Attachment 6
OMB Control Number: 0910-0674
Expiration Date: 03/31/2016

Leave box empty - For office use only

University of Illinois at Chicago
Research Information and Consent for Participation in Social Behavioral Research
The City of Chicago Flavored Tobacco Product Ban near Schools

You are being asked to participate in a research study. Researchers are required to provide a consent form such as this one to tell you about the research, to explain that taking part is voluntary, to describe the risks and benefits of participation, and to help you to make an informed decision. You should feel free to ask the researchers any questions you may have.

Principal Investigator Name and Title: Sandy Slater, PhD., Assistant Professor
Department and Institution: Institute for Health Research and Policy, University of Illinois at Chicago
Address and Contact Information: 1747 W Roosevelt Rd, Room 558, M/C 275, Chicago, IL 60608; Phone: 312-413-0475, Fax: 312-355-2801
Sponsor: Federal Drug Administration

Why am I being asked?

You are being asked to be a subject in a research study about the smoking behaviors of adolescents.

You have been asked to participate in the research because you are between 14 and 18 years old, are a student at _____, and you have reported that you have knowledge of flavored tobacco products.

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future dealings with the University of Illinois at Chicago. **If you decide to participate, you are free to withdraw at any time without affecting that relationship.**

Approximately 300 subjects may be involved in this research at UIC.

What is the purpose of this research?

The purpose of this study is to understand how the ban on the sale of flavored tobacco products within 500 feet of schools effects youth smoking and tobacco-purchasing behaviors. Your participation will help the researchers by providing valuable information that will enhance understanding of youth behaviors and inform future research studies.

What procedures are involved?

This research will be performed at the Institute for Health Research and Policy at the University of Illinois at Chicago.

You will need to come to the study site one time.

This visit will take about 90 minutes.

You will be asked to join a group of other people your age, with a researcher from UIC, to have a conversation about your experience and thoughts on youth smoking behaviors and purchasing of tobacco products. The discussion will be recorded. These tapes will then be transcribed for data analysis. The transcribed text and audio files of the group discussions will be stored on password-protected computers and locked filing cabinets at the University of Illinois at Chicago. No personal identifiers are ever connected to the transcriptions of the sessions. Therefore, remarks made during the focus groups cannot be linked to individuals.

What are the potential risks and discomforts?

To the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life. Questions of a highly personal nature will not be asked. The discussion will be recorded for later transcription, but only the UIC research team will have access to the information. We will only use first names to identify participants and after the information is gathered it will be kept confidential without any names or identifiers. The information will only be used to inform the research project and will not be made available to the public.

Are there benefits to taking part in the research?

Taking part in this research study may not benefit you personally, but we may learn new things that will help others. The information collected from the study will also help researchers who are working to promote healthy youth behaviors.

What other options are there?

You have the option to not participate in this study.

What about privacy and confidentiality?

The people who will know that you are a research subject are members of the research team and the other participants in the group discussion. Otherwise, information about you will only be disclosed to others with your written permission, or if necessary to protect your rights or welfare (for example, if you are injured and need emergency care or when the UIC Office for the Protection of Research Subjects monitors the research or consent process) or if required by law. Auditors from the State of Illinois may also monitor this research.

Study information which identifies you and the consent form signed by you will be looked at and/or copied for checking up on the research by the Federal Drug Administration.

When the results of the research are published or discussed in conferences, no information will be included that would reveal you or your child's identity.

- The group discussion will be recorded, but will only be reviewed by the researchers.
- The transcribed text and audio files of the group discussions will be stored on password-protected computers and locked filing cabinets at the University of Illinois at Chicago.

Although we ask everyone in the group to respect everyone's privacy and confidentiality, and not to identify anyone in the group or repeat what is said during the group discussion, please remember that other participants in the group may accidentally disclose what was said.

What are the costs for participating in this research?

There are no costs to you for participating in this research.

Will I be reimbursed for any expenses or paid for participation in this research?

You will receive $30 for completing this study. This money will be awarded to you after you have completed the focus group.

Can I withdraw or be removed from the study?

If you decide you want to participate, you are free to withdraw consent and discontinue participation at any time. You may leave the study at any time without penalty by informing the researcher that you no longer wish to participate.

Who should I contact if I have questions?

Contact the researcher Sandy Slater at 312-413-0475 or email address: sslater@uic.edu

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research.

What are my child's rights as a research subject?

If you feel you have not been treated according to the descriptions in this form, or if you have any questions about your rights as a research subject, including questions, concerns, complaints, or to offer input, you may call the Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.

Remember:

If you agree to participate in this study, you will be asked to take part in a 90 minute conversation with other participants at UIC. No individually identifiable information will be collected.

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Signature of Subject

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I will be given a copy of this signed and dated form.

_____ _____

Signature Date

_____

Printed Name

_____ _____

Signature of Person Obtaining Consent Date (must be same as subject's)

_____

Printed Name of Person Obtaining Consent

Paperwork Reduction Act Statement: 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. The OMB control number for this information collection is 0910-0674 (expires 03/31/2016). The public reporting burden for this information collection has been estimated to average 10 minutes per response to complete the questions asked in this participant form, its corresponding youth assent form, and the Recruitment Script (the time estimated to read and review). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRAStaff@fda.hhs.gov.