

Population Assessment of Tobacco and Health (PATH) Study Parent Consent and Permission for Youth Interview Form

Key Information

Introduction

We invite your child 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 and allow your child to participate in 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 about your child. This takes about 15 minutes to answer.
- We ask your permission for your child to complete an interview. This takes about 45 minutes to answer. Your child must agree to participate too.
- 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 and your child 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 PATH Study?

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. What we learn may help to improve the health of millions of people in the United States.

Why was my child selected for this study?

First, your household was selected by chance from a list of addresses to represent many others like it in the country. Second, your child is in the 13- to 17-year-old age group being asked to participate in this study.

What would you like me to do?

We'd like you to answer a few questions about your child. The questions ask about your child's age and education, your relationship with your child, what your child knows and how they feel about tobacco and nicotine, and any tobacco or nicotine use.

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 15 minutes to complete.

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.

We are also asking your permission for your child to participate in the PATH Study.

What does my child's participation involve?

An interview

We ask your child questions about different areas of life, including their attitudes, knowledge, and personal experiences with tobacco and nicotine and experiences with tobacco and nicotine advertising.

We also ask about substance use, mental health, relationships with friends and family, and overall physical health.

Your child should complete the interview in a private location. Your child reads or hears the questions and answers by clicking on the screen. The questions take about 45 minutes to answer.

Your child can skip any questions they do not want to answer. You will not see your child's answers.

Follow-up interviews every year or two

The PATH Study will interview your child every year or two until the study ends.

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.

When your child turns 18

When your child turns 18, they will be invited to join the study as an adult.

What other information will the PATH Study collect?

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

We may use your child's personal information to get information from public health records, such as state and federal vital statistics records, and health and cancer registries on your child's health. Health registries are part of public health agencies that collect information from hospitals, clinics, laboratories, and doctors' offices.

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

Participating does not help you or your child individually. The data collected by the study may help your community and people in the United States be healthier.

The interviews involve no risk of injury. There is a small risk that your answers or your child's answers could be exposed. We take several steps to protect your privacy and your child's privacy, and to prevent this from ever happening.

Can I or my child change our minds about participating?

Yes. You and your child may refuse to participate in the study and can stop at any time. If you don't want to participate or don't want your child to participate, you will not lose any benefits. Your child must also agree by clicking the agreement box on the screen stating they agree to take part in the study.

If you or your child stops participating in the PATH Study, we won't ask for any more data. We will use the data already collected.

Can the sponsors stop this study?

Yes. If this happens, we will notify you.

Do I or my child receive anything for completing the interview?

- You will receive \$15 for completing the interview about your child as a thank-you for participating.
- Your child will receive \$35 upon completing the youth interview as a thank-you for participating.
- Your child will receive a Certificate of Appreciation showing 2 hours of community service credit.
- Each year your child is in the study, they can receive up to \$10 per year when you update any changes to your child's contact information.

How do you protect my privacy and my child's?

We take several steps to protect your and your child's identity and the privacy of your data. The information you provide will not be shared with your child; and information your child provides will not be shared with you, the child's school, or the authorities.

We take additional steps to protect your identity and your child's identity.

- 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 and your child's answers will be combined with answers from others 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. This means the Federal government certifies that PATH Study researchers can't be forced by any person or court of law to give your name or your child's 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 and your child may 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 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 that 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.

Consent Agreement

By clicking on "I agree":

- You agree to answer questions about your child and give your permission for your child to participate in an interview now and in the future.
- You agree to being contacted again about future interviews, and possibly other study activities with you and your child.
 - Your child must also agree by reviewing a form. That form states that they agree to take part in the study but have the right to stop at any time and may refuse to participate in this or any future interviews.
- You agree to having the study securely keep your child's 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 your child to the study to learn about and confirm any cancer diagnosis in the future.

Participant Consent and Permission

I have read the information about this study and have been given the chance to ask questions. I understand that my child must also agree to participate. I can print a copy of this form.

I agree to answer questions about my child.

☐ Yes

☐ No

I give permission for my child to complete interviews.

☐ Yes

☐ No