

ATTACHMENT E.

INFORMED CONSENT FOR RESEARCH Computer Based Screening for Women's Health Flesch-Kincaid Reading level: 7.9

INTRODUCTION

This is to ask you to be in a research study. This study is to find out if asking women about their health and giving information on what to do about certain risks can improve women's health. Doctors and their staff at John H. Stroger Hospital are doing this study. The study is being sponsored by the Centers for Disease Control and Prevention (CDC). Authority to collect this data is granted by Sections 301 and 391 (Part J) of the Public Health Service Act (42 U.S.C. 241).

WHAT DO I HAVE TO DO IF I AM IN THE STUDY?

Being part of the study means that:

1. You will be put in one of 3 options. If you decide to be in this study you will be put into one of the options by chance, like flipping a coin. Neither you nor the study staff may choose which option you are in.
2. You will hear and read questions on a computer in each of the 3 options and answer by touching the screen. The computer will ask you personal questions about your physical and mental health, the number of days that you were too ill to work, and how often you use health care services. You may also be asked about your experiences with partner violence. The difference between the options is which questions are asked and what information you are given. We will also ask you questions on how to best contact you. The interview will last anywhere from 15-30 minutes and will take place in the clinic. I will be available to help you if you have any questions or need help with the computer.
3. In a year, we will call you to ask you the same questions again over the phone. That interview will take about 20 minutes and will include questions on your experiences with violence. You can call us at 1-800-277-4481 to set up the interview or you can let us know how to best get in touch with you.

WHAT ARE THE RISKS OF BEING IN THIS STUDY

We are asking for your permission to review your medical records and to ask you questions about your health some of which are sensitive. This may make you feel uncomfortable. In addition, there is a small chance of possible loss of privacy, but we have strict procedures to prevent that from happening. Your answers will not have your name on them. We will give you a code number to keep your answers separate from everybody else's. Your answers to these questions will not be shared with anyone outside of the study team. We keep all information locked in our offices and you will never be identified in any report. We will keep your records private as much as allowed by law. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Officials from the hospital or the government may check the records to make sure your rights are protected.

WHAT ARE THE BENEFITS TO TAKING PART IN THIS STUDY

We hope that being in the study will be good for you, however we don't know if this will be the case. We hope that this study will show us better ways to ask women in clinics about their health.

WHY WOULD THE DOCTORS TAKE ME OFF THIS STUDY EARLY?

The study doctors may stop you from taking part in this study at any time if they decide it is in your best interest, if they decide it is dangerous for you to continue, or if the study is ended.

WHAT ARE MY RIGHTS AS A RESEARCH PARTICIPANT?

You can choose freely not to be in this project. The decision is up to you. The project begins in the clinic after you agree to participate and ends once all the study information is collected.

If you choose *not* to be in the project, you will receive the care that you and your doctor agree on; and this choice to not participate in the project will not be held against you in any way. You can also drop out of the project at any time without penalty.

WHAT ARE THE COSTS TO ME?

There is no cost for the study related activities.

WILL I RECEIVE ANY COMPENSATION?

You will be given \$10 for your time after this first interview is completed and \$15 after the telephone interview in one year.

____ I understand what has been read to me, and I agree to take part in the study on women's health.

____ I know that I have a choice to be in the study or not or to stop at any time during the study.

Subject's Name: (Please Print)_____

Subject's Signature: _____

Date: _____

Person who read the consent form, explained the study in detail, and answered all questions to the subject's complete satisfaction:

Name: (Please Print) _____

Signature: _____

You can choose to receive a copy of this form or we can just give you information on how to contact us if you have any questions.

WHAT DO I DO IF I HAVE ANY QUESTIONS OR PROBLEMS

You can call the staff toll free at 1-800-277-4481. You can leave a message here Monday-Friday 9-5 and someone will get back to you within 2-3 hours.

You can also speak with any of the following doctors:

Laura Sadowski, MD 312-864-3646

Doctor, Principal Investigator

Romina Kee MD 312-864-3630

Doctor, Co- Investigator

Sarita Massey MD 312-864-5906

Doctor, Co- Investigator

In addition, you can contact the Quality Coordinator (Funeka Sihlali) about your rights as a participant or if you feel that you have been harmed in any way at 312-864-4821 during business hours or the Office of the Associate Director of Science at the CDC at 1-800-584-8814.