

To: Rachel Diana, PhD

From: Benjamin Neter, Continuing Review Junior Coordinator

**CC**: <u>commercialirb@vt.edu</u>

**Research Coordinator** 

**Date:** 12/12/2019

**Event ID: 162055** 

Re: Continuing Approval for National Science Foundation Protocol # Context resolution and

variability: Identifying le / PI: Diana / BRANY File # VT18-1077-568(TRX) / 18-1077

**Protocol Title:** Context resolution and variability: Identifying learning strategies to optimize hippocampal representations

Your application for continuing approval and minor deviation log, was approved by BRANY IRB under expedited review categories 4, 6, 7, as provided in 45 CFR 46.110. This approval requires that all procedures and activities are performed in accordance with relevant state law and local law (including tribal law, when applicable).

This study is now re-approved effective 12/12/2019 through 12/11/2020, including:

- National Science Foundation Protocol (BRANY Stamped 12/12/19)
- Research Subject Consent Form (Version A)
- Research Subject Consent Form fMRI (Version A)
  - o 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 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).

## Additional items reviewed/approved by BRANY IRB:

- Data Collection Tool (#23408972.0)
- Data Collection Tool (#23408974.0)
- Recruitment Advertisement (#23408978.0)
- Recruitment Advertisement (#23408982.0)
- Recruitment Advertisement (#23415049.0)

## Important Note(s):

- a. 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 IRB prior to implementation, except when necessary to eliminate an apparent immediate hazard to the subject.
- b. All subjects are to be consented with the stamped, BRANY IRB-approved consent form(s).



- c. Unanticipated problems (including serious adverse events, if applicable) must be reported to BRANY IRB within 5 days of discovery using xForm#16 (Reportable Event xForm)
- d. Any complaints or issues of non-compliance must be immediately reported to BRANY IRB.

BRANY IRB approval will expire on 12/11/2020. Your continuing review application (#xForm11) (including the Supplement for Multi-center Studies, when applicable) must be filed at least one month prior to the expiration date in order to avoid expiration of IRB approval. If the study is completed prior to this date, you are required to report study closure via xForm # 04.

If you have any questions or require any additional information, please contact me at Neter or bneter@brany.com. Thank you.

<sup>\*</sup>All study materials previously reviewed and approved by BRANY IRB remain approved.