STANFORD UNIVERSITY

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

Certification of Human Subjects Approvals

Date: November 30, 2018

To: Michael J. Gardner, MD, Orthopaedic Surgery
Arlene J. Garcia BS, Blake Schultz PGY-2021, Julius A Bishop M.D., Malcolm Debaun PGY-2020, Natalie Josephine Anna Tanner B.S.

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

eProtocol Title: Prospective Validation of the Integrated Antibiotics Decision Model (IADM) as a Way to Avoid Invasive Procedures in Acute Arthritis

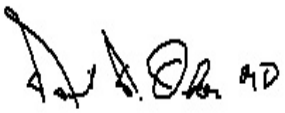
eProtocol #: 39862 **IRB 6 (Registration #:** 4947)

The IRB approved human subjects involvement in your research project on 11/30/2018. **'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 11/30/2019 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.



David D Oakes, M.D., Chair

Approval Period: 11/30/2018 - 11/30/2019

Review Type: EXPEDITED - CONTINUING REVIEW

Funding: Orthopaedic Surgery

Expedited Under Category: 2

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