

March 17, 2017

Gyongyi Szabo, MD, PhD
University of Massachusetts
Gastroenterology

Dear Dr. Szabo:

The IRB reviewed the following:

Type of Submission:	Study
Review Type:	Non-Committee
Project Title:	The Association and Significance of Proton Pump Inhibitors and Hepatic Encephalopathy
Investigator:	Gyongyi Szabo, MD, PhD
IRB ID:	H00012102
Funding Agency:	Departmental
Grant Title:	None
Grant ID:	None
IND or IDE:	None
IRB Review Date:	3/17/2017
Documents Reviewed:	PPI HE Final IRB.docx HIPAA Waiver IRB PPI HE (2).doc PPI HE Data Collection Sheet

The IRB approved the research from 3/17/2017 to 3/16/2018 inclusive. Before 1/30/2018 or within 30 days of closing the study, whichever is earlier, you are required to submit a completed Continuing Review Progress Report and necessary attachments to request continuing approval or study closure.

If continuing review approval is not granted before the expiration date of 3/16/2018, approval of this research expires on that date.

In conducting this research, you are required to follow the requirements listed in the INVESTIGATOR MANUAL.

NOTE: As of **May 1, 2016**, GCP training is required to support all **new** clinical trial IRB submissions. Training for investigators and staff submitting clinical trial **continuing reviews** will be required as of **May 1, 2017**.

The GCP training may be accessed through <http://www.citiprogram.org>. Please see the “[Good Clinical Practice \(GCP\) Training at UMMS](#)” Brochure for more information, including instructions on how to access and complete the GCP training requirement.

Sincerely,

Andrea Robinson, CIP
IRB Protocol Specialist

cc: Fasullo, Matthew