



A collaboration between the NIH and FDA

Population Assessment of Tobacco and Health Study Youth Assent for Interview Form

Introduction

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 describes what we'll be doing. Please read it or ask me to read it to you. Then, if you decide to be in the study, I'll ask you to verbally agree to participate and I will enter that information in the computer.

Why are you doing this study?

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

Why was I selected for this study?

We can't talk to every young person in America 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.

Your parent or guardian has given permission for you to participate.

What would you like me to do?

We'd like you to answer some questions over the telephone. You should be in a private location where others cannot hear your answers during the interview. The interviewer will ask you questions over the telephone and enter your answers into a computer. Your parents or guardians will not see your answers. The interview will take about 45 minutes to complete.

We'll ask about:

- What you think about tobacco use and tobacco advertising.
- What you know about tobacco.
- Your experiences with tobacco.

- Your friends' experiences with tobacco.
- 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 or not. We'd like you to be part of the study even when you turn 18. We're studying adults, 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'll collect personal information, such as your name, address, and date of birth. We'll 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 will 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 will be destroyed when the PATH Study is over.

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, we will use the information you already gave us.

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 to improve the health of your community and millions of Americans.

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.

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 will combine your answers with those from many other people in the study. We will 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 will destroy your personal information when the study is over.

Also, 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 may 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.

Do I get anything for doing the interview?

Yes. You'll receive \$35 after you finish the interview this time and in future years as a thank-you for participating. Also, each year you're in the study, you'll receive up to \$10 as a thank-you when your parent updates any of your contact information that has changed.

Can the people in charge of this study stop it?

Yes. If this happens, we will tell you.

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

Yes. If you have questions now, you may talk to the interviewer.

If you have any questions about the study, call Westat's toll-free number, 1-888-311-1819, weekdays 9:00 a.m. to 9:00 p.m. and weekends 11:00 a.m. to 7:00 p.m. Eastern Time.

If you have questions about your rights and welfare as a PATH Study participant, call Westat's 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 verbally telling the interviewer that you will participate, you agree to participate in the PATH Study and answer interview questions. You also 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.

I have read the information about this study or someone has read it to me. I have had a chance to talk about it and ask questions. I agree to take part in the study.

THANK YOU