

BRANY SBER IRB

DATE: 09/02/2020
TO: Martha Ann Bell, PhD
CC: commercialirb@vt.edu; Julie C Dunsmore, PhD
FROM: Raffaella Hart, MS, CIP, BRANY SBER IRB (IRB00010793)

SUBMISSION TYPE: SBER-Continuing Review (Event ID# 172770), Replacement PI (Event ID #172772)
PROTOCOL NUMBER: VT18-547-568(TRX) / VT# 18-547
STUDY TITLE: Cross-cultural study of parental beliefs about emotions, self-construal and emotion socialization

IRB ACTION: **Approved - SBER**

APPROVAL DATE: 08/21/2020
EXPIRATION DATE: 08/20/2021
REVIEW TYPE: Expedited Review, Continuing Review and Change of PI

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 the following categories: 4, 6 and 7.

BRANY IRB has also determined that **Martha Ann Bell, PhD** is qualified by training and experience to conduct the research, and to replace Julie C Dunsmore, PhD as the Principal Investigator for this research. *As the replacement Principal Investigator, you are responsible to abide by all previous IRB determinations and stipulations of IRB approval for this study.*

The BRANY IRB approval date for this change of principal investigator and continuing review is 08/21/2020, which is the date the conditions of approval were satisfied.

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

This study is now re-approved *effective 08/21/2020 through 08/20/2021*, including:

- a. SBER Continuing Approval Application-2020-08-18-10-22
- b. 14-Change of Principal Investigator (PI) Application-2020-08-18-10-28
- c. Protocol (Version B/6-17-20)
- d. Parent Subject Information and Informed Consent Form (Version C)
- e. Child Assent Subject Information and Consent Form (Version B)
 - Refer to the enclosed document(s) with tracked changes for all modifications.
 - **Re-consent Required:** If the research remains open to accrual at your site, use the enclosed to obtain consent from new subjects. For previously consented subjects still active or in follow-up (not including subjects in long term survival

BRANY SBER IRB

follow-up for whom the revisions are not applicable), you can either use the enclosed to re-consent, or use the previously provided consent form addendum or letter (BRANY stamp version 5/31/19).

- f. Online advertisement 8_5_20 (BRANY stamp 9/2/20)
- g. Recruitment letter for mailing revised 8_5_20 (BRANY stamp 9/2/20)

All other previously IRB-approved items remain approved.

2. IRB Approval Period and Expiration of IRB Approval:

BRANY SBER IRB approval will expire on 08/20/2021, 12 months from the approval date of 08/21/2020.

In order to be able to conduct your study in an uninterrupted manner, you must apply for and undergo continuing review, and be granted continued BRANY SBER IRB approval for this study before 08/20/2021.

If you do not receive approval before this date, you must cease and desist all research involving human subjects, their tissue, and their data until approval is granted. However, changes can be implemented if they are in the best interest of the subject due to safety evaluations or eliminating/reducing risks to them. The determination of “best interest to subject” must be made by the BRANY SBER IRB. Alternatively if your study has concluded please submit 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.