Cover page – Informed Consent Document

Date of document: 9/23/2021

Clinical Trial registry number: NCT05229718

Title: UNDERSTANDING AND OPTIMIZING CARE FOR YOUNG ADULTS WITH TYPE 1 AND TYPE 2 DIABETES MELLITUS TRANSITIONING TO THE ADULT DIABETES CARE SETTING

Date: 9/23/2021
Trial registry number: NCT05229718

UNDERSTANDING AND OPTIMIZING CARE FOR YOUNG ADULTS WITH TYPE 1 AND TYPE 2 DIABETES MELLITUS TRANSITIONING TO THE ADULT DIABETES CARE SETTING

Thank you for your interest in this research study. Please read the information below, and if you agree to participate, you can start the survey. The survey is estimated to take less than 10 minutes.

The purpose of this research study is to understand the different challenges young adults with diabetes face when taking care of their diabetes. We also want to learn what the clinic and the doctors can do better to help young adults with diabetes feel more supported and confident with their diabetes care.

We are asking patients who are (1) between the ages of 18 and 30 years old with type 1 or type 2 diabetes mellitus; (2) are new to the MGH Diabetes Center as of September 1, 2021; (3) self-manage their diabetes; and (4) are not currently pregnant, to be part of this study. We hope to enroll at least 50 patients into the study.

WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?
You will be asked to complete this survey, and two more surveys over the course of 9 months. Each survey should take less than 10 minutes to complete. The surveys can be completed online, or if you prefer, you can complete it by telephone, secure Zoom videoconferencing, or a paper version by mail. The surveys will ask about:

- Your age, race, ethnicity, gender, and schooling
- How often you experience certain symptoms related to your mental health
- Your experiences with your diabetes care

We will also review your hospital medical record for demographic information, number of office visits you attend, and results of blood work that your diabetes doctor orders (like your HbA1c). We may contact you by phone, mail, or Patient Gateway after completion of the surveys to see if you would be interested in taking part in an interview portion of this study. We hope to interview up to a total of 10 subjects. If you complete the survey portion of this study, you do not have to take part in the interview portion if you don't want to.

Participation in this study is completely voluntary. Even if you initially agree, you may stop taking part in this study at any time. Deciding not to participate will not affect medical care you receive at the MGH Diabetes Center or Mass General Brigham now or in the future, or any benefits you receive now or have a right to receive.

WHAT ARE THE RISKS AND BENEFITS OF THE STUDY?
Fatigue or discomfort may arise from answering the survey which may create a degree of inconvenience or emotional upset. After completing the survey, you may become more aware of your feelings regarding your own diabetes self-management or mental health, which could be discomforting. You may choose to stop the survey at any time if they feel uncomfortable.

Please note that your survey answers will not be shared with your diabetes care team. However, you may contact your diabetes care team and share your responses to the survey if you would like them to help with any symptoms or questions you may have about your mental health or diabetes care.
There is no direct benefit to you by taking part in this study, but your participation will help us improve our approach to diabetes care for patients like you.

WILL MY HEALTH INFORMATION STAY CONFIDENTIAL?
If you participate in this study, we will remove all information that identifies you (for example, name, medical record number, and date of birth), and assign you an anonymous ID. The information we get about you from your survey responses and medical record will be linked to this anonymous ID so that it won't be possible to link any information back to you. Your de-identified information will not be used or shared with other researchers. While the research team will make every effort to securely protect your data, there is a risk that confidentiality could be breached.

We are required by the Health Insurance Portability and Accountability Act (HIPAA) to protect the privacy of health information obtained for research. This is an abbreviated notice, and does not describe all details of this requirement. During this study, identifiable information about you or your health will be collected and shared with the researchers conducting the research. In general, under federal law, identifiable health information is private. However, there are exceptions to this rule. In some cases, others may see your identifiable health information for purposes of research oversight, quality control, public health and safety, or law enforcement. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy.

WHAT DO I DO IF I HAVE QUESTIONS OR PROBLEMS?
If you have any questions about this study, please contact one of the study investigators, Janaki Vakharia, MD at jvakharia@mgh.harvard.edu. In addition, you may contact the Principal Investigator for this project, Deborah Wexler, MD at 617-726-8767. If you would like to speak with someone **not** directly involved in this research study, or any concerns or complaints you may have about the research, you can contact the Human Research Committee number for your Center at (857) 282-1900.

Thank you very much for your participation.