Cleveland Clinic Institutional Review Board (IRB)
Federalwide Assurance (FWA 00005367)

Cleveland Clinic

January 26, 2021

Mollie Lumpkin, PharmD, BCPS, BCCCP

RE: IRB# 20-1347: Evaluation of a protocol for rifaximin discontinuation in critically-ill patients with liver disease receiving broad-spectrum antimicrobial therapy

Dear Dr. Lumpkin:

Your new study application received on 11/23/2020 was **approved** on 1/14/2021 as **Exempt Human Subject Research**.

This study was reviewed by an IRB member and determined to be exempt human subject research that meets the research regulatory requirements.

This is minimal risk research using/involving secondary research for which consent is not required and the research involves only information collection and analysis involving the investigator's use of PHI when that use is regulated by HIPAA for the purposes of health care operations, research, or public health activities and purposes.

The documents reviewed include: New Study Application 11/23/2020, Protocol, and Data Collection Sheet.

The stamped approved Data Collection Sheet is available online under the Approved Documents tab. Any additional variables you propose to collect must be submitted to the IRB for review and approval prior to collection.

Waiver
A waiver of Informed Consent and waiver of HIPAA authorization is approved to allow access to PHI by the research team however, sharing or releasing identifiable data to anyone other than the study team is not permitted without additional IRB approval.

Changes or amendments that would impact the exempt status of this project require IRB review and approval prior to implementation. Unanticipated problems including adverse events and deviations are to be reported in accordance with IRB Policy 60: Adverse Events and IRB Policy 70: Unanticipated Problems.

Continuing review is not required for this research, but there will be alternative reporting requirements which the IRB will relay via correspondence.

Please note that human subjects research at Cleveland Clinic has been impacted by COVID-19. The study team is responsible for compliance with the enterprise-wide restrictions related to research. This information is available on the Intranet, including the Center for Clinical Research homepage.

The PI is responsible to ensure research team members are knowledgeable of the study protocol and appropriately trained.

If you have any questions regarding study changes or modifications, please call the IRB office at 216-444-2924.

Sincerely,

Bridget Howard

Bridget Howard, Esq., CIP

Executive Director, IRB and Human Research Protections

BH/pharm/rf

This letter is available online under the Correspondence tab

2018 Rule