Informed Consent Form to be in a Research Study and Authorization to Use and Disclose Protected Health Information

Sponsor / Study Title:	**Medtronic MiniMed, Inc. ("Medtronic") / "Medtronic Evaluation of Extended Wear Infusion Set (EWIS) in Patients with Type 1 Diabetes"**
Protocol Number:	**CEP298**
Principal Investigator: (Study Doctor)	**Bruce A. Buckingham, M.D.**
Telephone:	**650-804-0476 (24 Hours)**
Address:	**Clinical & Translational Research Unity (CTRU) 800 Welch Rd. Palo Alto, CA 94304**

Why am I being asked to be in this study?

You are being asked to be in a study that involves research with human subjects. Being in this study is voluntary. Before you decide if you would like to be in the study, it is important you understand why the study is being done and what it will involve. Please read this form carefully and ask your doctor any questions you may have. After reading this form and asking any questions you have, if you decide to be in this study you will sign and date the last page of this form.

You are being asked to be in this study because you have Type 1 diabetes and are on the Medtronic MiniMed™ 670G pump therapy. If you agree to be in this study you will wear your MiniMed 670G™ insulin pump system and will be given 12 Medtronic Extended Wear infusion sets) to wear(you will wear each infusion set for at least 174 hours (7 days and 6 hours) or until infusion set failure, if this occurs before 174 hours). The infusion set with the longest length (43 in) will be used for this study. You will change insulin reservoirs at least every 174 hours, independent of infusion set wear. You will be asked at each subsequent office visit if you have used any non-study glucose meter(s), any pump other than the MiniMed™ 670G Insulin Pump and if you have replaced any part of the infusion sets before using all 12 sets (reservoir, tubing or any aspect of insulin set) with your own infusion set (reservoir, tubing or any aspect of infusion set) during the study.

The MiniMed 670G™ insulin pump system mentioned above is approved by the U.S. Food and Drug Administration (FDA) for use in patients who have diabetes and who are 7 years old or older. The FDA has not approved the infusion sets that is mentioned above for use and the device will therefore be considered investigational for this study.

Study purpose:

The purpose of this study is to collect data to support 6 or 7 days wear for infusion sets.

System and Device descriptions:

The Medtronic Extended Wear infusion set (Investigational)

The Medtronic Extended Wear infusion set is an infusion administration set like your currently FDA approved infusion set, with a pre-loaded inserter, inserted into the subcutaneous (under

the skin) tissue, and is connected to a Medtronic MiniMed medication reservoir (for use with a Medtronic MiniMed insulin pump). The infusion sets may enhance patient wear time to 7 days by maintaining insulin formulation stability. This is the only investigational product used during this study.

MiniMed™ 670G Insulin Pump (not supplied by Medtronic)
The MiniMed™ 670G Insulin pump is a pump that can give continuous insulin at set and variable rates. The pump also displays the glucose values detected by the Guardian™ Sensor (3) and stores that data so that it can be used to better manage your diabetes. When the pump's Auto Mode is turned on, the pump will use information from the Guardian™ Sensor (3) to automatically figure out how much insulin you need. The data in the pump will be uploaded to the CareLink system described below.

Guardian™ Sensor (3)
The Guardian™ Sensor (3) glucose sensor measures your glucose level when you wear it. It is inserted through your skin and connects via a transmitter to the insulin pump.

Guardian™ Link (3) Transmitter
The Guardian™ Link (3) Transmitter is a device that reads the signal from the glucose sensor and it then transmits this information to the insulin pump. In this study the Guardian™ Link (3) Transmitter will be connected to the Guardian™ Sensor (3).

Transmitter Charger
The Charger is used to recharge the Guardian™ Link (3) Transmitter(s) as needed. It uses disposable batteries and it comes with a user guide that explains how to re-charge.

Tester
The Tester works as a sensor simulator. It can be used to make sure the transmitter works when you change sensors.

One-press Serter
The One-press Serter is a spring-loaded insertion device that is used to place the Guardian™ Sensor (3) under your skin.

CONTOUR®NEXT LINK 2.4 Blood Glucose Meter
The CONTOUR®NEXT LINK 2.4 Blood Glucose meter measures blood glucose level by fingerstick and it uses CONTOUR®NEXT test Strips. In this study, the blood glucose measurements from the CONTOUR®NEXT LINK 2.4 study meter will be uploaded to CareLink™ Personal for Clinical Research.

Abbott™* Precision Xtra™* Blood Glucose & Ketone Meter
This meter can measure both blood glucose and blood ketone levels, but in this study, it will only be used to measure blood ketone levels.

Medtronic CareLink™ Personal Therapy Management Software for Diabetes (MMT-7333) for Clinical Research system: (CareLink)
You will be required to use the Medtronic CareLink™ Personal Therapy Management Software for Diabetes (MMT-7333) For Clinical Research system. This system allows your device to send

information over the internet using a telecommunication network (such as a cellular network, wireless network, etc.). This can be done from your home, office, or any other location using a personal computer. The information available from the Medtronic CareLink Personal Therapy Management Software for Diabetes for Clinical Research is the same information the study doctor would collect from your device during an in-person office visit. For this study, the information gathered from the CareLink system will be added to the health information collected for the study. Separate instructions with more information about how to use the CareLink system will be provided to you.

Medtronic takes steps to protect the privacy of the health information sent to the Medtronic CareLink Network over the Internet. However, Medtronic cannot guarantee the health information is protected against unauthorized interception.

Direct Relation to Your Participation in this Study

Though the pump is commercially available and approved for subjects 7 years and older, the infusion sets used in this study are investigational as they are not approved by the FDA. This is the only part of this study directly related to your participation.

All other procedures and devices in this study are considered standard of care and not directly related to your participation in this study.

How long will I be in the study? How many people will be in the study?

A total of up to 300 subjects will be enrolled in this study in the United States in order to have 240 subjects complete the study. Your participation in the study may last approximately 12-16 weeks. The overall study is expected to last approximately 12 months after the first subject enrollment to completion of all the data entry.

What are my responsibilities during the study?

Being in this study, it is important that you:

- Tell the study doctor about your medical and medication history;
- Attend all visits scheduled with the study doctor;
- Call the study doctor's office to reschedule a missed visit/transmission as soon as possible;
- Transmit your device information weekly using the Medtronic CareLink™ Personal Therapy Management Software for Diabetes (MMT-7333) for Clinical Research;
- Inspect your infusion site on a daily basis for signs of infection;
- Test your blood glucose at least 4–6 times each day (before each meal and at bedtime);
- Return all used and unused infusion sets to the study site when your participation in the study ends;
- Report any injuries, hospitalizations, emergency room visits, symptoms or complaints to the study doctor or study nurse as soon as possible.
- Maintain and complete your daily logs and acetaminophen log(s).
- You will be required to provide your own insulin (either Eli Lilly and Company Humalog™ or Novo Nordisk A/S NovoLog and continue using your MiniMed 670G insulin pump system throughout the study.

What will happen if I am in this study?

Study Procedures:

You will be considered enrolled in this study once you sign and date this Informed Consent Form. If you decide to be in this study, the study doctor and study nurse will collect information about you and

your medical history. This includes any medication you currently take and any other information in your medical records related to your condition or treatment that may be relevant to your being in the study.

For this study, your study doctor will schedule 7 visits with you. These visits will be at the study site or completed on a phone call. You must make sure that you can come to each visit as scheduled or be available for a phone call.

None of the procedures in this study are experimental.

Visit 1 (Office): Screening and Consent

At this visit the following procedures will be done and data will be collected after you sign and date this consent form:

- Collection of general information such as age, gender, ethnicity, race, height, weight and the date of your diabetes diagnosis
- Review of your medications
- Blood tests, including HbA1c and TSH draw. HbA1c measures the amount of blood sugar in your hemoglobin. The HbA1c blood specimens will be sent to and tested by a Central Laboratory certified by the National Glycohemoglobin Standardization Program. TSH checks your thyroid stimulating hormone and may be optional if you had this test completed within 3 months prior to this visit. You may repeat the TSH draw to verify eligibility if not in range.
- Pregnancy test. If you are able to become pregnant, you will have a urine pregnancy test. If you are pregnant, you may not participate in this study.

Visit 2 (Office) Study & Training and Study Initiation Visit: may occur up to 28 days after Visit 1

At this visit the following procedures will be done:

- Your eligibility to be in the study will be confirmed before any study procedures will begin
- You will receive and be instructed on how to use the following to be used during your participation in this study:
    - CONTOUR® NEXT LINK 2.4 study meter (glucose meter)
        - You will be instructed to check your blood glucose at least 4-6 times each day
    - Abbott™ Precision Xtra™ ketone meter (ketone meter)
        - You will be instructed to test your blood ketone every time your blood glucose is greater than 250mg/dL at 3 or more hours after a meal
    - Guardian™ Sensor (3)
    - Guardian™ Link (3) Transmitter
    - One-Press Serter
    - Transmitter Charger
    - Tester
    - Medtronic Extended Wear infusion sets Daily Logs
    - Other study supplies
- You will be enrolled in and trained on use of CareLink and weekly uploads from your MiniMed™ 670G insulin pump system and glucose meter will be completed.
- Complete a study questionnaire
- You will be asked to consider avoiding use of products that contain Acetaminophen during your participation in this study. If you do use products that contain

Acetaminophen during this study, you will need to document the date and time you take the medication on an acetaminophen log that will be provided to you and use additional blood glucose meter readings to verify your glucose levels.

- You will discuss any questions, concerns, or problems you've been experiencing and any device performance issues

Visit 3 (Phone Visit): Follow Up and Study Procedures Reminder- Approximately 14 Days after Visit 2

At this visit the following will be done:

- You will be reminded to complete your weekly uploads, to check your blood glucose at least
  4-6 times each day and to complete your daily logs and acetaminophen log(s)
- You will be reminded to test your blood ketone every time your blood glucose is greater than 250mg/dL at 3 or more hours after a meal
- You will discuss wearing the infusion sets and inspecting the infusion site daily
- You will discuss what to bring to your next study visit
- You will discuss any questions, concerns, or problems you've been experiencing and device performance issues

***Visit 4 (Office)*: Approximately 30 days after Visit 2**

At this visit the following procedures will be done:

- You will receive additional studies supplies as needed
- The study site will collect used infusion sets
- Your daily logs and acetaminophen log(s) will be collected and reviewed
- You will be reminded to complete your weekly uploads, to check your blood glucose at least
  4-6 times each day and to complete your daily logs and acetaminophen log(s).
- You will be reminded to test your blood ketone every time your blood glucose is greater than 250mg/dL at 3 or more hours after a meal
- You will discuss wearing the infusion sets and inspecting the infusion site daily
- The study site will upload pump and glucose meter data into CareLink
  You will discuss any questions, concerns, or problems you've been experiencing and device performance issues

Visit 5 (Phone Visit): Follow Up and Study Procedures Reminder- Approximately 45 Days after Visit 2

At this visit the following will be done:

- You will be reminded to complete your weekly uploads, to check your blood glucose at least 4-6 times each day and to complete your daily logs and acetaminophen log(s).
- You will be reminded to test your blood ketone every time your blood glucose is greater than 250mg/dL at 3 or more hours after a meal
- You will discuss wearing the infusion sets and inspecting the infusion site daily
- You will discuss what to bring to your next study visit
- You will discuss any questions, concerns, or problems you've been experiencing and device performance issues

***Visit 6 (Office)*: Approximately 60 Days after Visit 2**

At this visit the following procedures will be done:

- You will receive additional studies supplies as needed
- The study site will collect used infusion sets

- Your daily logs and acetaminophen log(s) will be collected and reviewed
- You will be reminded to complete your weekly uploads, to check your blood glucose at least 4-6 times each day and to complete your daily logs and acetaminophen log(s).
- You will be reminded to test your blood ketone every time your blood glucose is greater than 250mg/dL at 3 or more hours after a meal
- You will discuss wearing the infusion sets and inspecting the infusion site daily
- The study site will upload pump and glucose meter into CareLink
- You will discuss any questions, concerns, or problems you've been experiencing and device performance issues

Visit 7 (Office) **End of Study Visit: Approximately 100 days after Visit 2 or within 7 Days after the last infusion set removal**

At this visit the following procedures will be done:

- The study site will collect used and unused infusion sets.
- Your daily logs and acetaminophen log(s) will be collected and reviewed
- The study site will upload pump and glucose meter into CareLink
- HbA1c test will be performed
- You will complete a study questionnaire
- You will discuss any questions, concerns, or problems you've been experiencing and device performance issues

You will be exited from the study at the end of this visit.

If you are in California, ask the study doctor for the estimated recovery time of your participation in this study.

What are the possible risks, side-effects, discomforts and inconveniences?

The risks of the infusion sets may include, but are not limited to:

- Localized infection
- Skin irritation/redness
- Bruising
- Discomfort/pain
- Bleeding
- Irritation
- Rash
- Hyperglycemia (high blood sugar) secondary to infusion set occlusion(blockage) or infusion site failure including diabetic ketoacidosis (DKA - A serious condition that occurs when the insulin levels are low, blood glucose level are elevated, and the body uses fat for energy)
- Hyperglycemia (high blood sugar) secondary to site falling off including diabetic ketoacidosis
- Anxiety associated with insertion

Risks with Insulin Administration and Pump:

Risks with the use of an insulin infusion pump may include the risk of malfunction of the components of the system (pump, software, infusion set and reservoir) as well as the risk of use

error during use of the system. Device deficiencies or use errors can result in administration of too much or too little insulin which may include, but are not limited to:

- Hypoglycemia (low blood sugar)
- Hyperglycemia (high blood sugar)
- Diabetic ketoacidosis
- Severe hypoglycemia (severe low blood sugar) with or without associated seizure, coma or death
- Kinked cannula (tube) leading to hyperglycemia (high blood sugar)
- Infusion set disconnection from pump leading to hyperglycemia (high blood sugar)
- Subject removes the reservoir from the pump but forgets to disconnect the infusion set from the body which results in hypoglycemia (low blood sugar) or severe hypoglycemia (severe low blood sugar).
- Dislodged cannula leading to hyperglycemia (high blood sugar)
- A pump error may lead to under delivery or over-delivery of insulin
- Battery failure – no insulin delivered
- Insulin deterioration leading to hyperglycemia (high blood sugar)
- Incomplete priming; fails to prime tubing and/or cannula, leading to hyperglycemia (high blood sugar)
- Remove a reservoir, without suspending and reconnecting after a while resulting in a hypoglycemia (low blood sugar)
- Subject not filling pump reservoir when needed leading to hyperglycemia(high blood sugar)
- Magnetic Resonance Imaging resulting in pump/transmitter malfunction
- Inaccurate insulin delivery due to sudden altitude changes
- Hypoglycemia (low blood sugar) or hyperglycemia (high blood sugar) from manual bolus
- Hypoglycemia (low blood sugar) or hyperglycemia (high blood sugar) from computer hacking

Risks with hyperglycemia (high blood sugar) may include, but are not limited to:

- Diabetic ketoacidosis
- Symptomatic ketosis(the body burns stored fats instead of carbohydrates)
- Cardiovascular event
- Dehydration (losing more water/fluid in the body than is being taken in by drinking water)
- Potassium and sodium imbalance (which can lead to muscle spasm and weakness)
- Shock
- Altered mental status
- Coma
- Acidosis (a buildup of acid in the blood which can lead to weakness and nausea)

Risks with hypoglycemia (low blood sugar) may include, but are not limited to:

- Seizure
- Coma
- Altered mental status
- Loss of consciousness
- Cardiovascular event
- Death
- Risk of rebound hyperglycemia with ketosis

Risks with Sensors may include, but are not limited to:

- Skin irritation or reaction to adhesives
- Bruising
- Discomfort
- Redness
- Bleeding
- Excessive bleeding due to anticoagulants (blood thinners)
- Pain
- Rash
- Infection
- Irritation from tapes used with glucose-sensing products
- Raised bump
- Appearance of a small "freckle-like" dot where needle was inserted
- Allergic reaction
- Syncopal episode secondary to needle insertion (fainting or passing out)
- Soreness or tenderness
- Swelling at insertion site
- Sensor fracture, breakage or damage
- Minimal blood splatter associated with sensor needle removal
- Residual redness associated with adhesive and/or tapes
- Scarring
- Scab
- Blister
- Itchiness
- Inflammation
- Anxiety
- Incorrect sensor glucose reading which can result in incorrect diabetes management
- Subject over-treating secondary to alarms which can result in hyperglycemia (high blood sugar) or hypoglycemia (low blood sugar)
- Anxiety associated with insertion

Risks with Transmitter may include, but are not limited to:

- Skin irritation or reaction to adhesives
- Bruising
- Discomfort
- Redness
- Pain
- Rash
- Infection

- Irritation from tapes used with glucose-sensing products
- Raised bump
- Allergic reaction
- Soreness or tenderness
- Residual redness associated with adhesive and/ or tapes
- Scarring
- Scab
- Blister
- Itchiness
- Inflammation

Risks with Serters may include, but are not limited to:

- Improper insertion may lead to device performance issue or hyperglycemia (high blood sugar)

Risks with frequent finger stick testing may include:

- Potential risks associated with frequent meter testing of blood glucose and blood ketones include discomfort and ecchymosis (discoloration) at tips of fingers
- Potential risks associated with finger stick testing may include, but are not limited to discomfort and bruising and a small risk of infection.

Risks with Closed Loop Therapy:

Risks with Closed Loop may include, but are not limited to:

- Hypoglycemia
- Severe hypoglycemia
- Hyperglycemia
- Diabetic ketoacidosis User Entry Error
    - Patient administering boluses by entering false carb doses leading to hypoglycemia or hyperglycemia
    - Patient entering false glucose values for any reason leading to hypoglycemia and hyperglycemia
    - Patient entering false BG values for calibration leading to hypoglycemia or hyperglycemia
- Sensor failure resulting from patient failure to calibrate leading to hypoglycemia or hyperglycemia
- Sensor over-reading resulting in hypoglycemia
- Sensor under-reading resulting in hyperglycemia
- Sensor missed transmission, or any other fault resulting in no SG value, leading to hyperglycemia or hypoglycemia
- Voluntary insulin delivery (with the pump or with a syringe) immediately prior to entering Auto Mode may result in severe hypoglycemia despite shutting down insulin delivery by the algorithm
- Patient takes insulin via injection while in Closed Loop (Auto Mode)
- Hypoglycemia or hyperglycemia related to entering or exiting Closed Loop (Auto Mode)
- Insulin over-delivery due to potential interference from acetaminophen

Risks with hyperglycemia may include

- Diabetic ketoacidosis Symptomatic ketosis
- Cardiovascular event

- Dehydration
- Potassium and sodium imbalance
- Shock
- Altered mental status
- Coma Acidosis

Risks with hypoglycemia may include:

- Seizure
- Coma
- Altered mental status
- Loss of consciousness
- Cardiovascular event
- Death
- Risk of rebound hyperglycemia with ketosis

Potential risks with acetaminophen use may include, but are not limited to:

- False elevation of sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person

Pregnancy:

If you are or you become pregnant, there may be risks to you or your unborn child that are not yet known.

There may be additional risks related to this study that are not yet known.

What are the possible benefits of the study?

If you agree to be in this study, it is possible that you will not have any direct medical benefits; however, you may gain an increased awareness of new technologies for diabetes management.

The information from this study may benefit other patients with Type 1 diabetes in the future.

What happens when I end being in the study?

After your participation in the study ends, you will continue to receive the standard medical care for your condition from your doctor.

What other treatment choices do I have if I am not in the study?

You do not have to be in this study to be treated for your Type 1 diabetes.

If you decide not to be in this study, there is other care available to you. You may be treated in other ways, for example you may continue to use your insulin pump without joining the study. You should discuss other treatments and their possible risks and benefits with your doctor.

Who is paying for this study?

The study site will receive payment from Medtronic for work involved in collecting study data and managing the study at the site and for procedures done solely for the study.

Will I be paid for being in this study?

You will be paid (below) for your time spent keeping a detailed diary, completing questionnaires and other documentation, for your hours missed from work or other normal activities, for transportation and other related costs that may be incurred for your study participation and study visits.

You will be paid according to the following schedule:

Visit	Payment
Study Office Visits	$50 each
Study Phone Visits	$25 each
Unscheduled Study Office Visit	$50 each
Unscheduled Study Phone Visit	$25 each

You will only be paid for visits you complete. If you have any questions regarding your compensation for participation, please contact the study staff. You will be paid as soon as possible after your participation in the research study has ended.

What will I have to pay for if I am in this study?

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.

You will be required to provide your own insulin (either Eli Lilly and Company Humalog™ or Novo Nordisk A/S NovoLog™).

Conflict Of Interest Disclosure

Dr. Buckingham is a paid advisor to Medtronic MiniMed Inc., the company sponsoring this study.

What happens if I am injured or hurt during this study?

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 study doctor 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, care will be provided to you. You will not be responsible for any of these costs.

If you receive Medicare benefits, and if the sponsor of this study pays for any study-related treatment, complications or injuries, personal information about you, your treatment, and your participation in this study will be provided to the sponsor, who is required by law to provide it to Medicare.

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

Do I have the right to refuse to be in this study or to leave this study?

Being in this study is voluntary. You may choose not to be in the study or to leave the study at any time for any reason. If you choose not to be in the study or to leave the study, this will not result in any penalty and you will not lose any benefits to which you are entitled. Your regular care and your relationship with the hospital or clinic and your doctors will not be affected.
You will be told about any new information that may make you change your mind about staying in the study. You may be asked to sign a new consent form if this occurs.

You may leave the study simply by telling the study doctor. If you choose to leave the study, you will need to return the used and unused infusion sets to the study site. All of your health information collected for the study cannot be removed from the study data and will be used as described in this form.
The study doctor may take you out of the study without your permission if:

- It is in your best interest.
- Your health or safety is compromised.
- You do not follow your study doctor's instructions.
- You join another research study.
- You begin using certain medications as explained by your doctor.
- You receive a red blood cell transfusion or erythropoietin.
- You become pregnant.
- You abuse illicit drugs or alcohol.
- If you have one severe hypoglycemic episode.
- You have one episode of diabetic ketoacidosis.
- You begin using pramlintide (Symlin), DPP-4 inhibitors, liraglutide (Victoza or other GLP-1 agonists), metformin, canagliflozin (Invokana or other SGLT2 inhibitors).
- You receive red blood cell transfusion or erythropoietin.
- You are taking oral, injectable, or IV glucocorticoids for 3 or more weeks.
- The study sponsor or a regulatory authority stops the study for any reason.

If this happens you will be told, and the reasons will be explained to you.

What is the role of the sponsor's representative?

Trained Medtronic personnel may be present at study visits. The role of the Medtronic person is to give technical support. All of these actions will be done under the careful direction of your study doctor.

What happens if you pass away while in the study?

If you pass away while you are in the study, the study doctor will ask your family or other authorized representative for permission to retrieve medical records surrounding your death. Your family or other authorized representative does not have to grant permission.

The study does not mandate that an autopsy be performed. If an autopsy is performed, a copy of the autopsy report and a copy of the death certificate, if available, will be sent to the sponsor as part of the information collected for the study.

How will the sponsor use the study information?

If you decide to participate in the study, Medtronic (including, for purposes of this section, its agents and contractors) and others who work with the study will see health information about you. This consent form and Authorization to Use and Disclose Health Information ("Authorization") govern how your health information is disclosed and used.
The Authorization section below describes how your health information may be used and/or disclosed by your doctor (the study investigator), the hospital or clinic, and their respective

staffs. You agree to allow access to and use of your health information in accordance with the Authorization, as well as disclosure to Medtronic.

This consent form describes the study, and what Medtronic will do with the study data, including your health information received during the study. Medtronic will keep your health information confidential in accordance with all applicable laws and regulations. Medtronic may use your health information to conduct this research, as well as for additional purposes, such as overseeing and improving the performance of its device, new medical research and proposals for developing new medical products or procedures, and other business purposes. Any reports or publications about the study or any other research will not include your name or a description of you. Information received during the study will not be used to market to you; your name will not be placed on any mailing lists or sold to anyone for marketing purposes. U.S. Food and Drug Administration (FDA) regulations, as well as other applicable laws, control Medtronic's work in developing and assuring the safety and quality performance of its medical devices. Medtronic may disclose your health information to the FDA, as well as to other U.S. and foreign government authorities responsible for assuring the safety of medical devices. Medtronic also may disclose your health information to institutional review boards and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research. You agree to allow Medtronic to use study data in these ways. You also agree to allow FDA and other governmental authorities to inspect your health information.

To participate in the study, you will need to sign and date this consent and Authorization to Use and Disclose Health Information form.

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 and date 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 and dating 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 collect data to support 6 or 7 days wear for infusion sets.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study device works and is safe.
- To compare the study device to other devices.
- For other research activities related to the study device.

Do I have to sign and date this authorization form?
You do not have to sign and date this authorization form. But if you do not, you will not be able to participate in this research study.

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

If I sign and date, 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 (for example, 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 the study doctor listed on page one of this consent form.

What Personal Information Will Be Obtained, Used or Disclosed?
Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to:

- All information collected during the research described in the Informed Consent Form for the Evaluation of Extended Wear Infusion Set (EWIS) in Patients with Type 1 Diabetes ("the Research"); and
- Health information in my medical records that is relevant to the Research.

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 Study Doctor
- 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
- Advarra Institutional Review Board, and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research
- To the Researchers and to the sponsor of the Research, Medtronic MiniMed, Inc. and its agents and contractors (together "Medtronic"); and
- The Food and Drug Administration

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 or when the research project ends, whichever is earlier.

_____ _____

Signature of Adult Participant Date

_____

Print Name of Adult Participant

Where can I find out about the study results?

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.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00037217.

What Does My Signature on this Consent Form Mean?

Your signature on this form means that:

- You have read the information given to you in this form
- You accept the conditions of this form
- You agree to join the study

You will not give up any legal rights by signing and dating this consent form. You will receive a copy of this consent form.

California 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.

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

Statement of the Subject:

I have read this consent form and the research study has been explained to me. My questions have been answered to my satisfaction. I understand that by signing this form, I have not waived my legal rights nor released anyone from negligence. I choose to volunteer for the study. I have been given a copy of this form.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date

Person Obtaining Consent

_____ _____

Signature of Person Obtaining Consent Date

_____

Print Name of Person Obtaining Consent