CONSENT TO TAKE PART IN RESEARCH

Dartmouth Hitchcock

Title: Digital SMD - Developing Digital Tools for Improved Self-Management of Diabetes
Principal Investigator: Temiloluwa Prioleau

You are being asked to take part in a research study. Taking part in research is voluntary.

Your decision whether or not to take part will have no effect on the quality of your medical care. Please ask questions if there is anything about this study that you do not understand.

What is the purpose of this study?

This project aims to study diabetes related data with the goal of identifying patterns that could influence health outcomes and understanding connections between diabetes events and the circumstances in which they occur. This information will be used to develop and test solutions that can support people with daily management of their diabetes.

You can find more details here: https://www.t-prioleau.com/research.html

Will you benefit from taking part in this study?

There is little chance you will personally benefit from being in this research study.

What does this study involve?

Your participation in this study may last up to 1-hour. Upon receiving your consent to participate, you will be asked to:

1. Fill out a survey to tell us about yourself and how you manage diabetes.
2. Allow us **one-time** access to your diabetes-related medical record
3. Give us **one-time** access to your diabetes-device data (continuous glucose monitor & insulin pump)

What are the options if you do not want to take part in this study?

You can choose not to participate in this study and continue care as usual.

If you take part in this study, what activities will be done only for research purposes?

Requesting for you to fill out a questionnaire/survey, accessing your medical record, and uploading your diabetes-device data to a research platform called Tidepool (https://www.tidepool.org/) are the only activities that will be done only for research purposes. It is important to note that the selected research platform is approved by the Dartmouth-Hitchcock Information Systems (IS) Security department. This platform is used solely to get the raw data from the diabetes-devices for analysis.

What are the risks involved with being enrolled in this study?

Participating in this study presents a risk to your confidentiality. This risk will be minimized by deidentifying all data collected such that the data does not contain information that can be

connected to subjects. Additionally, research findings will be presented on the aggregated data and/or using randomly assigned subject number (e.g. subject 5).

Will my data be deidentified and used in the future for other purposes?
Your data will be stripped of identifiers (i.e. name and diabetes device serial number) and may be used for future research.

Other important items you should know:
• **Leaving the study:** You may choose to stop taking part in this study at any time. If you decide to stop taking part, it will have no effect on the quality of medical care you receive.

• **Number of people in this study:** We expect 50 people to enroll in this study here.

• **Funding:** There is no outside funding for this research project.

• **Product Development:** If the results of this research are used to develop a product sold for a profit, you will not share in the profit.

How will your privacy be protected?
The information collected about you as data for this study includes:

1. Self-report responses to survey questions about management behavior
2. Demographic data (i.e. birth year, gender, ethnicity, etc.)
3. Diabetes-related medical record including biomarkers including hemoglobin A1C, cholesterol, and urine microalbumin
4. Diabetes-device data (i.e. continuous glucose monitor (CGM) and insulin pump data)

The data collected will be maintained for the lifespan of the research project or indefinitely.

We are careful to protect the identities of the people in this study. Device identifiers and serial numbers which are protected health information will be removed and deleted from the dataset. We also keep the information collected for this study secure and confidential. Physical safeguards include locking the office and file cabinets with hard-copies of research documentation/data. Administrative safeguards include using random number coding of electronic research data and storing them on password-protected computers.

Who may use or see your health information?

By signing this form, you allow the research team to use your health information and give it to others involved in the research. The research team includes the study director plus others working on this study at Dartmouth-Hitchcock Medical Center and elsewhere. You also permit any health care provider holding health information needed for this study to give copies of your information to the research team.

The information collected for this study may be used by researchers or officials of the following institutions.

- Dartmouth College
- Dartmouth-Hitchcock Medical Center

In order to conduct this study, researchers need to use your health care information. This data is called Protected Health Information ("PHI"). PHI is protected by federal privacy laws (HIPAA). By signing this consent form, you give your permission to have your PHI collected, used and disclosed for purposes of this study. There is no intention to disclose your PHI to others outside of the study. There are protections in place to keep your PHI and research data confidential. However, HIPAA requires notification so you are aware *if your* PHI is disclosed to others, it may no longer be protected by federal privacy laws.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Identifiable data collected for this study will be used for research purposes which are determined to be reasonable and in line with expectations by a review committee. Once data collected for this research study is no longer identifiable, the data may be used or disclosed for other purposes.

Your permission to use your health information for this study will not end until the study is completed. During this study, you and others who take part in the study may not have access to the study data. You may ask for study data once the study is over. You have a right to receive a copy of the information in your medical record at any time.

It is possible for a court or government official to order the release of study data including information about you.

What if you decide not to give permission to use and share your personal health information?

If you do not allow use of your health information for this study, you may not take part in this study.

If you choose to stop taking part in this study, you may cancel permission for the use of your health information. You should let the researcher know if you want to cancel your permission. The study team will assist you in putting your wishes in writing. Information collected for the study before your permission is cancelled will continue to be used in the research.

What about the costs of this study?

There is no cost to you to partake in this study.

Will you be paid to take part in this study?

No. There is no payment associated with participating in this study.

Whom should you call with questions about this study?

If you have questions about this study or concerns about a research related problem or injury, you can call the research director for this study: Dr. Temiloluwa Prioleau at 603 646-8730 during normal business hours.

If you have questions, concerns, complaints, or suggestions about human research, you may call the Dartmouth-Hitchcock Health Institutional Review Board (D-HH IRB) at (603) 650-1846 or irb@hitchcock.org.

CONSENT

I have read the above information about **Digital SMD - Developing Digital Tools for Improved Self-Management of Diabetes** and have been given time to ask questions. I agree to take part in this study and I will be given a copy of this signed consent form.

Participant's Signature and Date PRINTED NAME

Researcher or Designee Signature and Date PRINTED NAME