STANFORD UNIVERSITY

Stanford, CA 94305 [Mail Code 5579]

David D Oakes, M.D. (650) 724-6695
CHAIR, PANEL ON MEDICAL HUMAN SUBJECTS (650) 725-8013

Certification of Human Subjects Approvals

Date: August 11, 2021

To: John Schoeneman Vorhies, MD, Orthopaedic Surgery
Xochitl Bryson BA, Nadine Javier BS, Amishi Jobanputra, Joanna Lind Langner, Katherine G. Hastings, Nicole Alexandria Segovia

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

eProtocol Effectiveness of a Six AM OR Start Time Program

eProtocol #: 46989 **IRB 6 (Registration** 6)

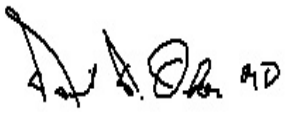
The IRB approved human subjects involvement in your research project on 08/11/2021. **'Prior to subject recruitment and enrollment, if this is: a Cancer-related study, you must obtain Cancer Center Scientific Review Committee (SRC) approval;** a CTRU study, you must obtain CTRU approval; a VA study, you must obtain VA R and D Committee approval; and **if a contract is involved, it must be signed.**'

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.

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: 08/11/2021 - (Does Not Expire)
Review Type: EXPEDITED - MODIFICATION
Funding: None
Expedited Under Category: 5, 7
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