Informed Consent Form

Official Title: Application of the Telemedicine for Reach, Education, Access, and Treatment Delivery Model to Engage Emerging Adults in Diabetes Self-Management Education and Support

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UPMC | CHILDREN'S HOSPITAL OF PITTSBURGH

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TREAT-ED PILOT STUDY

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Key Information

- The purpose of this study is to evaluate a virtual, group-based diabetes self-management support program.
- This study has minimal risks.
- Your participation is completely voluntary.
- You will be asked to participate in 4 group diabetes self-management education sessions over the course of 6 months.
- You will be asked to complete 2 surveys over the course of 6 months.
- You may also be asked to complete 1 interview at the end of the study.
- You will be eligible to receive up to $250 for participating in this study.

What is the purpose of the research study? The purpose of this research study called **TREAT-ED** (**T**elemedicine for **R**each, **E**ducation, **A**ccess, **T**reatment, and Diabetes Self-Management **Ed**ucation and Support) is to evaluate a virtual, group-based diabetes self-management support program designed specifically for young adults with type 1 diabetes. Topics that are relevant to young adults with diabetes will be presented during group sessions and participants will be given an opportunity to discuss, with their peers, how the topics relate to their experiences with diabetes care and blood glucose control and learn about resources that they can access to help with their self-management and transfer to and navigating adult care.

How does this research study work? You are being invited to participate in this study because you are an 18-26 year old patient with type 1 diabetes receiving care at UPMC.

As part of this study, you will be asked to complete 2 surveys. The surveys include questions about your diabetes such as how you feel about having diabetes, factors that may affect how you manage your diabetes now and in the future, and your experiences with your diabetes care. Each survey takes about 15-30 minutes to complete. If you decide you want to participate in this study you will complete the first survey after you sign this consent form and the second survey approximately 6 months later. The surveys will be completed electronically. You will receive a link through email or text to access the

surveys. You can alert a member of the research team if you would prefer to complete a hard copy of the survey or have a research team member administer the survey to you.

You will be asked to participate in 4 group sessions over the course of 4-6 months. Each session will last 30-45 minutes and will be conducted over Zoom. Groups will include up to 8 young adults and be led by a research-trained diabetes care and education specialist. You will be provided with expectations about participating in the group sessions, such as joining on time, staying for the duration of the session, and participating in a private location. The sessions will be audio recorded, but any identifiers will be removed and replaced with study IDs when transcribed. Prior to the sessions, a study team member will help ensure that Zoom is correctly installed on the device that you will use to join the group session. A study team member will also work with participants to arrange groups that can schedule sessions to occur at times that are convenient to all members.

At the end of the study, you may also be asked to participate in an interview (approximately 6 months after enrolling in the study). The purpose of the interview it to learn about your experiences participating in the study, including getting started, completing the survey, participating in group sessions, and any recommendations you have for this type of program in the future. The interview will be conducted by a trained researcher via Zoom and last about 60 minutes. Like the group sessions, the interviews will be audio recorded and any identifiers will be removed and replaced with study IDs when transcribed.

For communication purposes, you will be asked to provide your preferred method(s) of contact such as email, text message, telephone to receive study notifications and reminders.

Will you be collecting any identifiable medical information? We are also requesting your authorization or permission to review your medical records to gather information about your diabetes management from the past year and while you are participating in this study. We may obtain information about the following: demographic information, diagnoses, vital signs, prescriptions, diagnostic procedures, results from routine blood work, CGM reports, hypo/hyperglycemic events, diabetic ketoacidosis episodes, and visits with diabetes providers. This identifiable medical record information will be made available to members of the research team for an indefinite period of time. As part of this research study, some information that we obtain from you will be placed into your medical records, including that you are participating in this study. We will protect your privacy and the confidentiality of your research records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University. This authorization is valid for an indefinite period of time. However, you can always withdraw your authorization to allow the research team to review your medical records by contacting the principal investigator listed on the first page of this form and making the request in writing. If you withdraw, you will no longer be permitted to participate in this study. Any information obtained from you up to this point will continue to be used by the research team.

What are the possible risks and discomforts of this study? There is little risk involved with this study. There is no known physical risk and no invasive procedures are included. Participation in this study does involve the potential risk of minor psychological or emotional distress, but the study team has attempted to minimize the possibility of this risk. In addition, there is a rare risk of a breach of confidentiality (privacy). We will do everything possible to protect your privacy, but confidentiality during Internet and text messaging communication activities cannot be guaranteed, and it is possible that additional information beyond that collected for research purposes may be captured and used by

others not associated with this study. To reduce the chances of a breach of confidentiality, all researchers have been trained to protect your privacy.

Will I benefit from taking part in this study? There is no guarantee that you will directly benefit from this research study, but you may learn ways to better manage your diabetes during this time in your life by having more information about factors that impact diabetes management during young adulthood and how blood sugar levels relate to daily behaviors. The information presented in the sessions may also help with transfer to and navigating adult care.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study? Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed only for the purposes of this research study. You will be charged in the usual manner for any procedures performed as part of your standard medical care (care you would receive even if you were not participating in this research study).

How much will I be paid if I complete this study? If you agree to participate in this research study, you may receive up to $250. The study team will discuss payment options with you. You will receive:

- $50 for each survey (two surveys total) you complete at the beginning and end of the study
- $25 for each group session you complete during the study
- $50 if you are selected and complete an interview at the end of the study.

Payment to participants is considered taxable income regardless of the amount. A member of the study team will ask you for some personal information including your address and social security number. This information will be used for tax purposes only. All payments received for participating in a research study are taxable income, regardless of the amount. If a participant is paid $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and give a copy to the taxpayer. If you don't want to share your social security number, we will pay you a lesser amount with 24% income tax withheld. So, you would only receive 76% of the expected payment.

Will anyone know that I am taking part in this study? All records related to your being in this study are kept strictly confidential (private). Any information that includes your identity will be stored in locked files. Your identity will not be revealed in any description or publication of this research. While we may alert your diabetes providers that you are participating in this study, results will not be shared with your health care providers who are not part of the research team and will not affect your current or future medical care at any UPMC facility.

It is possible that, in addition to the study investigators listed on the first page of this form and their study team, authorized representatives from the University of Pittsburgh Office of Research Protections, and the study sponsor from the National Institutes of Health may review your identifiable data for the purpose of ensuring the appropriate conduct of this study. In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn you or someone with whom you are involved is in serious danger or harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results.

This website can be searched at any time. In addition, de-identified information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

To help further protect your privacy, this study is operating under a Certificate of Confidentiality granted by National Institutes of Health (NIH). This means that the study investigators and personnel are authorized by the NIH to protect the privacy of research subjects and may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify them by name or other identifying characteristic, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the U.S. Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). The protection afforded by the Certificate is permanent. All personally identifiable information maintained about participants in the project while the Certificate is in effect is protected in perpetuity. Research subjects may voluntarily disclose their research data or information. Subjects may disclose information to physicians or other third parties. They may also authorize in writing the investigator to release the information to insurers, employers, or other third parties. In such cases, researchers may not use the Certificate to refuse disclosure. Moreover, researchers are not prevented from the voluntary disclosure of matters such as child abuse, reportable communicable diseases, or subject's threatened violence to self or others.

At some point, de-identified information and/or biospecimens, if collected as part of a study, may be used by other researchers for future research studies. If this happens, we will not contact you for additional consent.

What are the alternatives to participating in this study? Your doctor may be involved as an investigator in this research study. Before agreeing to participate, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not obligated to be a part of any research study offered by your doctor or other staff member at the clinic where you receive care. You may choose not to be in this study and continue your current/usual care for diabetes.

May I withdraw, at a future date, my permission for participation in this research study? Yes. To do so, you can contact the Principal Investigator of this study, Dr. Ingrid Libman (see email listed above). Your participation is completely voluntary. Your decision whether or not to participate in this research, or to later withdraw from it, will not affect your current or future medical care at UPMC or your relationship with the University of Pittsburgh. If you withdraw, any information collected about you up until the time you withdraw will be kept, though no additional information will be collected if you withdraw. Per University of Pittsburgh policy all research records must be maintained for at least 7 years following final reporting or publication of a project. Records may be kept indefinitely. The Principal Investigator may also choose to withdraw a participant from the study without their consent. Circumstances that could lead to this type of withdrawal include suspension or cancellation of the study; the participants ceases or transfers care from UPMC; the participants is put in jail or placed on parole while taking part in the study; the participant is not cooperative during study sessions or exhibits any threatening, violent, or harassing behavior toward study staff or other participants; or if the study team thinks it will be in the participant's best interest not to be in the study. If you have any questions about your rights as a research participant, you may call the Human Subjects Protection Advocate of the Institutional Review Board at the University of Pittsburgh (1-866-212-2668).

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SUBJECT'S CERTIFICATION

- I have read the consent form for this study and any questions I had, including explanation of all terminology, have been answered to my satisfaction. A copy of this consent form will be provided to me.
- I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that those questions will be answered by the researchers listed on the beginning of this form.
- I understand that my participation in this study is voluntary and that I am free to refuse to participate or to withdraw my consent and discontinue my participation in this study at any time without affecting my future relationship with this institution.
- By signing this form, I consent to participate in this research study and provide my authorization to share my medical records with the research team.

_____ _____

Subject's Printed Name Date

_____

Subject's Signature

INVESTIGATOR'S (OR DESIGNEE'S) CERTIFICATION

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of the Person Obtaining Consent Date