



## Biomedical Sciences Institutional Review Board

Office of Responsible Research Practices  
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July 12, 2012

Protocol Number: 2012H0169  
Protocol Title: GASTROINTESTINAL MANIFESTATIONS OF THE PTEN HAMARTOMA TUMOR SYNDROME, Marty M. Meyer, Wendy L. Frankel, Robert T. Pilarski, Jonathan B. Rock, Peter P. Stanich, Digestive Diseases  
Type of Review: Initial Review  
IRB Staff Contact: Paul Montesanti  
(614) 292-9804  
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Dear Dr. Meyer,

The Biomedical Sciences IRB **APPROVED** the above referenced research.

**Date of IRB Approval:** July 9, 2012  
**Date of IRB Approval Expiration:** July 9, 2013

**In addition;** the research has been approved for a waiver of the consent process and a waiver of HIPAA research authorization (entire research study).

If applicable, informed consent (and HIPAA research authorization) must be obtained from subjects or their legally authorized representatives and documented prior to research involvement. The IRB-approved consent form and process must be used. Changes in the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before they are implemented (except where necessary to eliminate apparent immediate hazards to subjects).

This approval is valid for **one year** from the date of IRB review when approval is granted or modifications are required. The approval will no longer be in effect on the date listed above as the IRB expiration date. A Continuing Review application must be approved within this interval to avoid expiration of IRB approval and cessation of all research activities. A final report must be provided to the IRB and all records relating to the research (including signed consent forms) must be retained and available for audit for at least 3 years after the research has ended.

It is the responsibility of all investigators and research staff to promptly report to the IRB any serious, unexpected and related adverse events and potential unanticipated problems involving risks to subjects or others.

This approval is issued under The Ohio State University's OHRP Federalwide Assurance #00006378. All forms and procedures can be found on the ORRP website – [www.orrp.osu.edu](http://www.orrp.osu.edu). Please feel free to contact the IRB staff contact listed above with any questions or concerns.

Karla Zadnik, OD, PhD, Chair  
Biomedical Sciences Institutional Review Board

