UTHealth
The University of Texas
Health Science Center at Houston

Committee for the Protection of Human Subjects
6410 Fannin Street, Suite 1100
Houston, Texas 77030

Dr. Brian Gulbis, PharmD
UT-H - GEN - Default Department Code

NOTICE OF APPROVAL TO BEGIN RESEARCH **August 01, 2016**

HSC-MH-16-0660 - Validation of ICD-9-CM/ICD-10-CM Codes for Automated Electronic Scoring of APACHE II, APACHE III, and SAPS II

Number of Subjects Approved: Target: /Screen: 0

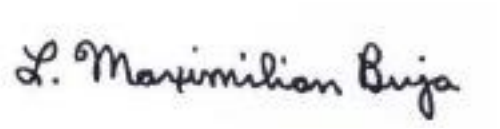
PROVISIONS: This approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered by the Committee for the Protection of Human Subjects, e.g. study documents, informed consent, etc.

APPROVED: By Expedited Review and Approval

REVIEW DATE: August 1, 2016

APPROVAL DATE: August 1, 2016

EXPIRATION DATE: July 31, 2017

CHAIRPERSON: L. Maximilian Buja, MD 

Subject to any provisions noted above, you may now begin this research.

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 DETERMINATION:
Waiver of Consent Granted

INFORMED CONSENT: When Informed consent is required, it 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 only copies of the stamped approved informed consent form can be used when obtaining consent.

HEALTH INSURANCE PORTABILITY and ACCOUNTABILITY ACT (HIPAA):

Waiver for Retrospective Chart Review granted:
Information to be accessed: Medical Record #, Date of Birth, Dates of Service/Treatment
Information to be retained: Medical Record #, Date of Birth, Dates of Service/Treatment

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 and HIPAA documents if required, in a manner that ensures subject confidentiality.