Please check all that are applicable:

I am an adult participant in this study.

Print your name here:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I am the parent or guardian granting permission for a child in this study (the use of "you" refers to "your child" or “your ward.”)

Print child’s name here:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\*\*\*\*\*\*\*\*\*\*\*\*\*

Are you participating in any other research studies? \_\_\_\_\_ Yes \_\_\_\_\_No

**PURPOSE OF RESEARCH**

You are invited to participate in a research study of the inControl Advice System. The purpose of this study is to reduce the frequency of low blood sugars and low blood sugars requiring assistance to treat. Low blood sugar is the number one fear of many individuals and families with someone who has type 1 diabetes, and this fear often prevents optimal glycemic control. It is expected that this protocol will yield increased knowledge about using a decision support system to help control the glucose level. This inControl Advice will be tested in human research for the first time. You were selected as a possible participant in this study because you or your child have had Type 1 diabetes for at least 1 year and use Multiple Daily Injections (MDI) to take your daily insulin.

You are being asked to participate in this study because:

* You are at least 15 years old or older
* You have had Type 1 Diabetes Mellitus for at least 1 year

If you decide to terminate your participation in this study, you should notify Dr. Bruce Buckingham at 650-804-0476.

This research study is looking for 132 participants with Type 1 diabetes using basal/bolus intensive insulin therapy including carbohydrate counting, and use of pre-defined parameters for glucose goals, carbohydrate ratio, and insulin sensitivity for at least 1 month. Stanford University expects to enroll up to 70 research study participants.

**VOLUNTARY PARTICIPATION**

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

**DURATION OF STUDY INVOLVEMENT**

Your participation in this study will require up to 3 in person visits and 6 phone/email visits over approximately 14 weeks.

**PROCEDURES**

If you choose to participate, Dr. Buckingham and his research study staff will describe the study, train you and provide the necessary supplies and devices, and will answer any questions you have.

The first visit will be a screening visit at the Clinical Research Unit that will last about 2 hours. You will be trained on the use of a blinded study continuous glucose monitor (CGM) and study glucometer. You will wear the blinded CGM at home for 2-weeks to obtain a baseline understanding of your glycemic control. You will return to the Clinical Research Unit (CRU) at Visit 2 to determine if you met final eligibility for the study. If you are eligible, you will be randomized to one of two groups: Group A participants will use the unblinded study CGM with the Decision Support System (DSS) at home for 12 weeks. You will receive training on the use of the inControl Advice and the study insulin pens if you are randomized to Group A. Group B participants will use only the unblinded study CGM at home for 12 weeks. Participants in both groups will complete baseline questionnaires and receive training on the use of a study CGM, if needed. The six phone/email visits will occur every two weeks. You will be asked to download the study equipment and send it to the study team. At the completion of the study, Visit 3, you will be asked to return to the CRU to return the study equipment, obtain a repeat Hemoglobin A1C and complete final questionnaires.



Figure 1: Study Technology

**Visit 1**

**SCREENING (will take about 2 hours to complete)**

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

These tests and procedures include the following:

* You will be asked to fill out a medical history form. You will be asked about your diabetes history, past and current medical conditions, surgical history, menstrual history (females), allergies, medications and supplements, social history (including drinking, smoking and drug habits), and whether or not you have various symptoms. You will also be asked about your average daily insulin use over the past 7 days.
* Physical exam and vital signs (blood pressure, heart rate)
* Review your medications and supplements.
* Height and weight
* Standard blood tests (2 teaspoons of blood) to check certain salts, blood sugar, kidney function, liver function, blood counts, HbA1c (your blood glucose average over 8-12 weeks), Hematocrit (percentage of red blood cells in your blood), and thyroid levels (TSH). If you are female and of child-bearing potential, your blood sample will also 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.
* The HbA1c will be collected sent to a laboratory outside of Stanford.
* You may have these blood tests performed locally.
* You will be asked not to take medications containing acetaminophen (like Tylenol) 24 hours prior to wearing the continuous glucose monitor sensor and while you are wearing the sensor.
* **If female and sexually active, you must agree to use a highly effective form of contraception to prevent pregnancy while a participant in the study.** A negative pregnancy test will be required for all premenopausal women who are not surgically sterile prior to putting on study equipment. If you become pregnant during the trial, you will be discontinued from the study.

**Insulin is not well tested in pregnant women. It is not known if insulin can result in birth defects or miscarriages. Please inform the study team immediately if you become pregnant during the study. If you are attempting to become pregnant, you should not participate in this study.**

The study physician may ask that you repeat your screening lab tests. These tests may be conducted locally.

If the screening tests demonstrate you are eligible to participate in the MAIN STUDY:

* You will receive training on the use of a blinded CGM and receive the appropriate supplies. You will wear the blinded CGM at home for approximately 2 weeks to obtain baseline glucose assessment.
* You will receive training on the use of the study glucometer and receive the appropriate supplies. You will use the study glucometer for all fingerstick BG testing and calibrations during the trial. Do no use alternate testing sites.
* You will be asked to perform fingerstick BG testing according to the CGM manufacturer guidelines.
* You will be asked to perform fingerstick BG testing according to the Glycemic Treatment Guidelines as you will be asked to follow study guidelines for the treatment of low or high blood glucose.
* You will be provided a blood ketone meter and supplies to use as advised in the Glycemic Treatment Guidelines.
* You will use your home insulins dosed according to your pre-defined home parameters for carbohydrate counting.
* You will be asked to confirm that you have an emergency glucagon kit available at your home per usual care guidelines. Otherwise, the study physician will provide you a prescription to obtain this kit.

You will return approximately 14 to 21 days after screening so the study team can evaluate your usage of the blinded CGM.

**Visit 2 – Final Eligibility Assessment and Randomization**

If you are a female, you will have a urine pregnancy test. The test must be negative for you to participate in the study. The results of the pregnancy test will be provided to you.

During this visit, the use of the blinded CGM will be assessed by the study team. The study physician will review the CGM data from the previous two week to assess if your insulin parameters need to be adjusted prior to randomization. To reduce your risk of low blood sugar when transitioning from the home basal insulin to Tresiba, you will be asked to perform fingerstick blood glucose measurements a minimum of four times daily for the first 2 weeks of Tresiba use (premeal and bedtime, for CGM calibrations, to confirm low or high CGM alarms, and for symptoms of low or high blood sugar). The CGM low alarm will be set to 70 mg/dL and the high alarm set to 300 mg/dL. If the CGM alarms, you should perform a fingerstick to assess your blood glucose. During the first 2 weeks of Tresiba use, you will be asked to confirm that the CGM is working prior to bedtime. If the CGM is not functional, you are strongly advised to measure their blood glucose around 3am using the study provided blood glucose meter.

If you meet final eligibility, you will be randomized with a 67% chance of being in Group A and a 33% chance of being in Group B. Neither you nor your doctor can choose which treatment you are assigned.

**Group A will use the study CGM and DSS at home for 12 weeks**

**Group B will use the study CGM alone at home for 12 weeks**

Group A participants will receive training on the use of the inControl Advice APP and the study insulin pens. The study physician may adjust your insulin parameters at this visit. Both Group A and B will receive training on the use of the unblinded CGM and study glucometer if not already trained. Group A subjects will be instructed that the bolus calculator they will use is experimental. In both Group A and B, the subjects will be advised to always assess the safety of insulin dosing prior to injection and to be mindful of the risk for both hyper and low blood sugar. Both groups will wear the study equipment for 12 weeks at home.

You will complete a questionnaire to assess the impact of DSS on diabetes-relevant psychosocial measures such as fear of low blood sugar and high blood sugar scales. In addition, you will complete structured questions related to system performance and usability surveys on the DSS. These questionnaires will be administered at Visit 2 and Visit 9. Completion of these questionnaires will take about 60 minutes. You will use only your study identification number when completing these questionnaires. You will not use your name, date of birth, or any information that could identify you.

**Visit 3-8: Telephone Phone Check Ins (Day 17-102/approximately 15 minutes)**

**[Group A & B]**

The study team will contact you during weeks 2, 4, 6, 8, 10 to review:

* your compliance with the study equipment
* your blood glucose values
* remind you to download the study CGM
* discuss any issues that you may have experienced

Fingerstick BG at least 4 times daily during the first 2 weeks of using the study insulin (pre-meal and bedtime, for CGM calibrations, to confirm low or high CGM alarms, and for symptoms of low or high blood sugar).

**END OF STUDY:**

**Visit 9: Study Conclusion Visit (approximately 90 minutes)**

**[Group A & B]**

You will either come to the CRU or complete the following closer to home: HgbA1c and questionnaires. Data will be downloaded from study equipment by one of several methods: (a) you will download the equipment and send the files to study staff, (b) at the CRU by study staff; or (c) equipment mailed to the study team for downloading. You are required to return the study equipment, including unused insulin and its associated equipment.

The study physician will review the CGM data, and you will be instructed how to transition back to your home insulins and the doses to be used. There may be a risk of severe low blood sugar and/or severe high blood sugar during the transition back to your usual home basal insulin from the study basal insulin (Tresiba). We will be ask you to perform fingerstick BGs before meals, at bedtime, and at 3AM for the first 3 days on the home insulin.

**Follow-up Phone Contacts for Both Groups: Post-study**

A study team member will contact you within 3-7 days after initiating home insulin to assess for any problems transitioning from the study insulin to the home insulin, including any episodes of blood glucose values 300 mg/dL.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study Procedures | Screening Visit | Final Eligibility Visit | Phone Contacts | Study Conclusion Visit |
| Visit | **1** | **2** | **3-8** | **9** |
| Duration | **~2 Hours +**  **2 weeks** | **~2 Hours** | **~ 30 minutes** | **~ 90 minutes** |
| Days | **1-15** | **16** | **17-102** | **103** |
| Location | **CTRU** | **CTRU** | **OPTX** | **CTRU** |
| Informed Consent | X |  |  |  |
| Clinical exam & medical history | X |  |  |  |
| Inclusion/Exclusion Criteria | X |  |  |  |
| Screening Labs | X |  |  |  |
| Pregnancy test for premenopausal female not surgically sterile | X | X |  |  |
| Hemoglobin A1c | X |  |  | X |
| Study CGM & Study Glucometer use | X | X | X |  |
| Randomization |  | X |  |  |
| DSS Equipment Use (Group A only) |  | X | X |  |
| Study Insulin Use (Group A only) |  |  | X |  |
| CGM Downloads |  | X | X | X |
| Assessment of Blood Glucose values |  | X | X | X |
| Questionnaires | X |  |  | X |

CTRU = Clinical & Translational Research Unit

OPTX = Outpatient

(~) approximately

Women of Childbearing Potential

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk.

To confirm to the extent medically possible that you are not pregnant, you agree

to have a pregnancy test done before beginning this research study.

You must agree to avoid sexual intercourse or use a birth control method judged to be effective by the investigator and which will not interfere with the proposed investigation. You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

**PARTICIPANT RESPONSIBILITIES**

As a participant, your responsibilities include:

* Follow the instructions of the Protocol Director and study staff.
* Use the study devices as instructed.
* Keep the study devices in a safe place, away from children and for your use only.
* Do not use acetaminophen (like Tylenol) 24 hours prior to wearing the continuous glucose monitor sensor and while you are wearing the sensor.
* Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
* Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
* Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
* Complete your questionnaires as instructed.
* Ask questions as you think of them.
* Return all study devices when requested.
* Tell the Protocol Director or research staff if you change your mind about staying in the study.

**WITHDRAWAL FROM STUDY**

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Dr. Bruce Buckingham at 650-804-0476.

If you are withdrawn from the study for any reason, you must return all study devices to Dr. Bruce Buckingham or the research team immediately upon their request.

The Protocol Director may also withdraw you from the study for one or more of the following reasons:

* + Failure to follow the instructions of the Protocol Director and study staff.
  + The Protocol Director decides that continuing your participation could be harmful to you.
  + Pregnancy
  + You need treatment not allowed in the study.
  + The study is cancelled.
  + Other administrative reasons.
  + Unanticipated circumstances.

**POSSIBLE RISKS,DISCOMFORTS, AND INCONVENIENCES**

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

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

* Risk 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 possible symptoms of high blood sugars such as thirst and frequent urination.
* Accidentally mixing up short-acting and long-acting insulins, which may cause low blood sugar or high blood sugar.
* Risk of severe temporary low blood sugar (hypoglycemia) that can lead to unconsciousness, hypoglycemic seizure, hospitalization or even death.
* Risk of prolonged high blood sugar leading to diabetic ketoacidosis, hospitalization, and even death.

**Risks associated with changing from Lantus or Levemir insulin to Tresiba:**

* Risk 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 possible symptoms of high blood sugars such as thirst and frequent urination
* Risk of severe temporary low blood sugar (hypoglycemia) that can lead to unconsciousness, hypoglycemic seizure, hospitalization or even death.
* Risk of prolonged high blood sugar leading to diabetic ketoacidosis, hospitalization, and even death.

**Risks associated with continuous glucose monitor (CGM) insertion:**

* Failure or lack of sensitivity of the continuous glucose monitor sensor that requires replacement / insertion of new sensor
* Fingerstick for calibration of the continuous glucose monitor
* Discomfort from insertion of sensor
* Bruising less than ½ inch
* Bleeding less than ¼ teaspoon
* Sensitivity to adhesives with use of continuous glucose monitor resulting in skin irritation, redness, blistering, scarring, systemic allergic reaction or secondary skin infection
* Swelling or redness at insertion site
* Psychological reaction to viewing the continuous glucose monitor information or attending to continuous glucose monitor alarms or fingerstick blood glucose values.
* Breakage of the continuous glucose monitor 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.

**Risk of insulin pen use:**

* Leaving an insulin needle attached to the pen, contributing to air bubbles accumulating within the insulin and pen and leading to improper dosing of insulin or insulin contamination.
* Sharing insulin pens may result in a bloodborne pathogen (a bacteria or a virus that can cause disease)

**Risks and side effects related to blood glucose collection via fingerstick:**

* Pain at site of lancet (finger-pricking needle) use
* Bleeding at site of lancet use
* Incorrect information from a false low or false high fingerstick value
* Infection at site of lancet use

**Risks associated with performing a serum (blood) or urine pregnancy tests females who are able to become pregnant):**

* False positive or false negative results

**Risk of sharing the Continuous Glucose Monitor**

We will use the continuous glucose monitor equipment with other study subjects. The sensors will not be shared. The transmitter wirelessly sends your glucose information from the sensor to the receiver. The transmitter, which snaps into the sensor, will be cleaned thoroughly with a diluted mixture of bleach or another appropriate cleaner after use. The FDA approved the continuous glucose monitor as a ‘single use device’. This means that they recommend that only one person use this device as there is a rare risk that a bloodborne pathogen, such as Hepatitis B, may be spread if used with multiple patients.

**Risk of Sharing an Insulin Pen:**

Insulin pens should never be used for more than one person, even when the needle is changed. The insulin pen provided to you during this trial will be properly labeled with your name to ensure that the correct pen is used exclusively by you.

**Risks of Sharing the Drug**

Do not share the study insulin with anyone. It is prescribed only for you. It could hurt someone else. Keep it out of reach of children and people not able to read or understand the label.

**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 of 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 of Videotaping/Audiotaping:**

With your permission, we may photograph or videotape your participation in this trial. Photographs and videotapes will be used in presentations at conferences, potential study subjects, and potential research donors. Your willingness to have photos taken is independent of your participation in this trial. Your photo or videotape will not be used without your consent. Your identity can remain anonymous.

|  |  |
| --- | --- |
| \_\_\_\_\_ | I agree to be photographed/videotaped during this trial. |
| Initials |  |
| \_\_\_\_\_ | I agree to be photographed/videotaped during this trial but would like to remain anonymous. |
| Initials |  |
| \_\_\_\_\_ | I do **NOT** **CONSENT** to being photographed/videotaped during this trial. |
| Initials |  |

**Risks for Women:**

Pregnancy and Contraception

The study insulin used in this study can harm an unborn or nursing baby. Therefore, you cannot be in this study if you are pregnant or nursing a baby. A pregnancy blood test will be done at screening before starting this study if you are a woman able to become pregnant. You MUST NOT become pregnant while on this study.

You and your partner must use an approved form of birth control during this study. Examples of birth control you may use are:

|  |  |
| --- | --- |
| * Birth Control Implant | * Birth Control Pills |
| * IUD (intrauterine device) | * Birth Control Patch |
| * Depo-Provera | * Sterilization |

The birth control methods listed below are less effective. They may be used if combined with other birth control methods:

|  |  |  |  |
| --- | --- | --- | --- |
| * Condoms | | * Diaphragm | |
| * Jellies or foam | | * Rhythm | |
| * Withdrawal | | * Cervical cap | |
| * Sponge |  | |

Ask your doctor for more details about the proper birth control method for you. If you become pregnant during this study, you must tell your doctor right away. Your doctor will discuss your treatment and the effect on the pregnancy.

**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.

**POTENTIAL BENEFITS**

During this study, you may benefit from wearing a continuous glucose monitor to help you better manage your diabetes. You will also be benefitting diabetes management for other people with the information we will obtain from this study.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

**ALTERNATIVES**

You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment for your T1DM even if you choose not to be in this study. The usual treatment would include continuing your home insulin regimen. Your usual care will not be affected if you decide not to participate in this study. The alternative is not to participate.­­­­

**PARTICIPANT’S RIGHTS**

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

**ClinicalTrials.gov**

A description of this clinical trial will be available on [*http://www.ClinicalTrials.gov*](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.

**CONFIDENTIALITY**

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law**.** However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain data or information on the safety and effectiveness of the inControl Advice System; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

**Authorization To Use Your Health Information For Research Purposes**

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

**What is the purpose of this research study and how will my health information be utilized in the study?**

The purpose of this study is to assess the efficacy of the inControl Advice System versus a CGM alone when utilized by patients on multiple daily injections. The researchers hope to reduce the frequency of hypoglycemia and severe hypoglycemic events using the inControl Advice System.

**Do I have to sign this authorization form?**

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study, including receiving any research-related treatment.

Signing the form is not a condition for receiving any medical care outside the study.

**If I sign, can I revoke it or withdraw from the research later?**

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to:

Dr. Bruce Buckingham, MD

SUMC, Department of Pediatric Endocrinology

780 Welch Road, Room CJ320H

Palo Alto, CA 94306

**What Personal Information Will Be Obtained, Used or Disclosed?**

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

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

Information collected but not limited to:

• Name

• Telephone number(s) including home, cell, and work

• Work and home addresses

• Email address

• Birthdates and dates significant to study (dates of visits,

enrollment, consent, off-study)

• Photographs that may include the subject's face or sites at

which devices are worn (if permitted)

• Serial numbers of devices used in the study

• Information related to the subject's diabetes including data

downloaded from diabetes devices such as BG meter, ketone meter,

insulin pump, and closed loop systems, and any other devices used

• Medical records including those containing medical history,

physical exam, as well as lab and test results needed to ensure

eligibility criteria are met, and/or to review for medical issues

of concern or that may arise during participation in the study

• Results of questionnaires about the study, diabetes management

or possible complications of diabetes.

**Who May Use or Disclose the Information?**

The following parties are authorized to use and/or disclose your health information in connection with this research study:

* The Protocol Director, Dr. Bruce Buckingham, and his research team
* The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
* Research staff

**Who May Receive or Use the Information?**

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

* The Office for Human Research Protections in the U.S. Department of Health and Human Services
* The University of Virginia
* The Food and Drug Administration
* Mount Sinai Medical Center, another site participating in this study.

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

**When will my authorization expire?**

Your authorization for the use and/or disclosure of your health information will end on December 31, 2045.

**Will access to my medical record be limited during the study?**

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Signature of Adult Participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_    
Print Name of Adult Participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Signature of Legally Authorized Representative (LAR) Date

(e.g., parent, guardian or conservator)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name of LAR

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
LAR’s Authority to Act for Participant

(e.g., parent, guardian or conservator)

**FINANCIAL CONSIDERATIONS**

Payment

You will be paid $150 when you complete the MAIN STUDY. **You will receive payment after the study equipment and data has been returned to the study team.** You should get your payment by check about4 weeks after finishing the study. The income may be reported to the IRS as income.

* Completion of Visit 1 – $50
* Completion of Visit 2 – $50
* Completion of Visit 9 – $50

Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your social security number to receive payment.

Should you withdraw from the study, you will be paid for the visits that you completed. If the study leader says you cannot continue, you will be paid for the visits that you have completed.

Costs

If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with the study that are not a part of your routine medical care. However, there may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the study visits. You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. **You will also be responsible for any co-payments and/or deductibles as required by your insurance.** Participation in this study is not a substitute for health insurance.

Sponsor

This study is paid for by a grant from the National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK-NIH). TypeZero Technologies, Inc. (Charlottesville, VA) has received money from grant funding for using the inControl Advice in this study. The insulin, the insulin pens and its associated supplies are provided without costs by Novo Nordisk (Denmark). The continuous glucose monitors may be provided by Dexcom, Inc. (San Diego, CA).

Consultative or Financial Relationships

Dr. Bruce Buckingham is on the Medical Advisory Board for Novo-Nordisk, a company providing research support for this study. Dr. Buckingham has received consulting fees and research support from Dexcom Inc, who is providing devices at a research discount for this study.

**COMPENSATION for Research-Related Injury**

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

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

You do not waive any liability rights for personal injury by signing this form.

**CONTACT INFORMATION**

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about thisresearch study, its procedures, risks and benefits, or alternative courses of treatment, or if you feel you have been hurt by being a part of this study, please contact the Protocol Director, Bruce Buckingham M.D. You may contact him now or later at his office (650) 725-6549 or mobile phone (650) 804-0476.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906.  You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

Appointment Contact: If you need to change your appointment, please contact Liana Hsu at (650) 725-3939.

**EXPERIMENTAL SUBJECT’S BILL OF RIGHTS**

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

* be informed of the nature and purpose of the experiment;
* be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
* be given a description of any attendant discomforts and risks reasonably to be expected;
* be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
* be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
* be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
* be given an opportunity to ask questions concerning the experiment or the procedures involved;
* be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
* be given a copy of the signed and dated consent form; and
* be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future studies that may be of interest to you?

\_\_\_\_ Yes \_\_\_\_ No

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

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Signature of Adult Participant Date

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Print Name of Adult Participant

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Signature of Legally Authorized Representative (LAR) Date

(e.g., parent, guardian or conservator)

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Print Name of LAR

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LAR’s Authority to Act for Participant

(e.g., parent, guardian or conservator)

The IRB determined that the permission of one parent is sufficient for research in accordance with 21 CFR 50.55.

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(If available) Signature of Other Parent or Guardian Date

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Print Name of Other Parent or Guardian

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Authority to Act for Participant

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Signature of Person Obtaining Consent Date

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Print Name of Person Obtaining Consent