

CONSENT FORM

Human Subject's Bill of Rights: Persons who participate in a medical experiment are entitled to certain 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 to be reasonably expected; be given an explanation of any benefits to the subject to be reasonably expected, if applicable; be given a disclosure of any appropriate alternatives, drugs, or devices that might be advantageous to the subject and to be informed of their relative risks and benefits; be informed of the avenues of medical treatment, if any are available to the subject after the experiment, should complications 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the experiment or the procedures involved; be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice; be given a copy of the signed and dated consent form, and be given the opportunity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 or 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.

Please check one of the following:

You are an adult.

You are the parent or guardian granting consent for a minor.

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

General Consent for a Glucose Sensor

Introduction: You either have diabetes, hypoglycemia or some other problem with blood glucose control and are about to use a new glucose sensor OR you are an adult who wishes to use a glucose sensor. We have created this document for two purposes. First, we want you to be aware of the possible side effects of using a glucose sensor. Although these side effects are rare, we feel you should be aware of them. Second, we sometimes review the records of our patients using this sensor and may publish these results.

You are invited to participate in a research study of glucose sensors. We hope to learn how better to use these sensors. These sensors are made by Abbott Diabetes Care, Medtronic MiniMed, and DexCom.



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STANFORD UNIVERSITY - Research Consent Form

Protocol Title: General Use of a Glucose Sensor – Both Sensors Form

Protocol Director: Darrell M Wilson, MD – IRB#76856 Panel 4 PUT ID OR IMPRINT HERE

Revision M Page 2 of 7

IRB Approval Date: 9 Dec 2008 IRB Expiration Date: 8 Dec 2009

This research study is looking for 50 people who either have diabetes, hypoglycemia or some other problem with blood glucose control and are about to use a new glucose sensor OR participants who are adults who wish to use a glucose sensor. Stanford University expects to enroll 50 research study subjects.

This research study is expected to take approximately 3 to 7 days for each sensor wear period. There may be multiple wear periods.

Any data that may be published in scientific journals will not reveal the identity of the patients. Currently, there are three different glucose sensors available for clinical use. Depending on the situation, you will likely be wearing only one of these sensors, but in some cases, we are asking you to test more than one sensors.

All of the sensors are on the tip of a small needle and will need to be inserted under the skin. In general, you will wear the sensor for approximately 5 days at a time before you have to change the sensor. During this time, you must also check blood glucoses with a standard clinical glucose meter. If you have diabetes, you should not depend on the sensor's glucose values to monitor your insulin doses.

The following discomforts and potential risks of these glucose sensors include:

- Pain, bruising, bleeding, and potential infection at the subcutaneous (under the skin) site where the sensor is inserted.
- These are new systems and we are currently learning how to best use them. The blood glucose values it calculates are estimates, and may not reflect your actual values.
- It is also possible, but unlikely, that part of what is inserted under the skin may remain under the skin (a piece of the device could chip off, or the device could break and part of the device could remain under the skin).

The Food and Drug Administration (FDA) has approved some of these sensor systems, primarily for use in patients with diabetes. Not all of the sensors are FDA approved, and those that are approved are not approved for all age groups. In some cases, after discussing the current FDA status of a particular sensor, we may ask you to wear one that is not FDA approved.

We may remove the sensor if we do not detect sufficient benefit or if significant side effects are discovered. At the discretion of the study director, subjects may be taken out of this study due to unanticipated circumstances. Some possible reasons for withdrawing a subject from the study:

- the investigator decides that continuation could be harmful to you
- you need treatment not allowed in the study
- the study is canceled



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- other administrative reasons

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 wish to participate in this study, you must sign this form. If you decide to participate, you are free to withdraw your consent, including your authorization regarding the use and disclosure of your health information 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. Wilson at 650-723-5791.

USE AND DISCLOSURE OF YOUR MEDICAL INFORMATION

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?

As described in the associated consent (this document) we are using information for glucose sensors to improve their function. Your health information may be used in scientific publications.

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: Darrell Wilson at 650 723 5791.

What Information Will Be Used or Disclosed? - Your health information related to this study, including, but not limited to, your diagnosis, growth hormone dose, related records, physical examinations, x-rays, MRI's, and the like may be used or disclosed in connection with this research study.

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, Darrell Wilson, M.D.
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary.
- Other members of the study team, here at Stanford University and its satellite clinics, and at the sites where sensor post marketing study databases are maintained (some of which are sponsored by companies that make and sell glucose sensors, including Medtronic, Abbott, and Dexcom).
- Other members of the Division of Pediatric Endocrinology and Diabetes who might assist in your child's management or the conduct of this study.
- Other staff of the Stanford University Medical Center who might assist in your child's management or the conduct of this study.

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
- Makers of the various sensors, including Abbott, Medtronic, and DexCom.

Your information may be redisclosed if the recipients described above are not required by law to protect the privacy of the information.



Expiration - Your authorization for the use and/or disclosure of your health information will continue until 15 March 2105.

Signature of Subject

Date

Signature of Legally Authorized Representative

Description of Representative's Authority to Act for Subject

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

The alternative is not to participate.

You will be told if any new information is learned which may affect your condition or influence your willingness to continue participation in this study.

While participating in this study, you should not take part in any other research project without approval from all of the investigators. This is to protect you from possible injury arising from such things as extra blood drawing, extra x-rays, interaction of research drugs, or similar hazards.

If you do not wish to be in this study, your diabetes will be managed without the data from the glucose sensor as clinically indicated.

No payment will be provided for participation in this project.

You or your insurance company will be responsible for some or all of the cost of this sensor system. If you do not buy the sensor yourself, you will not be able to keep the sensor. In some cases, we may require a deposit for using the sensor. The deposit will equal the cost of the system, about \$800. If you do not return the sensor, we will keep the deposit so that we may replace the sensor.

Dr. Buckingham is paid by Medtronic-Minimed to give lectures on diabetes, and he has received financial support from Medtronic-Minimed for conducting research studies.



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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, (Dr. Wilson or his associates at (650) 723-5791). You should also contact him/her at any time if you feel you have been **hurt by being a part of this study**.

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, Stanford, CA 94305-5401.

Records relating to your participation in this study will be protected against release to unauthorized people. Members of the health care staff who care for you have access to your file.

Any data that may be published in scientific journals will not reveal the identity of the subjects. Patient information will be provided to Federal and regulatory agencies as required. The Food and Drug Administration for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

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 researchers 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.

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 Parent, Guardian or Conservator

Date

Authority to act for participant



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(If available) Signature of Other Parent

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 50.51, 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 participant has been provided with the Experimental Subject’s Bill of Rights, if appropriate, that I have discussed the research project with the participant and explained to him or her in nontechnical 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 participant to ask questions and that all questions asked were answered.

Signature of Person Obtaining Consent

Date

Print Name of Person Obtaining Consent

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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Assent Form for Minors 7 to 17 Years of Age

We are doing a research study to test 2 different blood glucose monitors. We are asking you to help us test these monitors because you have diabetes. Being in this study will not change your diabetes, but it might help us learn a better way to test blood sugars. Depending on the situation, we are asking you to test only one or both of the sensors.

One monitor is called the MiniMed CGMS. It measures blood sugar through a needle (called a sensor) placed under your skin. It will hurt a little when we put the needle under your skin, but it should feel better in a short while. You must keep this sensor on for 3 days. You can do all of the things you normally do when the sensor is in your skin. We will tape it down to make sure it will not come off.

The other monitor is called a GlucoWatch that you can wear on your arm or your leg. It looks like a big watch and it tests your blood sugar by sending a small electric current to your skin. It will do this every 10 minutes while you are awake during the day. It will not be on when you are sleeping [or] you don't have to wear the GlucoWatch when you are sleeping or bathing. It may sting a little or it may not hurt at all, but we won't know until we test it on you. Your skin under the GlucoWatch might get itchy, dry or flaky after wearing it for 4 days. If your skin gets sore, you should stop using the GlucoWatch.

You will still need to test your blood sugars with your blood glucose meter because we are learning about how well the sensors work.

You do not have to help us test these monitors if you don't want to. If you agree to test a monitor but change your mind later, just tell us. No one will be angry with you.

If you have any questions about this, call Dr. Wilson at (650) 723-5791 and he will be happy to answer them.

Do you understand this study and are you willing to participate?

YES

NO

Signature of Child

Date



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