

T1D-CATCH Interview ORAL CONSENT SCRIPT

Hello, my name is [name], and I am from [Einstein/Montefiore] and would like to talk to you about a research study called the **Type 1 Diabetes Collaboration Around Technology with Community Health Workers (T1D-CATCH)**, which is the study that has to do with using community health workers to help young adults with type 1 diabetes (T1D) with their diabetes technology management and social needs. We are asking to interview you because you are a provider, community health worker or member of the Community Health Worker Institute who has been involved in the T1D-CATCH Study. You do not have to participate, it is your choice.

If you say yes, we will ask you to answer some questions about your experience with the T1D-CATCH study. Your responses will help us inform the study going forward, as well as help our team develop a standardized care program for young adults with type 1 diabetes. The questions will determine the study's intervention feasibility and acceptability. It will be one phone call from 20 to 30 minutes long.

You do not have to answer all the questions if you don't want and you may stop at any time.

Our team will not share your personal information with someone who is not on the study team and who is not supposed to see or know about your information. The study team plans to protect your privacy.

You will receive no direct benefit from this interview.

We will compensate you \$50 in the form of a ClinCard gift card.

We will do our best to keep your information safe by using a special code as identifier. We do plan to share the information from this study with other researchers. Your study information will be kept as long as it is useful for this research.

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. If you do not provide your verbal consent, you may not participate in the research.

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers
- Organizations and institutions involved in this research, including those that fund the research, if applicable
- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

Information from this study may be used in future research studies by our study team. Your information may also be given to other researchers (without links to your identity) for future research studies.

There are several people and groups who may see your study information in order to make sure the study is being done correctly. This includes:

- the research team and staff who work with them
- groups that review research such as the Einstein IRB, and the Office for Human Research Protections

As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study were requested or subpoenaed by government agencies or the courts, we would use the Certificate to attempt to legally refuse to provide that information. These requests are rare – in only a few cases did researchers have to use the Certificate, and it was honored most of the time, but not every time. There are several kinds of situations to which the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for review or evaluation of our research. The Certificate does not prevent you or a member of your family from voluntarily sharing information. Similarly, if an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

If you change your mind and don't want your information used for the study anymore, you can call the person in charge of this study. His/her name is Shivani Agarwal and she can be reached at **844-566-6682 x32**. Or, you can call Einstein Institutional Review Board at **718-430-2253**. They will let you know how to write to the Principal Investigator to let her know you want to stop participating. Just remember, if we have already used your information for the study, the use of that information cannot be cancelled.

Do you have any questions? You may ask me now, or contact **Shivani Agarwal** about your questions or problems with this study.

May I begin?

CONSENT TO PARTICIPATE

Printed name of participant

Date

Printed name of the person
conducting the consent process

Signature

Date