

STANFORD UNIVERSITY

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Certification of Human Subjects Approvals

Date: January 20, 2020

To: Subhas Banerjee, MD, Medicine - Med/Gastroenterology and Hepatology
Sheila Bautista BS, Monique Theresa Barakat MD, PhD

From: David D Oakes, M.D., Administrative Panel on Human Subjects in Medical Research

eProtocol Evaluation of the Association Between Opiate Use, Biliary Dilatation and Abnormal Liver Function Laboratory Studies

eProtocol #: 41605

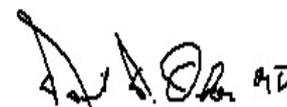
IRB 8 (Registration 6208)

The IRB approved human subjects involvement in your research project on 01/20/2020. **'Prior to subject recruitment and enrollment, if this is: a Cancer-related study, you must obtain Cancer Center Scientific Review Committee (SRC) approval; a CTRU study, you must obtain CTRU approval; a VA study, you must obtain VA R and D Committee approval; and if a contract is involved, it must be signed.'**

This protocol has been approved under the Extended Approval Process and **approval does not expire**. Proposed changes to approved research must still be reviewed and approved prospectively by the IRB. No changes may be initiated without prior approval by the IRB, except where necessary to eliminate apparent immediate hazards to subjects. (Any such exceptions must be reported to the IRB within 10 working days.) Unanticipated problems involving risks to participants or others and other events or information, as defined and listed in the Report Form, must be submitted promptly to the IRB. (See Events and Information that Require Prompt Reporting to the IRB at <http://humansubjects.stanford.edu>.) It is your responsibility to report the completion of the protocol to the IRB within 30 days.

Please remember that all data, including all signed consent form documents, must be retained for a minimum of three years past the completion of this research. Additional requirements may be imposed by your funding agency, your department, HIPAA, or other entities. (See Policy 1.9 on Retention of and Access to Research Data at <http://doresearch.stanford.edu/policies/research-policy-handbook>)

This institution is in compliance with requirements for protection of human subjects, including 45 CFR 46, 21 CFR 50 and 56, and 38 CFR 16.



David D Oakes, M.D., Chair

Approval Period: 01/20/2020 - (Does Not Expire)

Review Type: EXPEDITED - MODIFICATION

Funding: None

Expedited Under Category: 5

Assurance #: FWA00000935 (SU), FWA00000934 (SHC)

