

Dr. Michael Beauchamp
UT-H - MS - Neurobiology & Anatomy

NOTICE OF CONTINUING REVIEW APPROVAL

August 28, 2012

HSC-MS-05-0516 - *Functional Magnetic Resonance Imaging of Multisensory Integration & Multisensory Influences On Touch Perception--fMRI, MEG and TMS Studies & Rapid Sensory Processing in Well and Poorly Compensated Young Adults with Dyslexia & fMRI of Functional Brain Organization in Stroke Recovery, Epilepsy, and Traumatic Brain Injury & Neural Mechanisms of Optimal Multisensory Integration & Translation of near-infrared spectroscopy for use in clinical neuroimaging of deaf children after cochlear implantation & Mechanism of Rapid Object Recognition in Human Ventral Temporal Cortex*

PI: Michael Beauchamp

PROVISOS: 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 consents, etc.

NOTE: If this study meets the federal registration requirements and this is an investigator-initiated study, or if the PI is the study sponsor or holds the IND/IDE applicable to this study, and no one else has registered this trial on the national registry, you are required to register this trial on the national registry at www.clinicaltrials.gov in order to publish results in any of the key peer-reviewed journals. For further information write to clinicaltrials@uth.tmc.edu or call 713-500-7909.

APPROVED: By Expedited Review and Approval

REVIEW DATE: August 26, 2012

APPROVAL DATE: August 28, 2012

EXPIRATION DATE: 07/31/2013

CHAIRPERSON: F. Gerard Moeller, MD



Upon review, the CPHS finds that this research is being conducted in accord with its guidelines and with the methods agreed upon by the principal investigator (PI) and approved by the Committee. This approval, subject to any listed provisions and contingent upon compliance with the following stipulations, will expire as noted above:

CHANGES: The 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. Attached is the approved and validated informed consent form. You must discard all previous informed consent documents being used and replace them with this stamped validated version. **Please note that 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 which ensures subject confidentiality.