



May 12, 2016

Qiang Cai, MD, PhD  
Emory University  
School of Medicine  
Division of Digestive Disease  
Atlanta, GA 30332

**RE: Determination:** No IRB Review Required – Not Research  
**Title:** Same Site Submucosal Tunneling for a Repeat Peroral Endoscopic  
Myotomy: A Safe and Feasible Option  
**PI:** Qiang Cai, MD, PhD

Dear Dr. Cai,

Thank you for requesting a determination from the IRB. Based on our review of the materials that you have submitted, we have determined that your proposed case report “Same Site Submucosal Tunneling for a Repeat Peroral Endoscopic Myotomy: A Safe and Feasible Option” does not require IRB review and oversight as it does not meet the definition of “research” as set forth in Emory policies and procedures and federal rules, if applicable.

As you have indicated, you will be performing a case report of one patient, presenting to Emory Hospital. The purpose of this case report is to suggest that submucosal tunneling during a repeat Peroral endoscopic myotomy (POEM) procedure can be done at the site of the initial tunneling attempt. Additionally, Hypotension during POEM is a rare complication that should be recognized as a potential result of tension capnothorax, it can however, be managed with close supportive care. You have confirmed that no identifiers, as defined by HIPAA, will be included in the case report. All images have been de-identified.

HHS regulations define research at 45 CFR 46.102(d) as follows:

*Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.*

Please note that this determination does not mean that you cannot publish the results. This determination could be affected by substantive changes in the study design, subject populations, or identifiability of data. If the project changes in any substantive way, please contact our office for clarification.

Thank you for consulting the IRB.

*Jennifer Truell*

Jennifer Truell, MA, MPH  
IRB Analyst Assistant