KAISER PERMANENTE

Institutional Review Board
Kaiser Permanente Southern California

January 07, 2021

KPSC Principal Investigator(s)
Amandeep Sahota, MD, KPSC - Transplant
1526 N. Edgemont St., Los Angeles, CA 90027

KPSC Co-Investigator(s)
Libby Stein, Rasham Mittal

Study Title: To Scan or Not to Scan: Utilization of Transient Elastography in an Integrated Tertiary Care Center (#12674)

On **01/07/2021**, a subcommittee of the Kaiser Permanente Southern California (KPSC) Institutional Review Board (IRB) reviewed and approved your new study.

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):

Data Abstraction Sheet	12/15/2020

In accordance with 45CFR 46.116, informed consent was waived by the IRB based on the following determination(s):

- The research involves no more than minimal risk to the subjects;
- The research could not practicably be carried out without the requested waiver or alteration;
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

- Whenever appropriate, the subjects or legally authorized representatives 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 available at http://irb.kp-scalresearch.org/5/HIPPA_Privacy_Rule_Instructions_for_Researchers.pdf
- Submit a complete final closure report of research activities.

And if applicable,

- Submit for IRB review, modifications to the study or any IRB-approved study document(s) before they are implemented **except** when necessary to eliminate apparent immediate hazards to one or more subjects. If you determine that an immediate modification is critical to eliminate hazards to one or more subjects, you must notify the IRB within five business days of having carried out such changes to your study.
- Submit Unanticipated Serious 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 Isabel M Sanchez on
01/07/2021 10:25:52 AM PST

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