**GenIC Clearance for CDC/ATSDR**

**Formative Research and Tool Development**

**Youth Audience Message Testing of Substance Use Prevention Messages**

**Attachment 2 – Parent/Legal Guardian Consent Form**

**Contact: Jasmine Kenney, MPH**

Communication Branch

Division of Overdose Prevention (DOP)

National Center for Injury Prevention and Control (NCIPC)

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Youth Audience Message Testing of Substance Use Prevention Messages

PARENT/LEGAL GUARDIAN Consent form

|  |  |
| --- | --- |
| Sponsor / Study Title: | Centers for Disease Control and Prevention (CDC) / “Youth Audience Message Testing of Substance Use Prevention Messages” |
| Protocol Number: | 11815-JRKenney |
| Principal Investigator: | Jasmine Kenney |
| Primary Contact:  Telephone: | Everett Long, PhD  704-657-5338 |
| Address: | Fors Marsh Group LLC  4250 N. Fairfax Dr. Suite 520  Arlington, VA 22201 |

CDC estimates the average public reporting burden for this collection of information as 20 minutes per response, including the time for reviewing instructions, searching existing data/information sources, gathering and maintaining the data/information needed, and completing and reviewing the collection of information. 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. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30333; ATTN: PRA (0920-1154).

**What is the key information?**

Your child has been selected as a potential participant in a research study. The purpose of the study is to get thoughts, feelings, and perceptions from youth ages 13–17 about drug use prevention and mental health messages.

This form describes the study’s purpose, procedures, benefits, risks, and precautions. It also describes your right to withdraw consent for your child’s participation at any time. A member of the study team is available to read through this form with you and discuss all the information in it if you wish.

Fors Marsh is a private company conducting research on behalf of the Centers for Disease Control and Prevention (CDC) to understand youths’ thoughts, feelings, and perceptions about drug overdose prevention and mental health messages. Insights from this work will inform content development and strategy for CDC’s educational campaign to prevent drug overdose among youth.

**What do I need to know about this study?**

If you provide consent for your child’s participation in the research study, they will be asked to participate in four online activities, where they will review and respond to questions, statements, messages, and graphics about drug overdose prevention and mental health. During the study, each participant will be asked some questions about their awareness, thoughts, and feelings about the topics of drug overdose, mental health, and messages about these topics. The messages will be presented in various ways including, but not limited to, written, graphic, video, or audio.

Participants will complete four online activities, each lasting about 45 minutes, for an estimated total participation time of up to 180 minutes (3 hours). Participants will have up to 2 weeks to complete the activities and submit their answers. Participants will not have to answer any questions that they do not want to and may choose to exit the study if they choose. Incentives will be paid out in relation to the amount of activities completed by the participant.

**What are the potential risks of being in this study?**

There are minimal risks associated with this study. Participants will be asked to discuss their thoughts and feelings about drug use, drug overdose, and mental health, which may cause them discomfort or make them feel uncomfortable.

There is a possible risk of breach of confidentiality. This risk is minimized by protections described in the “Who will see the results of this study or my information?” section below.

There may be other risks that are unknown.

**Does participating in this study provide any benefits?**

There are no personal benefits to participants for taking part in the study. Participants may learn about substance use, mental health, and drug overdose prevention. Participants will contribute to the creation of government sponsored campaign that will reach youth nationwide to reduce substance use and drug overdose among other young people.

**Are there alternatives to participating?**

This research study is for research purposes only. The only alternative is to not participate in this study.

**Will it cost me anything for my child to participate in the study?**

There are no costs to participate in the study. Participants will receive up to $250 as a token of appreciation for their participation, which will be paid online via gift card. The final total amount will be based on how many activities they have fully completed. After participating in the online journal, they will receive an email with information on how to access the honoraria as well as contact information of who to contact if they have any questions about how to receive the payment.

**Does my child have to be in this study?**

Your child’s participation is voluntary, which means they can stop or leave the study at any time. They may choose to not participate, or they may leave the study for any reason without penalty. Incentives will be paid out in relation to the amount of activities completed by the participant.

Their part in the research may stop at any time for any reason, such as, the sponsor decides to stop the study.

**Who will see the results of this study or my child’s information?**

Only individuals working on the project will have access to this information. There is a small risk that others might find out what participants say, despite all of our best efforts. In the case of a breach of confidentiality, appropriate steps will be taken to notify participants and their parents/legal guardians. By signing this form, you consent to have any typed responses your child provides on the online platform be used in the study report.

Your child’s name and other personal information (for example, contact and demographic information) will not be linked to their responses and will not be shared with the sponsoring agency or distributed for future research studies. This means that no one outside of the activity moderator or research team members will be able to link what the individual says back to them.

The Investigator, the sponsor, or persons working on behalf of the sponsor, and under certain circumstances, the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify your child by name. This means that absolute confidentiality cannot be guaranteed. Everything your child shares will be kept private to the extent allowed by law. This means that we will not share anything they provide with anyone outside the study unless it is required to protect them, or if required by law. However, if your child shows a direct threat of harm to themselves or others, we have the right to act out of concern for their safety and concern for others. This includes reporting any information about self harm to the parent or caregiver.

All of the information we collect, including online discussions, responses, or other information collected during the activities, will be stored on a password-protected computer and/or in locked cabinets that only the study team can access. We will collect some personal information about your child, like their age and race, but we will not collect any information that could identify them personally.

After two years, the collected information will be destroyed by securely shredding documents or permanently deleting electronic information. Results from this project might appear in professional journals or scientific conferences or shared with other study teams. No individual participants will be identified or linked to the results. We will not disclose your child’s identity in any report or presentation.

**Whom to contact about this study**

During the study, if you have questions, concerns or complaints about the study such as:

* Payment or compensation for being in the study, if any;
* Responsibilities as a research participant;
* Eligibility to participate in the study;
* The Investigator’s or study site’s decision to withdraw your child from participation;

**Please contact the Investigator at the telephone number listed at the top of this consent document.**

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

* By **mail**:

Sterling Institutional Review Board

6300 Powers Ferry Rd

Suite 600-351

Atlanta, GA 30339

* or call **toll free**: 888-636-1062
* or by **email**: info@sterlingirb.com

Please reference the following number when contacting the Study Subject Adviser:11815-JRKenney

**Statement of Consent**

Please mark a box and sign below. By signing this form, you have not waived any of your legal rights.

 Yes, I agree to have the child for whom I am the parent/legal guardian of participate in this project. I have read, understand, and had time to consider all of the information above. My questions have been answered, and I have no further questions. I will receive a copy of this signed and dated consent document.

 No, I do not agree to have the youth for whom I am the parent/legal guardian of participate in this project. I have read, understand, and had time to consider all of the information above. My questions have been answered, and I have no further questions.

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Participant’s Printed Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Parent/Legal Guardian’s Printed Name

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Parent/Legal Guardian’s Digital Signature Date