BRANY

BRANY SBER IRB

DATE: 01/20/2021
TO: Kristin Pondel
FROM: Raffaella Hart, MS, CIP, BRANY SBER IRB (IRB00010793)

SUBMISSION TYPE:	SBER-Initial Review (Event ID# 178156)
PROTOCOL NUMBER:	21-001-821
STUDY TITLE:	HHS COVID-19 Public Education Campaign Vaccine Readiness Creative Testing Survey.
IRB ACTION:	**Approved - SBER**
APPROVAL DATE:	01/20/2021
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. 21-001-Pondell_SBER Study Application-2021-01-13.pdf
   b. IRB Abstract.docx
   c. HHS COVID-19 Public Education Campaign Creative Testing Survey Protocol 1.12.21.docx
   d. HHS COVID-19 Public Education Campaign Draft Creative Testing Questionnaire 18 JAN 2021_clean.docx
   e. Informed Consent Form_Quant_IRB edits_clean.docx
   f. Email Invitation.docx

   Modifications are in accord with those required by the IRB, and were incorporated as indicated in the redlined versions contained within the IRBManager record.

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. When documented consent is required, each subject must receive a copy of his/her signed consent/permission/assent document, and 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.
   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. **Consent – Waiver of Documentation**
   BRANY SBER IRB determined that your request for waiver of documentation of informed consent satisfies the criteria set forth in 45 CFR 46.117(c)(3).

5. **Study Personnel**
   The following study personnel have been approved to participate in this research project.
   a. Kristin Pondel
   b. Stephanie Miles
   c. Lauren Angel
   d. Leah Hoffman
   e. Lindsey Strausser

6. **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 01/20/2022.** 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.