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Approval Notice

Institutional Review Board
Kaiser Permanente Southern California

November 18, 2015

KPSC Principal Investigator(s)
Brian Lim, MD, KPSC - Gastroenterology
10800 Magnolia Ave, Riverside, CA 92505

KPSC Co-Investigator(s)
Albert Ko, MD, Armen Eskandari, Charles Chaya, MD, Vida Jahangiri

Study Title: The Effect of an Algorithm Based on 2012 International Consensus Guideline on the Practice Pattern for the Management of Pancreatic Cystic Neoplasms (#10848)

Study Expiration Date: 10/25/2016

On **11/17/2015**, a subcommittee of the Kaiser Permanente Southern California (KPSC) Institutional Review Board (IRB) reviewed and approved your new study until 10/25/2016.

In accordance with the requirements for research activities that present no more than minimal risk to subjects set forth in 45 CFR 46.110 the study referenced above qualified for expedited review under the following research category:

- Category 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)

Study Document(s):
Pancreatic Cyst-pre-and-post

In accordance with 45CFR 46.116 the requirement to obtain informed consent was waived by the IRB based on the following determinations:

(1) The research involves no more than minimal risk to the subjects;
(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
(3) The research could not practically be carried out without the waiver or alternation;
(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

- The requirement that written Privacy Rule authorization be obtained from study participants was waived.

The KPSC Principal Investigator (PI) is required to:

- Review the document entitled HIPAA Privacy Rule Instructions for Researchers.
- Submit a complete progress or final report of research activities.

Cc
Area Research Chairperson Pharmacy Services Director Academic Affairs

And if applicable,

- Submit for IRB review modifications to the research and/or IRB approved research documents.
- Submit Adverse Event report(s) according to IRB policies and procedures and consistent with federal regulations.
- Submit Protocol Violation report(s) and other Unanticipated Problem Reports according to IRB policies and procedures and consistent with federal regulations.

Sincerely,

Signature applied by Daria Galindo on
11/18/2015 11:10:10 AM PST

Armida Ayala, MHA, PhD
Director
Human Research Subjects Protection Office
Institutional Review Board

Cc
Area Research Chairperson Pharmacy Services Director Academic Affairs