

Statement from Hennepin Healthcare

June 7, 2019

From the beginning, the intent of the sedation research conducted at Hennepin Healthcare has been to save lives. For many years, sedatives, including ketamine, have been important lifesaving medications used both inside the hospital and outside and they have been shown to prevent deaths. While the intent of this work was always clear to us, the communities we serve were not aware of this research and its purpose. The lack of engagement on our part before implementing research has understandably created mistrust.

Hennepin Healthcare apologizes for not involving the community in a proactive way in the research and design discussions before we began these studies. We deeply regret this and we are committed to engaging a cross section of community members as we evaluate potential research projects.

We have already taken important first steps to improve:

- The community is now at the table. The new Public Research Advisory Board (PRAB) is a group of informed, engaged community members who bring the eyes and ears of the public directly into our research review process. They started meeting in January.
- A Community Advisory Board (CAB) brings multiple perspectives from the community to help our organization better understand community needs beyond research.
- We have required our entire research staff to receive additional professional education and training led by experts in human subject research ethics and regulations.
- We improved tools and processes used by researchers to apply for and receive Institutional Review Board (IRB) approval and we are modifying how medical studies are monitored.
- We provided Mental Health for First Responders training to paramedics in partnership with NAMI and we will be providing implicit bias and de-escalation training for all EMS and security personnel.
- We are being transparent as we learn by making information about what has happened in the past available for all to see, including the outside reviews that are posted on the front page of our public website, hennepinhealthcare.org, along with a complete list of changes that we have made.

Hennepin Healthcare, the FDA, and the communities we serve share a common goal; to safely develop better ways to treat our patients, always with the patients' best interests in mind. As a public research institution we embrace a culture of continuous improvement and look forward to continuing to partner with the community to learn together and improve patient care.