Form Approved

 OMB No. 0990-0459

 Exp. Date 08/31/2023

**Please save a copy**

 **for your records.**

**FOCUS GROUP PARTICIPANT CONSENT FORM**

|  |  |
| --- | --- |
| Study Title: | COVID-19 Public Education Campaign Creative Testing |
| Telephone: | 571-858-3757 (24 hours) |

**What is the key information?**

You are being asked to participate in a research study collecting information about educational messaging related to COVID-19. This form describes the purpose, procedures, benefits, risks, and precautions of the information collection. It also describes your right to withdraw at any time. A member of the study staff is available to read through this form with you and discuss all the information if you wish.

This information collection is being done to help refine and enhance public education messaging related to COVID-19 that will eventually be disseminated to the public.

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

If you agree to be part of the research study, you will be asked to participate in a focus group where you will discuss your perceptions and reactions to messaging related to COVID-19. The focus group will last about 90 minutes and you will be audio and video-recorded while you respond to questions, and other simple written activities that have been designed to facilitate discussion. You do not have to answer any questions that you do not want to.

People from the project team will be observing the session via livestreaming. They will take notes and listen, but they will not interact with the group. You will only be talking to the moderator and a small group of other participants.

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

There are minimal risks associated with this project. 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 project or my information?” section below. Please help protect the privacy and confidentiality of others by not discussing anything from this session outside of the group. If you share stories about others during the group, please avoid using real names or other identifying information. The study staff will do its due diligence to remove any personally identifying information from the transcripts of the session.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990-0459. The time required to complete this information collection is estimated to average 10 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, to review and complete the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance Officer

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

This study is for research purposes only. Although you may not directly benefit from participating in this study, others may benefit because the findings of this study will be used to inform messaging and public education efforts pertaining to COVID-19.

**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 to participate in the project?**

There are no costs to participate in the project. Participants in the focus groups will receive $75 for their participation; you will be paid at the end of your participation in this study.

**Do I have to be in this project?**

Your participation is voluntary, which means you can stop or withdraw at any time. You may choose to not participate, or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled.

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

**Who will see the results of this project or my information?**

Everything you say during the focus group will be heard by the study staff. We will be very careful to only let people working on the project see your information. There is minimal risk that others might find out what you say, despite all of our best efforts. In the case of a breach of confidentiality, appropriate steps will be taken to notify participants.

The focus group will be audio and video-recorded and transcribed. The session may also be livestreamed to other members of the project team and/or members of the sponsoring agency so they can observe remotely. By signing this form, you consent to being audio and video-recorded and livestreamed during the focus group.

Your name and other personal information (for example, contact and demographic information) will not be linked to your responses and will not be shared with the sponsoring agency or distributed for future research studies. This means that no one outside of the project team will be able to link what you said back to you. 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 you by name. This means that absolute confidentiality cannot be guaranteed. Everything you share will be kept private to the extent allowed by law. This means that we will not share anything you provide with anyone outside the project unless it is required to protect you, or if required by law. However, if you show a direct threat of harm to yourself or others, we have the right to take action out of concern for you and concern for others.

All of the information we collect, including anything you say in the focus group, information collected during screening, and audio files will be stored on a password-protected computer and/or in locked cabinets that only the project team can access. We will collect some personal information from you, like your age and race, but we will not collect any information that could identify you personally. After three years, all of 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 project teams. No individual participants will be identified or linked to the results. We will not disclose your identity in any report or presentation.

**Whom to contact about this study:**

If you have questions, concerns or complaints about the study, please contact the Principal Investigator at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

1. By mail:

Study Subject Adviser BRANY IRB

1981 Marcus Ave, Ste 210

Lake Success, NY 11042

1. or call toll free: 516-470-6900
2. or by email: info@brany.com

Although the focus groups will primarily ask that you provide feedback and input on messages and creative assets, we recognize the topic of COVID-19 may bring up some discomfort. If you need any additional support, please contact one of the following.

Substance Abuse and Mental Health Services Administration (SAMHSA) Disaster Distress Helpline

* Call 1-800-985-5990
* Text TalkWithUs to 66746

Suicide Prevention Lifeline

* Call 1-800-273-8255
* Online chat: <https://suicidepreventionlifeline.org/> and click “Chat”

**Statement of Consent**

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

 Yes , I agree to 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 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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Subject’s Printed Name

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