Date: May 29, 2018, 10:55am  
Action Taken: Approved  
Principal Investigator: Mairym Llorens  
Faculty Advisor: Louis Goldstein  
Co-Investigator(s):  
Project Title: Speech and Ticking in Tourette's  
Continuing Review ID: UP-17-00301-CR001  
Funding: Departmental/Institutional Funding  

This study has been determined to qualify for the USC Human Research Protection Program Flexibility Policy. If there are modifications that increase risk to subjects or if the funding status of this research is to change, you are required to submit an amendment to the IRB for review and approval.
The University Park Institutional Review Board (UPIRB) designee determined that your project qualifies for exemption from IRB review under the USC Human Research Protection Program Flexibility Policy. The study was approved on 05/25/2018 and is not subject to 45 CFR 46 regulations, including informed consent requirements or further IRB review.

If there are modifications that increase risk to subjects or if the funding status of this research is to change, you are required to submit an amendment to the IRB for review and approval.

Consent and recruitment documents are not required to be uploaded for exempt studies; however, researchers are reminded that USC follows the principles of the Belmont Report, which requires all potential participants to be informed of the research study, their rights as a participant, confidentiality of their data, etc. It is recommended that you utilize the Information Sheet For Exempt Research and revise the template to be specific to your study. This document will not be reviewed by the IRB. It is the responsibility of the researcher to make sure the document is consistent with the study procedures listed in the application.

**Per USC Policy, someone may not collect data about people he or she oversees in a professional capacity. Please ensure that someone on the study (represented in 2.1, with the required human subjects certification) is able to serve as an independent data collector. Further, data must be stripped of any identifying information before being provided to people who have the supervisory relationship in order to protect the confidentiality of the participant responses.**

Researchers are reminded that as mandated reporters, they must report all instances of suspected child abuse, per USC policies at http://policy.usc.edu/mandated-reporters/

You are responsible for ensuring that your project complies with all
federal, state, local and institutional standards. Please check with all participating sites to make sure you have their permission (including IRB/ethics board approval, if applicable) to conduct research prior to beginning your study.

All submissions, including new applications, contingency responses, amendments and continuing reviews are reviewed in the order received.

Attachments:

Social-behavioral health-related interventions or health-outcome studies must register with clinicaltrials.gov or other International Community of Medical Journal Editors (ICMJE) approved registries in order to be published in an ICJME journal. The ICMJE will not accept studies for publication unless the studies are registered prior to enrollment, despite the fact that these studies are not applicable “clinical trials” as defined by the Food and Drug Administration (FDA). For support with registration, go to www.clinicaltrials.gov or contact Jean Chan (jeanbcha@usc.edu, 323-442-2825).

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