

Attachments:

- REVISED_Community Web-Panel Survey Consent Form.2023.07.24.pdf
- REVISED_Community Focus Group Consent Form.2023.07.24.pdf
- Expedited Review Approved by Chair - IRB ID: 2023/02/5.pdf

**SOLUTIONS IRB***Approval Notification*

To: Catherine Lesesne , clesesne@deloitte.com
From: Ayn O'Reilly, IRB Chair
Subject: Protocol #2023/02/5
Date: 07/25/2023

The protocol **Menthol-Flavored Tobacco Products Policy Evaluation** has been approved by the IRB Chair under the rules for expedited review on **07/25/2023**. The expedited review categories applicable to the study approval are:

(7) Research on individual or group characteristics or behavior

The approval of your study is valid through 07/24/2024, by which time you must submit an annual report either closing the protocol or requesting permission to continue the protocol for another year. Please submit your report by **06/26/2024** so that the IRB has time to review and approve your report if you wish to continue it for another year.

This project should be conducted in full accordance with all applicable laws and regulations, and must adhere to the project plan that has been approved by Solutions IRB. **You must notify Solutions IRB immediately of any proposed changes that may affect the status of your approval or the risk to participants.** You must also report any unanticipated problems involving risk to participants or others to Solutions IRB immediately.

Any changes to the approved study documents must be approved prior to use.

Upon any inquiries or reports about the conduct of this study, or on the receipt of any participant or other complaints, or in conjunction with a routine compliance audit, you may be asked to provide documentation to Solutions IRB related to this study and are expected to immediately comply with any such requests.

Please refer to your sponsor/regulatory office guidelines on the timeline to send IRB decision letters, if applicable.

Upon completion of the research project, please notify Solutions IRB so that we can close out your study as appropriate.

We look forward to continuing to partner with you to ensure the ongoing protection of participant rights. If you have any questions or need additional information, please contact us at reviews@solutionsirb.com or call 1-855-226-4472.

If you have any questions, feel free to contact me.

Thanks,

A handwritten signature in black ink, appearing to read "Ayn O'Reilly".

Ayn O'Reilly
IRB Chair
PO Box 1041
Yarnell, AZ 85362
855.226.4472
reviews@solutionsirb.com

Application Sections Requested Files**Summary of Activities**

Full Protocol/Investigator Brochure (if applicable)

04/28/2023 Research Protocol.VF.2023.05.01.docx

Application Files**IRB CF Revisions**

06/19/2023 Community Focus Group Consent Form.VF.2023.05.31_revised.docx
06/19/2023 Community Web-Panel Survey Consent Form.VF.2023.05.31_revised.docx

Recruitment Materials

05/01/2023 Focus Group Informational Advertisement.VF.2023.05.01.docx

05/01/2023 Web Panel Survey Informational Advertisement.VF.2023.05.01.docx
05/01/2023 Sample Social Media Focus Group Recruitment Ad.VF.2023.05.01.pdf
05/01/2023 Briana_Oliver_CITI_Training_Cert.pdf
05/01/2023 Katherine_Moran_CITI_Training_Cert.pdf
05/01/2023 Kelly_McAleer_CITI_Training_Cert.pdf
05/01/2023 CITI-Research-Certificate-of-Completion-LZakalik.pdf
05/01/2023 GGopez_CITI_Training_CompletionReport9904770.pdf
05/01/2023 Lesesne CITI cert 2021-2024.pdf
06/27/2023 CompletionCertificate_EGwynn_062223.pdf

Personnel Training Certificates

05/01/2023 Community Focus Group Guide.VF.2023.05.01_IRB.docx
05/01/2023 Screener_Community Focus Group Guide.VF.2023.05.01_IRB.docx
05/01/2023 Screener_Community Web-Panel Survey.VF.2023.05.01_IRB.docx
06/12/2023 OSH Menthol Cognitive Interviewing Tool.V1.2023.05.24.docx

Data Collection Instruments

05/01/2023 Briana_Oliver_Resume.pdf
05/01/2023 Katherine_Ann_Moran_Federal_Resume_CDC.docx
05/01/2023 Kelly_McAleer_Resume.docx
05/01/2023 Catherine (Cathy) Lesesne CV 12-2021.docx
05/01/2023 GGopez ResumeV1.2023.01.10.docx
05/01/2023 lori-zakalik-deloitte-resume-March-2023.doc
06/27/2023 EPGwynn Resume.pdf

Personnel CV (resume)

05/01/2023 Community Web-Panel Survey.VF.2023.05.01_IRB.docx

Survey & Interview Questions

03/31/2023 Contract-Award-Notice.pdf

Grant Proposal

06/19/2023 IRB Solutions Revision Response.docx

Email Correspondence

07/24/2023 Solutions IRB Revision Response.V2.2023.07.24.docx

Consent Form

05/01/2023 Community Web-Panel Survey Consent Form.VF.2023.05.01.docx
05/01/2023 Community Focus Group Consent Form.VF.2023.05.01.docx
07/24/2023 REVISED_Community Web-Panel Survey Consent Form.2023.07.24.docx
07/24/2023 REVISED_Community Focus Group Consent Form.2023.07.24.docx

IRB Registration #: IORG0007116

Federalwide Assurance (FWA) #: IRB00008523