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Institutional Review Board #1
FWA #: 00000482

Notification of Expedited Continuing Review Approval

The following research activity has been re-reviewed and re-approved by the Institutional Review Board (IRB) at Rush University Medical Center in accordance with the Common Rule (45CFR46, December 13, 2001) and any other governing regulations or subparts. The Institutional Review Board at Rush also confirms that the project still meets the following categories under 45CFR46.110 for expedited review:

Category 8(c): Continuing review of research previously approved by the convened IRB as follows: where the remaining research activities are limited to data analysis.

Please note the date for continuing review. Although you will be notified near the time for continuing review, it is your responsibility to assure that your project receives ongoing IRB approval.

ORA Number: 11063003-IRB01-CR07
Principal Investigator: Mark Pollack
Project Title: Eszopiclone for the Treatment of PTSD

Date of approval: 4/9/2018
Due for continuing review: 4/9/2019

Review Type: Expedited

Who needs to be reconsented? No reconsent required

It is your responsibility to follow the guidelines below:

- Conduct the study in accordance with the relevant, current protocol and only make changes in the protocol after notifying the IRB, except when necessary to protect the safety, rights or welfare of subjects.
- Record and track number of subjects accrued as well as information regarding study drop-outs or withdrawals.
- Provide brief updates on the changing scientific literature as that literature pertains to the efficacy and safety of the specific procedure or intervention under study.

- Report any complaints from subjects as well as any and all serious or unexpected adverse events related to this study to the IRB.
- Maintain and use copies of the currently approved consent document related to this project (if applicable).
- Maintain a file of the consent documents bearing the signature of the subjects enrolled in this study.

{The below is a representation of an electronic record that was signed electronically and is the manifestation of the electronic signature.}

John Cobb
4/19/2018 6:53 AM
Signing for John Cobb

John Cobb, BA, CIP
IRB Manager, Research Regulatory Operations
Rush University Medical Center