



EAST CAROLINA UNIVERSITY
University & Medical Center Institutional Review Board
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Notification of Exempt Certification

From: Biomedical IRB

To: [Karissa Lambert](#)

CC:

Date: 8/23/2019

Re: [UMCIRB 19-001002](#)

A retrospective analysis of Orbera Intra gastric Balloon on blood pressure reduction in a gastroenterology practice in Eastern North Carolina

I am pleased to inform you that your research submission has been certified as exempt on 8/23/2019. This study is eligible for Exempt Certification under category #4c.

It is your responsibility to ensure that this research is conducted in the manner reported in your application and/or protocol, as well as being consistent with the ethical principles of the Belmont Report and your profession.

This research study does not require any additional interaction with the UMCIRB unless there are proposed changes to this study. Any change, prior to implementing that change, must be submitted to the UMCIRB for review and approval. The UMCIRB will determine if the change impacts the eligibility of the research for exempt status. If more substantive review is required, you will be notified within five business days.

The Chairperson (or designee) does not have a potential for conflict of interest on this study.