Office of Human Subjects Research
Institutional Review Boards

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Date: May 4, 2020

APPLICATION APPROVAL

Review Type:	Expedited
Principal Investigator:	Tinsay Woreta
Number:	IRB00249001
Title:	Prevalence of elevated liver enzymes in patients with Novel Coronavirus 2019 (COVID-19) infection and their clinical characteristics and outcomes
Committee Chair:	Richard Moore
IRB Committee:	IRB-3

Date of Approval: May 4, 2020

Date of Expiration: May 4, 2021

The JHM IRB approved the above-referenced Application.

To keep the JHM IRB application current we are assigning an Expiration Date as noted above. Prior to the expiration date, you will receive an email notification indicating that some action is required. If the Board has determined that a Continuing Review or Progress Report is required, you will need to submit Continuing Review or Progress Report prior to the expiration date. If the Board has determined that No Progress Report is required, you may run the administrative extend approval function.

IRB review included the following:

45 CFR 46.116: A waiver of consent was granted based on the following criteria: 1) the research involves no more than minimal risk to subjects; 2) the waiver will not adversely affect the rights and welfare of the subjects; 3) the research could not be practicably carried out without the waiver; and 4) the IRB will advise you if it is appropriate for participants to be provided with additional pertinent information after participation.

Your application included Howard County General Hospital as a research site. You may not conduct this research at that site until you receive notification of full site approval by the Howard County General Hospital RRC. If you have already received site approval, you may begin conducting research immediately.

Your application included Suburban Hospital as a research site. You may not conduct this research at that site until you receive notification of full site approval by the Suburban Hospital RRC. If you have already received site approval, you may begin conducting research immediately.

Your application included Sibley Memorial as a research site. You may not conduct this research at that site until you receive notification of full site approval by the Sibley Memorial RRC. If you have already received site approval, you may begin conducting research immediately.

Progress Report Required:

The Board determined that this research meets the criteria for submission of a Progress Report as an alternative to a Continuing Review Application. The Progress Report must be submitted using a Further Study Action and selecting progress report at least 6 weeks prior to the expiration date. Please note, the Progress Report **must** be submitted prior to the expiration date shown on this notice. If the Progress Report is not submitted prior to the expiration date all activity must stop. Before any research activity can resume, you must submit the progress report.

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

Changes in Research: All proposed changes to the research must be submitted using a Change in Research application. The changes must be approved by the JHM IRB prior to implementation, with the following exception: changes made to eliminate apparent immediate hazards to participants may be made immediately, and promptly reported to the JHM IRB.

Unanticipated Problems: All unanticipated problems must be submitted using a Protocol Event Report.

If this research has a commercial sponsor, the research may not start until the sponsor and JHU have signed a contract.

The JHMIRB is constituted to meet the requirements of the Privacy Rule at section 45 CFR 164.512(i)(1)(i)(B) and is authorized and qualified to serve as the Privacy Board for human subjects research applications conducted by Hopkins' faculty members. The JHM IRB reviewed your request to waive or alter authorization for the above-referenced project. The IRB determined that all specific criteria for a waiver or alteration of authorization were met, as follows:
(A) The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;
(1) An adequate plan to protect the identifiers from improper use and disclosure;
(2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
(3) Adequate written assurances that the protected health 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 protected health information would be permitted;
(B) The research could not practicably be conducted without the waiver or alteration; and
(C) the research could not practicably be conducted without access to and use of the protected health information.

Study documents:

HIPAA Form 4:
FINAL_Woreta_IRB00249001_HIPAAForm4_05042020

Supplemental Study Documents:
Data collection sheet_COVID-19 and Liver.xls
Data request for CROWN registry

Additional Supplemental Study Documents:
CADRE review Approval letter
Data agreement form

Protocol:
Updated study protocol_eForm S_COVID-19 and Liver

Johns Hopkins Study Team Members:

Jessica Wagner, James Hamilton, James Potter, Sarah Olson, Arunkumar Krishnan, Laura Prichett