

Population Assessment of Tobacco and Health Study

Youth Assent for Interview Form

Key Information

Introduction

You are invited to take part in a research study. The Population Assessment of Tobacco and Health (PATH) Study is sponsored by the National Institutes of Health (NIH) in partnership with the Food and Drug Administration (FDA). Westat, an independent research firm, is conducting the study. This form contains information that will help you decide whether to join the study.

Things You Should Know:

- The study is looking at tobacco use and health in the U.S. population. You don't have to use tobacco to take part in the study.
- We ask you to complete an interview. This takes about 45 minutes to answer.
- Your participation is voluntary.
- The PATH Study will continue for at least a few more years. We ask you to complete an interview now, and then every year or two until the study is completed.
- The interview involves no risk of injury. There is a small risk that your personal information or data could be exposed. We take several steps to protect your privacy and prevent that from ever happening.
- Participating does not help you individually. The data collected by the study may provide useful information to help people in the United States be healthier.
- Your parent or guardian has given permission for you to participate.

Taking part in the PATH Study is voluntary. You do not have to participate and you can stop at any time. Please take time to read this form and note any questions before deciding whether to take part in the PATH Study. Most questions will have an answer within this form or the Frequently Asked Questions on this website.

Detailed Information

Why are you doing this study?

We want to know more about tobacco and health in the United States. You don't have to use tobacco to take part in the study. What we learn from you and others in the study may help your community and millions of people in the United States.

Why was I selected for this study?

We can't talk to every young person in the United States so we had to pick a smaller number of young people by chance to take part in the study. This means your answers will represent the answers that many other young people like you would give if they were in the study, too.

What would you like me to do?

We'd like you to answer some questions. We call this an interview, even though you are doing it on a computer, tablet, or phone, rather than talking with another person.

We ask that you complete the interview in a private location. You can listen to the questions using headphones or just read them. You will answer by clicking on the screen. Your parents or guardians should not watch or see your answers. The interview will take about 45 minutes to complete.

We ask about:

- What you think about tobacco and nicotine use.
- What you think about tobacco and nicotine advertising.
- What you know about tobacco and nicotine.
- Your experiences with tobacco and nicotine.
- Your friends' experiences with tobacco and nicotine.
- Your life and your health.

You can skip any question you don't want to answer, and you can stop the interview at any time. You're in charge, but we hope you will answer all the questions because your answers are important.

The study will continue for at least a few more years. We'd like to interview you now, and then every year or two until the study ends. We may ask you to be part of other study activities, too, and you can decide if you want to participate or not. We'd like you to be part of the study even when you turn 18. We're studying adults too, so when you turn 18, you can be in the adult part of the study.

What other information will the PATH Study get about me?

We collect personal information, such as your name, address, and date of birth. We store this information in a highly secure location to protect it. We may use it to get information about you from public health records, such as health registries, cancer registries, and vital statistics databases. Health registries collect health information from hospitals, clinics, laboratories, and doctors' offices.

We protect your identity. Your personal information will not be shared with anyone but a small group of qualified researchers who work on the study, and it will be destroyed when the PATH Study is over.

Will anything good or bad happen to me if I'm in this study?

Being part of this study may not help you individually. However, the answers you give will be combined with the answers from many other young people and may help your community and millions of people in the United States be healthier.

The main bad thing that could happen is that people might find out personal information about you, but we have safeguards in place to keep this from happening.

Can I change my mind about being in this study?

Yes. Participation is voluntary. You can say no or stop whenever you want. You or your family will not lose any benefits if you say no now or stop later. If you're in the study for a while and then stop participating, we will use the information you already gave us.

Can the people in charge of this study stop it?

Yes. If this happens, we will tell you.

Do I get anything for doing the interview?

- You receive \$35 after you finish the interview as a thank-you for participating.
- You receive a Certificate of Appreciation showing 2 hours of community service credit.
- Each year you're in the study, you can receive up to \$10 per year when your parent updates any changes to your contact information.

How will you stop people from seeing my information?

We will keep your personal information, like your name and address, in a protected and secure computer file. We will keep your answers to the interview questions in a different file with answers from all the other people in the study.

This means:

- Your name will not be on your answers so people who work on the study will not know who you are.
- Your family will not know what you tell us and no one in your school or the authorities will know what you tell us.
- We combine your answers with those from many other people in the study. We report on this information only for groups of people, not individuals. This means we cannot put personal information about you in a report about the study.
- We destroy your personal information when the study is over.

We have a Certificate of Confidentiality. This means that no one doing the study can be forced to give anyone information about you, including your name. PATH Study researchers do have to give this information if a project funded by NIH requests it for an audit or program review.

You are free to tell anyone you want that you're in this important study.

PATH Study researchers are studying only tobacco and health. However, if we learn that you or someone else is harming you or others, we'll report this to the police or social services agency in your community to protect you or others.

Is there someone I can talk to if I have more questions?

If you have questions:

- You can read the Frequently Asked Questions on the PATH Study website.
- Call the study toll-free number at 1-888-311-1819. This number operates on weekday between 9:00 a.m. and 9:00 p.m. and weekends between 11:00 a.m. and 7:00 p.m. Eastern Time.

If you have questions about your rights and welfare as a PATH Study participant, call the Westat Human Subjects Protections office at 1-888-920-7631. Please leave a message with your first name, the name of the research study you are calling about (The PATH Study), and a phone number beginning with the area code. Someone will return your call as soon as possible. The Human Subjects Protections Office makes sure we're doing the study the right way.

Assent Agreement

By clicking on "I agree":

- You agree to participate in the PATH Study and answer interview questions.
- You agree to participate in future interviews and possibly in other activities if you choose.
- You agree to let the study securely keep your personal information, so we can look for public health records in the future.
- You also agree to let state cancer registries give medical information about you to the study about any cancer diagnosis in the future.

Participant Assent

I have read the information about this study. I have had a chance to ask questions. I can print a copy of this form from this website. I agree to take part in the study.

_____ I Agree.