University of Southern California
Department of Anesthesiology, Division of Critical Care
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INFORMATION SHEET

STUDY TITLE:
The Impact of a Multifaceted Delirium Preventing Strategy in the ICU involving Psychiatry: Effects on Delirium Incidence and Outcomes

"If you are giving consent for another person, "you" refers to that person."

You are invited to participate in a research study. Research studies include only people who voluntarily choose to take part. This document explains information about this study. You should ask questions about anything that is unclear to you.

PURPOSE OF THE STUDY

This study is about the occurrence of intensive care unit (ICU) delirium. Delirium is a serious disturbance in mental abilities that results in confused thinking and reduced awareness of a person's environment. This can affect memory and attention span, cause agitation, and may cause a person to hallucinate (see or hear things that are not there).

Some hospitals have psychiatrists routinely participate in ICU patient care with the ICU team, while other hospitals do not. We hope to learn which of two ways of ICU health care delivery is most beneficial. The first, and most common way, is the standard of care, which includes intensivists, surgeons, residents, and nurses discussing the patients' condition and treatments each morning on rounds. The second includes psychiatrists in the participation of ICU patient care. Our goal is to see if psychiatric participation is beneficial and reduces delirium in ICU patients.

PARTICIPANT INVOLVEMENT

If you agree to participate in this study, you will either be part of a group of patients who receive standard ICU care (without a psychiatry team regularly involved in your care), or a group of patients who, in addition to standard ICU care, have psychiatrists work with the ICU team. You will know which group you are in and your assignment to a specific study group is determined by when you were admitted to the ICU, and not by personal randomization. You will not have to undergo any additional tests or procedures to participate in this study. You will not be receiving any experimental treatments or medications. If you are in the standard of care group, you may need to see a psychiatrist based on your ICU course and symptoms. If you do need to see a psychiatrist for any reason during the study period, your participation in the study will not prevent you from getting this care. If you have a condition that requires prescription of

medications by the psychiatrists, these medications are given according to standard medical care and are not experimental or part of the study.
We will abstract information from the medical record about your hospital stay.

POSSIBLE RISKS

The risks to you while participating in this study are minimal. There is a risk that seeing a psychiatrist and some of the questions asked may make you feel uneasy or embarrassed. The same risk exists if you are in the group which does not get routine psychiatry care, but this risk may be less frequent. In both groups, there is a very small risk that people who are not directly involved with this study may learn your identity or your personal information.

PAYMENT/COMPENSATION FOR PARTICIPATION

You will not be compensated for your participation.

CONFIDENTIALITY

Your information will be kept confidential. We will only use personal health information for the purpose of identifying your eligibility for the study. Data that is coded will be stored separately from your identifying information (i.e. medical record number, date of birth, etc.), and all documents containing personal health information will be stored and maintained in a locked/password protected area accessible only to study staff. The information used from your hospital stay will be collected in a secure, password-protected, online data collection tool called RedCap. The data will be entered either on an encrypted laptop or computer belonging to the study personnel, or on a USC campus computer. This data tool is hosted through USC and has numerous security features which protect data from being accessed by non-study personnel, or distributed. Information about you will be coded. Information such as your name, address, date of birth, social security number, etc. will not be collected. Only study personnel will see your information. We will not collect any personal health information that is not pertinent to the study. Finally, your data will not be released to any other party for any reason.

The data will be stored on a password protected computer in the researcher's office for three years after the study has been completed and then destroyed. At the end of the study the coded identifying data will be destroyed (shredded or electronically) purged.

BENEFITS

You may not receive any direct benefit from taking part in this study. However, your participation in this study may help us learn if psychiatric participation reduces delirium in ICU patients.

ALTERNATIVES TO PARTICIPATION

Your alternative is to not participate. Your healthcare will not be affected whether you participate or not in this study.

WHAT HAPPENS IF YOU GET INJURED OR NEED EMERGENCY CARE?

If you think you have been hurt by taking part in this study, tell the study doctor immediately. If you require treatment because you were injured from participating in this study, treatment will be provided. You or your health plan/insurance will be billed for the cost of this treatment.

There are no plans to offer any type of payment for injury. However, by signing this form you have not given up any of your legal rights.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT, AND WHAT WILL HAPPEN IF YOU DECIDE NOT TO PARTICIPATE?

Your participation in this study is voluntary. Your decision whether or not to take part will not affect your current or future care at this institution. You are not giving up any legal claims or rights. If you do decide to take part in this study, you are free to change your mind and stop being in the study at any time. You will not lose any rights if you decide to stop being in the study.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

You may contact Catherine Kuza, MD at (323)442-5840 or David Sheski, MD at (323)442-4854 with any questions, concerns, or complaints about the research or your participation in this study. If you feel you have been hurt by taking part in this study, please contact Catherine Kuza, MD at (323)442-5840 or David Sheski, MD at (323)442-4854.

If you have questions, concerns, or complaints about the research and are unable to contact the research team, contact the Institutional Review Board (IRB) Office at 323-223-2340 between the hours of 8:00 AM and 4:00 PM, Monday to Friday. (Fax: 323-224-8389 or email at irb@usc.edu).

If you have any questions about your rights as a research participant, or want to talk to someone independent of the research team, you may contact the Institutional Review Board Office at the numbers above or write to the Health Sciences Institutional Review Board at LAC+USC Medical Center, General Hospital Suite 4700, 1200 North State Street, Los Angeles, CA 90033.

You will get a copy of this form.