Behavioral Research Informed Consent
Title of Study: **Relational Agents in Cervical Cancer Education (RACE): Phase II**

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When we say "you" in this consent form, we mean you; "we" means the researchers and other staff.

Key Information about this Study
You are being asked to participate in this research study because you are a patient with a diagnosis of cervical/vaginal dysplasia or cancer and are receiving care at the Karmanos Cancer Institute (KCI) or Stephenson Cancer Center (SCC). Participation in this research study is voluntary. The purpose of the study is to learn how best to provide HPV related cancer information to cancer survivors and understand how they share information with their families and communities. There may be no direct benefits and there are no foreseeable risks. The alternative to participation is to not participate. **Your total time in the study is anticipated to be one hour.**

Purpose
You are being asked to participate in a research study of how best to provide HPV related cancer information to cancer survivors and understand how they share information with their families and communities because you are a patient with a diagnosis of cervical/vaginal dysplasia or cancer and are receiving care at the Karmanos Cancer Institute (KCI) or Stephenson Cancer Center (SCC). This study is being conducted at Wayne State University. The estimated number of study participants to be enrolled is about 60. **Please read this form and ask any questions you may have before agreeing to be in the study.**

Study Procedures
If you agree to take part in this research study, we will schedule time to meet with you before you see your oncologist. During this meeting, we will ask you to complete a survey on a personal tablet (e.g., iPad). The survey has questions about you, such as your age, education, health and your knowledge and feelings about HPV risk factors and HPV vaccination. After you finish the survey, you will find out which group you are in. There will be two groups. If you are in the first group, you will be asked to view an interactive video on the iPad. If you are in the second group, you will be asked to review a brochure about Cancer and HPV vaccination. Both will take approximately 15-20 minutes. You will then meet with your oncologist. After meeting with your oncologist you will be asked to complete a second survey. This survey will again ask you about your knowledge and feelings about HPV risk factors and HPV vaccination. Your meeting with the oncologist will not be delayed or shortened because of the questionnaires. A follow-up survey will be sent to you via mail, phone, or email with your permission 6 weeks after your visit. If eligible, selected participants may be asked to complete a final in-depth interview over the phone to obtain feedback within 6 weeks of completing the follow-up survey. With your permission, this interview will be audio-recorded. **Your total time in the study is anticipated to be one hour.**

Benefits
As a participant in this research study, there may be no direct benefit for you; however, information from this study may benefit other people now or in the future.

Risks
The risks associated with being in the study are very small. There is a small chance that confidentiality could be compromised; however, we are taking precautions to minimize this risk. To minimize these risks your personally identifying information will not be attached to your survey responses, only a coded number will be used. The research staff is also trained on the safe handling and storage of personally identifying information and data. Some people may feel uncomfortable answering some of the questions in the surveys. There may also be other risks that we do not know about at this time.

Alternatives
The alternative to participating in this study is not participating in this study.

Study Costs
Participation in the study will be of no cost to you.

Compensation
For taking part in this research study, you will receive up to $15 in gift cards for your time and inconvenience. For completing the initial pre- and post-survey, you will receive $10 in gift cards. An additional $5 will be mailed to the participant upon completion of the follow-up survey six weeks post-intervention. If applicable, upon completion of the final in-depth interview participants will receive one final $10 gift card via mail.

Confidentiality
All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code name or number. Information that identifies you personally will not be released without your written permission. However, the study sponsor, the Institutional Review Board (IRB) at Wayne State University, Karmanos Cancer Institute KCI), or federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration (FDA), National Cancer Institute (NCI), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.) may review your records.
We will keep all data collected in this study completely confidential. We will assign you a code number rather than use your name. Your survey answers will be encrypted (scrambled) and sent over a secure/safe line to the computer of the researchers. This computer will be in a locked room; and all information on it will be protected by passwords. Only authorized research staff will know these passwords. We will **not** put your code number on the completed informed consent forms. We will store consent forms in separate locked cabinets. When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity.

Voluntary Participation/Withdrawal
Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you decide to take part in the study you can later change your mind and withdraw from the study. You are free to only answer questions that you want to answer. You are free to withdraw from participation in this study at any time. Your decisions will not change any present or future relationship with Wayne State University or its affiliates, or other services you are entitled to receive. Your decision about whether to participate, or later to withdraw, will not affect the quality of the medical care you might receive at KCI or its affiliates. There will be no loss of any other benefits to which you are entitled.

Participation in Future Studies
It is possible that we may want to contact you in the future to ask if you are interested in being in other studies about patient-physician communication. If you do not want to be in the studies, you can say no. You can refuse to be in those studies and still be in the study.

___I give my permission to be contacted for future studies on patient-physician communication.

Questions
If you have any questions about this study now or in the future, you may contact Radhika Gogoi, MD, PhD or one of her research team members at the following phone number (313) 576-9672. If you have questions or concerns about your rights as a research participant, the Chair of the Institutional Review Board can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call (313) 577-1628 to ask questions or voice concerns or complaints.

Consent to Participate in a Research Study

To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read, or had read to you, this entire consent form, including the risks and benefits, and have had all of your questions answered. You will be given a copy of this consent form.

Signature of participant _____ Date _____

Printed name of participant _____ Time _____

Signature of witness** _____ Date _____

Printed of witness** _____ Time _____

Signature of person obtaining consent _____ Date _____

Printed name of person obtaining consent _____ Time _____

**Use when participant has had this consent form read to them (i.e., illiterate, legally blind, translated into foreign language).

Signature of translator _____ Date _____

Printed name of translator _____ Time _____

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