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Institutional Review Board

FWA # (FWA00000873) IRB# (IRB00000673)

To: Somto Tagbo Nwaedozie, MD, Principal Investigator

From: Linda Jaros, Research Compliance Officer

Signature applied by Linda M Jaros on 08/13/2020 01:33:36 PM CDT

Date: August 10, 2020

Cc: Paul Matthew Yit Qune Yeung-Lai-Wah, Sherri M Kaiser

Re: **IRB#:** IRB-20-721
MCR Code: NWA10120

Study Title: Cardiac Conduction and Rhythm abnormalities requiring Pacemaker Placement after Trans-catheter Aortic Valve Replacement: The Marshfield Healthcare System Experience [CCRAPT study]

Item(s) Reviewed: Submission Components			
Form Name	Version	Outcome	
Initial Review Submission Packet	Version 1.0	Approved	
Marshfield IRB Application	Version 1.0	Approved	
Study Document			
Title	Version #	Version Date	Outcome
EDITED DATA FORM CCRAPT comments	Version 1.0	07/25/2020	Acknowledged
Approval Letter.Div of Educ	Version 1.0	07/13/2020	Acknowledged
Resident research proposal (CCRAPT) 01	Version 1.0	07/13/2020	Acknowledged

Item(s) Submission Date: 07/31/2020 03:39:03 AM CDT

Type of Review Conducted: Exempt

Reviewed Date: August 7, 2020

Review Decision: Approved

Your request for IRB exemption of the above-referenced project was reviewed and determined that the project is exempt from further IRB review (45 CFR 46.104 (d)(4)).

Please note that Dr. Zhang is not approved as a co-investigator on this study at this time. When his required Conflict of Interest training and disclosure requirements have been completed, he may work on this research study.

HIPAA Authorization Waiver: (45 CFR 164.512(i)(2)(ii))
The requirement to obtain authorization is waived. The waiver is for the specific PHI and uses/disclosures described in your waiver request. Any change to the type of PHI to be collected, used or shared, or to the uses and disclosures described in the waiver request, require prior IRB approval.

Data or Material Sharing: If your research involves the sharing of individual level data or specimens with any external party, an appropriate transfer agreement must be in place. To initiate an agreement, complete and submit a "Request to Transfer Data or Materials" form via iRIS. Contact Marla Ripp Fischer with any questions.

Ongoing Responsibilities: Although your project is exempt from further IRB review, you are required to seek prior review of any change to the research activity that would cause your answers to the questions on the Exemption Request Form to change. This is important since these changes may cause the activity to no longer qualify for exemption.

Please make such submissions as a new IRB Exemption Request via IRIS. The IRB will then re-evaluate the project to determine whether the proposed changes affect the exempt determination.