

CM4 - ~~Adult Consent for Biological Samples~~ Consent Pamphlet



Population Assessment of Tobacco and Health (PATH) Study Biological Samples Consent Pamphlet

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~~ three kinds of biological samples:

- Urine and
- ~~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 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.
- ~~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.

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 ~~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 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.

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**.