



ST. JOHN HOSPITAL & MEDICAL CENTER

Institutional Review Board
19251 Mack Avenue, Suite 340
Grosse Pointe Woods MI 48236
FWA: 00003217

DATE: February 8, 2016

TO: Vishal Patel, MD
FROM: St. John Hospital and Medical Center IRB

STUDY TITLE: [863248-1] The Prognostic Impact of Neutrophil-Lymphocyte Ratio in Patients with In Hospital Cardiac Arrest

IRB REFERENCE #: 863248-1
SUBMISSION TYPE: New Project

ACTION: **APPROVED**
APPROVAL DATE: February 8, 2016
EXPIRATION DATE: February 7, 2017
REVIEW TYPE: Expedited Review
PROJECT STATUS: Active

REVIEW CATEGORY: Expedited review category # 45 CFR 46.110 (f)(5)

This research presents Minimal Risk.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.

The St. John Hospital and Medical Center IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

Your protocol, #863248-1 was APPROVED along with the following documents:

- Application Form - Application for Patel Study (UPDATED: 02/4/2016)
- Data Collection - Data Collection for Patel Study (UPDATED: 02/4/2016)
- Other - Team List for Patel Study (UPDATED: 02/4/2016)
- Protocol - Protocol for Patel Study (UPDATED: 02/4/2016)

Informed consent and HIPAA waivers granted.

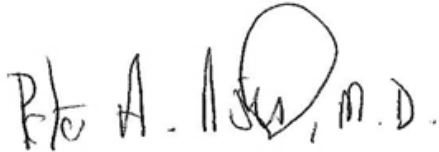
As part of the Institutional Review Board requirements, which are mandated by the FDA and OHRP, you are required to report back to the IRB in the event of any of the following: significant adverse reactions, changes to the previously approved materials, non-compliance issues or complaints regarding the study, major protocol deviations, and termination of the study. 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.

Please note that all research records must be retained for a minimum of seven years following the final closure of the study.

If you have any questions, please contact Lee Booze-Battle at (313) 343-3863 or lee.booze-battle@stjohn.org. Please include your study title and reference number in all correspondence with this office.

St. John Hospital and Medical Center's Institutional Review Board is in full compliance with Good Clinical Practices as defined under the U.S. Food and Drug Administration (FDA) regulations and the International Conference on Harmonisation (ICH-GCP) Guidelines, as adopted by the FDA.

Sincerely,

A handwritten signature in black ink, appearing to read "Peter A. Nickles, M.D.". The signature is stylized with a large, circular flourish at the end.

Peter A. Nickles, MD, Chairperson
Institutional Review Board
St. John Hospital and Medical Center