

**Attachment 5**

**Examples of Consent Materials**

**August 7, 2012**

## Consent for Interview to Test Survey Questions to be used in the Population Assessment of Tobacco and Health (PATH) Study

You are being asked to take part in a research study conducted 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 study is to help us test materials to be used in a study about tobacco use and its effects on health in the U.S. population. The findings from talking to you will help us evaluate whether the materials are easy to understand and questions are easy to answer.

Before we conduct health surveys, we first review materials with the help of people like you. It is important that they make sense and that everyone understands the information the same way. If you agree to take part in this, we will ask you to answer a series of questions about your household. In addition we will ask you how you came up with some of your answers. Our purpose is not to collect information about you. Instead, we are testing materials to be used in a later study.

The interview will last about one hour. You will receive \$XX as thanks for your time.

Your participation in this study is voluntary. You may choose not to answer any question, and you can stop this interview at any time.

Researchers from the NIH and FDA may be observing this interview so they hear your comments about the survey questions and materials.

There are no known risks to you for taking part in this interview. All the data we collect will be kept private. Your name will never be linked to your answers to the questions nor will it appear in any written reports or publications. There are also no direct benefits to you for taking part in this interview, but your answers will help us provide useful information that may lead to improved health policies.

With your permission, I will audio-record the interview. The recording allows us to more carefully study how well the questions are working. The recording and all study materials that identify you will be destroyed within three months after this study is completed.

If you have any questions about this study, contact Scott Crosse at (301) 294-3979. If you have any questions about your rights as a participant in this study, please call Sharon Zack at (301) 610-8828.

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I have read the information above and:

- I agree to participate in the interview.
- I agree to have my interview audio-recorded.

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Print Name:** \_\_\_\_\_

**Name of Researcher:** \_\_\_\_\_

## **Assurance of Privacy and Permission Form for Interview to Test Survey Questions (12-17 Year Olds)**

### **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 consent 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 you choose to take part, you will need to sign this form.

#### **Purpose of the research**

As part of this research study, we will conduct a health survey.

Before we conduct it, we want to first review the survey materials and questions with the help of people like you. The purpose of talking to you is to help us see whether the materials and questions are easy to understand. We want to be sure they make sense and that everyone understands them 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 work on today are about tobacco use. Your interview will show us how to improve these questions.

#### **What you will do**

If you agree to take part in this, you will read some materials and survey questions aloud. You do not need to answer the 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 half hour, and we will give you \$XX.

If you do not want to answer a question about the material you have read, just say so. The interviewer will move to the next one. You may also stop the interview at any time. If you do stop the interview, you will still receive \$XX. 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 you agree for us to 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 to 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 other 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 Scott Crosse at (301) 294-3979. If you have any questions about your rights as a research subject, contact Sharon Zack at the Westat Institutional Review Board at (301) 610-8828. For counseling services in Montgomery County, call (240) 777-4000.

**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.

\_\_\_\_\_  
Participant signature

\_\_\_\_\_  
Print participant name

\_\_\_\_\_  
Date

## **Parent Permission Consent Form for Interview to Test Survey Questions**

### **Accompanies the Assurance of Privacy and Informed Consent 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 a survey that will help develop programs to improve the health of people living in the United States. Before we conduct it, we want to first review the survey materials so we know they make sense and that everyone can understand them. The purpose of talking to your child is to help us test whether these materials, as well as some of the survey questions, are easy to understand.

If you agree to allow your child take part in this test, we will ask your child to read some study materials and survey questions. Then, we will ask your child what he or she thinks about the materials and questions. Our purpose is not to collect health information about your child, so your child will not answer the survey questions. Instead, he or she will help us test the questions to be used in a later survey.

The questions that we are working on today are about opinions, knowledge and experiences with tobacco. Your child's interview session will show us how to improve these questions.

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

An interviewer will ask your child to read aloud the survey materials and survey questions that we are testing. Then, the interviewer will ask what your child was thinking as he or she read them. 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 \$XX.

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 \$XX. While the interview is going on, researchers from the National Institutes of Health and Food and Drug Administration who are working with us on this project may listen to the interview.

### **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 taping, we will ask if we have your child's consent to 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 other 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 Scott Crosse at (301) 294-3979. If you have any questions about your child's rights as a research subject, contact Sharon Zack at the Westat Institutional Review Board at (301) 610-8828. For counseling services in Montgomery County, call (240) 777-4000.

**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.
- No**, I do not give my permission to ask my child to take part in this research study.

\_\_\_\_\_  
Print Participant name

\_\_\_\_\_  
Print Parent/Guardian name

\_\_\_\_\_  
Parent/Guardian signature

\_\_\_\_\_  
Date