



INDIANA UNIVERSITY
 OFFICE OF THE VICE PRESIDENT FOR RESEARCH
 Office of Research Compliance

NOTICE OF EXEMPTION - NEW PROTOCOL

DATE:	April 04, 2019
TO:	Stephen Sawada, Principal Investigator CARDIOLOGY
FROM:	KRONENBERGER, WILLIAM G. Chair - IRB-01
RE:	Protocol #: 1903050729 Protocol Type: Exempt Protocol Title: Diagnostic and Prognostic Value of New Echocardiographic and Doppler Methods For Assessment of Cardiac Function Funding Source: None

In accordance with 45 CFR 46.101(b) and/or IU HRPP Policy, the above-referenced protocol is granted exemption. Exemption of this submission is based on your agreement to abide by the policies and procedures of the Indiana University Human Research Protection Program (HRPP) and does not replace any other approvals that may be required. Relevant HRPP policies and procedures governing Human Subject Research can be found at: <https://research.iu.edu/compliance/human-subjects/guidance/index.html>.

Submission and Review Information:

Type of Submission:	Initial Protocol Application
Level of Review:	Exempt
Exempt Category(ies), if applicable:	Category 4: Secondary research uses of identifiable private information or identifiable biospecimens.
Date of Exemption Granted:	April 04, 2019
Authorized IRB Signature:	 Heather Cook

Regulatory Determinations:

- The PHI to be used or disclosed is determined to be necessary
- The explanation of how this research involves no more than minimal risk of loss of privacy to the subject is sufficient
- There exists an adequate plan to protect the identifiers from improper use and disclosure
- There exists an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research
- There exist adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule
- The explanation of how this research could not be practicably conducted without waiver of authorization is adequate
- The explanation of how this research could not be practicably conducted without access to and use of the individually identifiable health information is appropriate
- Study meets the criteria for approval defined by the HRPP Policy on IRB Review Process
- PHI to be used or disclosed:
 - o For collection and use: Patient demographics including age, gender, symptoms, risk factors for cardiovascular disease, medications, history of prior medical illnesses and surgical procedures, hemodynamic information including heart rate, blood pressure, information on

functional capacity, stress test data: any prior heart test results and therapeutic procedures. Data on outcome following the index echo exam will be collected including the occurrence of events including death, heart attack, heart failure, arrhythmia, hospitalizations, and noncardiac events interventional/therapeutic procedures, and length of survival and time from the index echo study to an event. Additional data collected will include symptom and medication status at the time of followup. All available echocardiographic and cardiac testing data will be collected.

Documents Approved with this Submission (for Amendments and Renewals, documents appearing in bold were either added or replaced with the submission):

Attachment Type - Document Version #
Protocol - Protocol Revision date 3.7.2019

NOTE: If you submitted and/or are required to provide subjects with an informed consent document, please ensure you are using the most recent version of the document to consent subjects.

The following key personnel are approved to participate in the above titled research activities:

Investigator Name	Role	Training
Stephen Sawada	Principal Investigator	Yes
Pantila Bateman	Key Personnel	Yes
Courtney Eytchison	Key Personnel	Yes
Judy Foltz	Key Personnel	Yes
Deborah Green-Hess	Key Personnel	Yes
Upasana Jarori	Key Personnel	Yes
Kavita Khaira	Key Personnel	Yes
Abhishek Khemka	Key Personnel	Yes
Ryan Mallory	Key Personnel	Yes
Ronald Mastouri	Key Personnel	Yes
Kutaiba Nazif	Key Personnel	Yes
Kate Tsarova	Key Personnel	Yes

Organizations:

Organization
Wishard Memorial Hospital IU Health Methodist Hospital HEALTH AND HOSPITAL CORPORATION OF MARION COUNTY IU HEALTH ESKENAZI HEALTH SYDNEY & LOIS ESKENAZI HOSPITAL IU Health University Hospital Indiana University Krannert Institute of Cardiology

You should retain a copy of this letter and all associated approved study documents for your records. Please refer to the assigned study number and exact study title in future correspondence with our office. Additional information is available on our website at <https://research.iu.edu/compliance/human-subjects/guidance/index.html>.

If you have any questions or require further information, please contact the HSO via email at irb@iu.edu or via phone at (317)274-8289.