University of California
San Francisco

Human Research Protection Program
Institutional Review Board (IRB)

Exempt Certification

Principal Investigator
Ishaan Swarup

Study Title: Assessment of Rates and Risk Factors of Repeat Subsequent Surgery in Pediatric Patients with Septic Arthritis of the Knee
IRB #: 20-30265
Reference #: 297743

Committee of Record: Mount Zion Committee
Type of Submission: Personnel Changes
Certification Date: 10/26/2020

IRB Comments:

This study qualifies as Exempt under the following Revised Common Rule (January 2018) category:
Category 4: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens

HIPAA Determinations:
The requirement for individual HIPAA authorization is waived for all subjects. The use or disclosure of the requested information does not adversely affect the rights and welfare of the individuals and involves no more than a minimal risk to their privacy based on, at least, the presence of the following elements:
(1) an adequate plan to protect the identifiers from improper use and disclosure; (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or if such retention is otherwise required by law; (3) adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule; (4) the research could not practicably be conducted without the waiver; and (5) the research could not practicably be conducted without access to and use of the requested information.

Exempt Category 4: Identifiability of the final data set:
Identifiable data set with free text

Conducting Research During the COVID-19 Public Health Outbreak: Please visit the Interim UCSF Policy on Human Subjects-Related Research Visits at San Francisco Campuses during COVID-19 Outbreak, which can be found at https://research.ucsf.edu/interim-ucsf-policy-human-subjects-related-research-visits-san-francisco-campuses-during-covid-19 to determine whether and how this Policy may affect this IRB approved or exempt study.

Modifications: For exempt research only, researchers can make *minor* changes to the study without notifying UCSF IRB. However, significant changes must be submitted to the UCSF IRB. The UCSF IRB website includes examples of minor vs. significant changes. All changes must follow UCSF guidance, and some changes are not allowed in the consent materials.

Study Closeout Report: This study does not have an expiration date. However, you are required to submit a study closeout report at the completion of the project.

For a list of all currently approved documents, follow these steps: Go to My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.

San Francisco Veterans Affairs Medical Center (SFVAMC): If the SFVAMC is engaged in this research, you must secure approval of the VA Research & Development Committee in addition to UCSF IRB approval and follow all applicable VA and other federal requirements. The UCSF IRB website has more information.