UCSF Benioff Children's Hospital Oakland

January 24, 2020

Ishaan Swarup, MD Orthopaedics Department UCSF Benioff Children's Hospital Oakland

RE: IRB # 2019-127, Firearm-Associated Fractures in Pediatrics

Dr. Swarup:

The IRB at UCSF Benioff Children's Hospital Oakland is in receipt of your new study application.

During review of the above-referenced study, it was determined that this study meets the qualification for Exemption pursuant to 45 CFR 46.104(4). The researchers will review charts from 1/1/2001 through to 1/1/2017 to include patients aged 0 – 18 years identified with both an external cause of injury code indicating gunshot injury and a diagnosis code indicating orthopaedic fracture (extremity, pelvis, or spine) with at least two years of follow up.

The criteria for a complete Waiver of HIPAA Authorization pursuant to 45 CFR §164.512(i) and a Waiver of Consent pursuant to 45 CFR §46.116(f)(3) are met and the requests for the waivers are approved.

Please inform us if the nature of the project changes in a fashion that might alter the Exempt status.

Please feel free to call the IRB administrative office at (510) 428-3754 if you have any questions.

Sincerely,

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Lynne Neumayr, MD Chair, Institutional Review Board