HPV Vaccine Intervention for Young Sexual Minority Men

NCT04032106

September 26, 2019

Consent

Please read the consent information below and indicate if you agree to participate in this study.

Study Consent Form

This is a consent form for participation in the Outsmart HPV Project. It contains important information about the project and what to expect if you participate. Please read the information carefully.

Why is this study being done?

The goal of this research study is to give young men information about the HPV vaccine and why it is important for them to get vaccinated. As a young man between the ages of 18-25, you have the chance to participate.

How many people will take part in this study?

About 2100 men will take part in this study.

What will happen if I take part in this study?

You will be asked to complete four online surveys over a period of about nine months. Each survey will take about 10-15 minutes and ask questions about you, your health, and the HPV vaccine. You don't need special knowledge about these topics to participate. You will be asked to view online information about the HPV vaccine for about 15 minutes. You will also receive text message/email communications about study activities. You may also be asked to give permission for the study team to get information from your doctors about whether or not you got the HPV vaccine. No other information will be given to the study team by your doctors.

How long will I be in the study?

You will be in the study for about nine months. You may be contacted in the future by the study team to see if you would like to take part in other studies. If you are contacted, you will be told what the study is about and asked to complete a separate consent form.

Will I be paid for taking part in this study?

You can receive up to $95 in Amazon gift cards for this study. This includes a $40 gift card for completing your first study session, which consists of two online surveys and viewing online information about the HPV vaccine. You can then receive a $20 gift card for completing a third online survey about three months after your first study session. You can then receive a $35 gift card for completing a fourth online survey about nine months after your first study session. By law, payments to study participants are considered taxable income. The study team reserves the right to withhold gift cards if a study account is suspected of being fraudulent (e.g., identical or similar contact information to an existing account already in the study).

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

Being in this study is completely up to you, and you can refuse to participate without penalty.

Can I stop being in the study?

You may leave the study at any time without any penalty to you.

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

Some of the survey questions may be sensitive for some people, but answering these questions is up to you. You will also be asked to provide information online, though efforts will be made to protect your study-related information and avoid online security concerns.

What benefits can I expect from being in the study?

You may learn new information about the HPV vaccine.

What are the costs of taking part in this study?

There are no costs to you for taking part in this study.

What happens to the information I provide?

You will be asked to provide information about you and your health as well as your contact information. This information will help the study to learn about you and allow for communication about the study. People with access to this information may include: the study team; offices at The Ohio State University, the University of Minnesota, the University of Michigan, and the University of Pennsylvania; and the federal agency that oversees the study. There is no set date for discarding this information. This is because the information may be analyzed for many years, and it is not possible to know when this will be completed. Your de-identified information may be used or shared with other researchers without your additional informed consent.

Will my information be kept confidential?

Efforts will be made to keep your study-related information confidential. All information will be kept in locked file cabinets and on secured computers. Reports on findings from this study will not use your name and will only report results as a group. We are required to protect the privacy of your health information.

The National Institutes of Health (NIH) issues Certificates of Confidentiality for all NIH-funded studies, including this study. This Certificate provides extra protection for you and your study information, documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable information collected about you as a part of this study in a lawsuit or legal proceeding. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, if the National Cancer Institute that is funding this study requests the information, or if the FDA tells us to release this information.

Please talk to the study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

Please visit the NIH website at https://humansubjects.nih.gov/coc/faqs to learn more.

What are my rights if I take part in this study?

You will be provided with any new information that develops during the course of the study that may affect your decision whether or not to continue participation. An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable.

Who can answer my questions about the study?

For questions about the study, you may contact us at [STUDY CONTACT INFORMATION WILL BE INSERTED FOLLOWING IRB APPROVAL]. For questions about your rights as a participant in this study, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

Do you consent to participate in this study?

Yes
No

[IF YES, PARTICIPANT CONTINUES WITH STUDY ACTIVITIES]

[IF NO, PERSON WILL RECEIVE THE FOLLOWING MESSAGE]: Thank you for your interest in Outsmart HPV. We appreciate your time!

[THE BELOW TEXT APPEARS AT THE BOTTOM OF THE WEBPAGE WITH THE CONSENT FORM]

If you have any questions or concerns, please contact [STUDY CONTACT INFORMATION].