STANFORD UNIVERSITY

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Ronald L. Ariagno, M.D. (650) 724-5008
CHAIR, PANEL ON MEDICAL HUMAN SUBJECTS (650) 723-8815

Certification of Human Subjects Approvals

Date: February 23, 2021

To: Sundeep Singh, MD, Medicine - Med/Gastroenterology and Hepatology
Alexa Rachel Weingarden MD, PhD, Akshar Patel BA, John Mark Gubatan MD, Aida Habtezion MD, MSc, Allison Ruoheng Ji, Andres Gottfried Blackmore MD, Arpita Sharma, David M Mikhail, Gulshan Singh, Gayathri Swaminathan, Lawrence Bai, Hong Namkoong, Steven Levitte, Tatiana Clorice Balabanis, Yeneneh Eshetu Haileselassie, Yoni Samuel Rubin

From: Ronald L. Ariagno, M.D., Administrative Panel on Human Subjects in Medical Research

eProtocol Immune Checkpoint Inhibitor-Mediated Colitis: Prospective Cohort Study and Registry

eProtocol #: 57160 **IRB 4 (Registration** 351)

The IRB approved human subjects involvement in your research project on 02/23/2021. **'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 07/28/2021 at Midnight. If this research is to continue beyond that date, it is your responsibility to submit a Continuing Review application in eProtocol. Research activities must be reviewed and re-approved on or before midnight of the expiration date. The approval period may be less than one year if so determined by the IRB. 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.) Upon completion, you must report 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.

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

Alteration of HIPAA Authorization under 45 CFR 164.512(i)(2)(ii), pursuant to information provided in the HIPAA section of the protocol application.

Ronald L. Ariagno, M.D., Chair

Approval Period: 02/23/2021 - 07/28/2021
Review Type: REGULAR - MODIFICATION
Funding: None

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