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EXEMPT DETERMINATION

DATE:	4 Apr 2019
TO:	Caitlin Krulikowski Fors Marsh Group LLC
PROJECT:	Centers for Disease Control and Prevention (CDC), CDC Enhanced Message Development and Testing to Prevent Excessive Alcohol Consumption Study – Phase 1 (Pro00033279)

DOCUMENTATION REVIEWED:

Protocol Version:	• Full Protocol (Not Dated)
Consent Form:	• FOCUS GROUP PARTICIPANT CONSENT FORM (Not Dated)
Other Material:	• Submitted As: "CDC Alcohol - Message Frame Focus Group_Worksheets"

Using the Department of Health and Human Services regulations found at 45 CFR 46.104(d)(2), the IRB determined that your research project is exempt from IRB oversight. The IRB also completed the necessary additional limited review considerations as set forth under the Revised Common Rule, 45 CFR 46.104(d). All study related documents will be removed from our active files and archived.

Please be advised that as Advarra IRB is not overseeing the conduct of the study, specific IRB details such as the IRB company name and contact information should be removed from the consent form and all study materials, and study materials should not state that the study is "approved" by an IRB. Study materials may include a general statement that the study was reviewed by an IRB, such as, "This study has been reviewed by an institutional review board (IRB), which is a committee that has reviewed this research study to help ensure that your rights and welfare as a research participant are protected and that the research study is carried out in an ethical manner".

Note: You will still be able to access this study via the Advarra CIRBI Platform under the "Archived" tab on your Dashboard for three years. After three years, the study will be removed from the system in accordance with IRB regulations.

The IRB granted this exemption with an understanding of the following:

1. The research project will only be conducted as submitted and presented to the IRB, without additional change in design or scope.

2. Should the nature of the research project change, or any aspect of the study change such that the nature of the study no longer meets the criteria found in 45 CFR 46.104(d)(2), you will resubmit revised materials for IRB review.

3. It is the responsibility of the investigator to ensure that the project meets the ethical standards of the institution. Specifically, the research involves no more than minimal risk to participants, the selection of subject is equitable, there are adequate provisions to maintain the confidentiality of any identifiable data collected, and when there are interactions with research subjects, they will be informed that the activity involves research, a description of the procedures, participation is voluntary, and the contact information for the researcher.

The IRB will evaluate the new information and make a determination at that time regarding the research project's status.

This project is not subject to requirements for continuing review.

If you have any questions or concerns, please use the Contact IRB activity on your Advarra CIRBI Platform .

Thank you for selecting Advarra IRB to review your research project.

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