

YOUTH ASSENT FORM FOR STUDY PARTICIPATION

Qualitative Study of Perceptions and Knowledge of Visually Depicted Health Conditions

(Must be accompanied by a Parent Permission Consent Form)

Introduction

Before you choose to take part of this study, you will need to read this Assent form so that you understand what the study is about and what you will be asked to do. This form also tells you who can be in the study, the risks and benefits of the study to you, how we will protect your information, and who you can call if you have questions. Please ask the researcher to explain anything you don't understand before you make your decision.

Purpose of the Study

This research study is being conducted by Siegel+Gale (S+G). The purpose of today's interview is to learn about the thoughts and beliefs that young people have about different health topics. You are one of 18 youth who will be talking to us.

Procedure: What will I do during the study?

You are invited to take part in an in-depth individual interview. You may choose to take part in the study or not. You can choose to leave the interview at any time.

The study will last up to 60 minutes. The interviewer will ask questions about a set of images that will show different health topics. You will be asked to share your opinions about these images.

Confidentiality: Who will see the information I provide during this study?

Everything you say during the interview can be heard by the interviewer, research assistants, and FDA study monitors. All participants will be asked to not share anything said or seen during the interview.

Interview discussions may be audio recorded and transcribed for reporting purposes. The report created using the audio transcripts will not link your comments to you. The interview may also be video streamed live to allow research staff to watch the study even though they are not here. No one outside of the interviewer and researchers will know what you have said during the discussions. We will not share anything you say here with your parent or guardian. Your full name will be used only during the check-in process and only your first name will be used during the course of the interview. The interviewer will also ask participants not to share any private, personal, or inappropriate information during the interview.

Before we interview you, personal information, such as your name, phone number, gender, race and ethnicity, education, and age, may be collected during the recruitment process. We will not keep this information or share it with anyone outside of the study, unless required by law. Your full name and phone number were used only for recruiting purposes and will not be connected to the answers you provide to us during the interview. If we use this information in a report or presentation, your name will not be used.

Audio files and transcripts will be stored securely on a password-protected computer and/or in a locked cabinet, with access provided exclusively to members of the research team only. For security purposes, audio files will be destroyed after transcription, with transcripts being retained for no more than three years.

Will I be paid for participating in this study?

All youth who participate in the study will receive a \$40 gift card as a token of appreciation. If your parent/guardian brought you here, they will also get \$25.

Study Benefits: What good will come from this study?

This study is not expected to directly benefit you. However, your opinions and responses will help us improve our understanding of the types of knowledge and perceptions that people have about various health topics.

Possible Risks or Discomforts:

There are minimal psychological, social, or legal risks to participating in this study. You will be asked to share your attitudes and opinions on some topics that may be considered sensitive in nature. You will also be asked to look at some pictures that may contain some potentially graphic health effects. Your participation is voluntary, and you can choose not to answer any of the questions.

Participation and Withdrawal: Do I have to be in this study? What if I want to drop out?

Your decision to take part in this research study is completely voluntary. You can refuse any part of the study and you can stop participating at any time. You can refuse to answer any question. If you decide to participate and later change your mind, you will not be contacted again or asked for further information.

Questions and Contacts: Who do I call if I have questions now or later?

You may ask questions or express concerns about this consent form, the study, your rights as a research subject, or report problems (e.g., any research related injuries) at any time before, during or after the study. You may contact the research team through the Principal Investigator of the study, Rolf Wulfsberg at S+G (212-453-0426) or Lynda Barnaby at S+G (212-453-0527). If you have any questions or complaints about your rights as a research participant, you may contact FDA IRB RIHCS (OC_RIHSC@fda.hhs.gov),

YOU WILL BE GIVEN A COPY OF THIS ASSENT FORM TO KEEP.

I have read, understand, and had time to consider all of the information above. I have no more questions about this study at this time. I agree to take part in this study

Printed Name of Participant

Signature of Participant

Date

Printed Name of Witness

Signature of Witness

Date

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