The Ohio State University Consent to Participate in Research

Study Title: Community Awareness, Resources and Education (CARE) – Project 3
Principal Investigator: Electra D. Paskett, PhD
Sponsor: National Cancer Institute (NCI)

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.

- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. **Why is this study being done?**

   Researchers at The Ohio State University and the University of Michigan are working together to understand cancer of the cervix. One of the areas they are studying is how stress you may experience in your life effects the way you respond to GARDASIL®. GARDASIL® is a vaccine approved by the Food and Drug Administration (FDA) to prevent some types of Human Papillomavirus (HPV) infection which can cause cancer of the cervix.

2. **How many people will take part in this study?**

   About four hundred and fifty (450) women in southern and eastern Ohio, as well as West Virginia, will take part in this study.
3. What will happen if I take part in this study?

If you decide to take part in this study, you will be asked to complete four visits to the clinic. At each of the first three visits you will receive the GARDASIL® vaccine. Before receiving the vaccine at each of the three visits, you will be asked if you could potentially be pregnant. If there is a chance that you may be pregnant, you may need to have a pregnancy test done to confirm that you are not pregnant because you may not continue on with the study if you are pregnant.

At the first clinic visit, you will have about 2 teaspoons of blood taken from a vein in one of your arms. If the staff is unable to get a blood sample, you will not be able to continue into the study. You will be given the option of returning at a later scheduled time to try again. If your blood cannot be drawn, that would be the end of your part in the study.

If you smoke, you will also be asked to give a sample of your saliva during this visit. You will then be asked to rinse your mouth with Scope mouthwash and to collect that into a cup. Next, a Pap smear and cervical sample will be collected by research staff. A Pap smear samples the cells of your cervix to screen for changes or abnormalities that could develop into cancer. It will involve a brief scraping of your cervix with a small brush. A second cervical sample will be collected using a swab that looks like a long Q-tip. Next, you will receive the first shot of the GARDASIL® vaccine. It will be injected into the muscle of your upper arm. After you get the shot, you will need to stay in the clinic for 20 minutes to make sure that you do not have any reaction to the shot. During that time, you will be asked to fill out a questionnaire about yourself, your health, behaviors and stress. You do not have to answer any of the questions you do not want to.

A few weeks after this first visit, research staff will call to talk to you about the results of your Pap smear and answer any questions you may have. A copy of those results will be sent to your regular doctor. If you do not have a regular doctor a letter will be sent to you instead.

Your second visit to the clinic will take place two months after your first. During this visit, you will be asked to provide another blood sample from a vein in one of your arms. You will receive a second GARDASIL® shot. After you get the shot, you will need to stay in the clinic for 20 minutes to make sure that you do not have any reaction to the shot. During that time, you will be asked to fill out a shorter questionnaire about yourself, your health, behaviors and stress. You do not have to answer any of the questions that you do not want to.

Six months after your first visit, you will return to the clinic again. During this visit, you will be asked to provide another blood sample, you will receive your third and final GARDASIL® shot, and be asked to complete another short questionnaire. These procedures will be similar to your second visit to the clinic. After this visit you will receive a form indicating that you have received the entire vaccine series. A form with the same information will be sent to your regular doctor if you have one.
Your fourth and final visit to the clinic will take place twelve months after your first visit. This visit will be similar to your first clinic visit except you will not receive a GARDASIL® shot. Research staff will collect a Pap smear and another cervical sample, just like your first visit. You will be asked to provide another blood sample from a vein in one of your arms, a saliva sample if you smoke, and a mouthwash rinse. Finally, you will be asked to complete a questionnaire about yourself, your health, behaviors and stress.

In the weeks following your final clinic visit, you will be contacted by a nurse practitioner to discuss the results of your Pap smear and answer any questions you may have. Again, a copy of your Pap smear results will be sent to your regular doctor and to you if you do not have one. If any abnormal results are found, we will ask for copies of your medical records relating to that issue.

4. How long will I be in the study?

You will be in the study for about 13 months. This includes four visits to the clinic and two telephone calls to review the results of your Pap smear. Each visit will take about 45 to 60 minutes.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University or the University of Michigan.

6. What risks, side effects or discomforts can I expect from being in the study?

If you are pregnant or become pregnant while on the study, you will not be able to take part in the study because the effects of GARDASIL® HPV vaccine to a fetus are unknown at this time. You will need to confirm with the study team that you are not pregnant. The staff will ask about the start of your last period and your use of birth control if you are sexually active. If you become pregnant before you have received all three of the GARDASIL® shots, you will not be able to complete the study.

You may experience some brief cramping, pressure, and/or bleeding during and after the research staff collects samples from your cervix. This is no different from what might happen during your regular Pap test.

Collection of a blood sample may hurt or leave a bruise. Sometimes, a small clot, swelling of the vein, infection, or bleeding may occur where the needle is stuck into your skin. There is also a risk of fainting.
During this study, you will receive the GARDASIL® vaccine. You may experience some of the common side effects including headache, fever, nausea, and dizziness, pain, as well as swelling, redness, itching, and bruising at the injection site. Less commonly, severe allergic reactions and fainting have been reported. If any of these side effects continue or worsen, you will need to contact your regular health care provider for follow-up, and also inform study staff that you are experiencing the side effects. Because there is a chance that side effects may occur, it is important for you to remain at the clinic for 20 minutes after receiving the vaccine for observation.

Finally, you will be asked to complete questionnaires at each visit to the clinic as a part of the study. Some of these questions may make some people uncomfortable. You may refuse to answer any questions or stop questionnaires at any time. At the first and last visits, some of the questions will measure symptoms of depression. This measure will be scored after each study visit. If you score above a cutoff indicating that you may be at risk for clinical depression, you will be informed of this by telephone and encouraged to seek treatment.

7. What benefits can I expect from being in the study?

As part of this study, you will receive two Pap smears and a complete GARDASIL® vaccine series at no cost to you. The information collected may give the people doing the study ideas about how to prevent cervical cancer.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. Services provided throughout the study, including getting the GARDASIL® vaccine and collection of Pap smears, are currently available from a health care provider in your area, and you can get these services without being in the study.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.
Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician’s office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

10. What are the costs of taking part in this study?

There will be no additional costs to take part in this study. However, any follow-up testing such as additional Pap smears or procedures recommended based on abnormal Pap results will be the responsibility of the participant. If you have an abnormal Pap smear, the nurse practitioner will tell you about them. Because this is a research study, we will not treat any problems that we find; instead, you will need to get treatment from your healthcare provider.

11. Will I be paid for taking part in this study?

You will receive a $10 gift card at the completion of each clinic visit, a total value of $40 for all clinic visits. By law, payments to subjects are considered taxable income.

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.
13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact Electra D. Paskett at 614-293-7713.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Electra D. Paskett at 614-293-7713. Signing the consent form
Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

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Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

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