

**Study Information & Authorization Form  
HPV Vaccine Study**

- Research Title:** A Phase 3 Randomized, International, Placebo-Controlled, Double-Blind Clinical Trial to Study the Tolerability and Immunogenicity of V503, a Multivalent Human Papillomavirus (HPV) L1 Virus-Like Particle (VLP) Vaccine, Given to Females 12-26 Years of Age Who Have previously Received Gardasil™.
- Simple Title:** 3 Dose Schedule of Either the Merck 9-Type HPV Vaccine or Placebo.
- Protocol Number:** V503-006-00
- Researchers:**
- Principal Investigator: Dr. Shelly McNeil, MD, Infectious Disease, QEII Health Sciences Centre
- Co-Investigators: Dr. Joanne Langley, MD, Infectious Disease, IWK Health Centre  
Dr. Scott Halperin, MD, Infectious Disease, IWK Health Centre  
Dr. James Bentley, MD Gynaecologic Oncologist, QEII Health Sciences Centre
- Funding – Study Sponsor** Merck & Co., Inc.

**Introduction**

Your daughter is being invited to take part in the research study named above. This study is being conducted by Merck & Co., Inc. (study sponsor) using an investigational human papillomavirus (HPV) vaccine. The word investigational means the vaccine is still being tested and is not approved for sale in the United States or Canada.

Before you decide if you want your daughter to take part, it is important that you understand the purpose of the study, how it may affect your daughter, the risks and benefits of taking part and what you will be asked to do. This form provides information about the study to help you decide if it is in your daughter's best interest to take part. Your daughter does not have to take part in the study. Taking part is entirely voluntary. If you have any questions that this form does not answer, the research nurse or study investigator will be happy to give you more information.

We refer to the process of giving you information about the study as “informed consent”. This process starts with the first contact about the study and continues until the end of the study. You may decide today you want your daughter to take part in the study and change your mind later. You have the right to do this at any time during the study. This will not affect the care you or your family members will receive from the IWK Health Center in any way.

### **Why are the researchers doing the study?**

Human papillomavirus (HPV) is a common virus that causes genital infection. HPV is the most common sexually transmitted infection among males and females. At least 70% of sexually active people will get an HPV infection at some point in their lives. Most people who have HPV will not show any signs or symptoms, so they can pass on the virus without even knowing it.

There are many different types of HPV virus, some of which cause no harm and go away on their own within months. Some types of HPV cause genital warts, while other types cause most anal cancers and more than half of vulvar (vagina opening) and vaginal cancers. Other types of HPV can cause damage to the cervix (the lower part of the womb) that may lead to cervical cancer many years later. Cervical cancer is the second most common type of cancer and cause of death in women.

Since HPV infections tends to occur in teenagers and young adults, giving a vaccine before they come in contact with HPV may be one of the best ways to control the spread of the disease. Vaccines prevent disease by causing the body to make antibodies (substances made by your body to prevent infections).

Gardasil™ is a vaccine made by Merck & Co., Inc. The Gardasil™ vaccine gives protection against four types of HPV, including the two types that cause most cervical cancers (HPV 16 and 18) and the two types that cause most genital warts (HPV 6 and 11). Since the vaccine was approved in 2006 several million girls and young women have received the vaccine worldwide which has been very effective in the protection against HPV types 6, 11, 16 and 18.

However there are other types of HPV that are now known to also cause cervical and genital disease. Merck & Co., Inc. has developed a new vaccine that includes five other HPV types (31, 33, 45, 48 and 52) in addition to the four types in Gardasil™. The new vaccine is made from the empty shells of HPV viruses, so it is not possible to become infected with by receiving the study vaccine

The purpose of this study is to look at the immune response (level of protection) and safety of the 9-valent HPV vaccine when given in three injections (shots) in young girls and women aged 12 – 26 years who have previously received the three injections series of Gardasil™.

### **How will the researchers do the study?**

This study is being done in the United States and Canada. About 900 healthy adolescent girls and young women who have received the 3 injection series of Gardasil™ vaccine, with the last injection not less than 1 year ago, will be in the study. About 180

participants will be 12 – 15 years old, and about 720 will be 16 – 26 years old. In Canada, approximately 75 participants will be in the study, with about 30 here in Halifax. The study will last about seven months.

Enrollment in the study is expected to be complete approximately 8 months after the first participant has been enrolled. Once all participants have completed the last visit, the Sponsor will look at the data to see the safety and immune system response of the participants to the study vaccine. Depending on the data results, participants that were randomized to receive placebo (look-alike with no active ingredients) may be eligible to take part in a study extension to receive 9-valent HPV vaccine. You will receive information about this optional extension study when it is available.

All participants will receive three injections over six months on the same schedule of 0, 2 and 6 months. Participants will be assigned to one of the two treatment groups below.

Group A - Three injections of the HPV study vaccine.

Group B – Three injections of placebo (salt or saline water that has no active ingredients).

Your daughter will be assigned to either study treatment group randomly (by chance) by a computer program; neither you nor your doctor is allowed to choose which group your daughter is assigned to. Your daughter will have a 2 out of 3 chance of being assigned to the HPV study vaccine group and a 1 out of 3 chance of being assigned to the placebo group. The reason we use a placebo in this study is to keep people from knowing if they are getting the vaccine being studied or not, making the results more likely to be valid.

This is a double-blind study. That means that neither you nor the study staff will know whether your daughter received the HPV study vaccine or placebo. Only the nurse who gives your daughter the vaccine will know. If this information is needed in an emergency at any time throughout the study, it is quickly available.

There may be reasons why your daughter is not allowed to take part in this study. Some of these reasons may include:

- She is under 12 years of age or over 26 years of age.
- She has not received a 3-dose regimen of marketed Gardasil™ within a 1 year period as confirmed by medical or vaccination records.
- She has received the third dose of Gardasil™ within 12 months prior to day 1.
- She has ever had sex, or plans on becoming sexually active during the study.
- She is already taking part in or plan to take part in another clinical study of investigational products while in the study.
- She is pregnant or plans to become pregnant during the study.
- She has taken part in an HPV vaccine study (had received vaccine or placebo).

The study staff will discuss these and any other reasons why you may not be allowed to take part in the study.

**What will I/my child be asked to do?**

The study will last about 7 months and will include 4 visits at the Clinical Trials Research Center at the IWK Health Center. The length of the visit will depend on the procedures to be done at that visit, and will range from 30 minutes to one hour. The visit will be made to fit into your daughter's schedule outside of school or working hours. The following describes what will happen at each study visit.

**Visit 1 – Day 0**

- The study staff will explain the study to you and your daughter and answer any questions you may have. Your daughter will be given age appropriate study information to read. If you and your daughter agree to take part in the study and your daughter is eligible, you will sign and receive a dated copy of the authorization form to keep.
- The study nurse will ask you some questions about your daughter's health and medications. She will have a physical exam to make sure she is healthy enough to be in the study. Your daughter's height, weight, blood pressure, temperature, respirations and heart rate will be measured.
- A blood sample will be taken (about 2 teaspoons) to measure your daughter's baseline HPV antibody (protective) level.
- If your daughter has had at least one menstrual period, she must have a urine pregnancy test. The results of this test will only be discussed with your daughter. You will not be present during this discussion. If your daughter is pregnant, she will not be able to take part in the study.
- Your daughter will be tested for sexually transmitted infections (STI) if medically necessary. If your daughter tests positive for any of these tests she will receive appropriate counselling and referral for any necessary treatment. These results will be kept private between your daughter and the study doctor and nurse.
- Your daughter will be randomly assigned to receive either the study injection (9-valent HPV vaccine or placebo) in her upper arm muscle.
- Your daughter will be asked to wait in the clinic for 30 minutes after her injection to watch for any reactions to the study vaccine she received.
- You will be shown how to complete the Vaccination Report Card (VRC) at home, to record your daughter's daily temperature for 4 days after injection and for 15 days after injection, record any reactions at the injection site or other side effects as well as any medications your daughter takes.

**Visit 2 - Month 2**

- Review main study points and reconfirm your consent for your daughter to continue in the study.
- You will answer health questions about your daughter and update her medical history.
- Review any medications your daughter is taking.

- Review and collection of your daughter's VRC.
- Your daughter's vital signs will be measured (blood pressure, heart rate, respirations and temperature).
- Your daughter will have a urine pregnancy test if appropriate. It must be negative to receive study vaccine.
- Your daughter will have a blood sample (2 teaspoons) taken for HPV antibody testing.
- Your daughter will be tested for sexually transmitted infections (STI) if medically necessary. If your daughter tests positive for any of these tests she will receive appropriate counselling and referral for any necessary treatment. These results will be kept private between your daughter and the study doctor and nurse.
- Your daughter will receive the 2nd vaccination of either the HPV study vaccine or placebo in her upper arm muscle.
- Your daughter will be asked to wait in the clinic for 30 minutes after her injection to watch for any reactions to the study vaccine she received.
- You will be given new VRC to complete the same way as after your daughter's first injection.

### Visit 3 – Month 6

- Review main study points and reconfirm your consent for your daughter to continue in the study.
- You will answer health questions about your daughter and update her medical history.
- Review any medications your daughter is taking.
- Review and collection of your daughter's VRC.
- Your daughter's vital signs will be measured (blood pressure, heart rate, respirations and temperature).
- Your daughter will have a urine pregnancy test if appropriate. It must be negative to receive study vaccine.
- Your daughter will be tested for sexually transmitted infections (STI) if medically necessary. If your daughter tests positive for any of these tests she will receive appropriate counselling and referral for any necessary treatment. These results will be kept private between your daughter and the study doctor and nurse.
- Your daughter will receive the 3rd vaccination of either the HPV study vaccine or placebo in her upper arm muscle.
- Your daughter will be asked to wait in the clinic for 30 minutes after her injection to watch for any reactions to the study vaccine she received.
- You will be given new VRC to complete the same way as after the 2nd injection.

Visit 4 – Month 7

- Review main study points and reconfirm your consent for your daughter to continue in the study.
- You will answer health questions about your daughter and update her medical history.
- Review any medications your daughter is taking.
- Review and collection of your daughter's VRC.
- Your daughter will have a blood sample (about 2 teaspoons) taken for HPV antibody testing.
- Your daughter will be tested for sexually transmitted infections (STI) if medically necessary. If your daughter tests positive for any of these tests she will receive appropriate counselling and referral for any necessary treatment. These results will be kept private between your daughter and the study doctor and nurse.

During the study, you should contact the study staff immediately if your daughter has any signs or symptoms that you see as serious.

If at any time during the study your daughter requires medical care or is hospitalized, you will be asked to inform your study nurse as soon as possible. We will ask you to sign a release of information form from your daughter's doctor's office or the hospital that allows us to obtain more information about her illness.

**What will happen to samples taken in this study?**

Blood samples will be used to check the safety of the vaccine and to test your daughter's protection against HPV. Part of the blood collected will also be used to develop new HPV tests and to set standards for HPV testing. The results of this test will not be revealed to you, your daughter or the study doctor. Your daughter's stored samples will not be labelled with information that directly identifies her, but a connection to her information will be kept at the study site. Your daughter's labelled samples will be sent to Merck & Co., for testing and storage for the duration of the study, about 10 years (counting from when the last participant in the study completed their last study visit), then destroyed. You should only agree to take part in this study if you agree to this use of your daughter's blood samples.

Any swabs taken for STI testing will be tested at the lab at IWK hospital and then destroyed.

**What are the burdens, harms and potential harms?**

The 9-valent HPV study vaccine has the four types in Gardasil™ plus five extra HPV types. Understanding the risks associated with Gardasil™ may help to predict what risks there may be with the new HPV vaccine.

Completed and Current Studies with Gardasil™

In clinical studies of Gardasil™ approximately 25,900 people received at least 1 injection of Gardasil™. In the first clinical study of the 9-valent HPV vaccine, which is ongoing, approximately 14,400 people have been enrolled (as of 05 Nov 09) and have received at least 1 injection of the 9-valent (9 HPV types) vaccine or Gardasil™. In additional ongoing trials of the 9-valent HPV vaccine, an additional 420 people have received the 9-valent HPV vaccine. In these studies, Gardasil™ and the 9-valent HPV vaccine have been generally well-tolerated.

In the completed studies, 9 people from a total population of 15,941 subjects had serious side effects judged by the study doctor to be related to Gardasil™ or the 9-valent HPV vaccine. These were;

- wheezing and shortness of breath,
- stomach upset with vomiting and diarrhoea,
- large bowel disease,
- muscular weakness,
- facial paralysis,
- pain and joint stiffness in the arm that was injected,
- vaginal bleeding
- severe headache with high blood pressure and abdominal pain.

#### Common Vaccine-Related Side Effects.

There were common side effects for Gardasil™ or the 9-valent HPV vaccine which occurred in 1 or more out of 100 participants. For Gardasil™ studies, which included a matching placebo vaccine group for comparison, the following side effects are included because they were reported more commonly in participants who received Gardasil™ than in participants who received placebo. They were:

- Pain, swelling, redness, itching and bruising at the injection site (Very common >1/10)
- Fever (Very common >1/10)
- Nausea (Common >1/100)
- Dizziness (Common >1/100)
- Headache (Very common >1/10)
- Pain in extremity (pain in arm or leg) (Common >1/100)
- Cold symptoms (Common >1/100)
- Feeling Tired (Common >1/100)
- Diarrhea (Common >1/100)

#### Common Systemic Side Effects (due to any cause):

The following additional side effects were not considered vaccine-related by the study doctor. They were reported in study participants receiving Gardasil™ or the 9-valent HPV vaccine. The side effects include:

- Vomiting (Common >1/100)
- Myalgia (Muscle pain) (Common >1/100)
- Cough (Common >1/100)
- Toothache (Common >1/100)

- Upper Respiratory tract infection (Cold symptoms) (Common >1/100)
- Arthralgia (Joint pain) (Common >1/100)
- Insomnia (sleeplessness) (Common >1/100)
- Migraine (a type of headache) (Common >1/100)
- Throat pain (Common >1/100)
- Flu symptoms (Common >1/100)
- Abdominal (stomach) pain (Common >1/100)
- Painful periods (Common >1/100)

Other side- effects reported by people who have received the Gardasil™ vaccine.

These reactions were reported voluntarily from a group of people of unknown size. It is not possible to estimate the frequency of these side effects or the relationship to the vaccine;

- fainting sometimes resulting in falling with injury, sometimes with shaking movements
- swollen glands (neck, armpit or groin)
- chills
- feeling weak
- tiredness
- hives
- autoimmune diseases
- autoimmune haemolytic anemia (decrease in red blood cells)
- idiopathic thrombocytopenic purpura ( low number of certain cell types with no known cause)
- acute disseminated encephalomyelitis (brain disease causing brain or spinal cord lesions)
- hypersensitivity reactions/severe allergic reaction
- difficulty breathing
- motor neuron disease (nerve disease causing muscle weakness)
- seizures (convulsion)
- impaired movement of a body part
- inflammation of the spinal cord
- blood clots in the lungs and blood vessels
- pancreatitis
- death
- guillan-barre syndrome (GBS); a neurological condition which usually causes temporary paralysis. Extremely rarely GBS causes permanent paralysis.

In a recent study participants received a fourth dose of Gardasil™ about 4 years after the third dose of Gardasil™. The frequency of side effects, especially injection site pain, redness and swelling was slightly higher than after the third dose of Gardasil™. These results did not raise any safety concerns over re-vaccination with Gardasil™.

There are other less common side effects that the study doctor can identify for you and they will be discussed with you. Like any drug or vaccine, there may be reactions that have not been seen before or a rare allergic reaction. Although the 9-valent HPV vaccine is made the same way as Gardasil™, there may be risks that are not yet known. Your

daughter will be asked to stay for 30 minutes after each vaccination to watch for and treat any rare allergic reaction if it were to occur. If this should happen Dr. McNeil or another doctor will see your daughter and she will be given advice about any necessary treatment.

Safety studies with HPV vaccines in pregnant women have not been done. It is not known how the study vaccines affect the unborn baby. If your daughter becomes pregnant during the study you must notify the study staff. Your daughter's vaccinations will be stopped until she has completed her pregnancy. The study doctor will advise you and your daughter about completing the other study visits. You will be asked about the progress of your daughter's pregnancy, her health (and her baby's) health following delivery and you will be asked to sign a separate consent form about this at the hospital where your daughter delivers.

Study injections will not be given if your daughter has a fever above 37.8°C or she is ill on the scheduled appointment date. The clinic date will be rescheduled.

Blood drawing from your daughter's arm may cause momentary pain, occasional light headedness and rarely fainting and infection. A numbing cream called EMLA<sup>®</sup> can be put on the blood taking area before we take the blood if desired.

If your daughter has a sexually transmitted infection (STI), finding out may be upsetting for her. She will receive appropriate treatment and counselling from the study doctor. These results will be kept private between your daughter and the study doctor and nurse.

### **What are the potential benefits?**

Your daughter cannot be promised any health benefit from participation in this study. If your child receives the 9-valent HPV vaccine, she may receive the same protection or more than the Gardasil<sup>™</sup> vaccine. She may benefit by being checked for an STI if needed and offered medical treatment. Knowledge gained from this study may help other people in the future.

### **What are the alternatives to participation?**

Your daughter does not have to take part in this study to receive HPV vaccine. Gardasil<sup>™</sup> has been approved for females between the ages of 9 and 26 years of age. The 9-valent HPV vaccine is not available outside of this study.

### **Can I withdraw my child from the study?**

Taking part in this study is your choice. You may decide not to enroll your daughter or you may withdraw her from the study at any time. This will not affect your daughter's care or your family's care at the IWK Health Center or QE II Health Center in any way. Your daughter must agree to take part in the study. If you decide to withdraw at any time during the study, the data collected up until that time will not be removed. Your daughter's participation may also be ended if in the opinion of the study staff it is not safe or reasonable to continue. Merck & Co., Inc. also has the right to end the study at any time. If the study is changed in any way that would affect your decision to allow your daughter to continue to participate, you will be told about the changes and you may be asked to sign a new consent form. You will be informed if new information that may affect your daughter's participation becomes available.

If your daughter does leave the study we will ask her to return for a follow-up visit as part of the study's ongoing assessments. She will have the same procedures done that she would have had at the last visit, if she had completed the study. This visit is optional but recommended if your daughter develops a health concern during the study that requires further follow-up.

**Will the study cost me anything and if so, how will I be reimbursed?**

There will be no costs to your family to take part in this study. As reimbursement for travel and parking expenses you will receive \$25 for each vaccine visit (3 visits), \$25 for each of the 3 vaccination record cards and \$25 for each other completed visit, paid after the final visit. It will take about 4-6 weeks after the last visit to receive the reimbursement. You will be asked to sign a form acknowledging receipt of this money for income tax purposes. If your daughter does not complete the study you will receive \$25 for each visit that she completed. The thermometer is provided free of charge and is yours to keep at the end of the study.

**Are there any conflicts of interest?**

There are no known conflicts of interest on the part of the researchers and/or the IWK. The sponsor Merck & Co. will cover the costs of conducting the study at the IWK Health Centre and the study nurses and research assistants will be compensated for the time, effort and expenses to conduct the study.

**What about possible profit from commercialization of the study results?**

If the study 9-valent HPV vaccine is licensed and sold after studies are completed, you will not receive any financial benefits.

**How will I be informed of study results?**

The general study results can be made available to you once the study is completed and reported (**this will likely be several years after your participation**). You will be informed of the vaccine group your daughter was placed in, and of her individual results. The summary of the results will be mailed to you if you want to receive them. You may want to provide these results to your daughter's family doctor. You will be asked to initial the last page of this form indicating if you wish to receive the results. It will be important that you notify us if there is any change in your address, so we are able to contact you with study results. You and your daughter will also be informed of any sexually transmitted infections by confidential means which may include email, telephone contact or visit to the study clinic. The study nurse will discuss your choice with you.

**How will my child's privacy be protected?**

Any information that is learned about your daughter will be kept as confidential as possible within the limits of the law. The information collected about your daughter during the study visits, will include her name, address, phone number, NS health card number, date of birth, medical history and medically related information. With your permission, we will let your daughter's regular doctor know about the study participation. Study information sent to the sponsor, Merck & Co., Inc. in the United States, will not include information that directly identifies your daughter; instead, a code number is

assigned to the study information. This coded information will be reported to the sponsor (including its parent and affiliated companies), the sponsor's representatives, its partners, and its agents, ethics committees that oversee the research, the Canadian Health Products and Food Branch (HPFB), the United States Food and Drug Administration (FDA) and other regulatory agencies. The sponsor and those working for the sponsor may also transfer coded information about your child to other countries to collect worldwide study data results where privacy laws may not be as strict.

Study staff will have access to your daughter's study record that contains information that directly identifies her. In addition, those parties working for the sponsor (such as clinical monitors and auditors) may be able to view your information for auditing and monitoring purposes but they will not be able to record any such information. These records may also be shown to the regulatory authorities in Canada, the US and the IWK Research Ethics Board as part of an audit. In addition, if you were to report an illness or injury or hospitalization, we may need access your daughter's health record (hospital chart) to collect information about the illness or injury.

If the results of the study are published in the medical literature, the publication will not contain any information which would identify your daughter. Study records will be stored in a locked area and will be kept for 25 years which meets or exceeds the requirements of the IWK Research Ethics Board, regulatory agencies in Canada, United States and the study sponsor.

You may take away your permission to collect, use and share information about your daughter at any time by writing to the study doctor. If you do this, your daughter will not be able to stay in this study. No new information that identifies your daughter will be gathered after that date. However, the information about her that has already been gathered may still be used and given to others as described in this form.

**What if I have study questions or problems?**

If you have any questions, please call the study nurse \_\_\_\_\_ at \_\_\_\_\_ You may also call the study coordinator, Robyn Sani at 470-7839, Monday to Friday between the hours of 9 am and 5 pm. If you are calling after 5pm or on the weekend/holiday, please call 476-8837 to reach the on-call study nurse. You may also reach Dr. McNeil by calling the QEII Health Sciences Centre at 473-2222 and asking for her to be paged. In the event that participation in this study has led to any reactions or serious events please contact your study nurse or coordinator as soon as possible. The matter will be reviewed with you and Dr. McNeil who will assist your daughter in obtaining appropriate medical care.

You will also be given with information about the study. You should keep this card with you at all times. If your daughter needs emergency medical treatment during the study you should show this card to the medical staff treating her. If needed, he medical staff can contact the study office and request information about the study vaccinations.

**What are my research rights?**

If your daughter becomes ill or injured as a direct result of participating in this study, necessary medical treatment will be available to her at no additional cost to you. Your

signature on this form only indicates that you have understood to your satisfaction the information regarding your daughter's participation in the study and agree to allow your daughter to participate as a subject. In no way does this waive your legal rights nor release the investigator, the research doctor, the study sponsor or involved institutions from their legal and professional responsibilities.

If you have any questions at any time during or after the study about research in general, you may contact the Research Office of the IWK Health Centre at (902) 470-8765, Monday to Friday between 9 am and 5 pm.

**Contact for future studies**

You will be asked if you are willing to be contacted for future studies by our staff. If you do wish to be included, we will collect information needed to contact you in the future. This information would include name, address, phone number and date of birth, which we would store in a secure area. If you wish to be contacted, we will ask you to initial the signature page of this form to indicate this. We will not collect this information until the final study visit, when we will reconfirm you still wish to do this. If you indicate you agree today and change your mind later, it is not a problem and it will not impact your care in any way.

**Study Title:** A Phase 3 Randomized, International, Placebo-Controlled, Double-Blind Clinical Trial to Study the Tolerability and Immunogenicity of V503, a Multivalent Human Papillomavirus (HPV) L1 Virus-Like Particle (VLP) Vaccine, Given to Females 12-26 Years of Age Who Have previously Received Gardasil™.

Participant ID: \_\_\_\_\_ Participant Code: \_\_\_\_\_

**Participant/Guardian Authorization**– I understand the nature of the study and understand the potential risk of reaction. I have read or had read to me this information and consent form and have had the chance to ask questions which have been answered to my satisfaction before signing my name. I understand that I have the right to withdraw my daughter from the study at any time without affecting my family’s care in any way. I understand that my daughter may have to leave the study without my consent. Under certain circumstances such as if she needs other treatment, does not follow the study plan, has a study-related injury, or for any other reason I have received a copy of the Information and Authorization Form for future reference. I freely agree to my daughter participating in this research study.

\_\_\_\_\_  
Name of Participant (print)

\_\_\_\_\_  
Signature of Participant (if applicable)

\_\_\_\_\_  
Name of parent/Guardian (print)

\_\_\_\_\_  
Signature of Parent or Guardian (print)

Date: \_\_\_\_\_ Time: \_\_\_\_\_

- I agree that my daughter’s coded information may be shared with other companies working with the sponsor. Yes or No: Initials \_\_\_\_\_
- I would like to receive a copy of the study results when available Yes or No: Initials \_\_\_\_\_
- I would like my daughter’s doctor to receive any STI test results. Yes or No: Initials \_\_\_\_\_
- I agree to be contacted and given information about future studies. Yes or No: Initials \_\_\_\_\_
- I agree to have my daughter’s doctor notified of her participation. Yes or No: Initials \_\_\_\_\_

**STATEMENT BY PERSON PROVIDING INFORMATION ON STUDY**

I have explained the nature and demands of the research study and judge that the Participant named above understands the nature and demands of the study.

Name (Print): \_\_\_\_\_ Position: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

**STATEMENT BY PERSON OBTAINING CONSENT**

I have explained the nature of the consent process to the participant and judge that they understand that participation is voluntary and that they may withdraw their daughter at any time from participating.

Name: \_\_\_\_\_ Position: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_