

**Covenant HealthCare**

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DATE: March 20, 2019

TO: Anthony Zacharek, MD

FROM: Covenant Medical Center Institutional Review Board

PROJECT TITLE: [1209592-2] Risk Factors for Trigger Finger Development Following Open versus Endoscopic Carpal Tunnel Release

REFERENCE #: C-18-13 TRIGGER FINGER

SUBMISSION TYPE: Continuing Review/Progress Report

ACTION: APPROVED

APPROVAL DATE: March 20, 2019

EXPIRATION DATE: March 20, 2020

REVIEW TYPE: Expedited Review

Thank you for your submission of Continuing Review/Progress Report materials for this project. The Covenant Medical Center Institutional Review Board has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a project design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All UNANTICIPATED PROBLEMS involving risks to subjects or others (UPIRSOs) and SERIOUS and UNEXPECTED adverse events must be reported promptly to this committee. Please use the appropriate reporting forms for this procedure. All FDA and sponsor reporting requirements should also be followed.

All NON-COMPLIANCE issues or COMPLAINTS regarding this project must be reported promptly to this committee.

This project has been determined to be a MINIMAL RISK project. Based on the risks, this project requires continuing review by this committee on an annual basis. Please use the appropriate forms for this procedure. Your documentation for continuing review must be received with sufficient time for review and continued approval before the expiration date of March 18, 2020.

Please note that all research records must be retained for a minimum of three years after the completion of the project.

If you have any questions, please contact Pam Bonds at 989-583-6486 or [pbonds@chs-mi.com](mailto:pbonds@chs-mi.com). Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Covenant Medical Center Institutional Review Board's records.