



Population Assessment of Tobacco and Health Study Adult Interview Consent 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.

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 be a tobacco user to take part in the study. What we learn will help to improve the health of millions of Americans.

Why was I selected for this study?

Your household was selected 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 over the telephone. We'll ask about your attitudes, knowledge, and personal experiences with tobacco; we'll also ask about substance use, mental health, your relationships with friends and family, and your general health. The interviewer will read the interview questions to you and will record your answers in a computer. You can skip any questions you don't want to answer. The questions take about 60 minutes to answer.

The PATH 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 also ask you to participate in other activities, but you can say no at any time. We'll 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 interviewer.

What other information will the PATH Study collect?

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 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.

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 participating, we won't ask for any more data from you. We will use the data already collected about you.

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

Participating in the study may not help you individually, but it may provide useful information on new ways to help protect the Nation's public health. The interview involves no risk of injury. The main risk, which is small, is your personal information or data could be revealed. We are taking several steps to protect your privacy and prevent that from ever happening.

How will you protect my privacy?

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

- We'll secure your personal information in a protected computer file.
- We'll secure your interview answers in a separate file.
- Your name will not appear on the interview. 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'll report on this information only for groups of people, not individuals.
- We'll destroy your personal information when the study is over.
- We won't put your personal information in any report about this study.

We've also obtained a legal document called a Certificate of Confidentiality. In this legal document, 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.

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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.

Do I get anything for completing the interview?

Yes. You'll receive \$50 after you finish the interview this time as a thank-you for participating. You can receive additional thank you gifts for participating in future interviews and other study activities. Also, each year you're in the study, you'll receive up to \$10 a year as a thank-you for updating your contact information on the PATH Study website or by mail.

Can the sponsors stop this study?

Yes. If this happens, we will notify you.

Whom can I contact if I have further questions?

You can ask the interviewer any questions you have about the study.

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 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 verbally telling the interviewer that you will participate, you give your consent to participate in the PATH Study. This participation includes completing an interview and being contacted again to complete future interviews and possibly other study activities if you choose.

You give your consent to having the study securely maintain your personal information so that we can use it when we look at public health records, and state health and cancer registries.

You also authorize state cancer registries to release medical information about you to our researchers to learn about or confirm any cancer diagnosis in the future.

I have read the information about this study or someone has read it to me, and I have been given the chance to discuss it and to ask questions. I consent to take part in this study.

THANK YOU