Improving Outcomes in Pediatric Diabetes: Building the Evidence Base to Inform Effective Diabetes Technology Interventions

Informed Consent Form

NCT05488119

October 17, 2025

Please check all that are applicable:

☐ I am an adult participant in this study

Print your name here:

_____

☐ I am the parent or guardian granting permission for a child in this study (the use of "you" refers to "your child" or "your ward")

Print child's name here:

_____

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FOR QUESTIONS ABOUT THE STUDY, CONTACT: Dr. Ananta Addala, 453 Quarry Rd, Palo Alto, CA 94304, [redacted].

DESCRIPTION:

You and/or your child are invited to join a research study.

This study wants to find better ways to help youth with type 1 diabetes and public insurance (like MediCal) use diabetes technology. The goal is to see if our educational sessions help more people get and use diabetes devices like continuous glucose monitor (CGM) systems and insulin pumps. We want to learn if our sessions are helpful, and if we should offer them to other people. We also want to learn about your experiences with diabetes devices. You were invited because you/your child has type 1 diabetes and is on public insurance. We hope to have 20 families join this study—20 parents and 20 youth.

If you and/or your child choose to join, you will be asked to do the following:

- Take two short surveys (15–25 minutes each, one when you enroll and one after the last session), and
- Attend six education sessions to help you learn more about diabetes and diabetes technology.

You can do the survey online on your own device, or we can help you complete the survey over the phone.

In the surveys, we'll ask about:

- What it's like living with diabetes
- Your thoughts about using diabetes technology
- Your family relationships
- How you feel about your quality of life
- How you feel about your diabetes care team
- How you feel about our educational sessions

There will be six educational sessions in total. You'll learn about:

- Managing diabetes
- Continuous glucose monitor (CGM) systems
- Insulin pumps and automated insulin delivery (AID) systems
- Myths about diabetes
- Any other topic you'd like to learn about

The sessions will be on Zoom. Our team will help you get Zoom set up on your phone or computer. These sessions will happen weekly at a time that works for you. You will be participating with other families. We ask that you do not share anything personal said during the group outside of the session, to respect others' privacy.

You can choose how to stay in touch with us—by phone, email, or Zoom call. You may also get email reminders to finish your survey using a safe online tool called REDCap. We'll ask for your contact info to help with things like planning visits, fixing missed survey questions, and sharing reminders about survey due dates.

You give consent for your video and audio recordings to be used for future analysis and transcription. The sessions will be recorded and transcribed. The recordings will be kept for no more than 5 years and will destroyed including all copies at our earliest convenience.

If you do not wish to be audio or video recorded, you cannot participate in this study.

Future Use of Private Information
Research using private information is an important way to try to understand human disease. You are being given this information because the investigators want to save private information for future research.

Identifiers might be removed from identifiable private information and, after such removal, the information 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 and/or your child have any questions.

It is possible that, based on information gained from this study, the researchers may have serious concerns (relating to matters such as severe depression, physical abuse, suicidal ideation etc.) about you and/or your child's health and/or safety; in such a case, the researchers may contact you and provide a referral for your care.

It is possible that, based on information gained from this study, the researchers may be required to report information (e.g., information relating to suicide, physical or sexual abuse) to the appropriate authorities.

There is low but some risk of privacy/confidentiality breach. There is a low probability of data loss or disclosure that might result in the loss of participant confidentiality. We will be extremely attentive to the need to protect privacy and comply with Stanford privacy policies while conducting the study.

There is minimal, but possible risk that participating in the educational sessions will feel uncomfortable for some. While discussion during the session is encouraged, there is never a time where you and/or your child will be forced to share personal information with other participants in the group. It is possible that you and/or your child will gain improved awareness of important healthcare tasks or new technology (e.g., checking blood sugars, new pumps/CGMs), which could help improve self-care and lifestyle. We cannot and do not guarantee or promise that you and/or your child will receive any benefits from this study.

Your decision whether or not to participate in this study will not affect your and/or your child's medical care.

TIME INVOLVEMENT: This research study will last for six weeks in total. Surveys will take no more than 25 minutes to complete, and the educational sessions are 60 minutes each. So, your active participation will be around 7 hours in total.

PAYMENTS: Each family who enrolls in the study will be provided $[redacted] for each session attended, up to $[redacted], in the form of a gift card. The gift cards will be issued at the completion of the study as one payment.

Payments may only be made to U.S. citizens, legal non-citizens, and those who are in a status that allows them to receive a taxable payment from a U.S. payer. You may need to provide your social security number to receive payment.

Costs:
There is no cost to you for participating in this study, other than the personal time it will take to participate in the study activities.

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 National Institute 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.

IRB Use Only
Approval Date: October 17, 2025
Expiration Date: Does Not Expire

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 wants to find better ways to help youth with type 1 diabetes and public insurance (like MediCal) use diabetes technology. The goal is to see if our educational sessions help more people get and use diabetes devices like continuous glucose monitor (CGM) systems and insulin pumps. We want to learn if our sessions are helpful, and if we should offer them to other people. We also want to learn about your experiences with diabetes devices.

Health information will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. When publishing or presenting the results of the study, participant identities will not be revealed. The study data will only be identified by a subject number. Any patient data held by research staff—whether identifiable or not—will be held in strictest confidence, with the need for confidentiality taking precedence over considerations of economy or convenience. Research staff will use, disclose, or request protected health information to the minimum amount necessary required to perform their specific job function and to accomplish the intended research purpose.

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: Dr. Ananta Addala, 453 Quarry Rd, Palo Alto, CA 94304, or call: [redacted]

What Personal Information Will Be Obtained, Used or Disclosed?
You and your child's health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, You and your child's health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, names of parent and patient, birth date, sex, gender, language, telephone number(s), postal code or area of residence, email address, medical record number, encounter number(s), medical diagnoses, medications, history of hospitalization(s) and emergency department visits, laboratory results and other relevant physical findings, insulin regimen and diabetes device usage, diabetes device downloads, and appointment attendance data.

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 (Dr. Ananta Addala)
- 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
- National Institute 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 12/31/2050 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).

WITHDRAWAL FROM STUDY: 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.

SPONSOR:
The National Institutes of Health is providing financial support and/or material for this study.

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. Ananta Addala. You may contact them now or later [redacted]

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Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr. Ananta Addala at [redacted]

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.

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

The IRB determined that the permission of one parent is sufficient in accordance with 45 CFR 46.408(b).

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____
Print Name of LAR

_____
LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent