

Attachment G.4

Consent Form for the DDI Patient Survey

Investigators' Statement

We are asking you to be in a research study. The study is being conducted for the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia. This type of research is called a survey. This survey will ask questions about your background. It will ask you how much it costs when you visit this clinic visit. Also, it will ask you what you might like or don't like about a diabetes screening program. The purpose of this consent form is to give you the facts you will need to help you decide whether or not to be in the study. Please read the form carefully. You may ask questions about the reason for the research or what we will ask you to do. You may ask whether there are possible risks and benefits or your rights as a volunteer. Please ask anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called 'informed consent'.

PURPOSE OF THIS RESEARCH

Diabetes is a common and serious disease in the U.S. Around 18 million Americans have diabetes but 5.2 million do not know they have it. Diabetes is serious but it can be controlled if it is diagnosed early. We are doing this survey to understand why people choose to be screened for diabetes. Some reasons might include features of the screening program, patient background as well as the cost of health care. This information will provide the CDC with some of the answers they need in planning and evaluating diabetes screening programs in this and other communities.

PROCEDURES

The survey for this research study has two parts. If you agree to be part of this study, you will use a laptop computer provided by a trained interviewer at the clinic. The first part is a short "game" to gauge your preferred features of a diabetes screening program. In the second part of the survey we ask that you fill out a short questionnaire. To maintain your privacy, you will be reading questions and entering your answers directly into a computer. While you complete the survey no one else will see your answers and the interviewer will not show any of your answers to someone else. The interviewer is here to assist you or answer any questions you may have. There are no right or wrong answers. We just want your honest opinion or answers. The survey will take approximately 20 minutes to complete. About 600 patients who are 40 years or older and have never before been diagnosed with diabetes will be asked to complete this survey.

BENEFITS OF THIS RESEARCH

You will get no direct benefit from being a part of this study. But your answers to our questions will be used to understand why so many people have diabetes without knowing that they do. This information may be used to create a low-cost diabetes screening program.

OTHER INFORMATION

Reimbursement

You will be given \$5.00 when you are done.

This Survey is Voluntary

Being in this research study is voluntary. You do not have to be in this research study if you do not want to. If you decide not to be part of this study, it will not change the medical care that you get at your clinic or anywhere else.

Withdrawal

If you decide to be part of this research study, you can change your mind at any time and stop without penalty, loss of benefits, or loss of medical care to which you may be entitled. You have the right to stop the survey at any time.

Confidentiality

The answers you give us will be kept private. Your name will not be on the survey. No individuals will be identified. The research will not use your name. Your answers to the questions will be stored on a computer without your name on it. The computers will be protected. In addition, the computer files are protected by a secret code.

Only the survey's research staff will see the answers to the survey questions. They will not know which answers were from which person. The interviewer will not need to see your answers. Everyone working this survey signs a confidentiality agreement. This is necessary for their job.

The results from this study may be written in medical journals. We will not use your name in any written report. Nothing in the report will be used that might let people know who you. The answers you give will be combined with those from 600 other people. The survey results will have summary information. This will include averages and percentages for everyone or some groups. No individual person will be identified in any report.

Signatures

Diane Manninen, PhD

Name of Investigator

Signature of Investigator

Date

Participant's Statement

I have read the consent form and I voluntarily agree to complete this survey. I have had the chance to ask questions. The Battelle Institutional Review Board Chairperson is the contact for my rights as a research subject at 1-877-810-9530 ext 500. I will receive a copy of this consent form.

Name of Participant

Signature of Participant

Date

(Please print first name and last name)