ATTACHMENT D

INFORMED CONSENT FOR RESEARCH

Computer Based Screening for Women's Health

Flesch-Kincaid Reading level: 7.5

INTRODUCTION

This is to ask you to be in a research project. This project will evaluate 4 different ways to screen women for health issues. The purpose of this project is to learn which of these ways of asking about women's health is the best. 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 project involves the following:

1. You will be put in one of 4 groups. If you decide to be in this project you will be assigned to one of the groups by chance, like flipping a coin. Neither you nor the study staff may choose which option you are in.
2. You will be interviewed by project staff and then you will answer questions in a private area with the help of a computer in each of the 4 groups. The difference between the groups is how and when the questions are asked and how we will give you the information at the end. In addition one of the 4 groups gets to watch a 2 minute video on women's health.
   The interview will include personal questions about your physical and mental health including quality of life, disabilities, experiences with violence, and how you use health care services. It will also include 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. You will have a phone interview about 1 week after the first interview. That interview will take about 20 minutes and ask less questions. 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 many questions about your health some of which are sensitive. This could cause you to 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 to these questions will not be shared with any one outside of the study. 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.

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 this project will be good for you, however we don't know if this will be the case. The benefit from this project is that we will learn better ways to screen women in clinics for health issues.

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 or
- You are not able to complete the study visits

WHAT ARE MY RIGHTS AS A RESEARCH PARTICIPANT?

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

If you choose *not* to be in the study, you will receive the care that you and your doctor agree on; and this choice to not participate in the study will not be held against you in any way. You can also drop out of the study 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?

As a token of appreciation of the time and effort of being interviewed, each person in the project will be given $20 after the first interview is completed.

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

___ I know that I have a choice to be in the study or not, and can 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.

<u>WHAT DO I DO IF I HAVE ANY QUESTIONS OR PROBLEMS</u>
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 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.