



**To the Mayor and Members of the City Council**

**June 3, 2025**

Page 1 of 2

**SUBJECT: PARTICIPATION IN NATIONAL EMS RESEARCH NETWORK**

This Informal Report provides information on a request for Fort Worth Fire Department's EMS system and the Office of the Medical Director (OMD) to participate in a multicenter research study network named LITES (Linking Investigations in Trauma and Emergency Services). This network was established in 2016 with funding from the U.S. Department of Defense and aims to enhance trauma care through extensive research and data collection. The University of Pittsburgh serves as the primary institution overseeing the network's operations and research initiatives. The LITES network facilitates multiple different studies, including observational and controlled trials.

Initial Study Request

The current request is for a Department of Defense-funded study called PAIN (Prehospital Analgesia Intervention trial). Information on this study is available at <https://www.litesnetwork.org/pain/>. This is a prospective, randomized controlled trial (RCT) of two FDA-approved and commonly used pain medications in the treatment of patients with trauma: Fentanyl and Ketamine. The FW EMS System currently uses both of these pain medications. Fentanyl is an opioid pain medicine while ketamine is not an opioid. Ketamine has different uses at different doses, but this study is only looking at the dosing used for pain. The goal of the study is to see if one provides better pain relief with fewer side effects.

Future Studies

We anticipate having additional study invitations as part of participation in the LITES network, but any additional study would be treated independently and would require additional consideration and agreement. The current request is only for participation in the PAIN study.

Patient Consent & Community Consultation

Normally, patients must be asked for, and must give, consent before being enrolled in a prospective research study. In emergency cases, such as trauma, the patient may not be able to understand the information provided to them about the risks and benefits of participation because of the extent of their injuries. As part of the strict federal patient protections surrounding research, research on such emergency conditions is governed by a process known as Exception From Informed Consent (EFIC) and must be approved by local ethics committees called Institutional Review Boards (IRB).

Community Consultation

A requirement of all EFIC studies is community consultation. This means the community must be provided information about the study, including the purpose, potential risks and benefits, confidentiality protections, and how to opt out of the study. There are different approaches to community consultation, but the plan must be approved by the local and national IRB. The plan proposed here in Fort Worth for the PAIN study involves both in person and virtual options, with social media engagement. Each session would provide information about the study, how to opt out of it, and what it involves, along with risks and benefits of the interventions. Additionally, on-line and in-person feedback will be solicited.

**To the Mayor and Members of the City Council****June 3, 2025**

Page 2 of 2

**SUBJECT: PARTICIPATION IN NATIONAL EMS RESEARCH NETWORK**Participation with JPS Hospital

Because PAIN is a study involving trauma patients, it involves partnering with trauma teams to assess the benefit and any side effects from the study drugs. We have been working with JPS Hospital for this study. JPS will act as the primary contact for the research network and will be responsible for helping us obtain IRB approval, conduct community consultation, and obtain follow up information. Once JPS is active as a site, we will approach THR-Harris, the other level 1 trauma center in town, with an invitation to participate.

Required Agreements & Funding

Fort Worth's participation in the LITES network and the PAIN study will require entering into agreements with JPS and the University of Pittsburgh. This is a Department of Defense (DOD) study and Fort Worth expenses will be covered through the study.

For questions regarding this information, please contact Dr. Jeffrey Jarvis, Medical Director at 817-953-6908.

**Jesus "Jay" Chapa**  
**City Manager**