

INFORMED CONSENT FORM: Shared Diabetes Trial Studies

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Print or Imprint the Name of the Subject

IRB# 79111 and #11978 Panel 1

Approved on meeting date – 21 July 2009 Expires – 2 Feb 2010



STUDY

INFORMED CONSENT

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

You are invited to participate in a research study of diabetes or other pediatric endocrinology disease. You are invited as a possible participant in this study because you have **already agreed** to be in another study, but have requested that some the study procedures be done here at Stanford University. We hope to help you complete some of those procedures here. **Please note that this consent is ONLY for those particular procedures and NOT for any core study you have may have already agreed to.**

This research study is looking for 50 people with diabetes, other pediatric endocrinology disease, or a family member of someone with diabetes or other endocrinology disease. We expect to enroll 50 participants at Stanford.

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.

Because this study only includes people who have already agreed to be part of another study, we estimate only a few subjects will be involved in this study.

If you decide to participate, we will conduct one or more of the following tests:

Blood test: The blood specimen will be forwarded to the laboratory that is conducting the

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study you have already agreed and will be conduct the tests outlined in that study. This should take about 15 minutes and should involve no more that 4 tablespoons of blood (60cc).

A mixed meal tolerance test: This test is to determine the level of glucose, insulin and c-peptide of insulin in the blood in response to a specific amount of standard meal consumed. This test involves drinking a standard meal, Boost or Sustacal, and obtaining multiple blood samples before and for 2 to 4 hours after drinking the glucose. To make the blood sampling easier, we will place a small tube in the vein we are going to take blood samples from, and leave that tube in place until the end of the test.

An oral glucose tolerance test: This test is to determine the level of glucose, insulin and c-peptide of insulin in the blood in response to a specific amount of glucose consumed. This test involves drinking a syrupy liquid (glucose) over a 5-minute period, and obtaining multiple blood samples before and for 2 to 4 hours after drinking the glucose. To make the blood sampling easier, we will place a small tube in the vein we are going to take blood samples from, and leave that tube in place until the end of the test.

An iv glucose tolerance test: This test helps determine the level of insulin response by the body. This test involves administration of glucose (sugar) by vein, and obtaining multiple blood samples for up to 60 minutes after the administration of the glucose. To make the blood sampling easier, we will place a small tube in the vein we are going to take blood samples from, and leave that tube in place until the end of the test.

Although there is more than one blood draw, your child will only have one needlestick. This is done by using a sterile catheter [a kind of tube] that is left in the arm so multiple blood draws can be done without pain. Numbing cream (EMLA® or Elamax®) can be placed on your child's skin prior to the blood draw to prevent or minimize pain from this and all needlesticks as desired.

RISKS: The risks of blood drawing include: commonly the occurrence of discomfort and/or a bruise at the site of puncture; occasionally, fainting; and less commonly, infection, or the formation of a small blood clot or swelling of the vein and surrounding tissue, or bleeding at the needle puncture site.

There may be unforeseen risks while participating in this part of the study.

BENEFITS: No benefit can be promised you from participation in this study

WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE

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ANY BENEFITS FROM THIS STUDY.

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.

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

Any data that may be published in scientific journals will not reveal the identity of the subjects. **Patient information** may 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

No payment will be provided for participation in this project.

The sponsor will pay for these studies.

The National Institutes of Health (NIH), which supports the General Clinical Research Center (GCRC)s providing financial support and/or material for this study.

At the discretion of the protocol director **subjects may be taken out of this study** due to unanticipated circumstances.

Some **possible reasons for withdrawing a subject** from the study include:

- failure to follow instructions
- the investigator decides that continuation could be harmful to you
- you need treatment not allowed in the study
- the study is canceled
- other administrative reasons

1) The purpose of this research is to obtain data or information on the safety and effectiveness of intervention you have consented to in the main study; the results will be provided to the sponsor, the Food and Drug Administration and other federal agencies as required.

2) If you think you have experienced a **research related injury** call Dr Wilson at 650-723-5791.

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If you have any **questions**, we expect you to ask us. If you have any additional questions later, Dr Wilson at 650-723-5791 will be happy to answer them.

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?

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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

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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 G313 Medical Center, Stanford CA 94305-5208.

What Personal Information Will Be Used or Disclosed?

Your health information related to this study, including, but not limited to all medical information collected from or about the subject in connection with this study. The results of blood samples and related records, physical examinations, x-rays, MRI's, etc, 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 M Wilson

The Stanford University Administrative Panel on Human Subjects in Medical Research

Other members of the study team, here at Stanford University and at the other study sites and data collection centers related this study.

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 National Institutes of Health, the Food and Drug Administration, as well as other federal and state agencies as required by law

Other members of the study team at the other study sites.

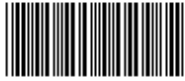
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Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will continue until 14 Jun 2095.

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 Subject

Signature of Legally Authorized Representative

Date

Description of Representative's Authority to Act for Subject

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.

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

In addition, 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, call toll free at 1-866-680-2906, or write the Stanford IRB, Administrative Panels Office, Stanford University, Stanford, CA 94305-5401

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;
- 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 rise;
- 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.

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.

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Signature of Participant

Date

(If consent is to be obtained from a legally authorized representative (e.g., parent(s), legal guardian or conservator), signature line(s) for the representative must be included on the consent form, as well as a description of his/ her authority to act for the subject.)

*Signature of Parent, Guardian or Conservator
Authority to act for participant*

Date

*(If available) Signature of Other Parent
Authority to act for participant*

Date

Signatures of both parents are requested, unless the person obtaining consent has determined that the other parent is not reasonably available.

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

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 of witness

Date