UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

A5298, Version 2.0, dated 08/29/12:

A Randomized, Double-Blinded, Placebo-Controlled, Phase III Trial of the Quadrivalent HPV Vaccine to Prevent Anal Human Papillomavirus Infection in HIV-Infected Men and Women

CONSENT TO PARTICIPATE IN A RESEARCH STUDY AND RESEARCH SUBJECT HIPAA AUTHORIZATION

Your contacts for this study at the Hospital of the University of Pennsylvania [HUP] are:

Principal Investigator:	Pablo Tebas, MD	(215) 349-8092
Anoscopists:	David Stein, MD	
	Robert Winn, MD	
Coordinator:	Joseph Quinn, RN, BSN	(215) 349-8092
Study Nurse:	Randee Silverman, RN	(215) 349-8092

24 Hour Emergency Number (215) 662-6059 Ask for the Immunodeficiency Program Doctor on call

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Introduction:

You are being asked to take part in this research study because you are a male over the age of 27 years who is infected with human immunodeficiency virus (HIV), the virus that causes acquired immune deficiency syndrome (AIDS). This is an ACTG (AIDS Clinical Trials Group) study sponsored by the National Institutes of Health (NIH). The doctor in charge of this study at this site is: Dr. Pablo Tebas. Before you decide if you want to be a part of this study, we want you to know about the study.

This is a consent form. It gives you information about this study. The study staff will talk with you about this information. You are free to ask questions about this study at any time. If you agree to take part in this study, you will be asked to sign this consent form. You will get a copy to keep.

Why Is This Study Being Done?

There are over 100 types of human papillomavirus (HPV) that infect humans. Some of these types infect the anal and mouth areas. HPV infections in these areas can damage the skin. Rarely, these damaged areas can turn into cancer. There are tests that can find these damaged areas so that they can be treated and removed. These tests will be described later in this consent form.

The main purpose of this study is to determine whether the quadrivalent HPV vaccine, Gardasil, prevents anal HPV infection in HIV-infected men and women. “Quadrivalent” means that the vaccine is directed at four of the HPV types.

Gardasil is approved by the US Food and Drug Administration for use in boys and men 9 to 26 years old for the prevention of genital warts caused by HPV types 6 and 11 and anal cancer caused by HPV 16 and 18. It is also approved for use in girls and women 9 to 26 years old for the prevention of genital warts, cervical cancer, vaginal cancer, vulvar cancer and anal cancer. It has not been approved for use in men and women aged 27 and older to prevent anal HPV infection.

About 464 men and 100 women will take part in this study; about 30 men and 5 women are expected to enroll at the University of Pennsylvania.

What Do I Have To Do If I Am In This Study?

Study visits

If you enter the study, you will be seen in the clinic (CTRC, 1 Dulles at HUP) about 5 times the first year. After that, the study visits are twice a year for the next 2 - 3 years. As part of the study, a High Resolution Anoscopy (HRA) is performed. For this procedure you will be seen by Dr. David Stein at

Drexel University or Dr. Robert Winn at the Mazzoni Center. This exam is not currently performed at Penn, but is a procedure that is done as standard of care in some patient populations. You will be in the study for a total of 3 to 4 years, depending on when you enter the study. The study staff will tell you about how long each visit could be. More details about the visits and procedures are below.

If you do not enter the study

If you decide not to take part in this study or if you do not meet the eligibility requirements, we will still use some of your information. As part of the screening visit, some demographic (eg, age, gender, race), clinical (eg, disease condition, diagnosis, any problems from biopsies done for this study), and laboratory (eg, safety tests) information is being collected from you so that ACTG researchers may help determine whether there are patterns or common reasons why people do not join a study. We will also use the information that we collect from you for the purposes of research.

Study vaccine

If you enter the study, you will be randomly assigned (as if by the toss of a coin) to get either the HPV vaccine or a placebo for the HPV vaccine. For men in the study,the placebo is made like the vaccine except it does not have the active HPV ingredient. For women in the study, the placebo us salt water. You and the study staff will not know your assignment. You will not find out your assignment until after the entire study is over and the results of the study are known. You and your doctor can be told of the assignment at any point if it is necessary for your health.

The injections are given to you at study entry and then again 8 weeks and 24 weeks later. The injections are given to you with a needle into the muscle of your shoulder or thigh. You will receive a phone call 2 - 3 days after each vaccination, so the study staff can talk to you about how you are doing.

Study procedures

The study staff can answer any questions you have about individual study visits and the procedures. The table below can be used as a quick reference, along with the explanations that follow. If you leave the study early, the study staff will ask you to have the procedures listed in the table below under Final Visit/Early Discontinuation.

Evaluation or procedure	Screening[1]	Entry[2] (day 0)	Week 8[3]	Week 24[3]	Week 28[3]	Visits every 6 months[4]	Final visit/early discontinuation
Consent signed	√						
Physical exam	√	√	√	√	√	√	√
Blood collected	√	√			√	√	√
Anal swabs	√	√			√	√	√
Anoscopy	√						√
Oral exam	√	√			√	√	√
Oral sample collection	√	√			√	√	√
Vaginal Swabs	√	√			√	√	√
Cervical exam and Pap test	√					Only yearly	
Pregnancy test	√	√	√	√	√	As needed	
Vaccine or placebo injection		√	√	√			
Phone call		√	√	√			
Questionnaires		√			√	√	√

1 Screening visit: Before you enter the study, you will need to come to the clinic to have evaluations done to make sure that you can take part in the study.

2 Study entry visit (day 0): If you meet the entry requirements, you will enroll in the study.

3 Study visits at Weeks 8, 24, and 28: These are important visits in the first year of the study.

4 You will be seen in the clinic twice a year for 2-3 additional years.

Explanation of study procedures

Consent signed
After you read the consent and have had a chance to ask questions about the study, you will sign the consent form if you want to be evaluated for the study.

Physical exam
You will have a physical exam and will be asked questions about your health and medicines. Because part of Gardasil (the study vaccine) is made in yeast, you will be asked about any allergies to yeast or any other ingredients in the vaccine. You will not be allowed to enroll in the study if you have such an allergy.For men only: At the screening visit, you will be asked about types of sexual activity you have had in the past year.

Blood collected
Blood will be collected from you for different tests. These include routine safety tests to evaluate your blood counts, liver, and kidneys. At entry, you will also have an HIV viral load (how much HIV is in your blood) and CD4 count (how many infection-fighting cells you have in your blood) done. You will be told the results of these tests. Some blood will be stored for tests that will be done later on in the study or after the study is over. These tests will evaluate the immune response to HPV. This blood will also be stored for future HIV- and HPV-related research. We cannot guarantee that you will be told the results of these tests. About 1-4 tablespoons of blood will be collected at these visits.

Vaccine or placebo injection
You will be given the quadrivalent HPV vaccine, or the placebo for the vaccine, at study entry and at weeks 8 and 24. The vaccine is given as an injection into the muscle of your shoulder or thigh.

You will be asked to stay in the clinic for about 15 minutes after each injection so the study staff can watch for any bad effects.

Phone call

Study staff will contact you by phone 2-3 days after each injection to talk to you about how you are doing.

Questionnaires
You will be asked to fill out questionnaires about alcohol, tobacco, and marijuana use, and recent sex you may have had, including how many people you have had sex with, use of condoms, and what type of sex you have had. We will also ask for your opinions about some of the study procedures, and procedures you may have had to treat warts or pre-cancer of the anus.

Anal swab
A doctor or nurse will insert a swab (like a long Q-tip) into your anus. The end of the swab will be rubbed against the skin inside the anus. This sample will be tested for HPV. You will not receive the result of the HPV test. A second swab will be inserted into your anus for an anal Pap test. This sample will be tested for pre-cancers of the anus. These are areas that have been damaged by HPV and might turn into cancer someday. You will receive the result of the Pap tests.

Anoscopy
You will be seen for high-resolution anoscopy (HRA). The HRA needed for screening may not have to be repeated if you had an HRA done recently by a certified provider (Dr. Stein or Dr. Winn) as part of your routine care. For this procedure, a speculum (a plastic tube used to see inside the anus) is inserted into your anus. Lubricant is used to make this more comfortable. Then a swab moistened with acetic acid (diluted vinegar) is placed in your anus. The doctor or nurse then reinserts the plastic speculum into your anus. A colposcope (a machine similar to a magnifying glass with a light source) is used to see the skin inside the anus.

If areas worrisome for pre-cancer or anal warts are found, a sample of skin about the size of a sesame seed will be taken. This is called a biopsy. Iodine may be used to help make pre-cancers show up, and an injection of lidocaine or other anesthetic may be given to numb the skin before a sample is taken. Please let the study staff know if you are allergic to seafood, shellfish, contrast dye for a CT scan, or iodine, or if you are allergic to lidocaine, novocaine, or tetracaine.

If you are diagnosed with a high-grade pre-cancer in screening or during the course of the study, you will be referred for treatment. The treatment and any follow-up after treatment are decided upon by your health care providers, not by the study. If you are diagnosed with high grade pre-cancer or warts during screening, you will need to wait until after the entry visit to receive treatment for these conditions. We ask that you wait about 4 weeks after the first entry vaccine before starting any treatments, but the timing of the treatments after the entry visit is up to you and your providers.

Other anal tests and treatment
The Pap test looks for damage to the anal skin by HPV. If your Pap tests show possible damage from HPV, you may be referred for additional HRA procedures other than what is listed above. These additional HRA procedures are not required by the study. Your doctor or nurse will discuss this with you further. Biopsies done during the HRA may show anal pre-cancer. Anal pre-cancers are areas of the anus that might turn into cancer if they are not treated or removed. You may also be diagnosed with anal warts. Your doctor or study nurse will discuss options available to you for treatment of these conditions. These treatments are not required by the study. The study staff will collect information about these HRAs and treatments, if performed, during study follow-up.

Oral exam and sample collection
The doctor or nurse will examine the inside of your mouth. If any problems are found, you will be referred for treatment. The treatment and any follow-up after treatment are not a part of the study.

You will be asked to provide a saliva sample by spitting in a tube for 5-10 minutes to obtain about one teaspoon of saliva. You will be asked to swish and gargle with a small amount of Scope brand mouthwash for 30 seconds and then spit into a cup. This sample will be tested for HPV and some of it will be stored for future HIV and HPV related research. You will not receive the results of these tests.

Additional tests for women

- Vaginal swab: you will be asked to insert a swab into your vagina and swab around the end of the vagina. This sample will be tested for HPV. You will not receive the results of the HPV test.

- Cervical Pap test: the doctor or nurse will insert a speculum into your vagina, which spreads the vagina open and allows access to the cervix (the opening of the uterus). Cells will be collected from the outer opening of the cervix. (If no cervix is present, cells from your vagina will be tested.) This may not have to be done if you had this exam and test done recently as part of your routine care.

  The cells will be checked for pre-cancers of the cervix. You will receive the results of the Pap test. If any abnormality is found, you will be referred for treatment or further evaluation. The treatment and any follow-up after treatment are not a part of the study. The study staff will collect information about these treatments, if performed, during study follow-up.

How Long Will I Be In This Study?

You will be in this study between 3 and 4 years depending on when you join.

Why Would The Doctor Take Me Off This Study Early?

The study doctor may need to take you off the study early without your permission if:
- your doctor feels it is in your best interest
- the study is cancelled
- you do not receive the first dose of the study vaccine as required by the study

The study doctor may also need to take you off the study vaccine without your permission if:
- you are not able to take the study vaccine as required by the study
- continuing the study vaccine may be harmful to you
- you need a treatment that you may not take while on the study
- you become pregnant or start breastfeeding while on study

If you must stop taking the study vaccine before the study is over, the study doctor will ask you to continue to be part of the study and return for some study visits and procedures.

What Are The Risks Of The Study?

The vaccine used in this study may have side effects, some of which are listed below. Please note that this list does not include all of the side effects seen with the vaccine. The list includes the more serious or common side effects with a known or possible relationship. If you have questions concerning the additional study drug side effects, please ask the medical staff at your site.

Human Papillomavirus Quadrivalent Types 6, 11, 16, and 18 Vaccine, Recombinant (Gardasil)

The following serious side effects have been associated with the use of Gardasil:
- Hypersensitivity (allergic) reactions, such as rash, fever, flu-like feeling, blisters, facial swelling, or even problems breathing. These reactions, in severe form, may be life threatening.
- Guillain-Barre Syndrome (a treatable and reversible form of paralysis)

In addition to the serious side effects listed above, additional side effects include:

- Soreness, tenderness, itching, redness, bruising, or swelling at the injection site
- Headache
- Fever
- Nausea and vomiting
- Dizziness
- Fainting may occur after receiving the injection, which may result in falling with injury.
- Shaking, stiffening and other seizure-like activity have also been reported.
- Tiredness
- Chills

Blood draw
Taking blood may cause some discomfort, lightheadedness, bleeding, swelling, or bruising where the needle enters the body, and in rare cases, fainting or infection.

Anal swabs, vaginal swabs and cervical tests
The swabs can be uncomfortable, and occasionally there can be some bleeding.

Anoscopy
The speculum can be uncomfortable, and the acetic acid can cause some pain and irritation in the anus. Some anal bleeding occurs with every anal biopsy. Serious bleeding is rare, about 1 in a 1000 biopsies. If serious bleeding occurs, a simple procedure may be necessary to stop the bleeding such as burning or cauterizing the area. An injection of lidocaine or other anesthetic may be given prior to a biopsy. It is possible that you may experience pain or dizziness from the injection. Rarely, you may experience an allergic reaction such as itching or swelling. Iodine may be used to help identify pre-cancerous areas of the anus. It is possible that you may have an allergic reaction to the iodine.

Oral specimen collection
The examination of the mouth may cause you to gag. The gargle and swish may also cause you to gag.

Questionnaires
You may be embarrassed by the detailed questions about sex, anal procedures, and the use of alcohol, tobacco, and marijuana.

ARE THERE RISKS RELATED TO PREGNANCY?

It is not known if the drug or drug combinations in this study harm unborn babies. If you are having sex that could lead to pregnancy, you must agree not to become pregnant or make a woman pregnant. You and your partner must use reliable birth control that you discuss with the study staff. You must continue to use birth control until 28 days after you get your last dose of study vaccine. You should discuss your birth control choices with your health care provider to choose the best way for you to both prevent pregnancy as required by this study and to prevent the spread of HIV to your partner(s).

If you can become pregnant, you must have a pregnancy test before you enter this study. (1 teaspoon of blood or a urine specimen will be collected.) This test must show that you are not pregnant. If you become pregnant or think you may be pregnant at any time during the study, tell your study staff right away. The study staff will talk to you about your choices.

You will also have a pregnancy test before each vaccination and any time you might be pregnant. You will be told the results of all pregnancy tests.

If you become pregnant while on study, you will stop receiving study vaccine. You will be asked to continue study visits and tests through the end of the study, except you will not have any more pregnancy tests while you are pregnant.

The study staff would like to collect information from you about the outcome of your pregnancy (even if it is after your participation in the study ends). If you are taking anti-HIV drugs when you become pregnant, your pregnancy will be reported to an international database that collects information about pregnancies in women taking anti-HIV drugs. This report will not use your name or other information that could be used to identify you. If you received Gardasil, your pregnancy will also be reported to a database that collects information about pregnancies in women who took the Gardasil vaccine

Are There Benefits to Taking Part in This Study?

Prior studies of Gardasil in HIV-infected men, HIV-negative women, and HIV-infected girls showed that nearly all men developed antibodies against HPV. It is not known whether these antibodies will prevent HPV infections, anal warts, or anal cancer, but these are possible benefits. Gardasil will not prevent these conditions caused by HPV types that are not contained in the vaccine. Gardasil does not treat HPV infections that are already present at the time of vaccination.

What Other Choices Do I Have Besides This Study?

Instead of being in this study, you have these options:

- You may choose not to participate.
- You may choose to have anal and oral exams and testing done outside of a clinical trial.
- You may choose to have no screening for anal and oral pre-cancers.
- You may choose to receive HPV vaccination outside the study.

Please talk to your doctor about these and other choices available to you. Your doctor will explain the risks and benefits of these choices.

What About Confidentiality?

We will do everything we can to protect your privacy. In addition to the efforts of the study staff to help keep your personal information private, we have obtained a Certificate of Confidentiality from the U.S. Federal Government. This certificate means that researchers cannot be forced to tell people who are not connected with this study, such as the court system, about your participation. Also, any publication of this study will not use your name or identify you personally.

People who may review your records include the ACTG, Office for Human Research Protections (OHRP), FDA, University of Pennsylvania Institutional Review Board (IRB)/Ethics Committee (EC), National Institutes of Health (NIH), study staff, study monitors, Merck (the company providing vaccine and for men, the placebo), and their designees. (An IRB/EC is a committee that watches over the safety and rights of research participants.) Having a Certificate of Confidentiality does not prevent you from releasing information about yourself and your participation in the study.

Even with the Certificate of Confidentiality, if the study staff learns of possible child abuse and/or neglect or a risk of harm to yourself or others, we will be required to tell the proper authorities.

For this study, you may be tested to confirm that you are HIV positive. By law we have to report the infection (Please note that it is likely that this has been reported previously) to the City of Philadelphia Health Department/PA Department of Health. We would report your name, gender, racial/ethnic background, and the month and year you were born. This is to keep track of how many people in the U.S. have HIV infection. It is also to make sure that states get enough money from the federal government to support the medical care of people living with HIV. The Health Department does not share the names of HIV infected people with anyone else. It removes all personal identifiers, such as your name, before giving information on the number of HIV infections to the federal government.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US 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.

HIPAA AUTHORIZATION

The authorization part of the consent gives more detailed information about how your personal health information may be used and disclosed by the University of Pennsylvania Health System (UPHS), the School of Medicine and the individual Principal Investigator, subject to University of Pennsylvania procedures.

What information about me may be collected, used or shared with others?
The following personal health information will be collected, used for research, and may be disclosed during your involvement with this research study:

- Name, address, telephone number, date of birth
- Personal and family medical history
- Current and past medications or therapies
- Information from questionnaires administered in the study
- Results of tests and procedures you will undergo during this research study
- Social Security Number
- Medical Record Number

Why is my information being used?
Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right.

Who may use and share information about me?
The following individuals may use or disclose your personal health information for this research study:

- The Principal Investigator and the Investigator's study team
- Authorized members of the workforce of the UPHS and the School of Medicine, and University of Pennsylvania support offices, who may need to access your information in the performance of their duties (for example: for research oversight and monitoring, to provide treatment, to manage accounting or billing matters, etc.).

- Institutional Review Board
- Office of Human Research

Who, outside of the School of Medicine, might receive my information?
As part of the study, the Principal Investigator, the study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures. This information may be disclosed to those listed below:

Individuals or organizations responsible for administering the study:

- Anoscopist: The doctor conducting the anoscopy procedure, Dr. David Stein or Dr. Robert Winn, may require us to provide your medical history and contact information for you.
- Pharmaceutical Sponsor: Merck and Co., Inc who supplies the vaccine for the study.
- ACTG Data Coordinating Center, Frontier Science Technology Research Foundation (FSTRF): Data for this study will be recorded on case report forms, keyed into a central database and electronically submitted to the Data Coordinating Center. The data will be cleaned and stored at this facility until it is ready to be analyzed.
- Statistical Data Analysis Center (SDAC): Approved data will be downloaded from FSTRF to the statistical data center for the AACTG at the Harvard School of Public Health. Specific study reports will be periodically provided to the study team and data safety review board to monitor if the trial is safe.
- Contract Research Organization (PPD, Inc): Monitors from PPD will visit the AACTG on a quarterly basis to review data and correct mistakes before the data are sent to SDAC for analysis.
- Government Agencies: Data from this study will be made available to the National Institutes of Health/Division of AIDS (DAIDS)/National Institute for Allergy and Infectious Disease (NIAID), for them to evaluate the safety and efficacy of the treatments being used in this study.

Regulatory and safety oversight organizations

- The Office of Human Research Protections
- The Study Monitoring Committee

Once your personal health information is disclosed to others outside of UPHS or the School of Medicine, it may no longer be covered by federal privacy protection regulations. Data are reported to the sponsor on Case Report Forms that identify you by your unique study number and not your name, date of birth or medical record number. Information regarding your health, such as side effects of the study drug you experience will be reported only by code number. All samples collected for analysis will be labeled with your study number, visit number and date of your visit.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?
Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?
Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, your personal health information that was collected before we received your written request may still be used and disclosed, as necessary for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study. You will also be given the UPHS and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your personal health information.

What Are the Costs To Me?

The quadrivalent HPV vaccine (Gardasil) or placebo will be provided to you at no cost.

This study will not provide you with HIV drugs. You, your insurance company, or your health care system will need to assume the cost of any HIV drugs that are prescribed to you by your doctors.

Taking part in this study may lead to added costs to you and your insurance company. In some cases it is possible that your insurance company will not pay for these costs because you are taking part in a research study. This study does not pay for treatments of anal, vaginal, cervical, or oral warts, or anal or oral pre-cancers that are diagnosed during your participation in the study. The study does not pay for HRA and biopsies that occur after screening and before the last study visit. The study does not pay for CD4 and viral load testing after the entry visit.

If you become pregnant while on this study, the study will not cover any cost related to your pregnancy, the delivery of your baby, or the care of your baby.

What Happens If I Am Injured or, If I Become Pregnant, My Baby is Injured?

We will offer you or your baby the care needed to treat injuries directly resulting from taking part in this research and be referred for further treatment, if necessary.. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. There is no program for compensation either through the NIH. You will not be giving up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form

Will I Receive Any Payment?

You will receive $10 for the screening visit and $35 for each of the study required visits (11). Payments will be given as cash. At the visit when an anoscopy is conducted, an additional compensation of $125 will be provided. $25 will be given as cash from the research staff who will meet you on site and the $100 will need to be a check which is processed through the University's accounts payable and may take 6-8 weeks to receive. The total amount of compensation for the study is $620 if all visits and the two required anoscopies are attended/conducted. If you are required by the study staff to come in for any additional unscheduled visits (usually to check a lab value), you will be compensated $25 for every visit.

Please note that if you receive more than $600.00 compensation in one year for participation in research studies at the University of Pennsylvania, you must provide a Individual Tax Identification number or Social Security Number for tax purposes.

What Are My Rights As a Research Subject?

Taking part in this study is completely voluntary. You may choose not to take part in this study or leave this study at any time. Your healthcare provider will treat you the same no matter what you decide.

We will tell you about new information from this or other studies that may affect your health, welfare, or willingness to stay in this study. If you want the results of the study, let the study staff know.

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any results of procedures performed as part of this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Results of research procedures performed as part of your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

What Do I Do If I Have Questions Or Problems?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal

Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

STORAGE OF SPECIMENS FOR FUTURE RESEARCH

Some of your blood, swabs, and oral specimens will be stored and used for testing that is required for this study.

If you agree, some of your blood, swabs, and oral specimens that are left over after all required study testing is done may be stored for future research that is not yet planned. These samples will be kept frozen indefinitely and will not identify you by name. You do not have to give permission for storage of these specimens. This will not affect your participation in the study and you may withdraw your permission at any time.

Please check one of the following boxes to indicate whether or not you wish to have your leftover specimens stored for research in the future.

☐ Yes, I agree to have my specimens stored for future research.

☐ No, I do not want to have my specimens stored for future research.

If you are undergoing surgical treatments for anal warts or pre-cancers, we will ask you to have an additional biopsy of these areas just prior to these procedures. These biopsies will be stored for HPV testing and for other future research that is not yet planned. You do not have to give permission for storage of these specimens. This will not affect your participation in the study and you may withdraw your permission at any time.

Please check one of the following boxes to indicate whether or not you wish to have additional biopsies obtained and stored for future research.

☐ Yes, I agree to have additional biopsies obtained and stored for future research.

☐ No, I do not agree to have additional biopsies obtained and stored for future research.

CONSENT

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania Health System and the School of Medicine to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania Health System and the School of Medicine to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you. You will also be given the University of Pennsylvania Health System and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your health information.

If you have read this consent form (or had it explained to you), all your questions have been answered and you agree to take part in this study, please sign your name below.

_____	_____
Participant's Name (print)	Participant's Signature and Date
_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff's Signature and Date