

ICPSR 36498

## **Population Assessment of Tobacco and Health (PATH) Study [United States] Public-Use Files**

*United States Department of Health and Human Services. National Institutes of Health. National Institute on Drug Abuse*

*United States Department of Health and Human Services. Food and Drug Administration. Center for Tobacco Products*

Informed Consent Documents for Wave 1

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# **Population Assessment of Tobacco and Health (PATH) Wave 1 Consent Forms**



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## **Population Assessment of Tobacco and Health (PATH) Study In-Person 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 using a computer. 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. You'll hear the interview questions in private, using headphones, and answer by touching a computer screen. You can skip any questions you don't want to answer. The questions take about 60 minutes to answer. After the interview, we'll ask you to participate in other activities, but you can say no.

The PATH Study will continue for at least 3 years. We'd like to interview you once a year. 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 you 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, we won't ask for any more data from you. We would like to use the data already collected about you, unless you ask us not to. You will not be able to withdraw your data after the study has ended; until then, you may request that your data be destroyed.

## **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 will do several things 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 may tell anyone you're participating in this study. We may provide your information to others if you have given them written permission to have it. Even though it is not what PATH Study researchers are studying, 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 a \$35 debit card 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.

### **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 questions later, you may call the PATH Study Survey Director, Scott Crosse, at 1-800-937-8281, ext. 3979.

If you have any questions about your rights as a PATH Study participant, call Westat's Human Subjects Protections office at 1-888-920-7631.

### **Do you have any questions now?**

## Consent signatures

By signing this form, 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 will receive a copy of this consent form for my records. I consent to take part in this study.

_____	_____/_____/_____
Signature of Participant	Month      Day      Year

_____	_____
Printed Name of Participant	ID # of Interviewer

_____	_____/_____/_____
Signature of Person Obtaining Consent	Month      Day      Year

**THANK YOU**



## **Population Assessment of Tobacco and Health (PATH) Study In-Person 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 affects 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 provide?**

We'd like to ask you a few questions about your child before we ask his or her 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 he or she feels 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 his or her attitudes, knowledge, and personal experiences with tobacco. We will also ask about substance use, mental health, relationships with friends and family, and overall physical health.

The interview will be conducted in private and take about 40 minutes. Your child will use a computer, hear questions through headphones, and enter his or her answers directly into the computer by touching the screen. Your child can skip any questions he or she does not want to answer. You will not see your child's answers.

The PATH Study will continue at least 3 years, so we'd like your permission to interview your child now and once a year until the study is over. 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, he or she will be invited to enroll into the study as an adult and sign a consent form.

## **What other information will you collect?**

Your child's personal information (such as name, address, date of birth) may be used 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.

## **Can I or my child change our minds about participating?**

Yes. You and your child may refuse to participate in any interviews 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 he or she agrees to take part.

If you or your child stops, we won't ask for any more data. We would like to use the data already collected about you and your child unless you ask us not to. You will not be able to withdraw your data or your child's data after the study has ended, but until then, you may request that the data be destroyed.

## **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 are taking 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 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 in the interview 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 secure personal information in a protected computer file.
- We'll secure interview answers in a separate file.
- Your names will not appear on the interview. Your answers can only be linked to a number, not to your names. This means that your answers cannot be used to identify you or your child.
- Your answers will be combined with answers from others 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 and your child's when the study is over.
- We won't put your personal information in any report about this study.

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 may provide your information to others if you have given them written permission to have it. Even though it is not what PATH researchers are studying, 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 \$10 in cash upon completion of the interview about your child and each future interview as a thank you for your participation.

Your child will receive a \$25 debit card upon completion of the youth interview and each future interview as a thank you for his/her participation. Also, each year your child is in the study, he/she will receive up to \$10 as a thank you when you update contact information for him/her.

## **Whom can I contact if I have further questions?**

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

If you have questions later you may also call the PATH Study Survey Director, Scott Crosse, at 1-800-937-8281, ext. 3979.

If you have any questions about your rights as a PATH Study participant, call Westat's Human Subjects Protections office at 1-888-920-7631.

## **Do you have any questions now?**

## Consent signatures

By signing this form, you give your consent to answer questions about your child, and your permission for this interview and future interviews with your child. You also give your permission for the researchers to contact you regarding future interviews with your child. Your child must also agree by signing a form. That form states that he or she agrees to take part but 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 understand I will receive a copy of this permission form for my records.

I agree to answer questions about my child.

☐ Yes

☐ No

I give permission for my child to complete interviews.

☐ Yes

☐ No

\_\_\_\_\_  
Signature of Parent/Guardian

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Month Day Year

\_\_\_\_\_  
Printed Name of Parent/Guardian

\_\_\_\_\_  
ID # of Interviewer

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Month Day Year

**THANK YOU**





## **Population Assessment of Tobacco and Health (PATH) Study In-Person Youth Permission 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 sign the form.

### **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 on a computer. We call this an interview, even though you'll do it on a computer, rather than talking with another person. You'll listen to the questions on headphones. Your parents or guardians will not watch or see your answers. You'll answer the questions by touching the computer screen. The interview will take about 40 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 be for at least 3 years so we will ask you to answer questions again once a year. 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 you 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, 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 would like to use the information you already gave us, unless you ask us not to. You will not be able to take back your information after the study is over; until then, you can ask that your information be destroyed.

## **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. Even though it is not what PATH researchers are studying, 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 a \$25 debit card 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 your contact information.

## **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 questions later, you may call Scott Crosse, at 1-800-937-8281, ext. 3979. He is in charge of doing the survey.

If you have questions about our rights as a participant, call Westat's Human Subjects Protections office at 1-888-920-7631. This office that makes sure we're doing this study the right way.

## **Do you have any questions now?**

## Assent signatures

By signing this form, 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. I will get a copy of this form.

_____	_____ / _____ / _____
Signature of Participant	Month      Day      Year

_____	_____
Printed Name of Participant	ID # of Interviewer

_____	_____ / _____ / _____
Signature of Person Obtaining Assent	Month      Day      Year

**THANK YOU**

## **Population Assessment of Tobacco and Health (PATH) Study Adult Biological Samples Consent Pamphlet (with buccal cell)**

### **Introduction**

The National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA), is sponsoring the PATH Study. This study is one of the most important national health studies ever done in the United States. By participating, you are an essential part of what is learned about tobacco products and health.

In addition to an interview, we ask adults to give biological samples. These samples are critical to the success of the study. We need samples from both tobacco users and non-users.

For this part of the study, we'd like you to give us three kinds of biological samples:

- Urine,
- Cells from inside your mouth (cheek cells), and
- Blood (taken with sterile equipment by medically trained and certified health professionals).

This pamphlet tells you more about why we want these samples, explains what you need to do, discusses the risks and benefits of giving samples, and describes what you get for participating.

After you've read this pamphlet or someone has read it to you, we will ask you to sign a form saying you agree to give samples.

### **Why do you want me to give you samples?**

We can learn a lot more about tobacco products and health by combining information from samples and interviews. The samples give valuable information on these topics we can't get any other way.

We will mainly test samples for chemicals associated with exposure to tobacco products and with health outcomes. We will not look for illegal drug use.

We will use information from samples and interviews for research purposes only. The study will keep this information private; it will only be seen by individuals working on the study.

## **If I say yes, what happens?**

A PATH Study interviewer will come to your home once a year for at least 3 years to interview you. At that time, the interviewer will ask you to give biological samples. Giving them is easy and quick; the interviewers and health professionals are trained to make you feel comfortable and respect your privacy.

- Each year, the interviewer will ask you to give a urine sample; this takes about 10 minutes. It's just like giving a urine sample at your doctor's office.
- In this year only, the interviewer will ask you to use a small collector to give cheek cells. The interviewer will show you how to gently stroke the inside of your cheek with the collector. This takes about 20 minutes.
- In some years, including this year, we'll ask if a health professional can collect a sample of your blood. If you agree to give a blood sample, the interviewer will schedule an appointment for a medically trained and certified health professional to come to your home at a time that's convenient for you. This person will draw a small amount of blood (about 3 tablespoons) from your arm using sterile equipment. It's just like giving a blood sample at your doctor's office. It takes about 20 minutes.
- Each time you give a sample, we will ask questions about your recent use of tobacco products. This takes about 4 minutes.

## **Do I have to give you samples?**

No. You decide whether to give us samples. You can decide to give us some samples but not others. Even if you don't give us samples, you can still be part of the PATH Study.

You can stop being part of the study at any time. If you stop, we'd like to keep the samples that you already gave us, but we'll destroy them if you tell us to.

## **Will you do research on my genes?**

If you agree, we may use your cheek cells and blood for genetic research in the PATH Study and possibly in future studies. We'll look at how genes affect health among people who do and don't use tobacco products. We'll also look at how people's background and lifestyle—like age, education, and smoking—may work together with genes to affect their health.

If you don't want us to use your samples for genetic research, we'll only use them for other kinds of tests. These other tests are mainly for chemicals associated with exposure to tobacco products and with health outcomes.

## **How will you store my samples?**

We'll ship your samples to a secure facility called a repository where they will be frozen and stored until they are tested. Your samples will be labeled with a code number only. This means your name won't be on the samples.

## How long will you keep my samples?

If you agree that your samples can be used for research in the PATH Study and in future studies, we will keep your frozen samples at the repository for an unlimited period of time. We may keep using your samples for research unless you decide to withdraw your samples from the study or we close the secure repository where they are stored, at which time the samples will be destroyed.

## Who will have access to my samples and data?

Only qualified researchers will have access to your samples. The PATH Study Biospecimen Access Committee will make sure these researchers are qualified and have procedures to protect the privacy of the results they get from your samples. These researchers won't be able to identify you because your name won't be on the samples. They will only have a code number on them.

## Will I get the results of tests done on my samples?

You won't get the results of any tests done on your samples. Your results will be combined with results from other people in the study to help us understand the health of the general population.

## What are the risks of providing samples?

- Giving us a urine sample has no risks.
- When you give us cheek cells, your cheek may feel a little sore.
- Giving a blood sample may hurt for a moment; rarely, it causes light-headedness, fainting, infection, bruising, hematoma, or bleeding. The health professionals who draw your blood are trained to make you feel comfortable and to make this a safe procedure.
- The risks from genetic research are very low. Only a code number will be on your samples, not your name. A Federal law (the Genetic Information Non-Discrimination Act, or GINA) will help make sure that health insurance companies or employers can't use what we find out from your genes.

## What are the benefits of providing samples?

You won't benefit personally from giving us samples. However, your samples may help to develop ways to improve the Nation's health.

## Do I get anything for providing samples?

Yes. In addition to the \$35 debit card for the interview, every year you provide samples you will get the following as a thank you:

- \$25 for your time providing cheek cells and a urine sample at a visit from an interviewer, and
- \$25 for your time providing a blood sample at a follow-up visit from a health professional.

## What are the costs to me?

Giving samples has no costs to you.

## What happens if I'm hurt as a result of taking part in this research?

You are not likely to get hurt while we are collecting your samples. Our procedures minimize any risks. If you are hurt, though, please see your doctor.

## How will you protect my privacy?

Your privacy is very important to the PATH Study.

- 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 samples and interview answers with a code number only, not your name.
- We'll store your personal information in a protected computer file separate from your samples and the rest of your data. Your samples and data will only be identified by a code number. We'll keep the key to the code in a password-protected database.
- We'll combine your results with the results 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, 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 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 may tell anyone you're participating in this study. We may provide your information to others if you have given them written permission to have it. Even though it is not what PATH researchers are studying, 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.

## What if I have questions about the study?

You can ask the interviewer any questions you have right now. Do you have any questions now?

If you have questions later you may call the PATH Study Survey Director, Scott Crosse, at 1-800-937-8281, ext. 3979.

If you have any questions about your rights as a PATH Study participant, call Westat's Human Subjects Protections office at 1-888-920-7631.



## Population Assessment of Tobacco and Health (PATH) Study Adult Consent for Biological Samples Signature Form (with buccal cell)

I have read the Biological Sample Consent Pamphlet or it has been read to me. My questions about the PATH Study have been answered and I understand the following.

- What is involved if I decide to give samples.
- I decide whether to give samples. I can decide not to give any sample and still be part of the PATH Study.
- I decide whether my samples are used in genetic research. I can decide not to have my samples used in this research and still be part of the PATH Study.
- I can tell the PATH Study to stop storing and using my samples at any time. Also, I can tell the PATH Study to destroy my samples.
- The PATH Study will store my samples in a secure facility and make sure only qualified researchers who have agreed to keep my information private have access to them.
- The PATH Study will use my samples for a variety of tests.
- I will not get results back from the tests done on my samples.
- What the risks and benefits are if I give samples.
- I can ask more questions at any time.
- I'll get a copy of this consent form.

I agree to give:

A sample of cheek cells.

☐ Yes

☐ No

A urine sample.

☐ Yes

☐ No

A blood sample.

☐ Yes

☐ No

I agree to the use of my sample for genetic research

☐ Yes

☐ No

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Month Day Year

\_\_\_\_\_  
Printed Name of Participant

\_\_\_\_\_  
ID # of Interviewer

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Month Day Year

**THANK YOU**

## **Population Assessment of Tobacco and Health (PATH) Study Adult Biological Samples Consent Pamphlet (without buccal cell)**

### **Introduction**

The National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA), is sponsoring the PATH Study. This study is one of the most important national health studies ever done in the United States. By participating, you are an essential part of what is learned about tobacco products and health.

In addition to an interview, we ask adults to give biological samples. These samples are critical to the success of the study. We need samples from both tobacco users and non-users.

For this part of the study, we'd like you to give us two kinds of biological samples:

- Urine and
- Blood (taken with sterile equipment by medically trained and certified health professionals).

This pamphlet tells you more about why we want these samples, explains what you need to do, discusses the risks and benefits of giving samples, and describes what you get for participating. After you've read this pamphlet or someone has read it to you, we will ask you to sign a form saying you agree to give samples.

### **Why do you want me to give you samples?**

We can learn a lot more about tobacco products and health by combining information from samples and interviews. The samples give valuable information on these topics we can't get any other way. We will mainly test samples for chemicals associated with exposure to tobacco products and with health outcomes. We will not look for illegal drug use.

We will use information from samples and interviews for research purposes only. The study will keep this information private; it will only be seen by individuals working on the study.

## **If I say yes, what happens?**

A PATH Study interviewer will come to your home once a year for at least 3 years to interview you. At that time, the interviewer will ask you to give biological samples. Giving them is easy and quick; the interviewers and health professionals are trained to make you feel comfortable and respect your privacy.

- Each year, the interviewer will ask you to give a urine sample; this takes about 10 minutes. It's just like giving a urine sample at your doctor's office.
- In some years, including this year, we'll ask if a health professional can collect a sample of your blood. If you agree to give a blood sample, the interviewer will schedule an appointment for a medically trained and certified health professional to come to your home at a time that's convenient for you. This person will draw a small amount of blood (about 3 tablespoons) from your arm using sterile equipment. It's just like giving a blood sample at your doctor's office. It takes about 20 minutes.
- Each time you give a sample, we will ask questions about your recent use of tobacco products. This takes about 4 minutes.

## **Do I have to give you samples?**

No. You decide whether to give us samples. You can decide to give us some samples but not others. Even if you don't give us samples, you can still be part of the PATH Study.

You can stop being part of the study at any time. If you stop, we'd like to keep the samples that you already gave us, but we'll destroy them if you tell us to.

## **Will you do research on my genes?**

If you agree, we may use your samples for genetic research in the PATH Study and possibly in future studies. We'll look at how genes affect health among people who do and don't use tobacco products. We'll also look at how people's background and lifestyle—like age, education, and smoking—may work together with genes to affect their health.

If you don't want us to use your samples for genetic research, we'll only use them for other kinds of tests. These other tests are mainly for chemicals associated with exposure to tobacco products and with health outcomes.

## **Will I get the results of tests done on my samples?**

You won't get the results of any tests done on your samples. Your results will be combined with results from other people in the study to help us understand the health of the general population.

## How will you store my samples?

We'll ship your samples to a secure facility called a repository where they will be frozen and stored until they are tested. Your samples will be labeled with a code number only. This means your name won't be on the samples.

## How long will you keep my samples?

If you agree that your samples can be used for research in the PATH Study and in future studies, we will keep your frozen samples at the repository for an unlimited period of time. We may keep using your samples for research unless you decide to withdraw your samples from the study or we close the secure repository where they are stored, at which time the samples will be destroyed.

## What are the risks of providing samples?

- Giving us a urine sample has no risks.
- Giving a blood sample may hurt for a moment; rarely, it causes light-headedness, fainting, infection, bruising, hematoma, or bleeding. The health professionals who draw your blood are trained to make you feel comfortable and to make this a safe procedure.
- The risks from genetic research are very low. Only a code number will be on your samples, not your name. A Federal law (the Genetic Information Non-Discrimination Act, or GINA) will help make sure that health insurance companies or employers can't use what we find out from your genes.

## Who will have access to my samples and data?

Only qualified researchers will have access to your samples. The PATH Study Biospecimen Access Committee will make sure these researchers are qualified and have procedures to protect the privacy of the results they get from your samples. These researchers won't be able to identify you because your name won't be on the samples. They will only have a code number on them.

## How will you protect my privacy?

Your privacy is very important to the PATH Study.

- 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 samples and interview answers with a code number only, not your name.
- We'll store your personal information in a protected computer file separate from your samples and the rest of your data. Your samples and data will only be identified by a code number. We'll keep the key to the code in a password-protected database.
- We'll combine your results with the results 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, 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 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 may tell anyone you're participating in this study. We may provide your information to others if you have given them written permission to have it. Even though it is not what PATH researchers are studying, 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 providing samples?**

Yes. In addition to the \$35 debit card for the interview, every year you provide samples you will get the following as a thank you:

- \$25 for your time providing a urine sample at a visit from an interviewer, and
- \$25 for your time providing a blood sample at a follow-up visit from a health professional.

## **What happens if I'm hurt as a result of taking part in this research?**

You are not likely to get hurt while we are collecting your sample. Our procedures minimize any risks. If you are hurt, though, please see your doctor.

## **What are the costs to me?**

Giving samples has no costs to you.

## **What if I have questions about the study?**

You can ask the interviewer any questions you have right now. Do you have any questions now?

If you have questions later you may call the PATH Study Survey Director, Scott Crosse, at 1-800-937-8281, ext. 3979.

If you have any questions about your rights as a PATH Study participant, call Westat's Human Subjects Protections office at 1-888-920-7631.

## Population Assessment of Tobacco and Health (PATH) Study Adult Consent for Biological Samples Signature Form (without buccal cell)

I have read the Biological Samples Consent Pamphlet or it has been read to me. My questions about the PATH Study have been answered and I understand the following.

- What is involved if I decide to give samples.
- I decide whether to give samples. I can decide not to give any sample and still be part of the PATH Study.
- I decide whether my samples are used in genetic research. I can decide not to have my samples used in this research and still be part of the PATH Study.
- I can tell the PATH Study to stop storing and using my samples at any time. Also, I can tell the PATH Study to destroy my samples.
- The PATH Study will store my samples in a secure facility and make sure only qualified researchers who have agreed to keep my information private have access to them.
- The PATH Study will use my samples for a variety of tests.
- I will not get results back from the tests done on my samples.
- What the risks and benefits are if I give samples.
- I can ask more questions at any time.
- I'll get a copy of this consent form.

I agree to give:

A urine sample.

☐ Yes

☐ No

A blood sample.

☐ Yes

☐ No

I agree to the use of my sample for genetic research

☐ Yes

☐ No

\_\_\_\_\_  
Signature of Participant

\_\_\_\_ / \_\_\_\_ / \_\_\_\_  
Month Day Year

\_\_\_\_\_  
Printed Name of Participant

\_\_\_\_\_  
ID # of Interviewer

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_ / \_\_\_\_ / \_\_\_\_  
Month Day Year

**THANK YOU**



## **Population Assessment of Tobacco and Health (PATH) Study In-Person Consent for Emancipated Youth 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 sign it.

### **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 who are taking part 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 many other young people like you would give if they were in the study, too.

### **What would you like me to do?**

We'd like you to answer some questions on a computer. We call this an interview, even though you'll do it on a computer, rather than talking with another person. For privacy, you'll listen to the questions on headphones. You'll answer the questions by touching the computer screen. The interview will take about 40 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 that you don't want to answer and you can stop the interview at any time. You're in charge, but we hope you'll answer all the questions because your answers are important.

The study will be for at least 3 years so we'll ask you to answer questions again once a year. 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 you 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 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.

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; this information will be destroyed when the PATH study is over.

## **Can I change my mind about participating?**

Yes, you can say no or stop whenever you want.

If you're in the study for a while and then stop, we won't ask for any more data from you. We would like to use the data already collected about you, unless you ask us not to. You will not be able to withdraw your data after the study is over; until then, you can ask that your data be destroyed.

## **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. This information may help to improve the health of your community and millions of Americans.

Being in the study has a small risk that people might find out personal information about you. We are taking steps and using safeguards to protect your privacy and keep this from happening at all.

## **How will you stop people from seeing my information?**

We'll keep your personal information, like your name and address, in a protected and secure computer file. We'll 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 won't be on your answers, so people who work on the study won't know who you are.
- No one in your school or the authorities will know what you tell us.
- We'll combine your answers with those from many other people in the study. We'll report on this information only for groups of people, not individuals. This means we can't put personal information about you in a report about the study.
- We'll 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.

We'll protect what you tell us, but you may tell anyone you are participating in this important study. We may provide your information to others if you have given written permission for them to have it. Even though it is not what the PATH researchers are studying, if we learn that you or someone else is harming you or others, we'll provide information to the police or a social services agency in your community to protect you or others.

## **Do I get anything for doing the interview?**

Yes. You'll receive a \$25 debit card 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 you update your contact information.

## **Can the people in charge of the study stop it?**

Yes. If this happens, we will tell you.

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

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

If you have questions later you may also call the PATH study Survey Director, Scott Crosse, at 1-800-937-8281, ext. 3979.

If you have any questions about your rights as a PATH study participant, call Westat's Human Subjects Protections office at 1-888-920-7631.

## **Do you have any questions now?**

## Consent signatures

By signing this form, you give your consent to participate in the PATH study and complete the interview. You also agree to being contacted again about participating in future interviews and possibly other study 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 to ask questions. I agree to take part in the study. I will get a copy of this form.

_____	____ / ____ / ____
Signature of Participant	Month      Day      Year

_____	_____
Printed Name of Participant	ID # of Interviewer

_____	____ / ____ / ____
Signature of Person Obtaining Consent	Month      Day      Year

**THANK YOU**