



February 18, 2019

Carlos Romero-Marrero, M.D.

RE: 17-252: Medical Records: Predicting Mortality in Patients with Cirrhosis Admitted to the ICU - Validation of the LIV-4 Score

Dear Dr. Romero-Marrero:

Your study renewal application received on 2/6/2019 was processed under expedited review on 2/17/2019 and **approved for the period 2/26/2019 to 2/25/2020** with use of Medical Records Renewal Application of 2/6/2019 with the current Protocol (2/26/2017), and Data Collection Sheet.

This is a minimal risk study using data collected for routine clinical practice.

The stamped approved data collection sheet is available online under the Approved Documents tab.

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.

Any changes or amendments 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.

This study may not continue beyond the approved **expiration date: 2/25/2020** Please submit a renewal application up to 30 days prior to expiration to allow sufficient time for IRB review or a completion report for closure.

If you have any questions or concerns, please contact the IRB Office at 216-444-2924 or email [IRB@ccf.org](mailto:IRB@ccf.org)

Sincerely,

A handwritten signature in black ink that reads "Bridget Howard".

Bridget Howard, Esq., CIP  
Executive Director, IRB and Human Research Protections

BH/jb/dm

This letter is available online under the Correspondence tab

