RESEARCH ADMINISTRATION

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To: Mohammed-Syed Jafri, M.D.
Gastroenterology

From: Jonathan Ehrman, Ph.D.
IRB Chair

IRB No.: 13949

Title: Evaluation of Liver Enzyme Levels in Patients with COVID-19

APPROVAL:	**May 14, 2020 – May 13, 2021**
DETERMINATION SENT:	**May 21, 2020**
Expedited Category:	5

On, May 14, 2020, the Henry Ford Health System (HFHS) Institutional Review Board (IRB) provided an expedited review of the initial submission for this minimal risk study.

The IRB provided the review pursuant to 45 CFR 46.110 and if applicable, 21 CFR 56.110.

The IRB determined that the Criteria for IRB approval is met pursuant to 45 CFR 46.111 and if applicable, 21 CFR 56.111.

The IRB grants a waiver of the requirements to obtain informed consent and, acting as a Privacy Board, also grants a waiver of authorization to use or disclose protected health information pursuant to Federal regulations.

This study is approved for the review of charts for patients who tested positive for COVID-19. An amendment via a Planned Change Form (PCF) must be submitted, reviewed, and approved prior to any changes to the study inclusion criteria.

CONTINUING REVIEW REQUIREMENTS:

The IRB determined that this study is eligible for Continuing Review waiver pursuant to 45 CFR 46.109(f)(1). **Therefore, you are not required to submit a Continuation Report annually.** However, the IRB requires that you contact the IRB Administration office via email on an annual basis determined by the initial approval date to confirm if the study is still open for enrollment. In addition, a Final report is still mandatory at the conclusion of this study.

In addition, the IRB requires that any research study initially approved on or after January 21, 2019, that is subject to the Revised Common Rule, meets the definition of a clinical trial, and is supported or regulated by a Federal department or agency, must ensure that one IRB-approved informed consent form used to enroll subjects is posted on a publicly available Federal Web site

after the clinical trial is closed to recruitment, and no later than sixty (60) days after the last study visit by any subject, pursuant to 45 CFR 46.116(h).

Any revisions to the protocol must be submitted for review and approved by the IRB prior to implementation. The IRB is expected to review all documents and activities that bear directly on the rights and welfare of participants of research. A copy of the signed and stamped form, indicating approval by the IRB, is enclosed for your files.

This protocol will be presented as an informational item at a subsequent IRB meeting.

Please contact the IRB Administration Office at 313-874-4464 if you have any questions or concerns.