

Institutional Review Board Statement

Name of Journal: World Journal of Radiology

Manuscript NO: 39330

Manuscript Type: Basic Study

An Optimized Cardiac MRI Inversion Recovery Sequence for Metal Artifact Reduction and Accurate Myocardial Scar Assessment in Patients with Cardiac Implantable Electronic Devices

El-Sayed Ibrahim, Mason Runge, Prachi Agarwal, Maryam Ghadimi-Mahani, Anil Attali, Thomas Chenevert, Chiel den Harder, Jadranka Stojanovska

Institutional review board statement: this study was reviewed and approved by the University of Michigan Institutional Review Board, ID # HUM0010224

Name: Jadranka Stojanovska, M.D., M.S.

Signature: 

Date: 04/13/2018

To: El-Sayed Ibrahim

From:

Michael	Geisser
Alan	Sugar

Cc:

James	Pool Jr
Mary	Burton
Tamara	Harper
El-Sayed	Ibrahim
Thomas	Chenevert
Jadranka	Stojanovska
Ladonna	Austin

Subject: Notice of Determination of “Not Regulated” Status for [HUM00102024]

SUBMISSION INFORMATION:

Title: Eliminating Image Artifact Through Single-shot Data Acquisition in Magnetic Resonance Imaging

Full Study Title (if applicable):

Study eResearch ID: HUM00102024

Date of this Notification from IRB: 5/26/2015

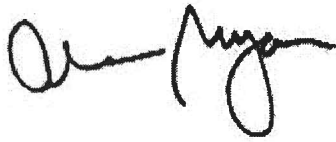
Date of IRB Not Regulated Determination: 5/26/2015

IRB NOT REGULATED STATUS:

Category	Outcome Letter Text
Quality Assurance and Quality Improvement Activities - Other	Based on the information provided, the proposed study does not fit the definition of human subjects research requiring IRB approval (per 45 CFR 46, 21 CFR 56 and UM policy). Although the results of your project may be published, program evaluations, self-assessment of programs or business practices, and other quality improvement projects do not require IRB review because in these cases, it is the activities rather than humans subjects that are the objects of the study.



Michael Geisser
Co-chair, IRBMED



Alan Sugar
Co-chair, IRBMED