

7/23/2019

Jenny Permuth, Ph.D.
H Lee Moffitt Cancer Center
12902 Magnolia Dr.
Tampa, FL 33612

RE: Expedited Approval for Continuing Review

IRB#: CR9_Pro00004781

Title: Discovery of a combined biomarker and imaging signature to differentiate between high-risk and low-risk intraductal papillary mucinous neoplasms of the pancreas - MCC# 16640

Secondary Title: Evaluating circulating miRNAs and infectious agents as biomarkers of high-risk pancreatic cysts and other pre-malignant and malignant lesions

Study Approval Period: 8/16/2019

Dear Dr. Permuth:

On 7/18/2019, the Institutional Review Board (IRB) reviewed and **APPROVED** the above application and all documents contained within including those outlined below. **Please note this study is approved under the 2018 version of 45 CFR 46 and you will be asked to confirm ongoing research annually in place of a full Continuing Review. Amendments and Reportable Events must still be submitted per USF HRPP policy.**

Approved Item(s):

Protocol Document(s):

[Protocol \(version 9.4, 08/30/2017\) - clean](#)

The IRB determined that your study qualified for expedited review based on federal expedited category number(s):

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with USF HRPP policies and procedures and as approved by the USF IRB. Any

changes to the approved research must be submitted to the IRB via an Amendment for review and approval. Additionally, all unanticipated problems must be reported to the USF IRB within five (5) business days.

We appreciate your dedication to the ethical conduct of human subjects research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,

A handwritten signature in blue ink that reads "V. Jorgensen MD". The signature is written in a cursive style.

E. Verena Jorgensen, M.D., Chairperson
USF Institutional Review Board