

April 15, 2016

MEMORIAL HERMANN HEALTH SYSTEM APPROVAL FOR MEMORIAL HERMANN – TEXAS MEDICAL CENTER

Thank you for choosing Memorial Hermann as your service provider for this research study.

IRB ID: HSC-GEN –16-0660 PRINCIPAL INVESTIGATOR: Brian Gulbis, PharmD

STUDY TITLE: Validation of ICD-9-CM/ICD-10-CM Codes for Automated Electronic Scoring of APACHE II, APACHE III, and

SAPS II

Approval is hereby granted by Memorial Hermann Health System to initiate this research study at the Memorial Hermann – Texas Medical Center location. This approval is subject to the Principal Investigator's acceptance of the following stipulations:

STUDY-SPECIFIC STIPULATIONS:

Data Security and HIPAA:

- 1. All data security computer devices used in this study must be password protected and/or data encrypted.
- 2. The Principal Investigator will please note to use a separate linking log to connect study data to the identifiable patient information. The linking log should be stored and secured in a separate location form the data collection tool.

Other Stipulations:

- 3. Please remember to acknowledge the Memorial Hermann Texas Medical Center in any publications resulting from this study, and provide a copy of the publication to the Vice President, Clinical Research at Memorial Hermann Clinical Innovation & Research Institute (Cheryl. Chanaud@memorialhermann.org) The methods of acknowledgement may include:
 - a. Memorial Hermann Texas Medical Center as an author's affiliation;
 - b. mention in an "acknowledgement" section; or
 - c. as a footnote.

Memorial Hermann Health Care System

Please sign and return a PDF copy of this letter to the Memorial Hermann Clinical Innovation & Research Institute to kristin.chandler@memorialhermann.org to indicate your acceptance of our terms and policies (quidelines attached).

This study may not be initiated until the letter is signed and returned to the Memorial Hermann Clinical Innovation & Research Institute.

If you have questions or need additional information, please contact the Memorial Hermann Clinical Innovation & Research Institute at (713) 704-5655.

APPROVED:		ACCEPTANCE:	
Glenn Winnier	8/15/2016		
Glenn Winnier, PhD Director of Clinical Research Operations	Date	Brian Gulbis, PharmD Principal Investigator	Date
Clinical Innovation and Pessarch Institute		· ····c.pa. ····cscigate.	

Rev. 10/21/15

CC:

James Maddock- Director, Pharmacy Patricia Tooley, RN, CIPP – System Executive for Privacy Compliance

Attachments:

Memorial Hermann Clinical Innovation and Research Institute Guidelines



MEMORIAL HERMANN CLINICAL INNOVATION & RESEARCH INSTITUTE GUIDELINES

MEDICAL RECORD ACCESS

Paper Medical records are available for 2008 and prior through Centralized Scanning Department (713-802-3907). The Investigator must provide three (3) business days' notice for paper requests and for all monitoring visits.

DATA SECURITY

All data security computer devices used in this study must be password protected and/or data encrypted.

CONTINUING IRB REVIEW

Memorial Hermann requires continuous approval by the IRB for all research studies. The Principal Investigator is responsible for maintaining continuing review approval during the conduct of the study.