

Population Assessment of Tobacco and Health Study

Adult Consent for Interview

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 60 minutes to answer.
- 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 your community and people in the United States be healthier.

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

What is the purpose of the study?

The study will look at tobacco use and health in the U.S. population. You don't have to use tobacco to take part in the study. What we learn may help to improve the health of millions of people in the United States.

Why was I selected for this study?

Initially, we selected your household by chance from a list of addresses. We selected you to represent many other people throughout the country.

Participation is voluntary. Because our information will be more useful and complete if you participate, we hope you'll agree to be part of the study.

What would you like me to do?

We'd like you to complete an interview. We ask about your attitudes, knowledge, and personal experiences with tobacco and nicotine; we also ask about substance use, mental health, your relationships with friends and family, and your general health.

We ask that you complete the interview in a private location. You'll read or hear the questions, and answer by clicking on the screen. You can skip any questions you don't want to answer. The interview will take about 60 minutes to complete.

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 ends. We may also ask you to participate in other study activities, but you can say no at any time.

We contact you occasionally to update your contact information, and we may send you letters and messages throughout the year. A Westat quality control person may call you to ask about your experience with the PATH Study.

What other information does the PATH Study collect?

We collect personal information, such as your name, address, phone number, and date of birth. We store this information in a highly secure location to protect it.

We may use your personal information to link to public health records, such as state and federal vital statistics records, and health and cancer registries. These registries are updated by state public health agencies to keep current information on the health status of patients who visit hospitals, clinics, laboratories, and doctors' offices.

What are the possible benefits and risks of participating in the study?

Participating does not help you individually. The data collected by the study may provide useful information to help your community and people in the United States be healthier.

The interview involves no risk of injury. There is a small risk that your personal information or answers could be exposed. We take several steps to protect your privacy and prevent that from ever happening.

Can I change my mind about participating?

Yes. You may refuse to participate in any interviews and you can stop at any time. If you don't participate or if you stop participating, you will not lose any benefits.

If you are in the study for a while and then stop, we won't ask for any more data from you. We will use the data already collected about you.

Can the sponsors stop this study?

Yes. If this happens, we will notify you.

Do I get anything for completing the interview?

- You receive \$50 for completing the interview. This is a thank-you for participating.
- You can receive additional thank you gifts for participating in future study activities.
- Each year you're in the study, you can receive up to \$10 per year for updating changes to your contact information with us.

How do you protect my privacy?

We take several steps to protect your identity and the privacy of your data.

- We secure your personal information in a protected computer file.
- We secure your interview answers in a separate file.
- Your name will not appear with your answers. Your answers can only be linked to a number, not to your name. This means that your answers cannot be used to identify you.
- Your answers will be combined with answers from other adults in the study and secured in a protected computer file.
- We report on this information only for groups of people, not individuals.
- We won't put your personal information in any report about this study.
- We destroy your personal information when the study is over.

We have a legal document called a Certificate of Confidentiality. The Federal government certifies that PATH Study researchers can't be forced by any person or court of law to give your name with any of your answers. 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're participating in this study. We can provide your information to others only if you have given them written permission to have it.

PATH Study researchers are studying only tobacco and health. However, if we learn that you or someone else is harming you, your child, or others around you, we will report this to the police or a 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:

- 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 weekdays 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 any 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 (PATH Study), and a phone number beginning with the area code. Someone will return your call as soon as possible.

Consent Agreement

By clicking on “I agree”:

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

Participant Consent

I have read the information about this study, and I have been given the chance to ask questions. I can print a copy of this consent form from the website. I consent to take part in this study.

_____ I Agree.