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

Cleveland Clinic

January 31, 2017

William D. Carey, M.D.

RE: IRB # 17-108: Medical Records: Exploring the burden of and evaluating the efficacy of an integrated care program to limit unplanned hospital readmissions among cirrhotic patients

Dear Dr. Carey:

Your new study application received on 1/29/2017 was processed under expedited review and **approved for the period 1/31/2017 through 1/30/2018** with use of Medical Records Application and Protocol (1/29/2017), Data Collection Sheet, and CITI certification for Dr. Bhagya Rao.

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

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. 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, you may contact the IRB Office at 216-444-2924 or email IRB@ccf.org.

Sincerely,

Bridget Howard

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

BH/jl

Expiration Date: 1/30/2018

A signed version of this letter is available online under the Correspondence tab