Overcoming Barriers and Obstacles to Adopting Diabetes

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

PURPOSE OF RESEARCH

You are invited to participate in a research study about 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 20 adults with T1D who are in their first year of CGM use and 20 adults with T1D who have not been using CGM regularly for the past 6 months and are willing to initiate use.

VOLUNTARY PARTICIPATION

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.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately 3 months. Surveys will require approximately 30 minutes each to complete and ONBOARD sessions and the focus group will require approximately 1 hour each.

PROCEDURES

If you choose to participate, Dr. Tanenbaum and her research study staff will ask you to complete an online survey and schedule four videoconferencing sessions to complete ONBOARD sessions, each three weeks apart. You have the right to refuse to answer particular questions. Your blood glucose meter and CGM will be

downloaded if available. If you are not currently using CGM, we will assist you in obtaining through your health care team and health insurance plan to begin using it. If you have had a hemoglobin A1c test in the 3 months prior to enrollment in the study, we will ask you for the result or collect the result from your medical record. The survey will take around thirty minutes to complete and each ONBOARD session will last approximately one hour. After you have completed the four ONBOARD sessions, we will ask you to complete another online survey, participate in a focus group, and download your blood glucose meter and CGM. The focus group will take around one hour to complete. If you have had a hemoglobin A1c test during the course of the study, we will ask you for the result or collect it from your medical record. The videoconferencing sessions will be audio and video recorded. The focus group will be audio recorded. If you don't want to be recorded, you cannot participate in this study. The audio tapes will be transcribed and any of your identifying information will be removed from the written transcription. After the audio tapes are transcribed, they will be erased. The table below shows the study timeline.

	Baseline	Week 3	Week 6	Week 9	Week 12
Online Survey	x				x
ONBOARD Session	x	x	x	x	
Focus Group					x
Meter/CGM download	x				x
Collect HbA1c result (if available)	x				x

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.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

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

- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research staff if you believe you might be pregnant.
- Complete your surveys as instructed.
- 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

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.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

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.

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.

POTENTIAL BENEFITS

You may or may not benefit from taking part in this study. It is possible that you may learn something useful for your diabetes management or use of CGM.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

ALTERNATIVES

The alternative to participating in this study is to not participate. You can talk to your doctor about CGM use.

PARTICIPANT'S 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.

ClinicalTrials.gov

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

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law**.** However, there is always some risk that even de-identified information might be re-identified.

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.

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 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 about barriers to uptake of continuous glucose monitoring in adults with type 1 diabetes. We hope to learn if an intervention, called 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.

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
780 Welch Road
Suite CJ320
Palo Alto CA 94304

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, blood glucose/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

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, 2045 or when the research project ends, whichever is earlier.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

FINANCIAL CONSIDERATIONS

Payment/Reimbursement
You may receive up to $100 as a gift card upon completion of the study ($25 for baseline assessment; $50 for all 4 intervention sessions; $25 for completing a focus group and survey at the end of the study).

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, other than basic expenses like transportation and the personal time it will take to come to all of the study visits.

Sponsor
Financial support for this study comes from the NIH and from the Stanford Diabetes Research Center.

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 might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you 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.

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 at 650-725-3955. You should also contact 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, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

Alternate Contact: If you cannot reach the Protocol Director, please contact Sarah Hanes at 650-736-6661.

May we contact you about future studies that may be of interest to you?

Please initial:

____ Yes ____ No

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____ _____

Signature of Adult Participant Date

_____

Print Name of Adult Participant