The University of Kansas Medical Center

Human Research Protection Program

APPROVAL OF SUBMISSION

January 13, 2021

Muhammad Shafiq
mshafiq@kumc.edu

Dear Muhammad Shafiq:

On 1/13/2021, the IRB approved the following submission:

Type of Review:	Flexible IRB Review
Reviewed by:	KUMC Human Research Protection Program
IRB#:	STUDY00146787
Title:	Clinical Outcomes of COVID-19 infection in Liver Transplant Recipients
Investigator:	Muhammad Shafiq
Funding:	None
Documents submitted for review:	• COVID-19 and Liver Transplant Recipients.docx • Data Collection Sheet - COVID-19 and Liver Transplant Recipients.xlsx • KUMC Flexible IRB Protocol - COVID-19 and Liver Transplant Recipients.pdf • Linking Sheet.xlsx
Special Determinations:	• Waiver of HIPAA authorization

This project was reviewed and approved under the KUMC Policy for Flexible IRB Review. It is eligible for Flexible IRB Review because it is minimal risk and is not associated with any federal funding or support. As such, you are under this KUMC policy, rather than federal regulations, when you conduct the research.

This review and approval is granted because you attested that it meets the criteria for Flexible IRB Review. If there is a change to any of the conditions listed below, you must promptly notify the IRB office so that the project can be re-reviewed under the federal regulations governing human subjects research.

Research eligible for Flexible IRB Review meets <u>all</u> the following characteristics:

- Not funded by a direct federal grant
- Not funded through a sub-award or pilot grant associated with federal dollars

- Does not include personnel on a federally-funded training grant
- Is not research conducted under a no-cost extension
- No data will be used to support a pending application for FDA approval or a grant application (e.g., data collection in response to a scored grant submission with plans to re-submit)
- Does not involve an FDA-regulated product or dietary supplement
- Does not involve registries about FDA-regulated products
- Is not conducted under a contract that requires the investigator to adhere to federal human subjects regulations (e.g., 45 CFR 46, 34 CFR 97 or other references to the HHS Common Rule)
- Does not involve any services that could be billed to a federal program

Your approved documents for this study are stored in the "Documents" tab in the eCompliance system.

If you have any questions regarding the human subject protection process, please do not hesitate to contact our office at 913-588-1240 or IRBhelp@kumc.edu.

Sincerely,

Rachel Marsh