

STANFORD UNIVERSITY - Research Consent Form

Protocol Title: **The Pediatric Diabetes Consortium: Current Treatment Modalities and Clinical Outcomes in Children with Type 1 Diabetes**

Protocol Director: **Bruce Buckingham, MD**

IRB Approval Date: **7/27/09**

IRB Expiration Date: **6/30/10**

CONSENT FORM

FOR QUESTIONS ABOUT THE STUDY, CONTACT: Bruce Buckingham, MD
650-723-5791 300 Pasteur DR. Pediatric Endocrinology, RM G313 MC 5208, Stanford, CA
94305-5208

Introduction to research studies

A research study is designed to answer specific questions, sometimes about a drug's or device's safety and effectiveness. Being in a research study is different from being a patient. When you are a patient, you and your doctor have a great deal of freedom in making decisions about your health care. When you are a research participant, 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

This study is being done to learn more about type 1 diabetes. The study involves the collection of information about patients with type 1 diabetes. This information is the same information that will be collected for your medical record. Several centers in the United States are taking part in the study. It is hoped that by putting the information together from several centers we can learn whether some ways of treating type 1 diabetes are better than other ways.

First, we want you to know that taking part in this study is entirely voluntary. You may choose not to take part or you may withdraw from the study at any time without fear of penalty or loss of medical care.

Information about the Study

The study involves just the collection of information that is being collected for your medical record. This will include information related to when you developed diabetes, how it was diagnosed, and how it was treated. As time goes on, we will update the information about your diabetes and how it is being treated each time we see you. We will record information on other medical problems and medicines that you take. The information also will include the results of blood tests that we get to take care of you and the blood sugar measurements you make at home. We will record whether anyone in the family has diabetes. We may record such things as about your education level (such as whether you went to college) and your income level. You won't have to give any information that you don't want to.

Inclusion Criteria

- Age < 19 years
- Cared for at one of the participating centers from the time of their diagnosis
- Clinical diagnosis of type 1 diabetes within the past 12 months
 - Patients in whom the diagnosis of type 1 or type 2 diabetes is uncertain can be enrolled.

Exclusion Criteria

- Clinical diagnosis of type 2 or other types of diabetes



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Duration of Involvement

Your chart could be followed up to 10 years.

Procedures

You will sign this consent and then attend your normal clinic visits.

Participant Responsibilities

- You should attend your clinic visits as scheduled.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

Risks and Inconveniences

The only risk for being part of the study is the unlikely chance that your information is viewed by someone outside the research team. However, we make special efforts to make sure that this does not happen.

Confidentiality

Each subject will be assigned an identification number. All data and other information sent to the Coordinating Center will be identified with this number. Subject names and contact information will remain solely at the clinical center, where the information will be maintained to protect access from unauthorized individuals.

Benefits

You will not receive any direct benefit for being part of the study. We hope that the information we learn will help other individuals with diabetes

We cannot and do not guarantee or promise that you will receive any benefits from this study. Your decision whether or not to participate in this study will not affect your employment/medical care.

TIME INVOLVEMENT: There is no special testing for the study. There are no special office visits for the study. You will be treated the same whether or not you are in the study. The study may last for as long as 10 years.

PAYMENTS: All office visits and testing are part of your usual medical care. These costs will be your responsibility just as they would be if you were not taking part in the study.

You will not receive any compensation for being in the study.

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



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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?

This study is being done to learn more about type 1 diabetes. The study involves the collection of information about patients with type 1 diabetes. This information is the same information that will be collected for your medical record. Several centers in the United States are taking part in the study. It is hoped that by putting the information together from several centers we can learn whether some ways of treating type 1 diabetes are better than other ways.

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 contact: Bruce Buckingham, MD 650-723-5791.

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, information related to when you developed diabetes, how it was diagnosed, and how it was treated. As time goes on, we will update the information about your diabetes and how it is being treated each time we see you. We will record information on other medical problems and medicines that you take. The information also will include the results of blood tests that we get to take care of you and the blood sugar measurements you make at home. We will record whether anyone in the family has diabetes. We may record such things as about your education level (such as whether you went to college) and your income level. You won't have to give any information that you don't want to.



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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 Bruce Buckingham, MD
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

The information collected for the study will be sent to the Jaeb Center for Health Research (the study coordinating center) in Tampa, Florida along with information from all other patients in the study. This information will be identified only by a code number assigned to you. A signed copy of this consent form and the child assent form (if applicable) will be sent to the Jaeb Center. The forms will be kept in a secure file cabinet separate from the data collected for the study.

Results of the study will be reported in medical journals and may be presented at scientific meetings. However, at no time will any of the subjects in the study be identified. Confidentiality of your records will be maintained, and all records will be kept in accordance with current legal requirements.

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
- Reviewers of your health information may include representatives of the Jaeb Center and the review board that oversees studies here. If your research record is reviewed by any of these people, they also may need to review your entire medical record.

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 on December 31, 2110.

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



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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 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 representative(s) must be included on the consent form, as well as a description of his/her authority to act for the participant:

Signature of Legally Authorized Representative

Date

Description of Representative's Authority to Act for Subject

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

Your individual privacy will be maintained in all published and written data resulting from the study.

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, Bruce Buckingham, MD 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.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, Stanford, CA 94305-5401.



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The extra copy of this consent form is for you to keep.

Signature of Adult Participant

Date

When consent is obtained from legally authorized representative(s) (e.g., parent(s), guardian or conservator), include signature lines for representatives and a description of their authority to act for the participant.

Signature of Parent, Guardian or Conservator

Date

Authority to act for participant

The IRB determined that the permission of one parent is sufficient for research to be conducted under 45 CFR 46.404, in accordance with 45 CFR 46.408(b).

Signature of Other Parent

Date

Authority to act for participant

