

Usability of Diabetes Dashboard Embedded Within a Patient Web Portal: A Prospective  
Longitudinal Study

NCT03786718

Informed Consent Document

December 13, 2018

# Informed Consent Document

Institutional Review Board

Informed Consent Document for Research

Principal Investigator: William Martinez, MD, MS Revision Date: December 13, 2018

Study Title: Longitudinal Usability of a Diabetes Dashboard Embedded within My Health At Vanderbilt

Institution/Hospital: Vanderbilt University Medical Center

This informed consent document applies to adults who are 21 years old or older

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Your participation in this research study is voluntary. You may choose not to participate and receive alternative treatments without affecting your healthcare/services or other rights. You are also free to withdraw from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to participate in it, you will be notified so that you can make an informed decision whether or not to continue your participation in this study.

## 1. Purpose of the study:

The purpose of the study is find out what patients think about a potential new feature within My Health At Vanderbilt for patients with diabetes and how patients might use the new feature. The new feature is a diabetes dashboard embedded in My Health At Vanderbilt (aka, the patient portal) that displays information about the patient's condition and provides resources to help patients understand and manage their diabetes. The dashboard allows participants to view their diabetes health data (A1C, blood pressure, cholesterol, and flu shot status) compared to goal status and compared to patients who are similar to them (same age group, same gender, same medications).

You are being asked to participate in a research study because you receive care at Vanderbilt University Medical Center (VUMC) and have type 2 diabetes.

## 2. Procedures to be followed and approximate duration of the study:

The study will last approximately 1 month.

At the start and prior to providing you access to the diabetes dashboard within My Health At Vanderbilt, we will ask you to complete a study questionnaire about your background and your knowledge, attitudes, and experiences with diabetes. This questionnaire will take about 20 to 30 minutes to complete.

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After completing the questionnaire, you will be given the access to your diabetes dashboard within My Health At Vanderbilt. You will have access to the dashboard for 1 month. You will be asked to use the dashboard for a minimum of 10 minutes during the 1 month. However, you can view and use the dashboard whenever you want for as long as you want during your 1 month of dashboard access. We will track how often you view the dashboard and what features you use.

At the end of the 1 month, you will be asked to complete a final questionnaire about your experience using the diabetes dashboard and the changes in your knowledge, attitudes, and experiences with diabetes. This questionnaire will take about 15 to 25 minutes to complete. In addition, some participants will also be asked to complete an interview with a member of the study staff. The interview will last about 30 minutes. The interview will be audio recorded and can either be done over the phone or in person. We will transcribe the recordings and study the transcripts to learn more about how we can improve the dashboard.

Authorized study personnel will retrieve the following information about you from your VUMC medical record: a list of your current and past medical problems, list of medications you have been prescribed, your vaccination history, and the date and value of your most recent diabetes related lab tests such as your blood sugar, blood pressure, kidney function, and cholesterol and your most recent diabetes-related eye test and foot exam. This information will be collected so that we can describe the health status and medical history of the people we interview.

### 3. Expected costs

There are no costs to participating in this project. However, you will need access to a desktop computer with internet access. You will NOT receive compensation for costs associated with computer use or internet access.

### 4. Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

The time it takes to participate may be inconvenient for some patients. Some patients may feel discouraged or upset to learn that some measures of their health (like A1C, blood pressure, or cholesterol) are worse than the recommended goal or worse than other patients who are similar to them (same age group, same gender, same medications). There is a risk of loss of confidentiality. All efforts, within reason, will be made to keep your personal information in your research record confidential. Some people might feel uncomfortable giving their opinions and providing feedback. Some may feel uncomfortable with the audio recording of the interview. You do not have to answer any question you do not want to answer. You may also stop the interview at any time should you feel uncomfortable.

### 5. Unforeseeable risks:

Because this diabetes dashboard is investigational, there may be unknown or unforeseeable risks associated with participation.

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6. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study.

The potential benefits from your participation may be helping the study investigators create tools to improve the health of patients with diabetes.

b) The benefits you might get from being in this study.

The educational features of the diabetes dashboard may improve your understanding of your health data (A1C, cholesterol, blood pressure, flu shot status) and of how to best manage your diabetes.

7. Compensation for participation:

Participants can receive \$40 for completing the questionnaire at the start of the study, \$5 for using the dashboard for at least 10 minutes during the study period (1 month), and \$35 for completing the questionnaire at end of study. Some participants will be invited to do an interview after they have completed the questionnaire at the end of the study. Participants who complete the interview will receive an additional \$40. After each questionnaire and interview, you will be asked to fill out a Request for Payment to Volunteer Subjects form and a check will be mailed to your home address.

8. Circumstances under which the Principal Investigator may withdraw you from study participation:

You may be withdrawn from the study if you: (1) do not complete the enrollment questionnaire within two weeks of signing this consent form, (2) do not use the diabetes dashboard for at least 10 minutes within My Health At Vanderbilt during the study period, or (3) do not complete the final questionnaire within two weeks from the last day you are provided dashboard access. If you are withdrawn from the study for any reason, you will be notified and a reason will be provided.

9. What happens if you choose to withdraw from study participation?

You can withdraw from the study at any time by contacting the study team listed on the consent form. If you withdraw from the study, we will delete your study questionnaire and delete any audio recording of your interview and we will not use any of it in our research. Withdrawing from the study will not affect your medical care at Vanderbilt.

10. Contact Information.

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If you should have any questions about this research study or possibly injury, please feel free to contact William Martinez, MD, MS at 615-933-3645 or email the study team at [DDS@VUMC.org](mailto:DDS@VUMC.org).

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For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

#### 11. Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. We will have a record of your name on this form. We will not record your name on the study questionnaire transcripts of the interviews, health data we retrieve from your medical record, or diabetes dashboard usage data we collect for your My Health At Vanderbilt account. Instead, we will identify each participant with a number (e.g., participant 1, participant 2). A document linking the participant number to a name will be stored separately on a password-protected computer and accessible only to the principal investigator and study coordinator. Any audio files will be deleted from recording devices after transcription is complete. Audio files and transcripts will be uploaded and stored on password protected, computer servers Vanderbilt University Medical Center. When we report the results of this work, we may include quotations from participants. We will never give the name or any other identifying information of the person we are quoting.

#### 12. Privacy:

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Vanderbilt University Medical Center may share the results of your study and/or non-study linked questionnaire and interview responses, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the VUMC Institutional Review Board, Vanderbilt University, and National Institutes of Health. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The sponsor and/or Vanderbilt may give or sell your health data, without identifiers, to others or use it for other research projects not listed in this form. The sponsor, Vanderbilt, Dr. William Martinez (Principal Investigator) and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

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The study results will be kept in your research record for at least six years after the study is finished. At that time,

the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will also be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. William Martinez in writing and let him know that you withdraw your consent. His mailing address is Vanderbilt University Medical Center, Division of General Internal Medicine, 2525 West End Avenue, Suite 450, Nashville TN 37203. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

If I participate in a study interview, I agree to have the interview be audio-recorded?

- ☐ Yes
- ☐ No

I have read and understood the consent document, and I voluntarily accept to participate in this study.

- ☐ Yes
- ☐ No

Please sign below to indicate that you read and understood the consent document, and that you voluntarily accept to participate in this study.

\_\_\_\_\_

Please print your FIRST name:

\_\_\_\_\_

Please print your LAST name:

\_\_\_\_\_

Please provide your date of birth:

\_\_\_\_\_

Please provide us with your phone number so we can contact you:

\_\_\_\_\_

Please provide us with your email address so that we can contact you:

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Thank you for your interest in this research study.

You can download or print a copy of your consent form on the next screen and keep it for your records.

We will contact you within one week to complete the study enrollment questionnaire and provide you with dashboard access.

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