
To: John Gabrieli
46-4033B
From: Leigh Finn, Chair
COUHES
Date: 07/27/2017
Committee Action: Amendment to Approved Protocol
COUHES Protocol #: 1610694401A004
Study Title: Understanding the Neural Bases of Emotion Dysregulation in Adult ADHD
Expiration Date: 10/19/2017

The amendment to the above-referenced protocol has been APPROVED following expedited review by the Committee on the Use of Humans as Experimental Subjects (COUHES).

This approval covers the following change(s)/modification(s):

- Xavier Paradis has been added to the protocol and will assist with this study and the added motor tasks.
- At the end of the scan, participants will have the option to perform a 10 minute motor task experiment including figure/foot taping, movement, and response inhibition, along with an addition of a behavioral tendencies questionnaire. With the participant's consent for these optional tests, these motor tasks will be video-recorded via a small portable video camera to enable re-scoring for accuracy.

If the research involves collaboration with another institution, then the research cannot commence until COUHES receives written notification of approval from the collaborating institution's IRB.

It is the Principal Investigator's responsibility to obtain review and continued approval before the expiration date. Please allow sufficient time for continued approval. You may not continue any research activity beyond the expiration date without COUHES approval. Failure to receive approval for continuation before the expiration date will result in the automatic suspension of the study and related research grants.

Information collected following suspension is unapproved research and cannot be reported or published as research data. If you do not wish continued approval, please submit Final Report Closure Form.

Unless informed consent is waived by the IRB, use only the most recent, IRB approved and stamped copies of the consent form(s).

Adverse Events: Any serious or unexpected adverse event must be reported to COUHES within 48 hours. All other adverse events should be reported in writing within 10 working days.

Amendments: Any changes to the protocol, including changes in experimental design, equipment, personnel or funding, must be approved by COUHES before they can be initiated, except when necessary to eliminate apparent immediate hazards to the subject.

Human subjects training is required for all study personnel and must be updated every 3 years.