

Attachment 11
Consent Materials
November 16, 2012

Table of Contents

<u>Section</u>		<u>Page</u>
CM	Consent Materials	
	CM1 – In-Person Adult Consent Form for Interview.....	1
	CM2 – In-Person Parent Permission Form for Youth Interview/Consent Form for Parent Interview.....	5
	CM3 – In-Person Youth Assent Form for Interview	9
	CM4 – In-Person Adult Consent Form for Biological Samples.....	13
	CM5 – In-Person Emancipated Youth Consent Form for Interview.....	18

CM1 – In-Person Adult Consent Form for Interview



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, will conduct 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.

You can decide not to participate. But our information will be more useful and complete if you do, so we hope you'll agree to be part of the study.

If you participate, you'll be helping your community and the Nation because information from the study will be used to develop new policies that benefit everyone's health.

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. The questions take about 75 minutes to answer. You'll hear the interview questions in private, using headphones, and answer by touching a computer screen. You can skip any questions that you don't want to answer.

The PATH study will continue for at least 3 years and possibly longer. We'd like to interview you once a year at about the same time each year. We may also ask you to participate in other activities, but you can say no at any time.

After you finish the interview, we'll ask if you're willing to provide three kinds of samples: urine, cells from inside your cheeks, and blood. You may choose to provide all, some, or none of the

samples. Our researchers may use your samples for a variety of biological tests, including genetic tests, to learn more about tobacco use and health.

We'll contact you occasionally to update your contact information, and we may send you letters and email messages throughout the year. A Westat supervisor on the PATH study may call you to ask about your experience with the Westat 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 registries. Health registries are a part of state public health agencies that collect information from hospitals, clinics, laboratories, and doctor's offices. We plan to search state cancer registries in the future to see if cancer records are found for any of our study participants. We may ask for your Social Security Number in the future to help with this search, but you may say no.

If you are a veteran, we may ask you in the future to sign a separate authorization form to allow us to request your Department of Veterans Affairs health records.

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, but 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 will provide useful information for new policies to help protect the Nation's public health. The interview involves no risk of injury. The main risk is a small one, that 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.

- 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 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, unless a Federal official asks for it to check on how we're doing on the study.

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 participating in the interview?

Yes. You'll receive a \$35 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 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 Institutional Review Board Administrator, Sharon Zack, at 1-800-937-8281, ext. 8828.

Do you have any questions now?

Consent signatures

By signing this form, you give your consent to participate in the PATH study and complete an interview and to be 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 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

CM2 – In-Person Parent Permission Form for Youth Interview/ Consent Form for Parent Interview



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, has been contracted to conduct the study.

What is the purpose of the PATH study?

The PATH study will look at the use of tobacco and its effects on health in the U.S. population. What we learn will help to improve the health of millions of Americans. You don't have to be 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.

Your child's participation in this study is a service to your community and the Nation because information from the study will help develop new policies to benefit everyone's health.

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 20 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 45 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 that 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 and possibly longer, so we'd like your permission to interview your child now and once a year at about the same time until the study is over. We may contact you occasionally to update your contact information, and we may send you letters and emails throughout the year as reminders of the next visit. A Westat supervisor also may call you to ask about your experience with the Westat 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. Then, once each year, he or she would be contacted to complete the adult interview and provide biological samples.

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 and vital statistics databases, to collect information on your child's health. Health registries are part of public health agencies that collect information from hospitals, clinics, laboratories and doctor's offices. We plan to search state cancer registries in the future to see if any cancer records are found for any of our study participants.

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 will benefit your community and the Nation, though, because it will help improve health policies and programs.

If you or your child feels uncomfortable about any of the questions, it's OK to skip those questions. The main risk is a small one, that 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 that 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.

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, unless a Federal official asks for it to check on how we're doing on the study.

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 taking part in the study?

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 Institutional Review Board Administrator, Sharon Zack, at 1-800-937-8281, ext. 8828.

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.

Parent/Guardian's Statement

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 that 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 take part in this study. 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

DCN

CM3 – In-Person Youth Assent Form for Interview



Population Assessment of Tobacco and Health (PATH) Study In-Person Youth Permission for Interview Form

Introduction

We'd like you to be part of a very important study on tobacco and health. It's called the Population Assessment of Tobacco and Health (PATH) study and it's sponsored by two agencies that serve public health, the National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA). Your parent or guardian has given permission for you to participate.

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 U.S. population. What we learn from you and others who are taking part in the study will help your community and millions of Americans to be healthier. You don't have to be tobacco user to take part in the study.

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.

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 45 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, and
- 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 still 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 at about this same time. 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 and vital statistics databases. Health registries collect health information from hospitals, clinics, laboratories and doctor's offices. We plan to search state cancer registries in the future to see if any cancer records are found for anyone in our study. This will help us in the future to find out how healthy you are.

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'd 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; but 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 will 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'll keep your personal information, like your name and address, in a protected and secured 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.

- Your family won't know what you tell us and no one in your school or the authorities will know what you tell us.
- We'll combine your answers with those from lots of 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.

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, unless a Federal official asks for it to check how we're doing on the study.

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 your rights as a participant, call Sharon Zack at 1-800-937-8281, ext. 8828. She's the leader of a group 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

CM4 – In-Person Adult Consent Form for Biological Samples



Population Assessment of Tobacco and Health (PATH) Study In-Person Adult Informed Consent for Biological Samples

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).

We'd like you to give us three kinds of samples:

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

This form:

- Tells you more about why we want these samples,
- Explains what you need to do,
- Explains the risks and benefits of providing these samples, and
- Describes what you get for participating.

The Westat interviewer can answer any questions you have.

After you've read this form or someone has read it to you, we'll ask you whether you agree to provide samples. If you say yes, we'll ask you to sign the form.

Why do you want me to give you samples?

We would like to use your samples along with other information to learn more about tobacco use and health. What we learn from your samples, along with many other people's samples, will help improve the Nation's health. We will use your samples to test for certain chemicals, proteins, and metals that may be associated with exposure to tobacco products and health outcomes.

If I say yes, what happens?

A Westat interviewer will come to your home once a year at about the same time for at least 3 years to interview you and to collect cheek cells and urine samples. We'll ask you to do the following.

- Use a small scraper to gently stroke the inside of your cheek. The interviewer will show you how. This will take about 5 minutes.
- Provide a urine sample. This also takes about 5 minutes.
- Answer some questions about your recent use of tobacco and other products. This takes about 2 minutes.

In some years, including this year, we'll also ask to collect a sample of your blood.

If you agree to give us a blood sample, the interviewer will schedule an appointment for a phlebotomist (a certified professional medically trained to draw blood) 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 procedures. It's just like giving a blood sample at your doctor's office. It takes about 10 minutes.

Do I have to give you samples?

No. You decide whether to give us samples or not. 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?

Yes. If you agree, we'll use your cheek cells and blood for genetic research in this study and possibly in future studies. We'll look at how genes affect health among people who do and don't use tobacco, and how people's background and aspects of their 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 biological tests to measure exposure to tobacco products.

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. We'll label your samples 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 review applications from researchers and decide if they are qualified and have procedures to protect the privacy of the results they get from your samples before they are approved to use the 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?

- There are no risks from giving us a urine sample.
- When you give us cells from inside your mouth, your cheek may feel a little sore.
- There may be a small risk when you give a blood sample. It may hurt for a moment, and there is a very small risk of infection, bruising, or bleeding. The professionals who draw your blood are trained to make you feel comfortable.
- The risks from genetic research are very low. Only a code number will be on your samples, not your name. In this way, identifying you will not be possible. 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 will help to develop strategies 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:

- \$10 for your time providing cheek cells at a visit from an interviewer, and
- \$25 for your time providing a urine sample and a blood sample at a follow-up visit from a health professional.

What are the costs to me?

There aren't any.

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

It is not likely that you'll be hurt while we are collecting your samples because measures are taken to minimize any risks. If you are hurt, though, please see your doctor.

How will you protect my privacy?

- 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. 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.

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 with any of your answers, unless a Federal official asks for it to check on how we're doing on the study.

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.

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 Institutional Review Board Administrator, Sharon Zack, at 1-800-937-8281, ext. 8828.

Do you have any questions now?

Consent signatures

I've read this document or it has been read to me. I've gotten answers to my questions about the study and I understand the following.

- What's involved if I decide to give samples.

- I choose whether to give samples. I can decide to refuse to provide any sample and still be part of the study.
- I can say no and tell you to stop storing and using my samples at any time. If I tell you to, you will destroy my samples.
- You will store my samples in a secure facility and make sure that only qualified researchers who have agreed to keep my information private have access to them.
- You 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 provide samples.
- I can ask more questions at any time.
- I'll get a copy of this consent form.

I agree to provide:

- | | | |
|--|---------------------------|--------------------------|
| A sample of cheek cells (buccal cells). | <input type="radio"/> Yes | <input type="radio"/> No |
| A urine sample. | <input type="radio"/> Yes | <input type="radio"/> No |
| A blood sample. | <input type="radio"/> Yes | <input type="radio"/> No |
| I agree to the use of my samples for genetic research. | <input type="radio"/> Yes | <input type="radio"/> No |

Signature of Participant

_____/_____/_____
Month Day Year

Printed Name of Participant

ID # of Interviewer

Signature of Person Obtaining Consent

_____/_____/_____
Month Day Year

THANK YOU

DCN

CM5 – In-Person Emancipated Minor Consent Form for Interview



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, will conduct 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.

You can decide not to participate. But our information will be more useful and complete if you do, so we hope you'll agree to be part of the study.

If you participate, you'll be helping your community and the Nation because information from the study will be used to develop new policies that benefit everyone's health.

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. The questions take about 75 minutes to answer. You'll hear the interview questions in private, using headphones, and answer by touching a computer screen. You can skip any questions that you don't want to answer.

The PATH study will continue for at least 3 years and possibly longer. We'd like to interview you once a year at about the same time each year. We may also ask you to participate in other activities, but you can say no at any time.

After you finish the interview, we'll ask if you're willing to provide three kinds of samples: urine, cells from inside your cheeks, and blood. You may choose to provide all, some, or none of the

samples. Our researchers may use your samples for a variety of biological tests, including genetic tests, to learn more about tobacco use and health.

We'll contact you occasionally to update your contact information, and we may send you letters and email messages throughout the year. A Westat supervisor on the PATH study may call you to ask about your experience with the Westat 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 registries. Health registries are a part of state public health agencies that collect information from hospitals, clinics, laboratories, and doctor's offices. We plan to search state cancer registries in the future to see if cancer records are found for any of our study participants. We may ask for your Social Security Number in the future to help with this search, but you may say no.

If you are a veteran, we may ask you in the future to sign a separate authorization form to allow us to request your Department of Veterans Affairs health records.

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, but 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 will provide useful information for new policies to help protect the Nation's public health. The interview involves no risk of injury. The main risk is a small one, that 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.

- 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 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, unless a Federal official asks for it to check on how we're doing on the study.

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 participating in the interview?

Yes. You'll receive a \$35 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 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 Institutional Review Board Administrator, Sharon Zack, at 1-800-937-8281, ext. 8828.

Do you have any questions now?

Consent signatures

By signing this form, you give your consent to participate in the PATH study and complete an interview and to be 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 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

DCN