM sensor stops working or cannot communicate with the system.
- Algorithm is not working as designed

Risks related to using a Continuous Glucose Monitoring Sensor:

Likely:

- Failure or lack of sensitivity of the CGM sensor that requires replacement and or insertion of new sensor.
- Discomfort from insertion of sensor into the skin.

Less Likely:

- Bruising less than ½ inch.
- Bleeding less than ¼ teaspoon.
- Inserting the sensor may cause infection, bleeding, or pain, and wearing the adhesive patch can irritate your skin.
- CGM sensor reads higher or lower than your actual glucose level.
- CGM sensor stops working or cannot communicate with the system.
- Skin irritation or allergic reactions to the sensor adhesives.
- Uncomfortable with study team members seeing your CGM values.

Rare but serious:

- Using an unsecured Wi-Fi could expose the system to viruses and hacking.
- Breakage of the CGM sensor under the skin with possible symptoms of skin irritation and inflammation. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Please call the study team or seek immediate medical assistance. Seek professional medical help if you have symptoms of infection or inflammation – redness, swelling or pain – at the insertion site.
- Bloodborne pathogens, such as Hepatitis B, if the shared CGM transmitter is not cleaned thoroughly with a diluted mixture of bleach or another appropriate cleaner after use per hospital approved cleaning procedure.

Risks associated with staying at the hotel for research purposes:

Likely

- Loss of privacy
- Disruption of daily routine similar to staying at a bed and breakfast

Risks of Fingersticks:

Likely:

- Pain at site of lancet (finger-pricking needle) use
- Bleeding at site of lancet use
- Small scar that may last for several weeks

Less Likely:

- Brusing
- Fainting or passing out
- Incorrect information from a false low or false high fingerstick value

Rare but serious:

- Local infection at site of lancet use

Risks associated with performing a pregnancy tests (women who can become pregnant):

Less Likely:

- False positive or false negative results.

Risk of Sharing the Insulin Pump, Continuous Glucose Monitor, Glucometer, and Ketone Meter:

The insulin pump, continuous glucose monitor, and ketone meter are 'single-patient use devices'. 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 spread if used with multiple patients. All devices will be cleaned thoroughly with a diluted mixture of bleach or another appropriate cleaner after use per approved cleaning procedure.

The CGM sensor will not be shared, and it will be discarded after use. The CGM transmitter may be reused.

The Glucometer & Ketone Meter Testing Kit will not be reused in this study.

Cybersecurity Risks:

Similar to other computer systems, medical devices may experience security breaches that may impact your safety. Manufacturers of these devices attempt to address these risks, but you should be aware that these risks do exist.

Connected Medical Devices, such as insulin pumps and CGMs, deliver care to you while collecting healthcare data through a wireless connection. Someone with advanced technical skills could potentially expose your personal health information or could potentially impact the safety of the device, such as changing your insulin pump settings which may cause hypoglycemia or hyperglycemia. We do what we can to decrease the chance of that happening, but it cannot be guaranteed.

Risks associated with having your blood drawn:

Having blood drawn may cause:

- ✓ pain (common),
- ✓ a bruise (sometimes),
- ✓ fainting or passing out (not very often), and
- ✓ infection (rare).

If the people doing the study are exposed to your blood or body fluids in a way that could give them a disease, your blood may be tested. The tests might check for:

- ✓ hepatitis,
- ✓ HIV (Human Immunodeficiency Virus), or
- ✓ other infections.

You and the person exposed would be told the test results. However, your name would be kept private. If your test is positive for hepatitis or HIV or any other infection that may affect your clinical care, we will tell you the results and help you understand what the results mean for you.

Risks from Completing Questionnaires:

- Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.
- There could be a risk of discomfort and harm (to psyche, reputation, employability, insurability, social status, criminal or civil liability) that may occur as a result of participation. If you do not wish to answer a question, you may skip it and go to the next question.

Other Unexpected Risks:

You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

The study devices (study insulin pump, study CGM) must be removed before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) or diathermy treatment. Participants may continue in the trial after temporarily discontinuing use if requiring one of these treatments.

Blood Donation:

If you participate in this study, it may affect your ability to donate blood. If you have any questions, call the organization where you donate blood and talk to one of their nurses.

Risks for women:

Being in this study might hurt your unborn baby, so you will not be able to join or stay in the study if you become pregnant. You should also not get pregnant during your study participation. If you have questions about birth control, please ask the study leader. If you are pregnant now or get pregnant during the study, please tell us right away.

If you are female and of child-bearing potential, you will be tested to find out if you are pregnant. This test must be negative in order to continue study participation. The results of the pregnancy test will be provided to you. Also, Virginia law requires release of the test results to your parent(s)/legal guardian if they request the results or request a copy of your medical records.

It is important that you contact the study doctor right away if you think you may be pregnant, if you have missed a period or it is late, or if you have a change in your usual menstrual cycle (heavier or lighter bleeding than usual or bleeding between periods).

Could you be helped by being in this study?

You may not benefit from study participation, but you may learn why carbohydrate counting and meal bolus treatments are important in how you manage your diabetes**.** In addition, information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include:

- You may continue your personal care for management of your diabetes developed by your doctor.

If you are an employee of UVA your job will not be affected if you decide not to participate in this study. If you are a student at UVA, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will be paid up to $350.00 by check, direct deposit, or gift card for finishing this study, after all study equipment has been returned to the study team and study downloads have been completed. You should get your payment about 6 weeks after your participation in the study is complete. The compensation payment may be reported to the IRS as income.

You will be paid for completing the study activities listed below:

- *Optional CGM Data Download (before the study): $25*
- AID+CC At-Home Data Collection: $100
- Hotel Admission: $100
- AID+InsuLearn-SMA At-Home Data Collection: $100
- *Optional CGM Data Download (after the study): $25*

If you are 18 years old or older, you will also be given a flat, one-time payment of $100 for your travel expenses to the hotel. If you are under 18 years of age, this one-time payment of $100 will be given to your parent/guardian.

If you do not finish the study, you will be paid for the study visits that you have completed.
If the study leader says you cannot continue, you will be paid the full amount for the study.

By agreeing to be in this study, you are donating your blood and bodily fluids (urine for pregnancy test) for research and giving up any property rights you may have to these specimens or the results of the research. The results of this research using your donated materials may have commercial value. However, you will not receive any payments.

Will being in this study cost you any money?

The following procedures/tests, which are being done for research purposes, will be provided at no cost to you or your health insurance:

- Hemoglobin A1c test
- Pregnancy test (if applicable)
- Study smart phone
- Insulin pump and infusion sets
- CGM supplies
- Glucose & Ketone Meter Testing kit, including test strips
- Any additional laboratory tests the study physician requested from you to participate in this study
- Hotel room and the meals provided during the Hotel Admission

You will be responsible for the cost of your insulin that is used during the study. As previously noted, the use of the Dexcom Apps on a personal phone may result in data and text charges.

You and/or your insurance company will be billed for any tests or care given beyond what is required in this study. In addition, you and/or your health insurance may be billed for other drugs or treatments that are given to help you control any side effects. You will be billed for any costs not covered by your health plan. You may be responsible for any co-payments or deductibles. You may wish to ask your insurance company for an estimate of what these costs might be or if pre-approval is required.

What if you are hurt in this study?

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study, you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover.

What happens if you leave the study early?

You can change your mind about being in the study at any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study. Some of the reasons for doing so may include:

a) Your study doctor is concerned about your health.
b) Your disease gets worse.
c) The side effects of the treatment are too dangerous for you.
d) You do not follow your doctor's instructions.
e) The study sponsor closes the study for safety, administrative or other reasons.

If you decide to stop being in the study, we ask that you notify the research team so any scheduled admissions may be cancelled. The study phone, study insulin pump, remaining study CGM and other supplies remain property of the CDT and will need to be returned. The study team may ask that data from the Glucose & Ketone Testing Kit be downloaded to review any event in more depth.

You will be asked to complete this visit and sign the Leaving the Study Early (last page of this consent form) if you choose to end the study early. Any data collected about you up until the time you leave the study must be kept in order to determine the results of the study.

How will your personal information be shared?

The UVA researchers are asking for your permission to gather, use, and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Social Security number ONLY IF you are paid to be in this study
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results.
- People or groups that oversee the study to make sure it is done correctly.
- The Lormar Foundation, and the people or groups it hires to help perform or review this research.
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study.
- Dexcom Inc will have access to your CGM data as it stored on their server. The CGM serial number will connect this data to you.
- Tandem Diabetes Care will have access to your insulin pump data as it is stored on their server. The insulin pump serial number will connect this data to you.
- Tax reporting offices (if you are paid for being in the study).
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.
- Local Health Agencies--State/Provincial law requires positive test results for certain communicable diseases, including HIV, hepatitis, sexually transmitted infections, and tuberculosis, to be reported to a local health agency.
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.
- Other participants may witness the study team attending to your needs (i.e. when your blood glucose level is low or high).
- Other participants will likely take photos of this event. Your face may be in these photos. Other participants may post these photos on social media without your permission. This may result in a loss of confidentiality and may help you decide if you would like to participate in the study or not.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

Information obtained from you during this study may be used in future research. Your information may be shared with other researchers inside of the University of Virginia. They will not be sent with information that could identify you, such as your name, address, or phone number. The data shared may include dates of your visits and information from your insulin pump and CGM, such as your glucose values, CGM values and the time and date of these values.

Some of the people outside of UVA who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

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.

Information obtained from you during this study may be used in future research. Your information may be shared with other researchers inside or outside of the University of Virginia. They will not be sent with information that could identify you such as name, address or phone number. The data shared may include dates of your visits and information from your insulin pump and CGM, such as your glucose values, CGM values and the time and date of these values.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form or complete the "Leaving the Study Early" part of this form and return it to the researchers. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

A copy of this consent form will be put in your medical record. (This is not the same as the record of this research study.) This means that everyone who is allowed to see your medical records will be able to find out that you are in this study. This is done so your regular doctors will know what you receive as part of this study. If you have other health problems during the study, they will be able to treat you properly.

Please contact the Principal Investigator listed BELOW to:

- Obtain more information about the study and ask any questions regarding study procedures or study treatments/interventions.
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:
Melissa Schoelwer, MD
University of Virginia
Department of Pediatric Endocrinology
Box 800386, Charlottesville, VA
Telephone: 434-326-2069

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22903
Telephone: 434-924-2620

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the UVA Study Tracking Number (at the bottom of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

You may also report a concern anonymously by calling the UVA Compliance Hotline phone number at 1-800-235-8700.

Would you like the study team to communicate with you by email or text message?

If you choose to communicate with the study team by unsecure email (email that is not encrypted) or text message to your personal phone, there is some risk that your health information could be read or accessed by someone else while the information is sent or saved by your email or phone provider.

Your personal email or phone provider may also share or release your information because they do not have to follow the privacy laws that UVA follows. Sometimes email and phone providers release information to marketing companies for use in direct advertising. If you choose to communicate by email or text messaging, UVA cannot control this potential loss of privacy but we want to tell you about this possible risk.

You do not have to agree to communicate with the study team by email or text message to be in this study. If you agree to texting or emailing, the study team will collect your phone and /or email address from you that you would like them to use to contact you. Please note, if you agree to text messaging, charges may apply depending on your data/text plan with your phone provider.

You do not have to agree to use email or text message to be in this study.

PLEASE INDICATE YOUR CHOICE BELOW:

Yes_____ I agree to be contacted by email or text.
If you agree to texting or emailing, the study team will collect your phone and /or email address that you would like them to use. Please note, if you agree to text messaging, charges may apply depending on your data/text plan with your phone provider.

No_____ I DO NOT agree to be contacted by email or text.

Would you like to be contacted about future studies?

The researchers in this study would like to know if you wish to be contacted regarding participation in additional studies that may be appropriate for you. By agreeing to be contacted, you will allow a qualified member of the study team to contact you in the future to ask if you want to participate in additional studies. You have no obligation to participate in any study.

Declining will have no influence on your present or future status as a patient in this clinic. You will receive the same care as any other patient seen in this clinic. There will be no penalty or loss of benefits to which you are otherwise entitled. Your clinic records will indicate that you do not want to be asked about future research by or through anyone but your treating physician.

Participation in research may involve some loss of privacy. However, your records will be handled as confidentially as possible. Access will be limited to the study team organizing the study. No information will be used for research without additional permission. Your contact information will not be shared with anyone outside of UVA without your permission.

You do not have to agree to be contacted about future research to be in THIS study.

PLEASE INDICATE YOUR CHOICE BELOW if you are willing to be contacted about any future research studies.

____ Yes, I agree to be contacted about future research studies.

____ No, I do not want to be contacted about future research studies.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information, and all your questions have been answered. If you sign the form, it means that you agree to join the study. You will receive a copy of this signed document.

Participants 18 years of age and older:

Consent From Adult:

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

Person Obtaining Consent:

By signing below, you confirm that you have fully explained this study to the participant, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT(SIGNATURE)	PERSON OBTAINING CONSENT (PRINT NAME)	DATE

Participants younger than 18 years of age:

Parental Permission (Parent 1)

By signing below, you confirm you have the legal authority to sign for this child.

_____	_____	_____
PARENT/GUARDIAN (SIGNATURE)	PARENT/GUARDIAN (PRINT NAME)	DATE

Parental Permission (Parent 2)

By signing below, you confirm you have the legal authority to sign for this child.

_____	_____	_____
PARENT/GUARDIAN (SIGNATURE)	PARENT/GUARDIAN (PRINT NAME)	DATE

Person Obtaining Parental Permission:

By signing below, you confirm that you have fully explained this study to the participant's parent, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

If you are unable to obtain parental permission from both parents/guardians, explain why not on the lines below

PERSON OBTAINING PERMISSION (SIGNATURE)	PERSON OBTAINING PERMISSION (PRINT)	DATE

Assent from Adolescent (15-17 years of age)

Consent from the parent/guardian MUST be obtained before approaching the adolescent for their assent.

PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

Person Obtaining Assent of the Adolescent (15-17 years of age))

Consent from the parent/guardian MUST be obtained before approaching the child for their assent.

By signing below, you confirm that the study has been explained to the child (less than 18 years of age), all questions have been answered, and the child has voluntarily agreed to participate.

PERSON OBTAINING ASSENT (SIGNATURE)	PERSON OBTAINING ASSENT (PRINT)	DATE

Notification of My Health Care Provider

Please indicate below whether you want us to notify your health care provider that you have agreed to take part in this study.

_____ Yes, I want the study doctor to notify my health care provider that I have agreed to take part in this study.

Health Care Provider Name: _____

Health Care Provider Address: _____

_____

The study team will send a copy of the consent form to the health care provider.

_____No, I do not want the study doctor to notify my health care provider that I have agreed to take part in this study, or I do not have a health care provider.

Leaving the Study Early

If you leave the study early the study leader will keep the data collected about you up until the time you leave the study to help determine the results of the study.

Check one option below:

____ I am withdrawing my consent from the intervention or treatment part of this study but agree to continue to have follow up information about me collected by the study team.

The follow up information will be collected by the study team:

- Obtaining information from my medical records if a medical event happened during study these records will be reviewed until the medical event has been resolved.
- Assessment of medical history or medications changes
- Assessment of glucose values <70 mg/dL and >300 mg/dL
- Assessment of ketone values measuring moderate or large range
- Assessment of adverse events, adverse device effects, drug issues, and device issues
- Discuss risk of severe hypoglycemia and/or severe hyperglycemia during the transition back to the subject's usual home basal insulin; participants will be advised that the study physician will be available for consultation during this transition period
- Return of study equipment
- Completion of any pending questionnaires

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below, you confirm that you have fully explained the implications of withdrawing from the study to the subject and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

SUBJECT IS A MINOR

Parental/ Guardian Permission

By signing below, you confirm you have the legal authority to sign for this child.

_____	_____	_____
PARENT/GUARDIAN (SIGNATURE)	PARENT/GUARDIAN (PRINT NAME)	DATE

Person Obtaining Consent

By signing below, you confirm that you have fully explained the implications of withdrawing from the study to the subject and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE