

PROTOCOLS



IRB Certificate of Determination

From: LSUHSC-NO Institutional Review Board (Federal Wide Assurance FWA00002762)

To: Smith, Alison

Date: Thursday, September 16th 2021

Re: Protocol ID: 1929

Protocol Title: A Multi-Center Prospective Evaluation of Pre-Hospital Ketamine Administration and ED Disposition in the Trauma Patient

Submission Type: Initial

The LSUHSC-NO IRB reviewed the **Initial** submission of the above-referenced protocol and found the study to meet the **Expedited** review criteria. The IRB made the following determinations:

IRB Review Action: APPROVAL

Effective Date: Thursday, September 16th 2021

This protocol is approved until Sunday, September 15th 2024. To continue research beyond this date, a *Renewal* application must be submitted and approved by no later than this date. Please consult the LSUHSC IRB website for submission deadlines for *Renewal* applications.

Approval comments (if any) to note:

The LSUHSC-NO IRB reviewed and approved the above-referenced research protocol using the Expedited Review procedure as authorized under federal regulations at 45CFR46.110 and 21CFR56.110.

This study is expedited under 46.110, Category #5.

Waiver of Informed Consent and HIPAA Authorization granted.

Approved attachments associated with the submission (if any) include:

Attachments

Data Collection Instruments	Data_Collection_Tool	KetamineData Collection Tool .pdf
Protocol	IRB Protocol	IRBprotocol_v1.pdf
Other	Martinez_CITI	Martinez_CITI.pdf

As the Principal Investigator, you are responsible for complying with, and assuring all study staff comply with, all federal regulations and HRPP policies and procedures, including post-approval study requirements, pertaining to human subjects research. HRPP policies and procedures, post-approval study requirements, and other information are available at the [LSUHSC IRB website](#).

Please note: Effective June 2020, the LSUHSC-NO IRB moved into the KualI system which impacted the numbering for studies. For studies approved prior to that date, the Protocol ID may not match the previous IRB number for the same study.