



September 23, 2017

Jason Yerke, PharmD

RE: 15-1234: Medical Records: Effectiveness of Venous Thromboembolism Prophylaxis in Patients with Liver Disease

Dear Dr. Yerke:

Your study renewal application received on 9/5/2017 was processed under expedited review on 9/20/2017 and **approved for the period 10/1/2017 to 9/30/2018** with use of the Medical Records Renewal Application dated 9/5/2017.

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: 9/30/2018** 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

Sincerely,

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

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

BH/jl/dm

This letter is available online under the Correspondence tab