Cancer Institutional Review Board

Office of Responsible Research Practices
300 Research Administration Building
1960 Kenny Road
Columbus, OH 43210-1063

Phone (614) 688-8457
Fax (614) 688-0366
www.orrp.osu.edu

May 4, 2015

Protocol Number:	2014C0205
Protocol Title:	COMPARISON OF CONFOCAL LASER ENDOMICROSCOPIC IN VIVO DIAGNOSIS AND EX VIVO EXAMINATION (INDEX STUDY) AGAINST SURGICAL HISTOPATHOLOGY OF CYSTIC PANCREATIC LESIONS, Somashekar Krishna, Darwin Conwell, Samer El-Dika, Wendy Frankel, Benjamin Swanson, Jon Walker, Digestive Diseases
Type of Review:	Initial Review
IRB Staff Contact:	Kellie Hall 614-292-0569 Hall.1451@osu.edu

Dear Dr. Krishna,

The Cancer IRB **APPROVED** the above referenced research.

Date of IRB Approval:	**May 1, 2015**
Date of IRB Approval Expiration:	**May 1, 2016**

In addition; the research has been approved for a partial waiver of HIPAA Research Authorization (recruitment purposes only).

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. Please feel free to contact the IRB staff contact listed above with any questions or concerns.

W.E. Carson III

William Carson, M.D., Chair
Cancer Institutional Review Board

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April 14, 2015

Protocol Number:	2013C0044
Protocol Title:	PRETEST PROBABILITY AND DIAGNOSTIC ACCURACY OF INVESTIGATIONS, DIFFERENTIATION AND MANAGEMENT OF SOLID AND CYSTIC PANCREATIC LESIONS, Somashekar Krishna, P. Mark Bloomston, Kevin Cronley, Samer El-Dika, Carmine Grieco, Jeffery Groce, Kavya Krishna, Feng Li, Peter Muscarella, Veeral Oza, Jean Park, Kyle Porter, Sheetal Sharma, Lawrence Shirley, Brett Sklaw, Benjamin Swanson, Jordan Thomas, Jon Walker, Michael Wellner, Digestive Diseases
Type of Review:	Continuing Review with Amendment
Approval Date:	April 6, 2015
IRB Staff Contact:	Anna Pavan 614-688-1070 Pavan.1@osu.edu

Dear Dr. Krishna,

The Cancer IRB **APPROVED** the Continuing Review of the above referenced research.

Date of IRB Approval:	**April 6, 2015**
Date of IRB Approval Expiration:	**April 6, 2016**

Administrative Note: Any future extensions to the data collection time period will not be approved without an informed consent process.

In addition, the IRB **APPROVED** the amendment request to for changes dated June 26, 2014 (Extend the study period to include November 30th, 2014, collect resected surgical specimens of a subset of the same patient population who received adjuvant chemotherapy will be analyzed for presence of biomarkers which could have predicted resistance to chemotherapy, add Tanios Bekaii-Saab, Wendy Frankel, Jacob Skeans, Jennifer Behzadi, Reshi Kanuru, Darwin Conwell, Mohamed Naem, Rachel Roth, and Wei Chen as co-investigators, Alice Hinton as key personnel, and remove Jordan Thomas as co-investigator) on April 6, 2015.

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.

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W. E. Carson III

William Carson, M.D., Chair
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