Overcoming Barriers and Obstacles to Adopting Diabetes Devices (ONBOARD) Trial (ONBOARD)

Informed Consent Form

NCT04672655

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ONBOARD
Overcoming Barriers and Obstacles to Adopting Diabetes Devices

FOR QUESTIONS ABOUT THE STUDY, CONTACT:

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Center for Academic Medicine
Division of Endocrinology & Diabetes, MC 5660
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453 Quarry Road
Palo Alto, CA 94304-5660

We are conducting this research study to provide adults with type 1 diabetes (T1D) with support for adopting continuous glucose monitoring (CGM). The duration of participation is 1 year (12 months). As a participant in the study, you will be provided 3 months of CGM supplies and asked to use them. At baseline and throughout your participation in the study, you will be asked to provide at home-hemoglobin A1c test kits and complete brief online surveys which will take up to 30 minutes to complete. In additionally, you may be randomized to participate in four 60-minute online video sessions to support your use of CGM.

Your participation is entirely voluntary. You can choose to stop participating in the study at any time point.

- The study is expected to last approximately 3 years and we plan to enroll 178 participants.
- There are few to no reasonable risks or discomforts to patients. These include a potential loss of confidentiality, physical discomfort or skin irritation from wearing a sensor.
- You may benefit from learning something new about diabetes management, however, there is no guarantee of any benefit from participating in this research study.
- The alternative to participating in this study is to not participate in the study and continue receiving the standard clinical care that you have been receiving from your healthcare provider.
- If you decide to terminate your participation in this study, please contact the investigator Dr. Molly Tanenbaum.

DESCRIPTION:

You are invited to participate in a research study on barriers to uptake of continuous glucose monitoring (CGM) in adults with type 1 diabetes (T1D). We hope to learn if an intervention, called ONBOARD, leads to sustained use of CGM and improved outcomes in adults with T1D. You were selected as a possible participant in this study because you are an adult with T1D.

If you decide to terminate your participation in this study, you should notify Molly Tanenbaum, PhD at 650-725-3955.

This research study is looking for 178 adults with T1D who have not been using CGM regularly for the past 6 months and are willing to initiate use.

You will be asked to schedule a baseline visit with a member of our research staff and asked to wear about 3 months of continuous glucose monitoring (CGM) devices while enrolled in the study. You will have the option to use Dexcom G6 or Abbott FreeStyle Libre 2. We will schedule a virtual baseline visit, and prior to the baseline visit, we will mail you CGM supplies and a home hemoglobin A1c test kit and ask you to complete an electronic survey. The baseline visit can take up to 120 minutes to complete and will take place over a secure, HIPAA-compliant, videoconferencing software. We will collect HbA1c values at baseline, 3, 6, and 12- months from baseline through mail-in kits. You will be asked to return the mail-in kits using pre-addressed, postage paid cardboard mailer packages provided by the study. At baseline, you will receive initial standard introduction and education for Dexcom G6 or Abbott FreeStyle 2 CGM system and will be asked to actively use your CGM supplies. After you have completed use of supplies provided by the research study, you may opt to continue or discontinue use of CGM. If you decide to continue, you can do so through standard clinic and insurance procedures and will be provided resources and guidance from the research team.

At end of the baseline visit, you will then be randomized, which is 50/50 and is like flipping a coin, to receive the ONBOARD program or the CGM-only group. If randomized to the CGM-only group, there will be repeat A1c test kits mailed to you and follow-up surveys for you to complete at three additional time points (3 months, 6 months, and 12 months post-baseline).

If you are randomized to receive the ONBOARD program, you will schedule 4 60-minute sessions with the study interventionist (every 2 weeks). Sessions will be conducted via a secure, HIPAA-compliant, videoconferencing software and will be recorded to ensure consistency and quality of the intervention across participants. You have the right to refuse to answer particular questions. The videoconferencing sessions may be audio and video recorded and used solely for internal use and training purposes. Video and audio tapes will be destroyed at the end of the study. ONBOARD sessions cover topics affecting CGM adoption and use including: physical and social aspects of CGM use, how to interpret and use CGM data, and how to feel comfortable trusting your CGM data. Then, there will be repeat A1c test kits mailed to you and follow-up surveys emailed to you to complete at three additional time points (3 months, 6 months and 12 months post-baseline). We will also download data from your CGM at baseline and follow-up time-points. The table below shows the study timeline:

	Baseline	Between baseline and Month 3	Month 3	Month 6	Month 12
CGM start and training on CGM use	X				
A1c home test kit	X		X	X	X
Online survey	X		X	X	X

CGM downloads	X		X	X	X
ONBOARD sessions (for ONBOARD group)		X			

You give consent for your video and audio recordings to be used for internal use and training purposes of research staff.

DEVICES:
The Dexcom G6 CGM System is an FDA approved glucose monitoring system indicated for the management of diabetes in persons age 2 years and older. The Dexcom G6 is designed to replace fingerstick blood glucose checking for diabetes treatment decisions. The FreeStyle Libre 2 Flash Glucose Monitoring System is an FDA approved continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes in persons age 4 and older. In this study, both FDA-approved devices will be used according to their labeling.

TISSUE SAMPLING:
This research will not include whole genome sequencing.

Future use of Private Information and/or Specimens
Research using private information and/or specimens is an important way to try to understand human disease. You have been given this information because the investigators want to include your tissues in a research project.

As part of this study, we will be looking at hemoglobin A1c (HbA1c), a measure of the average glucose over a 3-month period. At baseline and at 3, 6, and 12-months from baseline, we will send you a home fingerstick HbA1c kit. After collecting the sample, we will ask that you mail it to the University of Minnesota in the included packaging. There will be no cost to you for the test or for mailing it to the University of Minnesota.

Your tissues (blood) will be used to obtain the test results and will be destroyed upon completion. No samples will be saved for future research.

Your blood sample for the A1c measurement will be sent to a lab outside of Stanford for analysis.

Identifiers might be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

RISKS AND BENEFITS:

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.

You may feel some pain (like a pinprick) when the glucose sensors are placed under your skin. In very rare cases, the skin at the sensor locations can become irritated or infected. Sensor tips may break off under the skin on very rare occasions. The adhesives used to secure the CGM can sometimes cause skin irritation or allergic reactions.

Incorrect sensor glucose readings can result in incorrect diabetes management. You can take a standard or maximum acetaminophen dose of 1 gram (1,000 mg) every 6 hours and still use the G6 readings to make treatment decisions. However, taking higher than the maximum dose of acetaminophen (e.g. > 1 gram every 6 hours in adults) may affect the G6 readings and make them look higher than they really are.

The Abbott FreeStyle Libre 2 Readers use lithium-ion batteries. While lithium-ion batteries are generally safe when used properly, they may present a fire hazard if they are damaged. Some users have reported Reader issues, including battery swelling, and in rare cases extreme overheating which may pose a fire hazard. Using a charging cable or power adapter that was not included FreeStyle Libre 2 Reader may increase the risk of a fire hazard. Readers, power adapters and yellow USB cables should not be exposed to water or other liquids. The reader must be stored between -4 °F and 140 °F. Abbott has updated their user manual and more information can be found at www.FreeStyleBattery.com.

A small drop of blood will be obtained by fingerstick to measure your blood glucose and HbA1c. Pain is common at the time of lancing. In some cases, a small amount of bleeding under the skin will produce a bruise. A small scar may persist for several weeks.

Some people may be uncomfortable with researchers having access to their diabetes data or knowing about their daily diabetes habits. Some of the questions you are asked may make you uncomfortable.

The benefits which may reasonably be expected to result from this study are that it is possible that you may learn something useful for your diabetes management or use of CGM. It is possible that the glucose information from the CGM will be useful for your diabetes management. You may or may not benefit from taking part in this study.
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:
Your participation in this study will take approximately 12 months.

PAYMENTS/REIMBURSEMENTS:

You will receive up to $100 in compensation via gift cards for completion of the baseline study visit, and 3-month, 6-month and 12-month assessment time points ($25 per time point) as payment for your participation.

Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your social security number to receive payment.

Costs
There are no costs to you for participating in this study.

Sponsor
Financial support for this study comes from the NIH.

COMPENSATION for Research-Related Injury:
All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you/your child might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you/your child in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

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

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.

The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed**.**
You have the right to refuse to answer particular questions.

CERTIFICATE OF CONFIDENTIALITY:
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a

court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects
The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of harm to self or others.

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?

The purpose of this research study is to learn if ONBOARD leads to sustained use of CGM and improved outcomes in adults with type 1 diabetes. Your health information will be used to learn about how the ONBOARD intervention affects glycemic variables and how you feel about diabetes. Information from this study may be submitted to the sponsor and the FDA.

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:

Molly Tanenbaum, PhD
Center for Academic Medicine
Division of Endocrinology & Diabetes, MC 5660
Stanford University School of Medicine
453 Quarry Road
Palo Alto, CA 94304-5660

What Personal Information Will Be Obtained, 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: name, telephone number, address, date of birth, email address, medical record number, hemoglobin A1c results, continuous glucose monitor values, clinical narratives, and device identifiers/serial numbers.

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, Molly Tanenbaum, PhD
- 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 National Institutes of Health
- The Food and Drug Administration
- University of Minnesota Laboratory

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 end on December 31, 2050 or when the research project ends, whichever is earlier.

_____ _____

Signature of Adult Participant Date

_____

Print Name of Adult Participant

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.

If you decide to withdraw your consent to participate in this study, you should notify Dr. Tanenbaum at 650-725-3955.

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

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

CONTACT INFORMATION:
Questions, Concerns, or Complaints: 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. Tanenbaum. You may contact her now or later at 650-725-3955

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr. Tanenbaum at 650-725-3955.

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, 1705 El Camino Real, Palo Alto, CA 94306.

Alternate Contact: If you cannot reach the Protocol Director, please contact the study coordinator at onboardstudy@stanford.edu or (650) 498-7634.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS:

As a research participant you have the following rights. These rights include but are not limited to the participant'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 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.

May we contact you about future studies that may be of interest to you?
____ Yes ____ No

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

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent