THE GEORGE WASHINGTON UNIVERSITY
WASHINGTON, DC

The Office of Human Research

2100 Pennsylvania Ave. NW

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Phone: 202-994-2715

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February 15, 2017

Protocol Number: 071252

Protocol Title: “The examination of the efficacy of various instrumentation and fixation techniques of the cervical spine inclusive of total disc replacement and anterior cervical plates and screws in various clinical scenarios".

Type of Review: Renewal Review—Expedited IRB Staff Contact: Warren Yu Phone: 202-741-3309 Email: Wyu@mfa.gwu.edu

Institutional Review Board Office of Human Research. OHR, 2100 Pennsylvania Ave NW, Suite 300-A Washington DC, 20037

Dear Dr. Chin,

IRB APPROVED BY EXPEDITED REVIEW the above referenced research. The Board was able to provide expedited approval under 45 CFR 46.110(b)(1) because the research meets the applicability criteria and one or more categories of research eligible for expedited review, as indicated below. Date of IRB Approval: Febrauary 13, 2017 Date of IRB Approval Expiration: February 13, 2019.

Expedited Review Category: 7

In addition; the research has been approved, for a waiver of the consent process (for the one being assessed), for a waiver of the assent process (for the one being assessed), for a waiver of the parental permission process (for the one being assessed) and for a waiver of HIPAA Research Authorization (entire research study for the one being assessed). If applicable, informed consent (and HIPAA research authorization) must be obtained from subjects or their legally authorized representatives and documented prior to research involvement. The IRB-

approved consent form and process must be used. Changes in the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before they are implemented (except where necessary to eliminate apparent immediate hazards to subjects). This approval is valid for two years from the date of IRB review when approval is granted or modifications are required. The approval will no longer be in effect on the date listed above as the IRB expiration date. A Continuing Review application must be approved within this interval to avoid expiration of IRB approval and cessation of all research activities. A final report must be provided to the IRB and all records relating to the research (including signed consent forms) must be retained and available for audit for at least 3 years after the research has ended. It is the responsibility of all investigators and research staff to promptly report to the IRB any serious, unexpected and related adverse events and potential unanticipated problems involving risks to subjects or others. Please feel free to contact the IRB staff contact listed above