

**STANFORD UNIVERSITY - Research Consent Form**

**Protocol Title: Control of Hyperglycemia in Transplant Patients in the Pediatric and Adult Intensive Care Units using a Continuous Glucose Sensor and Proportional-Integral-Derivative Algorithm**

**Protocol Director: Kimberly Fuld, DO**

**IRB Approval Date: September 16, 2009**

**IRB Expiration Date: February 17, 2010**

Please check one of the following:

\_\_\_\_\_ You are an adult subject in this study.

\_\_\_\_\_ You are the parent or guardian granting consent for a minor in this study.

Print minor's name here:

\_\_\_\_\_

The following information applies to the individual or to his/her minor child. If the subject is a minor, use of "you" refers to "your child".

\* \* \* \* \*

Are you participating in any other research studies? \_\_\_yes\_\_\_ no

**INTRODUCTION TO RESEARCH STUDIES**

A research study is designed to answer specific questions, sometimes about a drug or device's safety and its effectiveness. Being in a research study is different from being a patient. When you are a patient, you and your personal doctor have a great deal of freedom in making decisions about your health care. When you are a research subject, the Protocol Director and the research staff will follow the rules of the research study (protocol) as closely as possible, without compromising your health.

**PURPOSE OF RESEARCH**

You are invited to participate in a research study of high blood glucose (hyperglycemia) in transplant patients in the intensive care unit (ICU). We hope to learn the usefulness of using a continuous glucose sensor to assist in delivering insulin (a hormone which lowers blood glucose levels). Any changes in the amount of insulin you are receiving will be supervised by a physician. You were

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selected as a possible subject in this study because you are going to have, or have had, an organ transplant (liver, kidney, heart, bowel, and/or lungs).

**Your participation** in this study is entirely voluntary.

**Your decision** whether or not to participate will not prejudice you or your medical care. If you decide to participate, you are **free to withdraw** your consent, and to discontinue participation at any time without prejudice to you or effect on your medical care. If you decide to terminate your participation in this study, you should notify Dr. Fuld at 650-723-5791, or Dr. Basina at 650-723-6961.

This research study will include 30 pediatric and 30 adult transplant patients in the pediatric and adult intensive care units at Stanford University. All of the research study subjects will be at Packard Children's Hospital and Stanford University Hospital.

### DURATION OF STUDY INVOLVEMENT

Your time in this research study is expected to take approximately 1 day to 2 weeks.

### PROCEDURES

Background: In adult transplant patients, high blood glucose has been associated with increased illness and transplant rejection. Several studies in adult and pediatric ICU patients have shown improved outcomes with maintaining blood glucose (sugar) levels near normal range throughout the patient's ICU stay. Other studies have shown that attempts to attain near normal glucose values have resulted in an increased incidence of low blood glucose levels and an increased risk of mortality. All of these studies have been conducted using manual measurements of blood glucose levels every 1 to 3 hours. The blood sugars are measured either by a finger stick or drawing blood from an arterial or venous catheter (tube in the arm) by a bedside nurse. A physician then determines the appropriate insulin dose (insulin is a naturally occurring hormone that lowers blood glucose levels). We want to determine if the addition of continuous glucose monitoring will be more safe and effective in maintaining blood sugars in the normal range without periods of high or low

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blood sugars. There will be two groups of patients in this study, the control group and the treatment group. The control group will wear a glucose sensor to keep a record of you glucose levels, but these levels will not be seen by the nursing and physician staff and you will receive standard ICU care provided by the ICU physicians regarding decisions pertaining to blood glucose and insulin treatment. The treatment group will also wear a glucose sensor. However, the information from the treatment group's sensor will be sent to a computer which will calculate the insulin dose required to maintain blood glucose. Before there is any change in the amount of insulin you are receiving a physician will review the change and confirm that it is appropriate. We use the word "physician" to refer to a doctor or nurse practitioner who is trained in treating elevated glucose levels.

Components of the monitoring system are:

1. One small subcutaneous (just below the skin) sensor that measures glucose continuously. These sensors are approved by the FDA for children older than 7 years of age.
2. In the control group the results of the sensor signal will be sent to a "blinded" Minimed receiver which will store the glucose values. This device is not FDA approved. The only difference between this device and the device that is FDA approved is that the glucose values are not displayed on the screen. The glucose sensor is exactly the same as the FDA approved glucose sensor
3. A computer program (algorithm) that estimates the correct insulin dose based on the blood sugar level
4. An insulin pump which delivers insulin to the patient intravenously. Changes to the insulin delivery are entered by the physician manually. This is a standard infusion pump used in the intensive care unit.

The actual procedure of placing the glucose monitor is as follows:

- One subcutaneous (under the skin) glucose sensor is placed on the outer thigh, arm, buttock, or stomach. This should take approximately 5 minutes.
- The sensor will be connected to a small monitor that will continuously display the glucose (sugar) level.

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- The glucose monitor is also connected to a computer system with a program. This program will determine the insulin dose required to decrease the blood sugar levels to a normal range. Insulin is a naturally produced hormone by the body which can also be given as an intravenous medication to help decrease blood sugar levels.
- The calculated dose of insulin will then be entered to the insulin pump which is connected to an intravenous catheter.
- The insulin infusion rate is changed to normalize the blood glucose levels.
- As the insulin infusion rate is changed, the glucose levels are continuously monitored to assure there is no sudden drop in the blood glucose.
- The glucose level will be confirmed 4 – 6 times a day by testing blood glucose level with either a glucose meter or laboratory test.
- This study will not affect your/ your child's care in the ICU.
- Once you/your child are tolerating feeds we will discontinue the continuous glucose monitor and intravenous insulin.
- The sensor will be used for up to 7 days based on how well it is functioning, and daily assessment of the sensor site. The sensor is currently approved by the FDA for 3 days of wear. We have conducted a previous study which shows the sensor can function well for up to 7 days. We will inspect the site where the sensor is inserted on a daily basis to be sure there is not sign of infection or skin irritation. By using one sensor for 7 days we can decrease the need for a second sensor to be inserted.

At the end of the study, we will use the glucose values, both sensor and blood glucose, to look at the overall control of blood sugar in each of the groups.

### SUBJECT'S RESPONSIBILITIES

You should:

- Tell the Protocol Director or research study staff about any side effects.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

While participating in this research study, you should not take part in any other research project without approval from all of the Protocol Directors. This is to

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protect you from possible injury arising from such things as extra blood drawing, extra x-rays, the possible interaction(s) of research drugs, or other similar hazards.

### 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 choose to have a pregnancy test done before beginning this research study or to begin the study after the onset of your next menstrual period. 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.

If you are a man participating in this study and your partner is able to become pregnant, you and your partner must use adequate contraception while you are participating in the study. Your doctor will discuss with you what methods of birth control are considered adequate. You should inform your study doctor if your partner becomes pregnant.

### 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.

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If you withdraw from the study, the subcutaneous glucose monitor will be removed.

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- The Protocol Director decides that continuing your participation could be harmful to you.
- 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.

- Several studies have recently been published that showed an increased mortality in intensive care unit patients when their glucose values were targeted to 81-108 mg/dl. These studies did not use a continuous glucose monitor, and there was an increased incidence of low blood glucose levels in the group receiving intensive insulin treatment. We have therefore targeted the glucose level in our treatment group to 120 mg/dl, and our goal is not have glucose levels less than 90 mg/dl. Also, by using a continuous glucose sensor, we should be able to detect the possibility of a low blood glucose occurring before it happens based on glucose trend data.
- There may be minimal discomfort from placement of the subcutaneous glucose sensors.
- A small risk of bleeding or infection at the sensor insertion sites exists. If significant bleeding occurs, holding pressure at the site along with removal of the catheter should be adequate treatment. If an infection develops at the insertion site, you would be started on appropriate

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antibiotics (medications to fight infections) and the catheter would be removed.

- Should the insulin dose be inappropriate or there is an unexpected change in your status, the blood sugars may become too low. If this should occur in the treatment group, it would likely be immediately detected by the subcutaneous monitor and the device would alarm. The low blood sugar would be confirmed by a blood sample and be quickly treated by stopping the insulin along with administering glucose intravenously. The blood sugars would be closely and frequently monitored.
- You may experience minimal discomfort with finger sticks or venipuncture (needle inserted into a vein) for blood sample collection, however most, if not all, blood samples will be taken from a catheter that was placed in association with your surgery.
- The system may involve risks which are currently unforeseeable.

### POTENTIAL BENEFITS

Adult and pediatric studies have shown that maintaining glucose levels in the normal range has multiple benefits to patients. Some of these benefits have included: decreased ICU days, decreased days on the ventilator (a machine that helps you breathe), better blood pressures, less blood transfusions, improved kidney and liver function and decreased graft rejection.

**WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.**

### ALTERNATIVES

The alternative to participating in this study is not to participate.

### SUBJECT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

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If you decide not to participate, tell the Protocol Director. You will still receive care for your disease and will not lose any benefits to which you would otherwise be entitled.

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.

### CONFIDENTIALITY

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Your research records may be disclosed outside of Stanford, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to research study personnel.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed.

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.

Medtronic MiniMed is providing the glucose sensors and program to control the blood glucose levels in this study and are providing some financial support to do these studies. They will also have access to the information obtained during the research study. The results will be provided to the Food and Drug Administration and other federal and regulatory agencies as required.

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**USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION**

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?**

A small monitor will be placed under the skin on the upper thigh, abdomen, or buttocks. This monitor will continuously monitor blood sugar levels. In the treatment group, this information will be fed into a computer program. Based on your weight and sugar level, the appropriate insulin infusion rate will be determined. This dose will be programmed into an insulin delivery pump which will change the insulin infusion accordingly. The glucose monitor will continue to monitor the glucose levels and assure they are dropping at the appropriate rate. As the sugars drop, the insulin infusion dose will be adjusted to prevent dangerously low blood sugar levels. This is a constant process to continuously maintain the blood sugar levels within the normal range.

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The health information used in the study will include information such as the following: admitting diagnosis, severity of illness, number of ICU days, number of days on the ventilator, days on blood pressure support medications, other medications being administered, infections, blood sugar levels, kidney & liver function laboratories, need for dialysis, and number of blood transfusions. Some of this information may be submitted to Minimed (sponsor of the continuous glucose sensor) and the FDA since this product is still being tested in the ICU setting. Once the study is completed individual medical information may also eventually be included in any medical publication derived from this research. However, all personal information will remain confidential and each patient's data will be identified only with a unique ID number.

### **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. 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. Fuld or Dr. Buckingham at 300 Pasteur Drive Rm G-313 Stanford, CA 94305;

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650-723-5791 or Dr. Basina at 300 Pasteur Drive A175 MC 5303  
Stanford, CA 94305; 650-723-6961.

### What Personal Information Will Be 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: age, weight, ethnic background, gender, admitting diagnosis, severity of illness, number of ICU days, number of days on the ventilator, days on blood pressure support medications, other medications being administered, infections, blood sugar levels, kidney & liver function laboratories, need for dialysis, number of blood transfusions, and measures of inflammatory proteins in the blood stream.

### 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 Directors – Dr. Fuld, Dr. Buckingham, Dr. Basina and their research staff here at Stanford
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary.

### Who May Receive / 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
- Medtronic Minimed – Manufacturer of the continuous glucose sensor

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- 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 expire December 31, 2020.

**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 medical or billing decision about you (e.g., if included in your official medical record).

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Signature of Legally Authorized Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Description of Representative's Authority to Act for Subject

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### FINANCIAL CONSIDERATIONS

#### COSTS

The sponsor will pay for continuous glucose monitor, the computer with the insulin program, the insulin infusion pump, and the tubing to deliver the insulin intravenously. You or your insurance company will be responsible for all other routine care in the ICU.

#### SPONSOR

Medtronic MiniMed is providing financial support and/or material for this study.

#### CONSULTATIVE OR FINANCIAL RELATIONSHIPS

Dr. Buckingham is a paid advisor to, and receives payment for lectures from Medtronic MiniMed, the company sponsoring this study.

### CONTACT INFORMATION

- If you have any questions, concerns or complaints about this **research study**, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director. You may contact him/her now or later at Dr. Fuld or Dr. Buckingham at 650-723-5791 or Dr. Marina Basina at 650-723-6961.
- Emergency Contact: If you feel you have been **hurt by being a part of this study**, or need immediate assistance please contact

Dr. Fuld                      650-723-5791

Dr. Buckingham        650-723-5791

Dr. Basina                 650-723-6961

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- Alternate Contact: If you cannot reach the Protocol Director, please call the research team at 650-497-8850.
- Independent of the Research Team Contact: If you are not satisfied with the manner in which this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a research study subject, please contact the Stanford Institutional Review Board (IRB) to speak to an informed individual who is independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. Or write the Stanford IRB, Administrative Panels Office, Stanford University, Stanford, CA 94305-5401. In addition, please call the Stanford IRB at either (650)-723-5244 or toll free at 1-866-680-2906 if you wish to speak to someone other than the research team or if you cannot reach the research team.

### COMPENSATION

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 but this study does not provide financial assistance for additional medical or other costs. Additionally, Stanford is not responsible for research and medical care by other institutions or personnel participating in this study. You do not waive any liability rights for personal injury by signing this form.

### EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a human subject you have the following rights. These rights include but are not limited to the subject'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;

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- 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.

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YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PERSON OBTAINING CONSENT, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

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

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of LAR (Parent, Guardian or Conservator)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Authority to act for participant

\_\_\_\_\_  
(If available) Signature of Other Parent or Guardian

\_\_\_\_\_  
Date

\_\_\_\_\_  
Authority to act for participant

*The IRB determined that the permission of one parent is sufficient for research to be conducted under 21 CFR 50.52, in accordance with 21 CFR 50.55.*

**Person Obtaining Consent**

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the subject has been provided with the Experimental Subject’s Bill of Rights, if appropriate, that I have discussed the research project with the subject and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the subject to ask questions and that all questions asked were answered.

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\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

(e.g., staff, translator/interpreter, family member, etc.)

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