



DETERMINATION OF NON-HUMAN SUBJECT RESEARCH

December 31, 2020

To: Rosario Ligresti
From: Research Integrity Office, Hackensack Meridian Health
Re: Research Project Determination Letter

Title: Interventional management of STEMI-related cardiogenic shock is associated with poor outcomes in patients with liver cirrhosis, A Nationwide Analysis

Thank you for your submission to the Research Integrity Office (the administrative office for the Hackensack Meridian Health IRB). Upon review of the materials provided, it has been determined that your proposal, as submitted, does not meet the definition of research involving human subjects as defined by DHHS and FDA regulations. Therefore, review and approval by the Hackensack Meridian Health IRB is not required. This determination applies only to the activities described in the 'Human Subjects Research Determination Worksheet' and may not apply should any changes to the activities be made.

If you desire to make changes to the intent or design of your proposal, you should re-submit the amended proposal to the IRB to ensure that the changes do not change the nature of the project in such a way that would require IRB review and approval.

This determination is issued under the Federal Wide Assurance (FWA00000331) with the Office for Human Research Protections (OHRP).

If you have any questions, comments, complaints or concerns or wish to provide input, please do not hesitate to contact the Research Integrity Office at 201-880-3669 or by email at HMHIRB@hmhn.org.

Sincerely,

Daniel B. Alderson, MS, CIP
Manager, Research Integrity Office
Hackensack Meridian Health