

NOTICE OF APPROVAL TO IMPLEMENT REQUESTED CHANGES

HSC-MS-06-0385 - Comparative Analysis of Structural and Functional Characteristics of Essential Brain Regions as Measured by Functional Imaging and Electrophysiology and Hemispheric Laterality Predicted by Structural Connectivity and Fronto-basal-ganglia Circuits for Selective Stopping and Braking and Diffusion Imaging for Seizure Focus Localization AND Representation and Binding of Spatial and Temporal Episodic Memories in Human Hippocampus AND SCH: EXP: Exploring Sparsity and Spectral-Temporal Decomposition in Real-Time Network Modulation for Intractable Epilepsy AND The Neural Basis of Human Spatial Navigation AND Micro-scale Real-time Decoding and Closed-loop Modulation of Human Language AND Brain Networks of Noun Generation

PI: Dr. Nitin Tandon

Reference Number: 130574

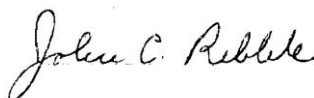
PROVISIONS: Unless otherwise noted, this approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered at this meeting, e.g. study documents, informed consent, etc.

APPROVED: By Expedited Review and Approval

CHANGE APPROVED: Addition of Xin Huang and Yuan Gao to study team

APPROVAL DATE: 11/13/2015

CHAIRPERSON: John C. Ribble, MD



Upon receipt of this letter, and subject to any provisions noted above, you may now implement the changes approved at this meeting.

CHANGES: The principal investigator (PI) must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the CPHS. ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.

INFORMED CONSENT: Informed consent must be obtained by the PI or designee(s), using the format and procedures approved by the CPHS. The PI is responsible to

instruct the designee in the methods approved by the CPHS for the consent process. The individual obtaining informed consent must also sign the consent document. **Please note that if revisions to the informed consent form were made and approved, then old blank copies of the ICF MUST be destroyed. Only copies of the appropriately dated, stamped approved informed consent form can be used when obtaining consent.**

UNANTICIPATED RISK OR HARM, OR ADVERSE DRUG REACTIONS: The PI will immediately inform the CPHS of any unanticipated problems involving risks to subjects or others, of any serious harm to subjects, and of any adverse drug reactions.

RECORDS: The PI will maintain adequate records, including signed consent documents if required, in a manner that ensures subject confidentiality.