



December 13, 2018

Dr. Suresh Nayudu
Medicine
Grand Concourse


Dear Dr. Nayudu :

Your protocol entitled "**Prior Appendectomy as a Risk Factor for Clostridium difficile Associated Colitis and its Recurrence.**" IRB # 12 13 18 04, meets the criteria for expedited review under 45 CFR 46.110 and was **approved** on December 13, 2018.

You are required to notify the Institutional Review Board, in writing, of any adverse events associated with this study. Any alterations to the protocol must be approved by the IRB prior to implementing.

An annual certification is due on **12/13/2019**. To ensure compliance with the annual certification deadline, please submit by **11/1/2019**. If the Institutional Review Board does not receive an annual certification by this date, the IRB will deem this study closed. **Continuation of a Protocol without annual review is a violation of the Code of Federal Regulations Title 45 Part 46.109 (e).**

Sincerely,



Jonathan Bella, MD
Chair, BronxCare Health System
Institutional Review Board

JB:ed