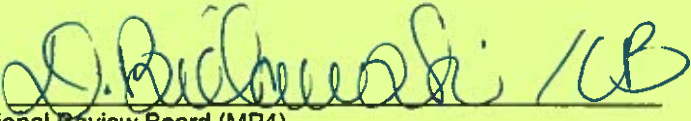

CONCURRENCE OF EXEMPTION

To: Tamam Mohamad
Internal Medicine
4160 John R - Ste 510

From: Sabrina Heidemann, M.D. or designee 
Chairperson, Medical/Pediatric Institutional Review Board (MP4)

Date: February 14, 2018

RE: IRB #: 015618MP4X

Protocol Title: Testing the hypothesis of improving ejection fraction with Entresto, which is defined as an increase of ejection fraction from the baseline before treatment by 10-15%

Funding Source:

Protocol #: 1801001161

Expiration Date:

The above referenced protocol has been reviewed and found to qualify for Wayne State University Institutional Review Board Exempt Category 8 according to the Flexible Review and Oversight of Research Not Covered by Federalwide Assurance policy.

- Receipt of Revised Medical Exemption Protocol Summary Form (revision received in the IRB Office 01/31/2018)
- Protocol (version 1.0 dated 12/20/2017) (received in the IRB Office 01/31/2018)
- Revised HIPAA Summary Form (revisions received in the IRB Office 01/31/2018)
- A waiver of HIPAA Authorization has been granted in accordance with the Privacy Rule and justification provided by the Principal Investigator in the HIPAA Summary Form. This waiver satisfies:
1) the use or disclosure of PHI involves no more than minimal risk to the privacy of individuals,
2) the research could not be practicably conducted without the waiver, 3) the research could not be practicably conducted without access and use of the PHI, 4) adequate steps taken to protect identifiers from improper use or disclosure and 5) adequate plan for destroying identifiers or links.

This proposal has not been evaluated for scientific merit, except to weight the risk to the human subjects in relation to the potential benefits.

Exempt protocols do not require annual review by the IRB.

All changes or amendments to the above-referenced protocol require review and approval by the IRB **BEFORE** implementation.

Adverse Reactions/Unexpected Events (AR/UE) must be submitted on the appropriate form within the timeframe specified in the IRB Administration Office Policy (<http://irb.wayne.edu/policies-human-research.php>).

NOTE: Forms should be downloaded from the IRB Administration Office website
<http://irb.wayne.edu> at each use.

Notify the IRB of any changes to the funding status of the above-referenced protocol.