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

Cleveland Clinic

December 16, 2020

Xaralambos (Bobby) Zervos, D.O.

RE: FLA 17-102: Medical Records: Liver Transplant a Single Institution Experience

Dear Dr. Zervos:

Your study renewal application received on 12/14/2020 was processed under expedited review on 12/16/2020 and **approved for the period 12/18/2020 to 12/17/2021** with renewal application 12/14/20 and data 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 research team is not permitted without additional IRB approval.

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.

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: 12/17/2021.** 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.

Sincerely,

Bridget Howard

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

BH/jl

This letter is available online under the Correspondence tab