

Institutional Review Board

FWA # (FWA00000873) IRB# (IRB00000673)

To: Somto Tagbo Nwaedozie, MD, Principal Investigator**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]**Review Decision:** Approved**Informed Consent/ 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

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

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.