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

Please check one of the following:

_____ You are an adult participant in this study.

_____ You are the parent or guardian granting permission for a child in this study.

Print child's name here:

_____

The following information applies to the adult participant or to the child or ward. If the participant is a child or ward, the use of "you" refers to "your child" or "your ward."

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Are you participating in any other research studies? _____ Yes _____No

PURPOSE OF RESEARCH

You are being invited to participate in this study because you are receiving care for your type 2 diabetes at our pediatric diabetes center. The study is being done to learn more about type 2 diabetes in youth. The study involves the collection of information about patients with type 2 diabetes. This information is the same information that will be collected for your medical record. Several other centers in the United States are also 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 2 diabetes are better than other ways. This study plans to enroll more than 500 members at all of the participating centers.

A company called NovoNordisk has provided funding for the study. However, the company has no involvement in the study.

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled. If you decide to terminate your participation in the study, you should notify Bruce Buckingham, MD at 650-723-5791.

INFORMATION ABOUT THE STUDY

The study involves just the collection of 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. 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. 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.

DURATION OF STUDY INVOLVEMENT

The study may last for as long as 10 years, but you can decide to stop being part of the study at any time.

PROCEDURES

If you choose to participate, you will sign this consent form and attend your normal clinic visits. Data will be collected at enrollment and at least once a year. You may be asked to complete additional follow-up questionnaires, and information may be obtained over the phone if it is not collected during a clinic visit.

RISKS AND INCONVENIENCES

There is an unlikely chance that your information may be viewed by someone outside the research team. However, we make special efforts to make sure that this does not happen.

BENEFITS

We hope that the information we get from the study will help us and others learn the best ways to treat type 2 diabetes in young people. This information might be useful to you and people like you with type 2 diabetes in the future.

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

ALTERNATIVE PROCEDURES AND TREATMENTS

You do not have to take part in this study. If you do not take part, your medical care will not be affected.

COSTS AND COMPENSATION

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.

FINANCIAL DISCLOSURE

Protocol Director Dr. Bruce Buckingham is a paid adviser to Novo Nordisk, the company whose products may be used in PDC related research protocols.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- 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.

WITHDRAWAL FROM STUDY

Your participation in this study is voluntary. If you decide to take part in the study, you can withdraw from the study at any time. If you have any doubts about this or any questions about the study now or in the future, you should speak with Dr. Bruce Buckingham at 650-723-5791 or one of the medical or research staff.

The investigator or persons overseeing this study may discontinue your participation in the study. Some possible reasons for this include:

- It is determined that you were not eligible for the study.
- The study is stopped.
- There are unanticipated circumstances.

If you leave the study early for any reason, the information that already has been collected will remain in the study database, but no further information will be collected for the study.

We hope that the study will last for 10 years. However, it could be stopped before that time.

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.

PARTICIPANT RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

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.

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. You have the right to refuse to answer particular questions.

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 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.

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.

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.

The data collected in the study will be reviewed by the staff at the Jaeb Center and the other centers where participants are enrolled. In addition, data may be provided to other researchers to use; however, the data that are provided will not contain any information that could directly identify you.

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.

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?

This study is being done to learn more about type 2 diabetes. The study involves the collection of information about patients with type 2 diabetes. 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 2 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 write to: Bruce Buckingham, 780 Welch Road, Third Floor, Palo Alto, CA 94304.

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.

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

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 people who work for this doctor's office
- The people who work for the Jaeb Center
- The scientific investigators who help run the study
- Any review board that oversees human investigations rules for your doctor's office
- Any federal agency that oversees clinical trials

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, 2028 or when the research project ends, whichever is earlier.

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 Participant Date

_____ _____
Signature of Legally Authorized Representative Date

_____
Description of Representative's Authority to Act for Subject

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, Bruce Buckingham, MD. You may contact him now or later at 650-723-5791.

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, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

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

_____ _____
Signature of Adult Participant Date

_____ _____
Signature of Parent, Guardian or Conservator Date

_____
Authority to Act for Subject

_____ _____
Signature of Other Parent or Guardian Date

_____
Authority to Act for Subject

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).