Informed consent is a process through which patients learn the important facts about a clinical research study to help them decide whether or not to participate.

During this process, details about the study, including the potential risks and benefits of participation, will be explained to you. You/your child are encouraged to bring up any concerns either of you may have and to ask as many questions as you like. Once you/your child have had an opportunity to ask questions, and if you decide to allow your child to participate, you will be asked to sign an informed consent form. You will receive a copy of the informed consent form to take with you. As appropriate, based on local guidelines, your child will also read and sign an informed assent form stating that he/she agrees to take part in the study.

Participation is voluntary, and participants may withdraw from the study for any reason at any time.

Is There any Cost to Participate?

Some of the tests or treatments used in this study may be part of standard care used to maintain your child's health, even if he or she did not take part in this study. You or your insurance company may be responsible for the standard care cost; however, all the study vaccine and study-related tests will be provided at no cost.

Your Responsibilities

While your child is in this study, you/your child must:

- Make every effort to attend all study visits. If you must reschedule, let the study staff know as soon as possible.
- Follow the instructions given by the study doctor and study staff.
- Tell the truth about your child's medical history, current medical condition, and any health changes he or she experiences.
- Let the study doctor or study staff know immediately if you decide to have your child stop participating in the study.

For more information, including possible risks and benefits of participation, please contact:

MERCK

V503-069_Patient Recruitment Brochure Cohort 1-4_V1.0

HEALTHY BOYS AND GIRLS AGES 9-14

NEEDED FOR A VACCINE CLINICAL RESEARCH STUDY

INFORMATION ABOUT A
Human Papilloma Virus (HPV)
Clinical Research Study

A Vaccine Study is Now Enrolling

Human Papilloma Virus (HPV)

The human papilloma virus (HPV) is a common sexually transmitted disease that can cause anal and genital diseases. Vaccines are available to protect against anal and genital diseases caused by HPV, and they are recommended for both male and female adolescents and young adults.

About Clinical Research Studies

A clinical trial is a research study that tries to answer questions about how medicines work in the people who take them. Researchers run studies to test whether an investigational medication is safe and effective. These studies may help doctors find new ways to help prevent, detect, or treat health problems. Clinical trials may also be referred to as research studies.

There are rules in place to help protect the rights, safety, and well-being of people who volunteer for research studies. These rules are put in place to make sure studies follow strict scientific and ethical guidelines.

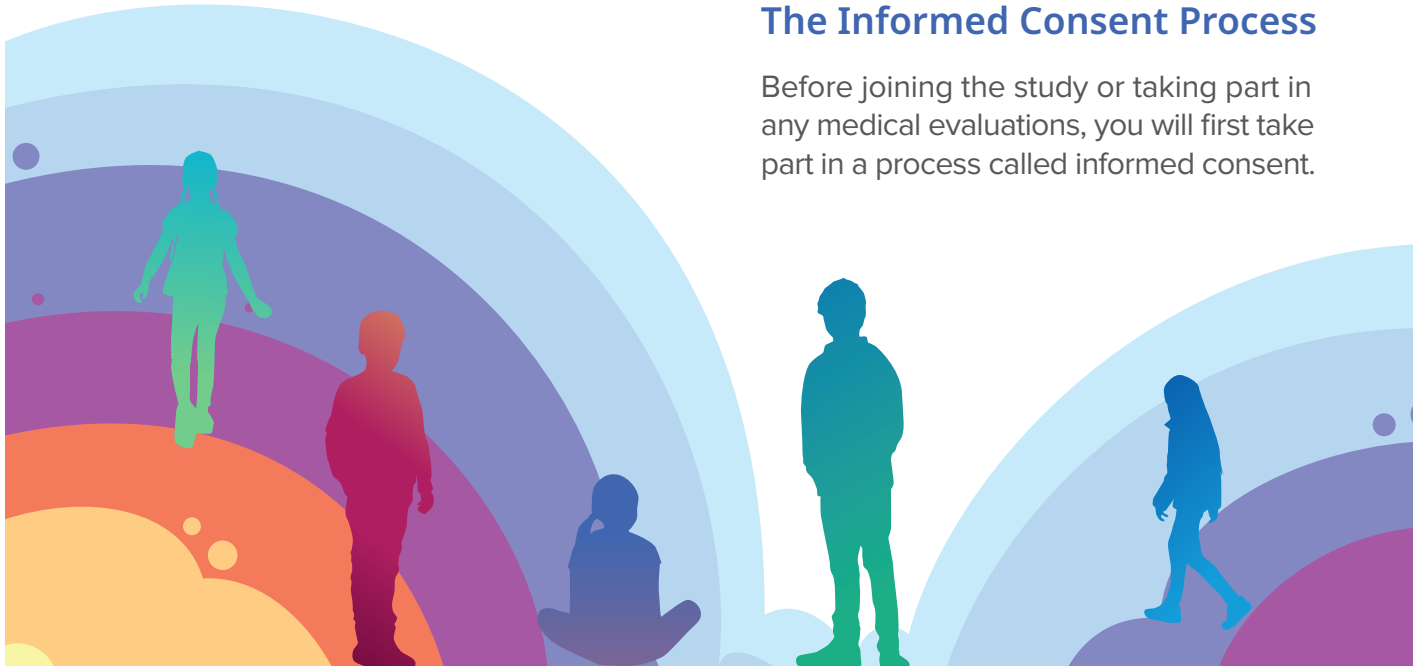
Before a clinical research study can begin, a review board or ethics committee must review and approve the study. In the U.S., this group is called an IRB or institutional review board and is composed of doctors, scientists, and members of the community.

About This Research Study

This clinical research study will test an HPV vaccine that is usually given in two or three separate doses 6 to 12 months apart. This study will evaluate the safety and effectiveness of the vaccine when given with different vaccination schedules. Researchers will look at the immune response to the trial vaccine depending on the length of time between doses.

Potential participants will first be evaluated to make sure they qualify to take part in this study. Examples of some of the evaluations include having his/her temperature taken, a physical exam, a review of medical history, and a review of current and past medications. If your child qualifies and agrees to participate in the study, he or she will have blood tests and will receive two doses of the study vaccine.

Participants will be assigned to one of four groups. Each group has different lengths of time for study participation, ranging from 3.5 to 8 years.



About the Study Vaccine

The study vaccine is approved in many countries to help protect against anal and genital diseases and cancers caused by some types of HPV. The study vaccine is given by injection (a shot).

Who Can Be in This Study?

For this study, we are looking for healthy boys and girls who are 9-14 years old and:

- Never received an HPV vaccine
- Have a parent or legal guardian who agrees that the study doctor or staff may be in contact while his or her child is in the study, will attend all study center visits, and comply with the study procedures.

Additional requirements apply, and the study doctor can discuss these with you.

The Informed Consent Process

Before joining the study or taking part in any medical evaluations, you will first take part in a process called informed consent.