



University of Maryland, Baltimore
Institutional Review Board (IRB)
Phone: (410) 706-5037
Fax: (410) 706-4189
Email: hrpo@som.umaryland.edu

EXEMPT DETERMINATION

Date: November 5, 2013

To: Eric Goldberg
RE: HP-00056664
Type of Submission: Initial Review
Type of IRB Review: Exempt

Determination Date: 10/30/2013

This is to certify that University of Maryland, Baltimore (UMB) Institutional Review Board (IRB) has reviewed the above referenced protocol entitled, “*Technical Challenges and Diagnostic Yield of Retrograde Single Balloon Enteroscopy: Experience of a Tertiary Care Referral Center*.”

Your protocol has been determined to be exempt under 45 CFR 46.101(b) from IRB review based on the following category(ies):

Category (4): Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. (“Existing” means “existing at the time the research is proposed.”)

The IRB made the following determinations regarding this submission:

- A waiver of HIPAA authorization for release of the PHI identified in the CICERO application has been reviewed and approved for this research study.

In conducting this research you are required to follow the requirements listed in the INVESTIGATOR MANUAL.

Investigators are reminded that the IRB must be notified of any changes in the study.

Research activity involving veterans or the Baltimore VA Maryland Healthcare System (BVAMHCS) as a site, must also be approved by the BVAMHCS Research and Development Committee prior to initiation. Contact the VA Research Office at 410-605-7131 for assistance.

In conducting this research you are required to follow the requirements listed in the INVESTIGATOR MANUAL.

Investigators are reminded that the IRB must be notified of any changes in the study. Research activity in which the VA Maryland Healthcare System (VAMHCS) is a recruitment site or in which VA resources (i.e., space, equipment, personnel, funding, data) are otherwise involved, must also be approved by the VAMHCS Research and Development Committee prior to initiation at the VAMHCS. Contact the VA Research Office at 410-605-7000 ext. 6568 for assistance.

The UMB IRB is organized and operated according to guidelines of the International Council on Harmonization, the United States Office for Human Research Protections and the United States Code of Federal Regulations and operates under Federal Wide Assurance No. FWA00007145.

If you have any questions about this review or questions, concerns, and/or suggestions regarding the Human Research Protection Program (HRPP), please do not hesitate to contact the Human Research Protections Office (HRPO) at (410) 706-5037 or HRPO@som.umaryland.edu.