OMB No. 0910-0796
Exp. 6/30/18

PARENT PERMISSION FOR STUDY PARTICIPATION

Qualitative Study of Perceptions and Knowledge of Visually Depicted Health Conditions

(Accompanies the Assurance of Confidentiality and Informed Consent Form for 12-17 Years Old)

Introduction

Before you choose to allow your child to take part in this study, you will need to read this Parent Informed Consent form so that you understand what the study is about and what your child will be asked to do. This form also tells you who can be in the study, the risks and benefits of the study to your child, how we will protect you and your child's 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 gather your child's knowledge and perceptions surrounding various health topics. Your child will be one of approximately 18 youth who will take part in this study.

Procedure: What will my child do during the study?

Your child is invited to take part in an in-depth individual interview. Your child may choose to take part in the study or not. Your child 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 depicting various health topics. Your child will be asked to share his or her opinions about these images.

Confidentiality: Who will see the information my child provides during this study?

Everything your child says during the interview can be heard by the interviewer, research assistants, and FDA study monitors. All participants will be asked to respect the confidentiality of the materials reviewed and not share any of the information discussed during the interview.

Interview discussions may be audio recorded and transcribed for reporting purposes. The report created using the audio transcripts will not link any of your comments to your child. The interview may also be video streamed live to allow research staff to observe the study remotely. No one outside of the interviewer and researchers will know what your child has said during the discussions. Your child's full name will be used only during the check-in process and only your child's first name will be used during the course of the interview. The interviewer will also instruct participants not to share any private, personal, or inappropriate information during the interview. Such comments will be removed from the transcripts.

Prior to the interview personal information, such as your child's name, gender, race and ethnicity, education, and age, may be collected during the recruitment process. This information will not be retained and or shared with anyone outside of the study, unless required by law. Both your and your child's full name and phone number were used exclusively for recruiting purposes and will not be connected to the answers your child provides during the interview.

Should information from this study be published in professional journals or presented at scientific conferences, your child's name will not be used in any report or presentation.
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 my child and I be paid for participating in this study?
All children who participate in the study will receive a $40 gift card as a thank you. You will receive a $25 gift card to cover any travel expenses.

Study Benefits: What good will come from this study?
This study is not expected to directly benefit you or your child. However, your child's 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. Your child will be asked to share his or her attitudes and opinions on some topics that may be considered sensitive in nature. Your child will also be asked to look at some pictures that may contain some potentially graphic health effects. Your child's participation is voluntary, and your child can choose not to answer any of the questions.

Participation and Withdrawal: Does my child have to be in this study? What if he/she wants to drop out?
Your child's decision to take part in this research study is completely voluntary. Your child can refuse any part of the study and your child can stop participating at any time. Your child can refuse to answer any question. If your child decides to participate and later changes his or her mind, you and your child 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 and your child's 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 and your child's rights as a research participant, you may contact FDA IRB RIHCS (OC_RIHSC@fda.hhs.gov),

YOU WILL BE GIVEN A COPY OF THIS CONSENT 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 give my permission for you to ask my child to take part in this research study and to allow the researchers to record the interview discussion.

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Printed Name of Youth Participant

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Printed Name of Parent/Guardian

_____ _____

Signature of Parent/Guardian **Date**

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Printed Name of Witness

_____ _____

Signature of Witness **Date**