Date: April 15, 2020

To: Maully Shah
CC: Tonia Morrison
From: The Committees for the Protection of Human Subjects (IRB)

Re: IRB 18-015818, **Protocol Title:** Indications, Implantation and Outcomes of Leadless Pacing.
Sponsor or Funder: Children's Hospital of Philadelphia, The (CHOP)

IRB AMENDMENT: EXEMPTION GRANTED

Dear Dr. Shah,

The amendment for the above-named study was reviewed by Dr. Barbara Engel, Chair of the IRB (or her authorized designee) on April 15, 2020. It has been determined that the study meets the exemption criteria per 45 CFR 46.104(d) 4(iii).

This amendment involves revising the end date for study inclusion from 11/17/2018 to 2/28/2020. These changes do not affect the IRB's previous risk-benefit assessment of the study. However, as this study now qualifies for exemption under the 2018 Common Rule Requirements, the IRB has transitioned the study to the revised Common Rule and updated its determination to exemption.

A waiver of HIPAA authorization per 45 CFR 164.512(i)(2)(ii) is granted for accessing identifiable information from the medical records.

If a full amendment is submitted in the future, please ensure that the end date of follow-up is updated in section 3.01 (1.0) of the eIRB application to 2/28/2020, for consistency with the rest of the study materials.

PLEASE NOTE: A determination of exemption by the IRB does not necessarily constitute authorization to initiate the conduct of a human subjects research study. The Investigator is responsible for satisfying any additional institutional requirements that may apply (e.g. execution of the appropriate agreement with the Office of Collaborative and Corporate Research Contracts for sending or receiving data or samples, etc.).

Main study documents reviewed:

- Protocol, version 1 (dated March 27, 2020)
- Data Elements to be Abstracted (attached December 10, 2019)

Please refer to the eIRB application for a complete list of all documents submitted to the IRB.

If you make a change in the research that could affect the exempt determination (including, but not limited to, funding changes), please submit an amendment to the IRB.
Staff change amendments are not required for exempt studies. It is the Principal Investigator's responsibility to ensure that all study team members have up to date human subjects training, no conflicts of interest, and appropriate credentials for their role in the research.

If you have any questions, please click on the IRB# (above) and contact the IRB analyst listed in the amendment workspace.

DHHS Federal Wide Assurance Identifier: FWA00000459

AM_018

**** *This memorandum constitutes official CHOP IRB correspondence.* ****

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