

## **Parent Permission for Cognitive Interviewing – Population Assessment of Tobacco and Health (PATH) Study**

### **Accompanies the Assurance of Privacy and Assent Form for 12-17 Year Olds**

Your child is being asked to take part in a research study run by the National Institutes of Health (NIH) in partnership with the Food and Drug Administration (FDA). Both the NIH and the FDA are part of the U.S. Federal Government. This consent form tells you about the study and what your child will be asked to do. The study is voluntary – you can choose to allow your child to take part in the study or not to. If you choose to allow your child to take part, you will need to sign this form.

### **Purpose of the research**

This research study includes questions that will provide information to help improve the health of people living in the United States. Before we conduct it, we need to review the materials and questions it uses to be sure they make sense to everyone. The purpose of talking to your child is to help us test whether the interview materials, as well as some of the questions, are understandable to other children your child's age.

If you agree to allow your child to participate, we will ask your child to read and answer questions. Then, we will ask your child what he or she thinks about the questions. The questions that we'll ask are about opinions, knowledge and experiences with tobacco. Your child's interview session will help us improve these questions.

### **Procedures that we will use**

An interviewer will ask your child to answer a series of questions that we are testing. Then, the interviewer will ask what your child was thinking as he or she read and answered the questions. The interviewer will ask if there were any words or questions that were confusing and if your child understood what was being asked.

The interview will last up to one hour, and we will give your child \$25 in cash as a thank you for participating. You will receive \$10 for any travel expenses.

We will ask that you not listen to or watch your child's interview as this may affect the answers he or she provides to the questions. Your child's answers will not be shared with you, your child's school or authorities.

Your child may find that some of the questions we are testing are personal or sensitive. Your child may choose not to talk about any question, for any reason. If your child does not want to talk about a question, he or she just needs to say so, and the interviewer will move on to the next one. Your child may also stop the interview at any time. If your child does stop the interview, he or she will still receive \$25. While the interview is going on, researchers from the NIH and FDA who are working with us on this project may listen to the interview.

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Public reporting burden for this collection of information is estimated to average 4 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0663). Do not return the completed form to this address.

## Recording the interview

We would like to audio record your child's interview. The recording allows us to more carefully study how well the survey materials and questions are working. At the bottom of this form, you will be asked if you are willing to have your child's interview recorded. Even if you agree, your child can still ask to stop the recording at any time, and the interviewer will turn off the machine. If your child decides to stop the recording, we will ask if we can keep the portion already recorded.

## Protecting information about you and your child

Materials with personal facts about you and your child such as names and phone numbers are not connected to the answers your child gives to the questions we are testing. Your child's answers will be private and cannot be used to identify your child. All of the researchers working on this study have signed a legal certificate guaranteeing that they will protect your child's privacy and promising not to tell anyone anything that he or she said.

Your name, your child's name, or other personal facts that would identify you or your child will not be used when we discuss or write about this study.

If you agree to have your child's interview recorded, we will keep the recording in a locked room. The recording will not be labeled with your child's name or other personal facts.

The recording and all study materials that identify your child will be destroyed within three months after this study is completed.

## Benefits and risks

There are no direct benefits from taking part in this study.

There are no known physical or psychological risks from taking part in this study.

If you have questions about how the project works, contact Jocelyn Newsome at 301-212-3734. If you have questions about your rights and welfare as a research participant, please call the Westat Human Subjects Protections office at 1-888-920-7631. Please leave a message with your full name, the name of the research study (PATH Testing) that you are calling about, and a phone number beginning with the area code. Someone will return your call as soon as possible.

## Please check the boxes next to the statements you agree to:

- **Yes**, I give my permission for you to ask my child to take part in this research study.
- **Yes**, I allow the researchers to record my child's interview.

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Print Participant name

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Parent/Guardian signature

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Print Parent/Guardian name

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Date

## **Youth Assent Form for Cognitive Interviewing - Population Assessment of Tobacco and Health (PATH) Study**

### **Must be accompanied by a Parent Permission Consent Form**

You are being asked to take part in a research study run by the National Institutes of Health (NIH) in partnership with the Food and Drug Administration (FDA). Both the NIH and the FDA are part of the U.S. Federal Government. This assent form tells you about the study and what you will be asked to do. The study is voluntary – you can choose to take part in the study or not to. If your parent permits you to take part in this study, you may still choose not to participate. If you choose to take part, you will need to sign this form.

### **Purpose of the research**

As part of this research study, we are conducting an interview about behavior and health.

Before we conduct it, we need to review the materials and questions with people like you. The purpose of talking to you is to help us see whether the materials and questions make sense. We want to be sure that everyone understands the materials and questions the same way. Our purpose is not to collect health information about you. Instead, we will test the materials and questions to be used in a later survey.

The questions that we will ask you today are about tobacco use. Your interview will help us to improve these questions.

### **What you will do**

If you agree to take part, you will read some materials and answer a series of questions. We will ask you if any words or questions were confusing and if you understood what was being asked.

The interview will last up to one hour, and we will give you \$25 in cash at the end to thank you for your participation.

If you do not want to answer a question about the material you have read, just say so. The interviewer will move on to the next question. You may also stop the interview at any time. If you do stop the interview, you will still receive \$25. Researchers from the NIH and FDA are working with us on this project. While the interview is going on they may listen to the interview.

Your parent or guardian will not listen to or watch your interview; but will wait for you in the lobby. Your answers will not be shared with your parents, school or authorities.

## **Recording the interview**

We would like to audio record your interview. The recording will help us be sure we did not miss anything about how well the questions are working. At the bottom of this form, you will be asked if you agree to have the interview recorded. Even if you agree, you can still ask to stop the recording at any time, and the interviewer will turn off the machine. If you decide to stop taping, we will ask if we can keep the part already recorded.

## **Protecting information about you**

Personal facts about you such as your name and phone number are not connected to the answers you give about the material we are testing.

Your name or other personal facts that would identify you will not be used when we discuss, or write about, this study.

If you agree to record the interview, we will keep the recording in a locked room. The recording will not be labeled with your name or other personal facts.

The recording and all study materials that identify you will be destroyed within three months after this study is completed.

## **Benefits and risks**

There are no direct benefits from taking part in this study.

There are no known physical or psychological risks from taking part in this study.

If you have questions about the study, contact Jocelyn Newsome at 301-212-3734. If you have questions about your rights and welfare as a research participant, please call the Westat Human Subjects Protections office at 1-888-920-7631. Please leave a message with your full name, the name of the research study (PATH Testing) that you are calling about, and a phone number beginning with the area code. Someone will return your call as soon as possible.

## **Please check the boxes next to the statements you agree to:**

- I choose to take part in this research study.
- I allow the researchers to record my interview.

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Participant signature

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Print participant name

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Date