STANFORD UNIVERSITY

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David D. Oakes, M.D. (650) 723-5215
CHAIR, PANEL ON MEDICAL HUMAN SUBJECTS (650) 725-8013

Certification of Human Subjects Approvals

Date: November 9, 2015

To: Dr Mindie Hoai Nguyen, M.D., M.A.S., Medicine - Med/Gastroenterology and Hepatology
Akiko Mizuta BA, Pauline Nguyen BS, Nghia Nguyen, Brittany Yee, Alina Kutsenko MD, Alexander Nguyen, An Le BA, Bing Zhang, Christine Yo-Rong Chang, Changqing Zhao, Christina K Wang, Derek Lin MD, Geon Woo Kim, George Taylor, Richard Hieu Xuan Le, Jacqueline Estevez, Joseph Khoi Hoang, Mingjuan Jin, Kristin Nicole Wong, Hyun Kyung Kim, Linda Nguyen, Long Nguyen MD, Marina Martin M.D., Michael Nguyen, Michael Steve Johanis SIMR student, Ngoc Tran, Nghiem Bao Ha BS, Peter T Nguyen, Nam Phuong Huynh Nguyen, Ramsey Cheung M.D., Sam Trinh, Sally Ann Tran, James Tojroob Yang, Vinh Vu, Vincent Lingzhi Chen, Vanessa Trieu, Vy Nguyen SIMR student

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

Protocol Epidemiology, Natural History and Clinical Outcome of Liver Diseases in Asian Americans and Other Ethnic Groups (SQL 78683)

Protocol ID: 13927 **IRB Number:** 6208 (Panel: 8)

The IRB approved human subjects involvement in your research project on 11/09/2015. **'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.'

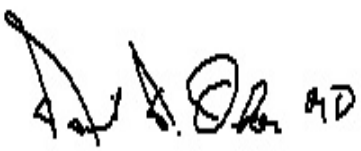
The expiration date of this approval is 05/31/2016 at Midnight. If this project is to continue beyond that date, you must submit an updated protocol in advance for the IRB's re-approval. If this protocol is used in conjunction with any other human use it must be re-approved. Proposed changes to approved research must 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.)

All continuing projects and activities must be reviewed and re-approved on or before Midnight of the expiration date. The approval period will be less than one year if so determined by the IRB. It is your responsibility to resubmit the project to the IRB for continuing review and 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, 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.

Waiver of Individual Authorization under 45 CFR 164.512(i)(2)(ii)(A),(B),(C), pursuant to information provided in the HIPAA section of the protocol application.



David D. Oakes, M.D., Chair

Approval Period: 11/09/2015 THROUGH 05/31/2016

Review Type: EXPEDITED - MODIFICATION

Funding: None

Expedited Under Category: 5

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