

Institutional Review Board Statement

Cleveland Clinic Institutional Review Board (IRB)

RE: 13-1033

Dear Dr. Thota:

Your response dated 8/28/2016 to the prior review of your renewal application on 8/19/2016 is acceptable. Your study is now fully approved for the period 9/4/2016 to 9/3/2017.

You are approved to continue this research with the use of the Renewal Application 8/3/2016.

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.

P. Thota

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.

Sincerely,

Bridget Howard, J.D.

Executive Director, IRB and Human Research Protections

BH/jl/ju

Expiration Date: 9/3/2017

A handwritten signature in black ink, appearing to read "P. Thoburn", with a horizontal line underneath the name.