

Informed Consent for Participation in a Discussion Group

ADOLESCENT INTERVIEW

Please read this assent form carefully. Take time to ask as many questions as you want. If there are any words or information you do not clearly understand, study personnel will be happy to explain them to you. This assent form must be signed before you can participate in the interview. **Your parent/guardian must also sign this form before you can participate.**

INTRODUCTION

Your child has been asked to participate in an interview as part of a research project. The purpose of the group is to hear thoughts from youth ages 15-17 about tobacco products. ICF Macro is conducting discussion groups on behalf of the U.S. Department of Health and Human Services to better understand adolescents' thoughts and knowledge about cigarette smoking. We have invited your child to participate in a discussion to share their thoughts and knowledge about cigarettes. Their part in this study involves being interviewed. The interview will be guided by an adult who is trained to get their opinion and encourage everyone to take part. The research is sponsored by the Food and Drug Administration (FDA).

Your child's participation is entirely voluntary.

PURPOSE OF THE RESEARCH STUDY

The purpose of this study is to better understand adolescents' thoughts and knowledge about cigarettes.

INFORMATION ABOUT THE STUDY

This research involves 12 interviews. If you and your child agree, they will participate in one of the 12 interviews. This interview will last about 1 hour. The discussion will be recorded, and notes will be taken. Only your child's first name will be used to help protect your privacy. All recordings will be destroyed at the end of the project.

YOUR CHILD'S ROLE IN THE STUDY

Participating in a research study can be an inconvenience. Please consider the study time commitments and responsibilities when your child is deciding whether or not they should participate. These include:

- Coming to the study site for the interview at the planned time;
- Providing truthful information about what they think about cigarette smoking

Subject's Initials _____

REIMBURSEMENT FOR STUDY PARTICIPATION

If you accompany your child to the facility, we will give you \$25.00 for your time and effort. Your child will receive \$30.00 in cash for their time and effort regarding their participation in the study. This will be given to you and your child at the end of the focus group session.

PRIVACY

As part of this study, the study staff may record personal information about your child that contains their name and other personal identifiers. Transcripts of the interview will only include their first name.

The collection and submission of the information will be accomplished with strict adherence to professional standards of privacy. Information from this study may be published in professional journals or at scientific conferences, but your child’s privacy will be respected and no names will be used in any report or presentation.

RESEARCH QUESTIONS AND CONTACTS

You or your child may freely ask questions about this assent form or the study now or at any time during the study. If you or your child have any questions about the research, or compensation, during this study you or your child may contact the study staff.

VOLUNTARY NATURE OF STUDY

Entering a research study is voluntary. It is your child’s choice to be in this study, and anyone who is asked to be in a research study may so no. No one has to become a research subject, and your child can choose not to talk about any topic.. If your child starts a research study, they may stop the interview at any time. They do not need to give a reason.

ASSENT STATEMENT BY PARTICIPANT 17 AND UNDER

I have read this assent form. I understand what I am being asked to do. I had a chance to ask questions, and my questions have been answered and any words I did not understand have been explained to me. I agree to be in this research study for the purposes listed above. I will receive a copy of this assent form for my records.

Print your name here if you want to be in this study

Sign your name here if you want to be in this study

Signature

Date

CONSENT STATEMENT BY PARENT OR GUARDIAN

I have read this consent form. I had a chance to ask questions, and my questions have been answered. I agree to allow my child to be in this research study for the purposes listed above. I will receive a copy of this consent form for my records.

By signing this consent form I am not giving up any of my or my child’s legal rights. I also understand that nothing in this consent is intended to change any applicable federal, state or local laws regarding informed consent.

Printed Name of Minor Research Subject (Child)

Name of Guardian (Print) Signature Date

Name of Person Obtaining Signature Date
Informed Consent

Name of Person Obtaining Signature Date
Informed Consent