

Attachment 10
Advance Materials
November 16, 2012

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AM1 - Advance Letter to Household



{DATE}

Dear Resident,

I am writing to ask your household to be part of an important national health study called the Population Assessment of Tobacco and Health (PATH) study. **This study will look at tobacco use and how it affects the health of people in the United States, but you do not 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. The National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA), is sponsoring the study.

We've hired Westat, an independent research firm, to conduct the PATH study. Within a few days, a Westat interviewer will come to your home to tell you more about the study and how you can help. The interviewer will wear an ID badge. It should look like the one shown on the right.



Please answer the interviewer's questions about the people in your household. It will take 15 to 20 minutes. We'll use your answers to decide who, if anyone, in your household may be selected for the study. **We will give you \$10 as a thank you for answering these questions.**

If we select someone from your household for the study, we'll give that person more information about it. **That person will receive up to \$70 as a thank you for participating.** For more information on the PATH study, please see the enclosed brochure and the study website at www.pathstudyinfo.nih.gov (if you have a smartphone, you can scan the QR code below to visit the website). Also, the interviewer can answer any questions you have. Or you can call us toll-free at 1-888-311-1819 (between 9:00 am and 5:30 pm Eastern Time), if you have any questions or would like to schedule an appointment.

You don't have to answer our questions. But we hope that you will. **Your answers are very important to the success of the PATH study.** Your household was selected by chance from a list of addresses. Including your household and many others in the study will make the results much more complete and useful.

All of the information you provide for the PATH study will be kept confidential. It will be protected under current laws and regulations, including the Privacy Act of 1974. We'll combine your answers with those

Population Assessment of Tobacco and Health (PATH) Study (NIDA)

given by other people. Your information will not be used in any way that could identify you, except as permitted by law.

This important study can only succeed with the help of households like yours. I hope you'll agree to be part of it.

Sincerely,

Kevin P. Conway, Ph.D.
PATH Study, NIH Project Officer

[PATH QR Code]

DCN

AM2 – Study Brochure

Population Assessment of Tobacco and Health (PATH) Study

What is the PATH study?

The PATH study is a new national study on tobacco and health. It will help in developing important policies on tobacco products to protect the public health of Americans.

The study will include people age 12 and older who may or may not use tobacco. We'll interview about 59,000 people at their homes.

- The topics that we'll ask about include:
 - Age, gender, and education.
 - Health, including tobacco use, use of medicines, and health conditions.
- We'll ask adults for samples of urine, cells from inside their cheeks, and blood.
 - People can choose whether or not to provide these samples.
 - People can also choose to provide some samples but not others.
 - A trained professional will collect the samples, using safe practices.
 - We may use samples for biological research, such as genetic research.
 - We will not ask people under the age of 18 for samples.
- We'll combine information from many people. We'll use the information for research purposes only. We'll keep people's information confidential.

Who is doing this study?

The National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA), is sponsoring the PATH study. Westat, an independent research firm, will conduct the study. Other research institutions and universities are also helping.

Why was my household selected? Why do you need information about people in my household?

We can't interview everyone. It would take too long and cost too much. So we've selected households by chance from a list of addresses.

Your household represents many others in the United States. Whether to participate is up to you. However, the interviews and samples we collect will be much more complete and useful if your household and many others say yes.

We'd like to talk to an adult in your household and ask a few questions about the people who live there. This information will help us select people to participate in the study.

What happens if someone in my household is selected?

If someone in your household is selected, we'll ask him or her to take part in an interview and to give samples. Then, the person can decide whether to be part of the study. If you're selected, we hope you'll say yes.

If the person who's selected is younger than 18 years old, we'll interview that person only if the parent or guardian gives permission and the young person agrees to participate. We will not ask youth to give samples.

Why should I be part of this study?

You should be part of this study because it will help to improve the health of millions of Americans.

The PATH study is the largest ever of its kind on tobacco and health. Whether you use tobacco or not, if you participate in the study, you'll be an important part of what is learned about tobacco products and how they affect health.

The study results will help, for example, in reducing tobacco use among youth and assisting tobacco users who want to quit in your community and the Nation.

How will you protect my privacy?

Everything you provide will be kept private.

- Your interview answers and samples will not be associated with your name.
- We will identify your interview answers and samples by a number only.
- Your name and contact information will be kept separately in secure computer files.

Will I get anything for being in the PATH study?

Yes. As a thank you for participating, if selected for the study, household members could get up to \$70.

\$10 will be given to the adult household member who completes a short interview that helps us decide who should be selected.

Based on the answers to the short interview, you or other members of your household may be selected to participate further. Each selected adult can get the following:

- \$35 for completing a longer interview,
- \$10 for time providing cells from inside the mouth (cheek cells) at a visit from an interviewer, and
- \$25 for time providing a urine sample and a blood sample at a followup visit from a health professional.

- Selected adults can choose to participate in the interview but not give samples. Or they can choose to give us some samples but not others.

Each selected youth can get \$25 for completing an interview.

How long does the study last?

Once a year for at least 3 years, we'll ask the same people to complete interviews, and we'll ask adults to give us urine samples and cheek cells. We'll ask for blood samples this year and 2 years from now.

Each year the interview will take a little over 60 minutes for adults and about 30 minutes for youth. If adults give samples, that will take about 5 minutes for the urine samples and cheek cells, and about 10 minutes for the blood samples.

As a thank you, we'll give adults \$35 for every interview and up to \$35 every time they give samples. We'll give youth \$25 for every interview. Each year adults and youth can decide whether they want to take part in the study.

How can I get more information about the PATH study?

The PATH study interviewer can answer any questions you may have about the study.

Also, for more information on the study, you can go to the PATH study website at www.pathstudyinfo.nih.gov (if you have a smartphone, you can scan the QR code below to visit the website) or call toll-free at 1-888-311-1819.

[PATH QR Code]