UMass Memorial Medical Center
HIPAA IRB WAIVER OF AUTHORIZATION***

Principal Investigator: Dr. Szabo
IRB Study ID #: H00012102

Protocol Title: The Association and Significance of Proton Pump Inhibitors and Hepatic Encephalopathy

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1. Indicate if you are requesting a waiver of authorization to review electronic/paper medical records just to find potential subjects or to conduct the entire study.

   I am requesting a waiver of authorization to review electronic/paper medical records

2. The HIPAA regulation requires reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request. List the PHI to be collected and its source(s).

   Progress notes from hospitalizations on the software: Soarian, Allscripts, and Salar Notes. We will obtain data from these three record systems including lab results (BMP, CBC, LFT), image studies including CT scan and ultrasound, and diagnosis/problems using ICD10 codes. No names are needed. We will be collecting age and sex for patients as well. All data collected will be from January 1, 2012 to January 1, 2017.

3. Explain why the research could not practicably be conducted without this PHI.

   This minimal information is needed to complete primary objectives of research project and it will be conducted in a retrospective manner providing minimal to no risk to patient.

4. Describe the plan to protect identifiers from improper use or disclosure. Be sure to indicate where PHI will be stored, who will have access (researchers must list all of the entities that might have access to the study's PHI such as IRB, sponsors, FDA, data safety monitoring boards, and any others given authority by law), and the procedure used to destroy them. (Note that identifiers must be destroyed at the earliest opportunity, unless there is a justification for retaining the identifiers or retention is required by law.)

   As this database is being made, the data collected in this study will all be stored on REDCap in a password protected file in the Hepatology Research Office. The document linking MRN with study ID will be stored separately on a UMass server with a password lock. The data stored will include information listed in Section 11 on proposal form.

   If other investigators would like to obtain data from this registry, a formal request will have to be made to the PI. External researchers as well as UMMS/UMass investigators will be allowed to request permission for the data. The PI will grant permission to release the data if the request meets certain requirements: 1) institution-specific permission (IRB) to use the data for research with documented

proof, 2) guarantee that data will be used for research purposes only, and 3) requesting investigators are affiliated with academic medical centers. The PI will review each proposal to release the data and determine if the eligibility requirements are met.

If the PI grants permission to release the data, the data will be sent electronically. The data will not have any personal identifiers (subject IDs only), and the data will be sent securely and directly by hospital secure email in a password protected file.

5. Explain why the research could not practicably be conducted if you had to obtain permission from the individuals to access their PHI for research purposes.

There will be no need to obtain permission from the subjects as there is no risk to them in performing a retrospective chart review. As this study will be conducted in a retrospective manner there is no personal interaction between the study personnel and subjects as they are no longer receiving hospital care. The difficulty of obtaining verbal consent would place a sizable time constraint on the possibility of reviewing and analyzing past data from January 1, 2012 and January 1, 2017.

By submitting this form, the PI attests the following:

a) The information listed in the waiver application is accurate and all research staff** will comply with the HIPAA regulations and the waiver criteria.
b) Protected health information for which a Waiver of Authorization has been requested will not be reused or disclosed to any person or entity other than those listed in this application, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB.

REMINDER: The PI is ultimately responsible for completing the required accounting of research disclosures for any PHI released under a waiver. The relevant forms are available on the IRB website and additional information regarding these obligations is available by contacting the Office of Clinical Research, UMass Center for Clinical & Translational Science (UMCCTS), or the UMass Memorial Medical Center Privacy Officer.

**Note: Research staff is defined as ALL study personnel (including PI) that is involved in the research.

***HIPAA Regulations allow IRBs to waive the use of authorization forms if all of the criteria listed above are met.