

Study Name: Increasing Understanding of Digital Advertising: Hookah Beliefs Survey
RTI Principal Investigator: Matthew Farrelly
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Attachment D: Consent to Participate in a Research Study

Why are we doing this research study?

This survey is part of a research study funded by the U.S. Food and Drug Administration (FDA) and conducted by RTI International. The mission of the FDA is to promote and protect public health. The purpose of this research study is to assess young adults' tobacco use. About 1,500 young adults aged 18-24 are being asked to take this survey.

What will happen if you participate in this research study?

This research study consists of a single online survey that will take about 15 minutes to complete. If you choose to participate, you will complete an online survey with questions about what you think about certain health beliefs. After the study is over, we will not contact you again unless we need to tell you about a privacy incident (described in the Risks section below).

Voluntary Participation

It is your choice to participate in this study. If you do not want to take the survey, that is okay. If you get to a question on the survey that you do not want to answer or makes you uncomfortable, you can skip it. You can drop out of the survey at any time for any reason by closing your Internet browser. There will be no penalty and you will not lose any benefits or rights you would normally have if you decide not to participate. You must complete the survey in one sitting. It is not possible to return to the survey to finish it later on your own. If you do choose to drop-out of the survey, you will not receive your \$5 Amazon digital gift card. If you have any questions about this study, you may call the Study Coordinator or RTI's Office of Research Protection listed below.

Risks

There are minimal risks to participating in this study. Some of the questions on the survey may be sensitive or personal. If you have any questions about this study, you may call the Study Coordinator at the telephone number listed on the last page of this form. **You may stop participating in this study at any time if you want to stop participating** for any reason. We will take care to protect the data you share. However, as with all studies, there may be risks which are currently unknown. There is a chance that privacy could be broken by accident or as the result of hacking. In the unlikely event that the study data are hacked, we will tell you within 5 business days of discovery. We will do our best to maintain the privacy of data collected during the study by using standard online data safeguards.

Benefits

There are no direct benefits to you from taking the survey. Indirect benefits include helping improve health-related media campaigns.

Use of Information

Information will be used solely for research purposes. Your responses will be combined with answers from many others and reported in summary form. When we analyze the results, your responses will be separated from the information that identifies you, and no identifying information will be included in any reports. Your responses,

which do not include identifying information, may be used for future research studies but will not be shared outside the research team. No additional consent will be obtained for future uses of the data for research.

Payment for Participating

You will receive a \$5 Amazon digital gift card as a token of appreciation if you complete the survey. If you decide to stop participating before the survey is over, you will not receive the \$5 Amazon digital gift card.

Confidentiality

Every effort will be made so that that no one will be able to know how you answered the questions. However, protection of your information cannot be guaranteed. The information collected from you during the survey will be kept in a secure database to which only authorized project staff members will have access. Your answers to the survey questions will be combined with answers from many others and reported in 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 an agreement to maintain the privacy of study data.

This research is covered by a special protection (called a Certificate of Confidentiality) from the FDA. This special protection makes sure that staff involved in this project protect your privacy. This means that project staff generally cannot provide your name, or any other information that could identify you, to anyone who is not connected with the project. Project staff cannot share this information in court or during other legal proceedings, unless you agree, even if there is a court order for the information. However, in other settings, project staff 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; or
- a law requires sharing information (for example, when project staff must report to FDA, or if project staff hear threats of harm to others or reports of child abuse).

The Certificate of Confidentiality does not prevent you from sharing any personal information or information about your involvement in this study with others, if you choose to.

Questions

If you have any questions about this study, you can call the Study Coordinator, Kim Hayes at nextupsurvey@rti.org or 919-541-1215. 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.

If you would like a copy of this consent form for your records, you can print out or take a screenshot of the screen(s) showing this information.

Do you agree to participate in the survey?

1. Yes, I agree to participate in the survey
2. No, I do not agree to participate the survey

[IF YES, GO TO PRIVACY STATEMENT]

[IF NO, GO TO END]

[INCLUDE THE STATEMENT BELOW IN SMALLER GREY FONT AT THE BOTTOM OF THE PAGE]

Paperwork Reduction Act Statement:

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0810. The time required to complete this information collection is estimated to average 3 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. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRASTAFF@fda.hhs.gov.

PRIVACY STATEMENT

Please find a private place to take this survey where no one can see your answers. Please do not complete the survey while driving.

END

Thank you for your time.