CDC's Cervical Cancer (Cx3) Study Provider Formative Research (Focus Groups)

Consent Form

Full study title: Follow-up Study of HPV Testing Among Women Undergoing Routine Cervical

Cancer Screening

Conducted by: Centers for Disease Control and Prevention (CDC) and Battelle Memorial

Institute

CDC Principal Investigator: Vicki Benard, Ph.D.

Battelle task leader: Diane Manninen, Ph.D.

Funded by: CDC Division of Cancer Prevention and Control, Atlanta, Georgia, U.S.A.

What is this purpose of this focus group?

For the past three years, this clinic has been one of 15 Illinois clinics serving National Breast and Cervical Cancer Early Detection Program (NBCCEDP) patients that the Centers for Disease Control and Prevention (CDC) selected to participate in the CDC Cervical Cancer Study (Cx3 Study). The Cx3 Study is a pilot study to provide HPV DNA tests, along with Pap tests, for cervical cancer screening in women 30-60 years of age. We are conducting a series of focus groups with providers at participating clinics to obtain information that will help in the interpretation of the study results. The results of the Cx3 study will inform CDC on their cervical cancer screening policies at a national level.

How many people will take part in these focus group discussions?

Approximately 75 providers at the 15 clinics that participated in the Cx3 study will be asked to participate in the focus groups.

What does it mean to participate in the focus group discussion?

You are being asked to participate in a focus group discussion with several other providers in this clinic. The focus group discussion is expected to last approximately one hour. You are being asked to participate because you have been identified as one of the providers who is currently performing Pap testing at the clinic. Participation in the focus group discussion is voluntary. Participating or not participating in the focus group discussion will not affect your employment in any way.

What types of questions will you be asking?

During the focus group we will ask you to discuss what you typically do during annual examinations and routine visits with female patients who are 30 years of age and older, your approach to cervical cancer screening (including Pap and HPV testing) for average risk patients in your practice, and system-level and other barriers to changing practice to follow national cervical cancer screening guidelines.

What are the risks and benefits of participating in the focus group?

One possible risk of participating in the focus group discussion is that you may feel uncomfortable sharing your opinions with other providers in the clinic. During the focus group we will ask a series of questions about your clinical practice. We will not be asking for any personal information. However, if you are uncomfortable sharing your opinions with others, you may choose to skip any questions that you do not wish to answer or you may request to provide us with your input privately. You will not benefit directly from being in the focus group. However, the information provided by you and other clinicians will provide valuable information to CDC to assist them in their efforts to provide cervical cancer screening to NBCCEDP women.

Will the information I give be kept confidential?

Responses provided during the focus group discussion will be heard by the other focus group participants and, therefore, an individual's responses cannot be kept completely confidential. However, the research team will not associate your responses with your name. Any interview notes will not contain your name or other identifying information and your responses will be combined with those from other providers in the study before they are shared with others. Neither your name nor the name of your clinic will be identified in published reports or publicly available data.

What if I have questions, comments, or concerns?

If you have any questions or concerns about the study or the informed consent process, please feel free to call the Battelle Study Leader, Diane Manninen, Ph.D at at 206-528-3140. If you have questions or concerns about your rights as a human subject, you may call the Battelle Human Subject Representative at 1-877-810-9530, ext. 500.

What do I need to do to participate in the focus group?

If you understand the study and agree to participate in the focus group, please stay and join in the discussion. By participating in the focus group you are acknowledging that you have read this consent form and have had the chance to ask questions about the study. Please keep this consent form for your records.