



Maimonides
Medical Center

IRB/Research Committee

4802 Tenth Avenue
Brooklyn, NY 11219

MEMORANDUM

DATE: January 14, 2019

TO: Kevin Kang

CC: Kevin Kang

RE: IRB Approval of 2018-12-11 - Effect of Level 1 Trauma Designation on Morbidity and Mortality of Operative Hip Fractures

On January 14, 2019, the above-mentioned study was reviewed and approved by the Maimonides Medical Center (MMC) Institutional Review Board (IRB). This study satisfied the criteria for expedited review set forth in federal regulations 45 CFR 46.110, under the following category: expedited research review category #5 [Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). This category includes research involving materials that were previously collected for either non-research or research purposes, provided that any materials collected for research were not collected for the currently proposed research. Research may involve materials that will be collected solely for non-research purposes].

The IRB has reviewed and approved the following documents:

2018-12-11-MMC Linkage Worksheet.xlsx (Data Collection Tool(s)), 2018-12-11-MMC Sample Data Sheet.xlsx (Data Collection Tool(s)), Kevin Kang CV (CV/Resume/BioSketch), Protocol (Protocol)
IRB Application xForm

Approval Period: Approval is granted in accordance with federal regulations 45 CFR 46 and 21 CFR 50 and 56. The IRB approval begins on January 14, 2019, and expires on January 13, 2020.

Enrollment: The IRB approved the request to screen 2000 and to enroll 2000. Over enrollment without the IRB approval of an amendment is considered a protocol deviation.

Informed Consent: The requirement to obtain informed consent from the subjects has been waived by the IRB in accordance with 45 C.F.R. § 46.116(d).

HIPAA requirements: HIPAA waiver

Amendments: Any proposed changes to a research project must be reviewed and approved by the IRB before they are initiated. All researchers involved in the study must be approved by the IRB prior to starting research activities.

Audits: If an external audit is conducted, the PI must promptly report the findings in writing to the IRB.

All Applicable Clinical Trials must be registered at <http://www.clinicaltrials.gov/> prior to enrolling any patients into the trial.

You may direct questions to the IRB at IRB@maimonidesmed.org.

William Solomon, M.D.

Chairman, IRB