

**To:** Andrew Nencka, PhD

**Date:** 10/2/2017

**Re: Project Full Title:** Development of a Voxel-Wise Database of Physical Parameters for Neuroimaging  
**PRO ID:** PRO00015756  
**6 Year Renewal Title:** 6 Year Renewal for PRO00015756  
**6 Year Renewal ID:** [CPR00016318](#)

**IRB Approval Date:** 9/29/2017  
**IRB Expiration Date:** 9/28/2018

The MCW/FH Institutional Review Board #5 has determined that the project continues to satisfy requirements of 21 CFR 56.111 by expedited review Category 4. Therefore approval of this submission is granted.

The consent form is effective as of 9/29/2017. Signed consent forms for each subject must be kept on file as part of the study records.

All project activities must be conducted according to the protocol that was approved by the IRB.

Any and all proposed changes to this submission must be reviewed and approved by the IRB prior to implementation. When necessary to eliminate hazards to subjects, changes may be made first. This should be followed promptly by submission of a protocol deviation via a Reportable Event and Amendment.

In accordance with federal regulations, continuing approval for this submission is required prior to 9/28/2018. The Continuing Progress Report (CPR) must be received by the IRB with enough time to allow for review and approval prior to the expiration date. Failure to submit the CPR in a timely manner may result in the expiration of IRB approval.

A Final Report must be submitted to the IRB within 30 days of when all study activities < and data analysis > have been completed.

All Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO) must be reported promptly to the MCW/FH IRB according to IRB Standard Operating Procedures (SOPs).

If you have any questions, please contact the IRB Coordinator II for this IRB Committee, Harry Brammer, at 414-955-8348 or [hbrammer@mcw.edu](mailto:hbrammer@mcw.edu).

Sincerely,

Kathryn Gaudreau  
David Clark, PhD  
IRB Chair  
MCW/FH Institutional Review Board #5