



A collaboration between the NIH and FDA

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

Name of Child: _____

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 PATH Study?

The PATH Study will look at the use of tobacco and how it may affect the health of people in the United States. What we learn will help to improve the health of millions of Americans. You don't have to be a tobacco user to take part in the study.

Why was my child selected for this study?

Your child was selected to take part in this study for two reasons. First, your household has been chosen by chance to represent many others like it in the country. Second, your child is in the 12- to 17-year-old age group being asked to participate in this study.

What information will I be asked to provide?

We'd like to ask you a few questions about your child before we ask their permission to do the interview. The questions will ask about your child's age and education, your relationship with your child, what your child knows and how they feel about tobacco, and any tobacco use.

The questions will take about 15 minutes to answer. Your participation is completely voluntary. If you do not want to participate, you will not lose any benefits. You may refuse to participate in this and any future interviews.

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

What does my child's participation involve?

The interview asks your child questions about different areas of life, including their attitudes, knowledge, and personal experiences with tobacco and tobacco advertising. We will also ask about substance use, mental health, relationships with friends and family, and overall physical health.

Follow-up interviews every year or two

A PATH Study interviewer will contact you every year or two to interview your child.

We may contact you occasionally to update your contact information, and we may send you letters and messages throughout the year as reminders of the next visit. A Westat quality control person also may call you to ask about your experience with the interviewer.

When your child turns 18

When your child turns 18, they will be invited to enroll into the study as an adult and sign a consent form.

What other information will the PATH Study collect?

We may use your child's personal information (such as name, address, date of birth) in the future to get information from public health records, such as health registries, cancer registries, and vital statistics databases, on your child's health. Health registries are part of public health agencies that collect information from hospitals, clinics, laboratories, and doctors' offices.

We will protect your identity and your child's. Your child's personal information will be secured and 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.

How long will the study last?

The PATH Study will continue for at least a few more years. We'd like to interview your child now, and then every year or two until the study ends. We may also ask your permission for you and your child to participate in other activities, but you can say no at any time.

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 signing a form that states 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.

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

Participating in the study may not have a direct benefit to you or your child individually. Information from the study may benefit your community and the Nation by improving health strategies and programs.

If you or your child feels uncomfortable about any of the questions, it's OK to skip those questions. The main risk, which is small, is your answers or your child's answers could be revealed. We take several steps to protect your privacy and your child's privacy, and to prevent this from ever happening.

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

The study has several safeguards in place to protect the identities of all participants, including yours and your child's. 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.

The researchers will take additional steps to protect your identity and your child's identity.

- We'll treat all of the information in this study as private. The information will be used only for research purposes.
- We'll label your interview answers with a code number only, not your names.
- We'll store your personal information in a protected computer file separate from your interview data. We'll keep the key to the code in a password-protected database.
- We'll combine your data with those of the thousands of other people in the study. In addition, we'll only put information about groups of people in our reports. This means we can't put information about individuals in any report about the PATH Study.
- We'll destroy all personal information that could identify you and your child, like your name, address, and phone number, after the study is over.

Also, we've 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 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.

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

You will receive \$15 upon completion of the interview about your child and each future interview as a thank-you for participating.

Your child will receive \$35 upon completion of the youth interview and each future interview as a thank-you for participating.

Also, each year your child is in the study, they will receive up to \$10 as a thank-you when you update your child's contact information.

Whom can I contact if I have further questions?

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

If you have any questions about the study, call Westat's toll-free number, 1-888-311-1819, 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 signatures

By verbally telling the interviewer that you will participate and allow your child to participate, you give your consent to answer questions about your child, and your permission to interview your child now and in the future. You also give your permission for the researchers to contact you regarding future interviews, and possibly other study activities with you and your child. Your child must also agree by telling the interviewer that they will participate. Your child has the right to stop the interview at any time and may refuse to participate in this or any future interviews.

You give your consent to having the study securely maintain your child's personal information to access public health records in the future, and authorize state cancer registries to release medical information about your child to the researchers to learn about and confirm any cancer diagnosis in the future.

I have read the information about this study and have been given the chance to discuss it and to ask questions. I understand that my child must also agree to participate by signing a form.

I agree to answer questions about my child.

☐ Yes

☐ No

I give permission for my child to complete interviews.

☐ Yes

☐ No

The interviewer will record your responses in the computer.

THANK YOU