Official Title: Quadrivalent Human Papillomavirus (qHPV) Vaccine in Cancer Survivors: Cross Sectional Survey and Phase II Open-Label Vaccine Trial

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CONSENT FORM

TITLE OF RESEARCH:	Human Papillomavirus (HPV) Vaccine in Cancer Survivors: Phase II Open-Label Vaccine Trial
IRB PROTOCOL NO.:	IRB-141204009
INVESTIGATOR:	Wendy Landier, PhD
SPONSOR:	National Cancer Institute
SUPPORTED BY:	Merck & Co.

For Children (persons under 18 years of age) participating in this study, the term "You" addresses both the participant ("you") and the parent or legally authorized representative ("your child").

Purpose of the Research

We are asking you to take part in a research study because you are a cancer survivor between 9 and 26 years of age, completed cancer therapy 1 to 5 years ago, and have not received any doses of the HPV vaccine. The purpose of this study is to see if the HPV vaccine works in cancer survivors like it does in healthy people.

HPV infection can cause warts and cancers in the reproductive system and other parts of the body, including the head and neck. The HPV vaccine is approved by the U.S. Food and Drug Administration (FDA) for males and females between 9 and 26 years of age. Studies in healthy people have shown that the HPV vaccine can prevent most diseases caused by the nine HPV subtypes that the vaccine protects against. However, no studies have reported if the HPV vaccine works in cancer survivors like it does in people who have never been treated for cancer. Cancer treatments can place cancer survivors at higher risk for getting HPV-related illnesses. This study may help us find better ways to protect cancer survivors from those diseases.

This is a Phase II study. A Phase II study is a research study that looks at a large number of patients to see if a drug is effective and to further evaluate its safety. This Phase II study will enroll 481 participants from 5 participating sites, and 55 of them will come from UAB/Children's of Alabama. Merck and Co. is supplying the vaccine for this study at no cost to the participants.

Explanation of Procedures

If you agree to participate in this study, the following procedures will be done:

Day 1 (Vaccine Dose # 1)

- You will be provided with educational fact sheets about HPV and the HPV vaccine.
- For females only: If there is any possibility of pregnancy, a pregnancy test (urine or blood) will be given. You will be asked to avoid pregnancy (if sexually active, to use contraception) beginning with the first vaccine dose and continuing for at least 4 weeks after all 3 vaccine doses have been administered (for about 7 months).
- You will have 16 ml (approximately 3 teaspoons) of blood drawn to check your body's general immune status (quantitative immunoglobulins) and your antibody levels to the nine HPV subtypes that are included in the HPV vaccine (Anti-HPV-6, -11, -16, -18, -31, -33, -45, -52, -58).
- You will receive the vaccine in the upper arm or thigh. Following the vaccination, you will be observed for 30 minutes to see if you have any side effects and/or allergic reactions.
- You will be provided with a thermometer, measuring tape, and a Vaccine Report Card and asked to record your oral temperature 4 hours after you receive the vaccine and then daily for 5 days, and to record any adverse symptoms daily until the 7th day after you've received the injection.
- You will be contacted about 1 week after receiving the vaccine to determine if you have any side effects. You will also be asked to return to the clinic within 24 hours for examination and treatment if you have any severe side effects after receiving the vaccine.

Week 8 (Vaccine Dose # 2)

- For females only: If there is any possibility of pregnancy, a pregnancy test (urine or blood) will be given. You will be asked to continue to avoid pregnancy (if sexually active, to use contraception) for at least 4 weeks after all 3 vaccine doses have been administered.
- You will receive the vaccine in the upper arm or thigh. Following the vaccination, you will be observed for 30 minutes to see if you have any side effects and/or allergic reactions.
- You will be provided with a Vaccine Report Card and asked to record your oral temperature 4 hours after you receive the vaccine and then daily for 5 days, and to record any adverse symptoms daily until the 7th day after you've received the injection. You will use the thermometer and tape measure that you received at the time of your first dose.
- You will be contacted about 1 week after receiving the vaccine to determine if you have any side effects. You will also be asked to return to the clinic within 24 hours for examination and treatment if you have any severe side effects after receiving the vaccine.

Week 24 (Vaccine Dose # 3)

- For females only: If there is any possibility of pregnancy, a pregnancy test (urine or blood) will be given. You will be asked to continue to avoid pregnancy (if sexually active, to use contraception) for at least 4 weeks after receiving this third vaccine dose.
- You will receive the vaccine in the upper arm or thigh. Following the vaccination, you will be observed for 30 minutes to see if you have any side effects and/or allergic reactions.
- You will be provided with a Vaccine Report Card and asked to record your oral temperature 4 hours after you receive the vaccine and then daily for 5 days, and to record

any adverse symptoms daily until the 7th day after you've received the injection. You will use the thermometer and tape measure that you received at the time of your first dose.

- You will be contacted about 1 week after receiving the vaccine to determine if you have any side effects. You will also be asked to return to the clinic within 24 hours for examination and treatment if you have any severe side effects after receiving the vaccine.

Week 28 (Month 7): Four Weeks Following Final Vaccine Dose

- You will have 10ml (approximately 2 teaspoons) of blood drawn to check your antibody levels to the nine HPV subtypes that are included in the HPV vaccine (Anti-HPV-6, -11, -16, -18, -31, -33, -45, -52, -58).

Month 24 (Two Years Following Vaccine Dose # 1)

- You will have 10ml (approximately 2 teaspoons) of blood drawn to check your antibody levels to the nine HPV subtypes that are included in the HPV vaccine (Anti-HPV-6, -11, -16, -18, -31, -33, -45, -52, -58) and to evaluate your body's immune response to the HPV vaccine (HPV-specific total immunoglobulins).

Throughout the study, you will be asked about your current health and any medications you are taking or blood products, transfusions, or vaccines you may have received. Information will also be collected from your medical records, including information about your past medical history, your cancer diagnosis and its treatment, any complications you may have had during or after treatment, your immune status, medications and vaccines you have taken or may be taking, and your current health status. If you develop a serious reaction to the HPV vaccine, your doctor or the study's principal investigator may remove you from the study. Should this occur, you will be notified regarding the reason for this decision.

Risks and Discomforts

You will have your blood drawn during this study. Drawing blood from a vein can cause minor pain and bruising at the site where the needle enters. Some people feel dizzy when blood is drawn. Rarely, infection may occur.

The HPV vaccine is believed to be safe when administered in the general population, but it has not been studied in cancer survivors. Common mild to moderate side effects reported in the general population have included skin redness, pain, swelling, and/or muscle soreness at the injection site. Fainting has been reported following vaccine administration and may result in falling with injury. As a precaution, participants will be observed for 30 minutes in the clinic following vaccine administration. Some patients may experience mild to moderate fever, chills, nausea, fatigue, or headache following the vaccine. These symptoms usually last a short period of time and go away by themselves. If you develop any of these symptoms and need advice regarding management, please contact your doctor or nurse.

Although rare, serious side effects can occur and are usually associated with an allergic reaction to the vaccine. If these serious side effects were to occur, they would generally happen within a few minutes to a few hours after receiving the vaccination. Call your doctor or nurse and seek medical attention immediately if you develop any of the following serious side effects that may be signs of a severe allergic reaction: Skin rash, hives, and/or itching; difficulty breathing, hoarseness, and/or wheezing; swelling of the face, lips and/or throat; seizures; fast heart beat, low blood pressure, shock. It is also possible that there may be other side effects that are currently unknown.

Information for Women of Childbearing Potential

If you are pregnant or nursing a child, you can ***not*** take part in this study. If you are female, of childbearing potential, and there is any possibility that you may be pregnant, a pregnancy test (urine or blood) will be obtained before the vaccine is administered. If you are female, sexually active, and capable of bearing a child, you must use a medically effective form of birth control from the time of the first vaccine dose until four weeks after the third vaccine dose. Effective birth control includes birth control pills, patch, IUD, condom, sponge, diaphragm with spermicide, or avoiding sexual activity that could cause you to become pregnant.

Benefits

The potential benefit to receiving the HPV vaccine is that it has been shown to be highly effective in preventing HPV infection. The information we learn from this study may help other cancer survivors in the future.

Alternatives

Your participation in this study is voluntary. The alternative to participating in this study is to ***not*** participate. The HPV vaccine is available without participating in this study. Another alternative would be to have the HPV vaccine administered by your Primary Care Physician. You will receive the same medical treatment whether or not you decide to participate.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with the UAB Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of the National Cancer Institute (NCI), Merck & Co. (the manufacturer of the nonavalent HPV vaccine), PPD Vaccines and Biologics Laboratory, Focus Diagnostics Laboratory and the Office for Human Research Protections (OHRP), and with researchers from other institutions that are involved in this study,

including City of Hope (COH), University of Michigan (UM), Emory University/Children's Healthcare of Atlanta (EU/CHOA), St. Jude Children's Research Hospital (SJCRH), H. Lee Moffitt Cancer Center (HLMCC), and the Consortium for Interventional Pediatric Research (CPIR). Data from this study will be entered into the clinical trials registry databank maintained by the National Institute of Health/National Library of Medicine (NIH/NLM). The information from the research may be published for scientific purposes; however, your identity will not be given out.

If any part of this study takes place at University of Alabama Hospital and Children's of Alabama this consent document will be placed in your file at that facility. The document will become part of your medical record chart.

Information relating to this study, including your name, medical record number, date of birth and social security number, may be shared with the billing offices of UAB and UAB Health System affiliated entities, along with Children's of Alabama and its billing agents so that the costs for clinical services can be appropriately paid for by either the study account or by the patient/patient's insurance.

Your medical record will indicate that you are on a clinical trial and will provide the name and contact information for the principal investigator.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution. However, you should return to see the study doctor for safety reasons so you can be taken off the study vaccine and referred for follow-up care.

You may be removed from the study without your consent if the sponsor ends the study, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

Cost of Participation

There will be no cost to you for taking part in this study. All vaccine doses and laboratory testing related to this study will be provided to you at no cost during the 2-year study period.

The costs of your standard medical care will be billed to you and/or your insurance company in the usual manner.

If you are in Medicare Advantage (Medicare managed care plan), you should contact someone at your plan before you start a clinical trial. They can provide more information about additional costs you could incur from participating in clinical trials.

Payment for Participation in Research

You will receive a $100 gift card at the Month 7 study visit and a $75 gift card at the Month 24 study visit. If you quit the study before the Month 7 or Month 24 study visit, you will not receive the gift card(s). If you complete the entire study, you will receive a total of $175 in gift cards. If you need assistance with transportation when you come to the clinic only for a study visit (when you have no other medical appointments on that date), you will be given a gas card in an amount consistent with the cost of gasoline required to travel to/from your home to the clinic on that date.

Payment for Research-Related Injuries

UAB, the National Cancer Institute, and Merck & Co, have not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Significant New Findings

You will be told by your doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, you may contact Dr. Wendy Landier. She will be glad to answer any of your questions. Dr. Landier's number is 205-638-2120. Dr. Landier may also be reached after hours by paging her at 205-638-9100.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Signatures

Your signature below indicates you that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

or

You are making a decision whether or not to have your child participate in this study. Your signature indicates that you have read (or been read) the information provided above and decided to allow your child to participate.

Signature of Participant	Date
Signature of Participant 14-17 Years of Age	Date
Signature of Parent or Guardian	Date
Signature of Principal Investigator or Other Person Obtaining Consent	Date
Signature of Witness	Date

University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF
PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name:
Research Protocol: Human Papillomavirus (HPV) Vaccine in Cancer Survivors: Phase II Open- Label Vaccine Trial

UAB IRB Protocol Number: IRB-141204009
Principal Investigator: Wendy Landier, PhD
Sponsor: National Cancer Institute

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____ Date: _____

or participant's legally authorized representative: _____ Date: _____

Printed Name of participant's representative: _____

Relationship to the participant: _____