ICF for: REDD-CAT (Re-Engineered Discharge for Diabetes Computer Adaptive Test) Pilot study

Principal Investigator: Suzanne Mitchell, MD

ClinicalTrials.gov: NCT03889600

Date: 3/10/2021

BMC and BU Medical Campus IRB
IRB NUMBER: H-38545
IRB APPROVAL DATE: 03/10/2021

RESEARCH CONSENT FORM
Pilot- Subject Verbal Consent

Basic Information

Title of Project: REDD-CAT Pilot

IRB Number: H-38545

Sponsor: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Principal Investigator: Suzanne Mitchell, MD
Study contact: alexa.bragg@bmc.org
Boston Medical Center, Dowling 5 North; 771 Albany St.; Boston, MA 02118
Study Phone Number: 617-414-6349

Overview

We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to join the study. We are doing the research to test a computer-based screening system called the Re-engineered Discharge for Diabetes – Computer Adaptive Test (REDD-CAT system). The REDD-CAT system will be used to help screen people with Type 2 Diabetes for social needs that may put them at an increased risk of being admitted or readmitted to the hospital and/or visiting the emergency room. If you agree, you will be asked to help us test the screening tool by answering questions about personal, social, and community factors that may affect you and your health.

Your active participation in the study will end once you complete the survey. You will find more information about what will happen in this study later in this form.

The main risks of being in the study are the possibility of feeling uncomfortable when answering some of the questions, as well as the potential of loss of confidentiality. You will find more information about risks later in this form.

Purpose

The purpose of the REDD-CAT (Re-Engineered Discharge for Diabetes Computer Adaptive Test) Pilot study is to test a newly developed screening tool to identify the social needs of patients with Type 2 Diabetes. From previous research, we know that social needs put patients at increased risk of becoming hospitalized or visiting the emergency room. In the portion of the study you are being invited to

participate in, we will use the responses of patients like you to help us design a larger study of the screening tool.

What Will Happen in This Research Study

In this study, we will ask you to respond to questions about personal, social, community, and societal factors that have the potential to impact your health. These questions will be asked either over the telephone, in person by a member of our research team, or via a secure link sent to your email address. If we are in person and you are comfortable using a computer you may choose to read the questions for yourself, otherwise the questions can be read to you.

We will ask you for some demographic information before we ask the survey questions.

Answering all of the questions will probably take you about 30 minutes.

If you are admitted to the hospital while you complete this survey, we will also review your medical record data for information about your health history. We will look at clinical values (i.e. hemoglobin A1c values, cholesterol, triglycerides, creatinine), other medical conditions you have, medications, insurance type, and number of ER visits and hospital admissions. We will review what is in your medical record for the time period starting 6 months before you enroll and for the 30 days after you leave the hospital. If you are not admitted to the hospital while you complete this survey, we will not collect this information.

The ways we will protect your privacy and confidentiality are described in a separate section later in this form.

You will be one of up to 30 people who will be asked to be in the study.

Risks and Discomforts

You might experience mental or emotional discomfort while participating in the study. You might feel uncomfortable answering questions that ask about your health and about social factors in your life. You do not have to answer any question that you do not wish to, and you have the option of withdrawing from the study at any time.

Potential Benefits

You will receive no direct benefit from being in this study. The primary goal of this research is to collect information about the scientific questions asked in this study. Your being in this study may help the investigators learn what social factors put people at the highest risk of being hospitalized.

Costs

There are no costs to you for being in this research study.

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Payment

You will receive $50 on a ClinCard (which is like a pre-paid credit card) for completing the survey.

Confidentiality

We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. However, we cannot guarantee complete confidentiality.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information are covered by a CoC**.** The CoC provides how we can share research information. Because we have a CoC, we cannot give out research information that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information.

If you agree to be in the study and sign this form, we will share information that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- Any people who you give us separate permission to share your information.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

Use and Sharing of Your Health Information

The research team has to use and share your health information to do this study, including information that may identify you. By agreeing to be in this study and signing this form, you are giving us your permission where needed to use and share your health information as described in this form.

Health information that might be used or shared during this research includes:

- Information that is in your hospital or office health records. The records we will use or share are those related to the aims, conduct, and monitoring of the research study.
- Health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

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The reasons that your health information might be used or shared with others are:

- To do the research described here.
- To make sure we do the research according to certain standards set by ethics, law, and quality groups.
- To comply with laws and regulations. This includes safety-related information.

The people and groups that may use or share your health information are:

- Researchers involved in this research study from Boston Medical Center, Boston University, and/or other organizations
- Other people within Boston Medical Center and Boston University who may need to access your health information to do their jobs such as for treatment, research administration, payment, billing, or health care operations
- People or groups that the researchers use to help conduct the study or to provide oversight for the study
- The Institutional Review Board that oversees the research and other people or groups that are part of the Human Research Protection Program that oversees the research
- Research monitors, reviewers, or accreditation agencies and other people or groups that oversee research information and the safety of the study
- The sponsor(s) of the research study, listed on the first page, and people or groups they hire to help them do the research

We ask anyone who gets your health information from us to protect the privacy of your information. However, we cannot control how they may use or share your health information. We cannot promise that they will keep it completely private.

The time period for using or sharing your health information:

- Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your privacy rights are:

- You have the right not to sign this form that allows us to use and share your health information for research. If you do not sign this form, you cannot be in the research. This is because we need to use the health information to do the research. Your decision not to sign the form will not affect any treatment, health care, enrollment in health plans, or eligibility for benefits.
- You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the Principal Investigator at the address listed on the first page of this form. If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality. If you withdraw your permission, you cannot continue to be in the study.
- When the study has been completed for everyone, you have the right to request access to the health information that we used or shared to make your treatment or payment decisions. If you ask for research information that is not in your medical record, we might not give it to you, but we will explain why not. You may use the contact information on the first page of this form to find out how to get your health information. You may also contact the HIPAA Privacy Officer at Boston Medical Center at DG-privacyofficer@bmc.org.

Re-Contact

We would like to ask your permission to contact you again in the future. This contact would be after the study has ended. *The participant will verbally indicate their preferred answer choice, which will be documented by the research staff conducting verbal consent.*

____Yes_____No You may contact me again to ask for additional information related to this study

____Yes_____No You may contact me again to let me know about a different research study

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be mailed a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

We may decide to have you stop being in the study even if you want to stay. Some reasons this could happen are if staying in the study may be bad for you, or if the study is stopped.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact Alexa Bragg at 617-414-6349. Also call if you need to report an injury while being in this research.

You may also call 617-358-5372 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

By agreeing to be in this research, you are indicating that you have read this form (or it has been read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study.