

DATE: February 16, 2021
TO: Jon C Sivoravong, DO
FROM: The University of Louisville Institutional Review Board
IRB NUMBER: 21.0088
STUDY TITLE: Inpatient Delirium Reduction and Early Acute Management (iDREAM)
REFERENCE #: 721488
DATE OF REVIEW: 02/16/2021
IRB STAFF CONTACT: Sherry Block [REDACTED]

The IRB Chair/Vice-Chair (or An IRB member) has reviewed your submission. The project described does not meet the “Common Rule” definition of human subjects’ research. The IRB has classified this project as Non-Human Subjects Research (NHSR). The project can proceed.

This submission has been determined to be quality improvement, and not human subjects research, based on the goal(s) stated in the protocol.

Institutional policies and guidelines on participant privacy must be followed. If you are using protected health information, the HIPAA Privacy rules still apply.

Any changes to this project or the focus of the investigation must be submitted to the IRB to ensure that the IRB determination above still applies.

Amendments for personnel changes or study closures are not required.

If you have any questions, please contact: Sherry Block [REDACTED]

We value your feedback; let us know how we are doing [REDACTED]

Sincerely,



Paula Radmacher, Ph.D., Vice Chair,
Biomedical Institutional Review Board
PR/slb