Study Title: User Evaluation of the Guide To Goals Application - a Care Coordination Tool to Translate ADA Clinical Standards of Care for Children with T2D into Practice

Document Title: Adult Consent Form (version 2)

NCT: NCT03926598

Document Approval Date: 04/01/2020

CONSENT DOCUMENT FOR ENROLLING ADULT PARTICIPANTS IN A RESEARCH STUDY

Georgia Institute of Technology

User Evaluation of the Guide To Goals Application - a Care Coordination Tool to Translate ADA Clinical Standards of Care for Children with T2D into Practice

Principal Investigator: Dr. Jiten Chhabra

You are being asked to be a volunteer in a research study.

Purpose:

The purpose of this study is to understand whether a computer application developed by Georgia Tech researchers for patients, families and caregivers of children with Type 2 Diabetes called Guide-To-Goals is easy to use or not. Results from this study will help researchers make this application better. You may quit at any time during the study if you want to. We expect to include 10 people in the study.

Exclusion/Inclusion Criteria:

In this study we will be including participants who are over the age of 12 and are from the following categories:

1. Existing patients of Childrens Healthcare of Atlanta (CHOA) with Type 2 Diabetes or caretakers of existing patients of CHOA with Type 2 Diabetes – 2 participants
2. Front desk staff at CHOA – 2 participants
3. Nurses at CHOA – 2 participants
4. Certified Diabetes Educators at CHOA – 2 participants
5. Physicians working at CHOA – 2 participants

Participants must also be fluent in English, either as a first or secondary language, as the Guide-To-Goals app is in English.

Individuals that are using a care coordination tool other than GTG to translate ADA clinical standards of care for children with Type 2 Diabetes during the study period will be excluded from this study in order to avoid confounding factors. Examples of care coordination tools include products that have the capabilities to send and receive electronic messages to the care team, receive and discuss care plans, and create and share health logs.

Procedures:

If you decide to be in this study, you will join a usability testing session to view the Guide-To-Goals application and provide feedback through discussion. The app will be made available to you on an Ipad provided to you by the research team for the duration of the session. Written data notes will be recorded during the session. Your anonymized feedback will be sent through a secure server to researchers. This data includes your age and gender and data generated by you while using the Guide-To-Goals app. This data also includes your comments and discussions with the research team during the usability testing session.

The structure of the usability session will be as follows:
1. Introduction to study team and session procedures with the help of the consent form (15 minutes)
2. Perform a set of specified tasks on the GTG application (15 minutes)
3. Post task interview with study team (15 minutes)
4. Fill out post-interview questionnaire (15 minutes)

Total duration of entire will not exceed an hour. If you choose to not be in the usability testing session you may stop at any time for any reason.

Risks or Discomforts:

Participation in this study involves minimal risk or discomfort to you. Risks are minimal and are not more than

those associated with viewing images on a screen. If at any time during the use of the app you feel uncomfortable and want to stop, you are free to do so.

Benefits:
You are not likely to benefit in any way from joining this study. This study will help researchers understand how to make the Guide-To-Goals applications more user friendly.

Compensation to You:
There is no compensation for participants, but we thank all participants for their contributions and time.

Confidentiality:
The following procedures will help to keep your personal information as confidential as possible in this study:

The data collected about you will be kept private to the extent required by law. Your records will be kept under a code number instead of a name to protect your privacy. Your records will be kept in locked file cabinets and on a password protected file server. Only study staff will be allowed to look at them. Your name and any other fact that might identify you will not appear when results of this study are presented or published. To make sure that this research is being carried out in the proper way, the Georgia Institute of Technology IRB may review study records. The Office of Human Research Protections may also look over study records during required reviews.

Costs to You:
Other than your time, there are no costs to you for being in this study.

Participant Rights:
- Your participation in this study is voluntary. You do not have to be in this study if you don't want to.

- You have the right to change your mind and leave the study at any time. You do not have to give a reason for wanting to leave. There would be no penalty to leaving.
- Any new information that may make you change your mind about being in this study will be given to you.
- You will be given a copy of this consent form to keep.
- You do not waive any of your legal rights by participating in this research.

Questions about the Study:

If you have any questions about the study, you may contact Jiten Chhabra at telephone (404)894.4195 or email jiten@imtc.gatech.edu.

Questions about Your Rights as a Research Participant:

If you have any questions about your rights as a research participant, you may contact

Ms. Melanie Clark, Georgia Institute of Technology Office of Research Integrity Assurance, at (404) 894-6942.

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

_____

Participant Name (printed)

_____ _____

Participant Signature Date

_____ _____

Signature of Person Obtaining Consent Date