

Initial Submission Approved for #2019H0034

Sent Date

05/30/2019 8:12 am

From

Matthew Carter <carter.1005@osu.edu>

To

Khalid Mumtaz <khalid.mumtaz@osumc.edu>

**Biomedical Sciences Institutional
Review Board**

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrb.osu.edu

05/30/2019

Study Number: 2019H0034

Study Title: Prospective validation of readmission risk score and interventions to prevent readmission in patients with decompensated cirrhosis

Type of Review: Initial Submission

Review Method: Expedited

Date of IRB Approval: 05/30/2019

Date of IRB Approval Expiration: 05/30/2020

Expedited category: #4, #5, #7

Dear Khalid Mumtaz,

The Ohio State Biomedical Sciences IRB **APPROVED** the above referenced research.

In addition, the following were also approved for this study:

- Partial Waiver of HIPAA Research Authorization

As Principal Investigator, you are responsible for ensuring that all individuals assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies, including the obligation to report any problems or potential noncompliance with the requirements or determinations of the IRB. Changes to the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before implemented, except where necessary to eliminate apparent immediate hazards to subjects.

This approval is issued under The Ohio State University's OHRP Federalwide Assurance #00006378 and is valid until the expiration date listed above. ***Without further review, IRB approval will no longer be in effect on the expiration date.*** To continue the study, a continuing review application must be approved before the expiration date to avoid a lapse in IRB approval and the need to stop all research activities. A final study report must be provided to the IRB once all research activities involving human subjects have ended.

Records relating to the research (including signed consent forms) must be retained and available for audit for at least 5 years after the study is closed. For more information, see university policies, [Institutional Data](#) and [Research Data](#).

Human research protection program policies, procedures, and guidance can be found on the [ORRP website](#).

A handwritten signature in black ink that reads 'Karla Zadnik'.

Karla Zadnik, OD, PhD, Chair
Ohio State Biomedical Sciences IRB

