OMB Control Number: 0925-0675
Expiration Date: 05/31/2016

PATH
Population Assessment of Tobacco and Health
A collaboration between the NIH and FDA

Parent Permission for Focus Group Participation – Population Assessment of Tobacco and Health (PATH) Study

Accompanies the Assurance of Privacy and Assent Form for 12-15 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 the study, we need to talk to people about certain topics of interest so that we understand how to questions in a way that will make sense to everyone. Today we will be discussing social media and tobacco-related content that your child may see on social media.

Procedures that we will use

A focus group moderator will ask the group questions about social media and tobacco-related content that they have seen. The focus group will last up to an hour and a half, and we will give your child $30 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 the focus group as this may affect the discussion. Your child's statements 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. Your child may also decide to leave the focus group at any time. If your child does stop participating, he or she will still receive $30. While the interview is going on, researchers from the NIH and FDA who are working with us on this project may listen to the focus group.

Recording the focus group discussion

We will audio record the focus group discussion. The recording allows us to more carefully analyze the details of the discussion.

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 statements your child gives during the focus group discussion. Your child's statements 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.

We will keep the focus group 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.

Yes, I give my permission for you to ask my child to take part in this research study and to allow the researchers to record the focus group discussion.

_____	_____
Print Participant name	Parent/Guardian signature
_____	_____
Print Parent/Guardian name	Date

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Youth Assent Form for Focus Group Participation - 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. If your parent permits you to take part in this study, you may still choose not to participate. 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

This research study includes questions that will provide information to help improve the health of people living in the United States. Before we conduct the study, we need to talk to people about certain topics of interest so that we understand how to questions in a way that will make sense to everyone. Today we will be discussing social media and tobacco-related content that you may see on social media.

What you will do

If you agree to take part, a focus group moderator will ask the group questions about social media and tobacco-related content that you have seen. The focus group will last up to an hour and a half, and we will give you $30 in cash as a thank you for participating.

If you do not want to answer a question, just say so. You may also stop participating in the group at any time. If you do stop participating, you will still receive $30. Researchers from the NIH and FDA are working with us on this project. While the focus group is going on they may listen to the interview.

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

Recording the interview

We will audio record the focus group discussion. The recording allows us to more carefully analyze the details of the discussion.

Protecting information about you

Personal facts about you such as your name and phone number are not connected to the statements you give during the discussion.

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

The recording of the focus group discussion will be kept 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.

I choose to take part in this research study and allow the researchers to record the focus group discussion.

_____

Participant signature

_____

Print participant name

_____

Date