171489

UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

TO: Dr. Shantanu Sinha

RE: Project #171489
RESUMBISSION: "In Vivo Strain Dynamics of Normal and atrophied Human Muscle".

Dear Dr. Sinha:

The above-referenced project was reviewed and approved by one of this institution's Institutional Review Boards in accordance with the requirements of the Code of Federal Regulations on the Protection of Human Subjects (45 CFR 46 and 21 CFR 50 and 56), including its relevant Subparts. This approval, based on the degree of risk, is for 365 days from the date of **IRB review and approval** unless otherwise stated in this letter. The regulations require that continuing review be conducted on or before the 1-year anniversary date of the IRB approval, even though the research activity may not begin until some time after the IRB has given approval.

The IRB has determined the investigational device associated with this study is a Non-Significant Risk Device in that it does not meet the criteria for a Significant Risk Device per the criteria outlined in 21 CFR 812.3(m) including that the device does not present a potential for serious risk to the health, safety, or welfare of a subject.

The IRB determined that this project presents more than minimal risk to human subjects in that the probability and magnitude of harm or discomfort anticipated in the research are greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Date of IRB review and approval: **8/2/2018**

On behalf of the UCSD Institutional Review Boards,

/mn

Anthony Magit, M.D.
Director
UCSD Human Research Protections Program
858-246-HRPP (858-246-4777); hrpp@ucsd.edu

Note: IRB approval does not constitute funding **or other institutional required approvals.** Should your studies involve other review committees such as Office of Clinical Trials Administration (OCTA), Office of Coverage Analysis Administration (OCAA), Conflict of Interest (COI), Protocol Review Monitoring Committee (PRMC), and committees under Environmental Health & Safety (EH&S) such as Institutional Biosafety Committee (IBC), Human Exposure Committee (HERC), and RSSC (Radiation Safety and Surveillance Committee), it is the researchers responsibility to ensure that all approvals are in place prior to conducting research involving human subjects or their related specimens.

Approval release date: 8/3/2018