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

1. **BRANY SBER IRB Determination**
   The BRANY SBER IRB has determined the activity mentioned above does not constitute research involving human subjects that is regulated by DHHS or FDA regulations and is therefore not subject to further BRANY SBER IRB review.

   BRANY SBER IRB concluded your proposed activity does not meet the definition of research involving human subjects according to DHHS regulations because, while the activity is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge, the activity does not involve human subjects because the data the investigator plans to collect is not about the individuals who will respond to the surveys/questionnaires.

   This determination requires that all procedures and activities are performed in accordance with relevant state and local law (including tribal law, when applicable).

2. **Documents Acknowledged with this Submission**
   a. VT IRB-19-612 Authorization Letter
   b. Abstract
   c. IRB-19-612-Research Protocol
   d. Consent to Take Part in a Research Study
   e. Expert Reviewer’s Rubric
   f. SBER Study Application xForm

3. **Provisions of BRANY SBER IRB’s Determination**
Although BRANY SBER IRB determined this activity is not research involving human subjects and the activity does not require further IRB review, any proposed changes must be reviewed by the BRANY SBER IRB prior to implementation. The BRANY SBER IRB will evaluate the proposed change(s) and determine whether the changes constitute human subjects research.

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.