

BRANY SBER IRB

DATE: 12/22/2020
TO: Scott Vanderbilt, MAMC
FROM: Raffaella Hart, MS, CIP, BRANY SBER IRB (IRB00010793)

SUBMISSION TYPE: SBER-Initial Review (Event ID# 177418)
PROTOCOL NUMBER: 20-078-821 /
STUDY TITLE: HHS COVID-19 Public Education Campaign Foundational Focus Groups

IRB ACTION: **Approved - SBER**

APPROVAL DATE: 12/22/2020
EXPIRATION DATE: Non-expiring
REVIEW TYPE: Expedited Initial Review

Thank you for your submission for the above-referenced study.

1. **BRANY SBER IRB Determination**

Your submission was **APPROVED** by the BRANY SBER IRB via expedited review under categories 6 and 7. This approval requires that all procedures and activities are performed in accordance with relevant state and local law (including tribal law, when applicable).

2. **Submitted Documents**

- a. SBER Study Application-2020-12-17-10-34.pdf
- b. Foundational FG Abstract.docx
- c. HHS COVID-19 Public Education Campaign Foundational FG Informed Consent Form_FINAL 12.16.2020_CLEAN-20201221.pdf
- d. HHS COVID-19 Public Education Campaign Foundational FG Informed Consent Form_FINAL 12.16.2020_REDLINE-20201221.docx
- e. HHS COVID-19 Public Education Campaign Foundational FG Screener_FINAL 12.16.2020.pdf
- f. HHS COVID-19 Public Education Campaign Foundational FG Testing Guide_FINAL 12.16.2020.pdf
- g. HHS COVID-19 Public Education Campaign Foundational Focus Groups Protocol.pdf

Modifications are in accord with those required by the IRB, and were incorporated as indicated in the enclosed redlined version.

3. **Provisions of BRANY SBER IRB Approval**

- a. This study requires consent of subjects to be obtained. You must continue to monitor the subject's willingness to be in the study for the duration of the subject's participation. Only use the current IRB-approved and stamped forms in the consent process. Each subject must receive a copy of his/her signed consent document. Consent forms signed by subjects in this study must be kept by the Principal Investigator for at least 3 years, or longer if required by your institution.

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- b. All research must be conducted in accordance with this approved submission. Any changes to the approved study must be reviewed and approved by the BRANY SBER IRB prior to implementation, except when necessary to eliminate an apparent immediate hazard to the subject.
 - c. Unanticipated problems (including serious adverse events, if applicable) must be reported to BRANY SBER IRB within 5 days of discovery using Form IRB-4 (Reporting Form for Events that Require Prompt Reporting to the IRB).
 - d. Any complaints or issues of non-compliance must be immediately reported to BRANY SBER IRB.
4. **Study Personnel**
The following study personnel have been approved to participate in this research project.
- a. Scott Vanderbilt, MAMC
 - b. Ashley Simpkins
 - c. Lindsey Strusser
 - d. Leah Hoffman
 - e. Erik Lund
5. **Non-Expiring IRB Approval Period:**
This study was reviewed under the Revised Common Rule (2018 requirements) and therefore **does not require continuing review in accordance with 45 CFR 46.109(f)(1)(i).**

However, BRANY SBER IRB requires you "check in" at least annually to ensure your study status is up to date and in compliance. **Your Annual Report to BRANY IRB is due on 12/22/2021.** If your research is completed before then, you must submit a notification of study closure to BRANY SBER IRB (use the xForm called: SBER-Study Status Change (Closed/Enrollment Closed)).

If you have any questions or require any additional information, please call me at 516-470-6909 or send an email to me at rhart@brany.com. Thank you.