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

Cleveland Clinic

July 27, 2015

John J. Vargo, MD

RE: IRB #15-839: Ventilation During Endoscopy Pilot Study (Linshom)

Dear Dr. Vargo:

Your response dated 7/24/2015 to the prior conditional approval of your new study by the convened IRB on **7/17/15** is acceptable. Your new study is now granted full **approval for the period 7/27/2015 to 7/16/2016**.

You are approved to begin this research with the use of New Study Application 7/7/15, Protocol 6/10/15, revised Consent 7/23/15, Feasibility Checklist, Photos.

The stamp-approved Informed Consent is available online under the Stamped Documents tab.

Written consent is required to document that each person has been adequately informed about this research and voluntarily agrees to participate prior to any involvement in the research.

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: 7/16/2016**. 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

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This letter is available online under the Correspondence tab