NOTIFICATION OF ENROLLMENT

Project Title: Ketamine versus Midazolam Prehospital Agitation

You are receiving this form because you or someone you care for was included in a research study examining patients with agitation. This research study is being done to find out if one of two drugs, ketamine or midazolam, is better for treating agitation. Agitation is a state of extreme emotional disturbance where patients can become physically aggressive or violent, endangering themselves and those who are caring for them. The Hennepin EMS System is undergoing a standard protocol change from one drug to the other; to compare which drug may be better the study doctors are collecting data on patients before and after the protocol change. Experts have recommended both drugs for agitation; previous studies from our hospital suggest both drugs have similar risk, but the two have never been compared in the same study at any hospital.

While you were being treated by the EMS personnel, trained research associates monitored your vital signs, such as your heart rate and blood pressure, and wrote down the medications and treatments you received. Data was collected from medical information and blood samples obtained as part of your regular care. In addition, the study doctors may check the medical record to examine what happened during the hospital stay. The study participation and information will be kept completely confidential.

There was no cost to you to participate in this study, and you will not be charged. You will not be paid for your participation. Because this study involves collection of data in a setting where usual care was conducted, you were not consented prior to enrollment. This is permitted under federal regulations for Waiver of Consent Research (45 CFR 46.116(d)).

Your participation in this study will be kept completely confidential. The collected information will be identified only by a number assigned when you entered the study. Participation is voluntary; if you do not want your data used it will be removed.

If you have any questions regarding your participation in this study, please contact Dr. Jon Cole at (612) 873-8791. If you want to talk to someone other than the study doctor, you can call the Office of Human Subjects Research at Hennepin County Medical Center at (612) 873-6882 or write to:

Dr. Craig Peine, MD
Chair, Human Subjects Research Committee
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