



March 12, 2019

Ming Han Cha, MD
Cleveland Clinic Akron General
1 Akron General Avenue
Akron, Ohio 44307

Dear Dr. Cha:

RE: 19007 Sedation Practices in Emergency Endoscopy (SPEED) Study, Version 1 dated January 29, 2019 - Chart Review

The Institutional Research Review Board at Cleveland Clinic Akron General has determined that the above study meets the requirements for expedited review. The IRRB has followed the requirements of the Common Rule for the expedited review procedures. A member of the committee reviewed the above research protocol. The protocol has been granted expedited approval on March 12, 2019 for chart reviews between the dates of January 1, 2013 to December 31, 2018. The study will access the following Protected Health Information (PHI): Name, Medical Record Number, Account Number, Birth Date, Admission Date, and Discharge Date. The committee waives the requirement for obtaining informed consent or authorization for the use of patient information necessary to conduct this study.

You are now approved to begin this study at Cleveland Clinic Akron General. This approval does not expire. The IRRB requests an annual progress update and a final report at the conclusion of the study.

HHS regulations and Institutional Research Review Board guidelines require that any changes in research methodology, protocol design or principal investigator have the approval of the IRRB before implementation and continuation of the protocol. You must promptly report any protocol violations and any serious adverse events that occur in your study subjects during the study or within 30 days of completion of the study, even if the event was not considered to be related to study participation.

If you have any questions concerning this approval, please call the IRRB office at 330-344-6947.

Sincerely,

A handwritten signature in blue ink that reads "Kalisha Washington".

Kalisha Roper-Washington, MA, CCRP
IRRB Coordinator
Assurance #FWA00001299 (Expires 07/05/2022)

/dp

cc: Roshan Razik, MD

The Cleveland Clinic Foundation

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