

**Experimental Study of Cigarette Warning Labels
Email to Parent or Guardian for Youth Study Participation
Screener & Session 1**

Greetings!

We have a new survey and your participation is requested. The survey is meant for children ages 13-17. If your child qualifies and completes the survey, your Global Test Market account will be credited with the Lifepoints stated in the invitation.

Please note that this survey must be taken on a desktop or laptop computer.

A new survey is available

Survey Number: [INSERT SURVEY #]

Reward for Survey Completion: 1,000 Lifepoints

Start Now!

You may also access the survey by copying

[INSERT URL LINK]

the following URL into your browser:

Best Regards –
Global Test Market Team

[GO TO PARENT PERMISSION]

PARENT PERMISSION

Introduction to the Study

We are talking to youth and adults to understand what people think about tobacco use. This research study consists of a screener and then 3 separate surveys. The screener survey today will take about 2 minutes, and the first full survey will take about 12 minutes, if your child qualifies. In a day or two another survey will take about 8 minutes, and then about 2 weeks later a final survey will take about 5 minutes.

Selection of Youth

About 10,000 youth and adults are being asked to take this survey. We need permission from a parent before we survey your child. Your child may choose whether or not to take the survey.

Types of Questions

Youth will be asked about their experiences with and opinions about tobacco. Youth will take the survey online.

Voluntary Participation

Your child can refuse to answer any and all questions. Your child can stop the survey at any time. You will receive 1,000 Lifepoints if your child completes the survey.

Risks

There are minimal psychological and social risks to participating in this study, such as it is possible that some questions might make your child mildly uncomfortable, depending on his or her responses.

Benefits

There are no direct benefits to your child from taking the survey. However, he or she will be contributing to important research. Results will help improve public education about the dangers of tobacco use.

Confidentiality

Every effort will be made so that that no one will be able to know how your child answered the questions. However, protection of your child's information cannot be guaranteed. The information that was collected from your child during the screener and surveys will kept in a secure database with access only to authorized project staff members. Your child's answers to the study questions will be combined with answers of many others and reported in a summary form. Upon completion of the study, we are required to store study data for at least 5 years. Study data will be stored securely on a password-protected computer without any of your child's personal information. Information from this study may be published in professional journals or presented at scientific conferences, but your child's identifiable information will not be included in any report or presentation. All research staff are committed to privacy and have signed a Privacy Pledge.

This research is covered by a Certificate of Confidentiality from FDA to help us protect your child's privacy. This means that the researchers cannot disclose your child's name or other information that could identify him/her in any civil, criminal, administrative, legislative or other proceedings (like a court trial), without your consent. Information collected for this research that could identify your child also cannot be used as evidence in a legal proceeding without your consent.

In addition, with the Certification of Confidentiality, researchers involved in this study generally may not provide your child's name, or any other information that could identify your child, to anyone who is not connected with the research. However, in the following situations, the Certificate does not prevent the researchers involved in this study from disclosing study information that could identify your child:

- if you consent to someone receiving your child's information from this study, including situations where the information is necessary for his/her medical treatment;
- when your child's study information is used for other scientific research, as allowed by federal regulations protecting research subjects;
- when information is needed by FDA, which is funding this study, in order to audit or evaluate federally funded studies;
- when a law otherwise requires disclosure (such as requirements to make certain reports to FDA, reporting threats of harm to self/others, or reports of child abuse), except this does not apply to disclosure in a legal proceeding.

The Certificate does not prevent your child from voluntarily providing information about him or herself or his/her involvement in this research study to others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document: Your child's tobacco use history.

Questions

If you have any questions about this study, you can call the Study Coordinator, James Nonnemaker, at 919-541-7064. If you have a question about your rights as a study participant, you can call RTI's Office of Research Protection toll-free at (866) 214-2043.

Do you agree to allow your child to take the survey?

1. Yes
2. No

[IF YES, GO TO P_INTRO]

[IF NO, GO TO END]

P_INTRO

It is important that your child be allowed to answer the questions in privacy. From this point on, your child should be able to read and answer all questions on his or her own. Press "Next" when your child is ready to begin. [GO TO YOUTH ASSENT (SESSION 1)]

END

Thank you for your time.

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 2 minutes per response to complete this screener survey (the time estimated to read and complete) and 12 minutes per response to complete the Session 1 survey (the time estimated to read and complete), if the participant qualifies. Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRASStaff@fda.hhs.gov.

**Experimental Study of Cigarette Warning Labels
Email to Parent or Guardian for Youth Study Participation
Session 2**

Greetings!

We have a new survey and your participation is requested. The survey is meant for children ages 13-17. This is a follow-up survey to a survey your child completed a few days ago, so your child is already qualified to complete this survey. If your child completes this survey, your Global Test Market account will be credited with the Lifepoints stated in the invitation.

Please note that this survey must be taken on a desktop or laptop computer.

A new survey is available

Survey Number: [INSERT SURVEY #]

Reward for Survey Completion: 1,000 Lifepoints

Start Now!

You may also access the survey by copying

[INSERT URL LINK]

the following URL into your browser:

Best Regards -
Global Test Market Team

[GO TO PARENT PERMISSION]

PARENT PERMISSION

Introduction to the Study

We are talking to youth and adults to understand what people think about tobacco use. The survey today will take about 8 minutes. In about two weeks, the final survey will take about 5 minutes.

Selection of Youth

About 10,000 youth and adults are being asked to take this survey. We need permission from a parent before we survey your child. Your child may choose whether or not to take the survey.

Types of Questions

Youth will be asked about their experiences with and opinions about tobacco. Youth will take the survey online.

Voluntary Participation

Your child can refuse to answer any and all questions. Your child can stop the survey at any time. You will receive 1,000 Lifepoints if your child completes the survey.

Risks

There are minimal psychological and social risks to participating in this study. It is possible that some questions might make your child mildly uncomfortable, depending on his or her responses.

Benefits

There are no direct benefits to your child from taking the survey. However, he or she will be contributing to important research. Results will help improve public education about the dangers of tobacco use.

Confidentiality

Every effort will be made so that that no one will be able to know how your child answered the questions. However, protection of your child's information cannot be guaranteed. The information that was collected from your child during the screener will be kept in a secure database with access only to authorized project staff members. Your child's answers to the study questions will be combined with answers of many others and reported in a summary form. Upon completion of the study, we are required to store study data for at least 5 years. Study data will be stored securely on a password-protected computer without any of your personal information. Information from this study may be published in professional journals or presented at scientific conferences, but your identifiable information will not be included in any report or presentation. All research staff are committed to privacy and have signed a Privacy Pledge.

This research is covered by a special protection (called a Certificate of Confidentiality) from the Food and Drug Administration (FDA). This special protection ensures that researchers involved in this study protect your child's privacy as much as possible within the law. This means researchers generally cannot provide your name, your child's name, or any other information that could identify either of you, to anyone who is not part of the research team. Researchers cannot share this information in court or during other legal proceedings, even if there is a court order for the information. However, researchers may share study information that could identify you if:

- you agree to share information (for example, to get medical treatment);
- the study information is used for other scientific research, as allowed by law;
- the FDA, which is paying for the study, needs information to check how their research money is being spent;
- a law requires sharing information (for example, when researchers must report to FDA, or if researchers hear threats of harm to yourself or others, or reports of child abuse).

Questions

If you have any questions about this study, you can call the Study Coordinator, James Nonnemaker, at 919-541-7064. If you have a question about your rights as a study participant, you can call RTI's Office of Research Protection toll-free at (866) 214-2043.

Do you agree to allow your child to take the survey?

1. Yes
2. No

[IF YES, GO TO P_INTRO]
[IF NO, GO TO END]

P_INTRO

It is important that your child be allowed to answer the questions in privacy. From this point on, your child should be able to read and answer all questions on his or her own. Press "Next" when your child is ready to begin. [GO TO YOUTH ASSENT (SESSION 2)]

END

Thank you for your time.

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 8 minutes per response to complete this survey (the time estimated to read and complete). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRStaff@fda.hhs.gov.

**Experimental Study of Cigarette Warning Labels
Email to Parent or Guardian for Youth Study Participation
Session 3**

Greetings!

We have a new survey and your participation is requested. The survey is meant for children ages 13-17. This is a follow-up survey to a survey your child completed a few weeks ago, so your child is already qualified to complete this survey. If your child completes this survey, your Global Test Market account will be credited with the Lifepoints stated in the invitation.

Please note that this survey must be taken on a desktop or laptop computer.

A new survey is available

Survey Number: [INSERT SURVEY #]

Reward for Survey Completion: 1,000 Lifepoints

Start Now!

You may also access the survey by copying

[INSERT URL LINK]

the following URL into your browser:

Best Regards -
Global Test Market Team

[GO TO PARENT PERMISSION]

PARENT PERMISSION

Introduction to the Study

We are talking to youth and adults to understand what people think about tobacco use. The survey today will take about 5 minutes.

Selection of Youth

About 10,000 youth and adults are being asked to take this survey. We need permission from a parent before we survey your child. Your child may choose whether or not to take the survey.

Types of Questions

Youth will be asked about their experiences with and opinions about tobacco. Youth will take the survey online.

Voluntary Participation

Your child can refuse to answer any and all questions. Your child can stop the survey at any time. You will receive 1,000 Lifepoints if your child completes the survey.

Risks

There are minimal psychological and social risks to participating in this study. It is possible that some questions might make your child mildly uncomfortable, depending on his or her responses.

Benefits

There are no direct benefits to your child from taking the survey. However, he or she will be contributing to important research. Results will help improve public education about the dangers of tobacco use.

Confidentiality

Every effort will be made so that that no one will be able to know how your child answered the questions. However, protection of your child's information cannot be guaranteed. The information that was collected from your child during the screener will be kept in a secure database with access only to authorized project staff members. Your child's answers to the study questions will be combined with answers of many others and reported in a summary form. Upon completion of the study, we are required to store study data for at least 5 years. Study data will be stored securely on a password-protected computer without any of your personal information. Information from this study may be published in professional journals or presented at scientific conferences, but your identifiable information will not be included in any report or presentation. All research staff are committed to privacy and have signed a Privacy Pledge.

This research is covered by a special protection (called a Certificate of Confidentiality) from the Food and Drug Administration (FDA). This special protection ensures that researchers involved in this study protect your child's privacy as much as possible within the law. This means researchers generally cannot provide your name, your child's name, or any other information that could identify either of you, to anyone who is not part of the research team. Researchers cannot share this information in court or during other legal proceedings, even if there is a court order for the information. However, researchers may share study information that could identify you if:

- you agree to share information (for example, to get medical treatment);
- the study information is used for other scientific research, as allowed by law;
- the FDA, which is paying for the study, needs information to check how their research money is being spent;
- a law requires sharing information (for example, when researchers must report to FDA, or if researchers hear threats of harm to yourself or others, or reports of child abuse).

Questions

If you have any questions about this study, you can call the Study Coordinator, James Nonnemaker, at 919-541-7064. If you have a question about your rights as a study participant, you can call RTI's Office of Research Protection toll-free at (866) 214-2043.

Do you agree to allow your child to take the survey?

1. Yes
2. No

[IF YES, GO TO P_INTRO]
[IF NO, GO TO END]

P_INTRO

It is important that your child be allowed to answer the questions in privacy. From this point on, your child should be able to read and answer all questions on his or her own. Press "Next" when your child is ready to begin. [GO TO YOUTH ASSENT (SESSION 3)]

END

Thank you for your time.

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 5 minutes per response to complete this survey (the time estimated to read and complete). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRStaff@fda.hhs.gov.