



**Date:** July 17, 2020

**To:** Maully Shah

**CC:** Anh Duc Mai

**From:** The Committees for the Protection of Human Subjects (IRB)

**Re:** [IRB 20-017719](#), **Protocol Title:** COVID 19 Clinical Registry for COVID 19 Associated Cardiac Rhythm Disorders

**Sponsor or Funder:** Children's Hospital of Philadelphia, The (CHOP)

**IRB SUBMISSION: EXEMPTION GRANTED**

Dear Dr. Shah,

The study referenced above was reviewed by the IRB on July 17, 2020. The IRB has determined it meets the exemption criteria per 45 CFR 46.104(d) 4(ii).

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

**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 Technology Transfer for sending or receiving data or samples, etc.).

**Document(s) Reviewed:**

- Data Elements (attached 5-26-2020)
- IRB Determination Document (attached 6-28-2020)

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 study workspace.

**DHHS Federal Wide Assurance Identifier: FWA00000459**

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