NAVAL MEDICAL CENTER CAMP LEJEUNE
CAMP LEJEUNE, NC 28547

CONSENT BY A SUBJECT FOR VOLUNTARY PARTICIPATION IN A CLINICAL INVESTIGATION at Naval Medical Center Camp Lejeune

PARTICIPANT ID #_____ **DATE: _ _ /_ _ _/_ _ _ _**
DD MMM Y Y Y Y

Key Information for
Impact of Ketamine on Acutely Suicidal Patients in the Emergency Department

You are being asked to decide if you want to volunteer for a research study about investigating the clinical effectiveness of ketamine as a medication treatment for the acutely suicidal patient in the Emergency Department. You can decide if you want to participate. You can ask questions about how being in the study will affect you. If you decide to be in the study you will be asked to sign the consent form after a researcher goes over it with you.

What is the study about and how long will it last?
In this study, we hope to learn whether or not treating a patient with suicidal thoughts with a medication called ketamine can effectively, safely, and rapidly reduce or get rid of those thoughts. Your participation in the research will last up to a week after discharge from the hospital.

What will you be asked to do?
While you are participating in this study you will be answering 2 self-questionnaires about suicidality at four different time periods. You will be randomly assigned to receive either the study medication (ketamine) or a placebo (saline) given by IV infusion over 40 minutes.

What are key reasons you may not want to volunteer in this study?
You may experience uncomfortable thoughts or feelings if you are treated with the study medication, ketamine, similar to a reaction to a bad dream.

What benefits may be expected by volunteering in the study?
You may not experience any direct benefit by volunteering in this study, but it will help us determine if ketamine can effectively, safely, and rapidly reduce or get rid of suicidal thoughts.

Do you have to agree to be in the study?
If you decide to participate in the study it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you decide not to volunteer. Military rank is of no consideration when you are deciding whether or not to participate in this study.

Please read this form carefully. Take time to ask the study doctor or study staff as many questions about the study as you would like. If there are any words or information that you do not understand, the study doctor or study staff will explain them to you. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. Before you take part in the research study, you must sign the end of this form.

1. Study Title:

You have been asked to voluntarily participate in a research study entitled Impact of Ketamine on Acutely Suicidal Patients in the Emergency Department," being conducted at the Naval Medical Center Camp Lejeune by medical researchers from the Emergency Department.

2. Why Is This Study Being Done?

The purpose of this study is to investigate the clinical effectiveness of ketamine as a medication treatment for the acutely suicidal patient in the ED.

3. Why Are You Being Asked to Take Part?

You are being asked to take part in this study because you expressed suicidal thoughts and have been determined by the mental health provider to require admission to the psychiatric ward.

This study includes only those people who voluntarily choose to take part. Please take your time to make your decision and feel free to ask any questions that you might have.

4. Screening Process to Qualify for Participation in This Study

Certain information must be collected, and you must be accepted for admission to psychiatric inpatient services before the researcher can confirm that you meet the qualifications to become a subject in this study. This is called the "Screening Process". Tests, such as blood, urine, or EKG may have been collected as a part of your regular medical care, although not necessarily. Females of child-bearing potential will receive a urine pregnancy test.

5. What Is Involved in This Study?

If you choose to take part in this study, you will be given two self-questionnaires to assess your degree of depression and suicidality.

Then, you will be randomly assigned into one of two groups. It is like flipping a coin. Neither you, your doctor, nor the investigator, will be able to choose the group to which you are assigned, and you will not find out which group you were in at the end of the study unless there was a safety concern during your participation.

- Group 1 - will be given the treatment
  - 0.5mg/kg ketamine, mixed in 100cc of Normal Saline, and infused over 40 minutes intravenously (i.e through an IV)
- Group 2 - will be given a placebo.
  - 100cc of Normal Saline infused over 40 minutes intravenously

If you take part in this study, you will have the following tests and procedures, independent of standard medical care:

- 2 self-questionnaires about suicidality given before the infusion, at 4 (+/- 1) hours after infusion, and at 24-36 hours after the infusion.
- I.V. Placement for the administration of the treatment or placebo.
- A follow-up phone call at 7-8 days post-discharge with a study team member. You will be asked to complete the same two questionnaires.

Prior studies have shown that slowinfusion of IV ketamine has anti-depressant and anti-suicidal effects. The experimental procedure being tested in this study is if 0.5mg/kg ketamine, mixed in 100cc of Normal Saline, and infused over 40 minutes intravenously will provide a clinically effective decrease in suicidal ideation.

The following are routine procedures that will be done if you decide to participate in this study:
- IV
- Medication infusion

The following procedures are part of regular medical care that may be done even if you do not join the study:
- Blood Draw
- History and Physical

6. How Many People Will Take Part in This Study?

A total number of 62 subjects are expected to participate in this study.

7. How Long Will You Be in This Study?

Your participation in this research project will be for a period of the duration of your admission plus 1-week post-discharge. However, it will take only 1-2 hours total hour of your time, completing questionnaires and responding to emails.

You may stop participating in this study at any time. However, if you decide to stop participating, we encourage you to talk to the researcher and your regular healthcare provider first.

8. When Should You Not Take Part?

In order to participate in this study, you must be active duty military, military dependent, or retiree.

If you have any of the following conditions listed below, you are not eligible to take part in this study:
- Less than 18 years old or greater than 89 years old
- Have a personal or family history of schizophrenia or schizoaffective disorder
- Currently pregnant or nursing
- Currently intoxicated
- Have previously participated in this study

9. What Are the Risks of The Study?

The risks and side effects related to the medication, ketamine, we are studying include:

Likely:
- Strange dreams or disturbances in visual and auditory perception, mood, body image, and time. You may experience feelings of floating, conscious dreams, or hallucinations. These symptoms will peak at 40 minutes and resolve within 120 minutes. To prevent emotional discomfort from vivid dreams, the researcher will discuss pre-conditioning, which is when you are encouraged to think of a pleasant place for your dream to occur. This process will decrease the discomfort.

Moderate:
- Increased salivation
- Nausea and vomiting
- Anxiety or paranoia
- Hallucinations

Rare:

- Reducing or stopping breathing, sense of choking, low blood pressure or low heart rate.

While on the study, you are at risk for these side effects. You should discuss them with the investigator and your regular healthcare provider. Other medications may be given to make the side effects less serious and make you more comfortable. Many side effects go away shortly after the interventions or medications are stopped, but in rare cases the side effects can be serious, long lasting or permanent.

Reproductive risks: Because the medications in this study can affect an unborn baby, you cannot participate in this study if pregnant. You should not breastfeed your baby for 24 hours after being given the medication while on this study. Please ask about counseling and other information about preventing pregnancy.

There also may be other side effects that are unknown, and we cannot predict.

For more information about risks and side effects, ask the Principal Investigator, Dr. Nathan Butler or the Research Coordinator, Ms. Catherine Christian.

10. Are There Benefits to Taking Part in This Study?

If you agree to take part in this study, there may or may not be direct benefit to you. Although it is possible you will feel a decrease in suicidal ideation, there is no guarantee that you will personally benefit from taking part in this study. We hope the information learned from this study will benefit other people with suicidal ideation in the future.

11. Are There Alternatives to This Study?

You may choose to not participate. You will then receive standard medical treatment that may or may not include any one of the procedure(s) or treatment(s) that are part of the planned research study.

12. What About Confidentiality?

We plan to hold all health information in strict confidence, but we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Authorized personnel from (the Institutional Review Board, Department of the Navy, Department of Defense, FDA) may have access to your research file for authorized purposes, including verification that your rights have been safeguarded.

A description of this clinical trial will be available on http://www.ClinicalTrials.govas required by U.S. Law. This web site will not include information that can identify you. At most, the Web site will include a summary of results. You can search this Web site at any time.

There is a possibility that identifiers (like your name or date of birth) might be removed from your identifiable private information or identifiable biospecimens and the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Privacy Act Statement

In accordance with the Privacy Act of 1974 (Public Law 93-579), this notice informs you of the purpose of this form and how it will be used. Please read it carefully.

1. Authority. Public Law 104-191; E.O. 9397 (SSAN); DoD 6025.18-R.

2. Purpose. Medical research information will be collected to enhance basic medical knowledge or to develop tests, procedures, and equipment to improve the diagnosis, treatment, or prevention of illness, injury, or functional impairment. This form is to provide the Naval Medical Center Camp Lejeune/TRICARE Health Plan with a means to request the use and/or disclosure of your protected health information.

3. Use. To any third party or the individual upon authorization for the disclosure from the individual for: personal use; insurance; continued medical care; school; legal; retirement/separation; or other reasons.

4. Disclosure. Voluntary. Failure to sign the authorization form will result in the non-release of the protected health information. This form will not be used for the authorization to disclose alcohol or drug abuse patient information from medical records or for authorization to disclose information from records of an alcohol or drug abuse treatment program. In addition, any use as an authorization to use or disclose psychotherapy notes may not be combined with another authorization except one to use or disclose psychotherapy notes.

   HIPAA: Release Authorization

   a. You have the right to revoke this authorization at any time. Your revocation must be in writing and provided to the facility where the research is being conducted. You are aware that if you later revoke this authorization, the research facility may have used and/or disclosed your protected information on the basis of this authorization.

   b. If you authorize your protected health information to be disclosed to someone who is not required to comply with federal privacy protection regulations, then such information may be re-disclosed and would no longer be protected.

   c. You have a right to inspect and receive a copy of your own protected health information to be used or disclosed, in accordance with the requirements of the federal privacy protection regulations found in the Privacy Act and 45 CFR 164.524.

   d. The Military Health System (which includes the TRICARE Health Plan) may not condition your treatment in MTFs/DTFs, payment by the TRICARE Health Plan, enrollment in the TRICARE Health Plan or eligibility for TRICARE Health Plan benefits on failure to obtain this authorization. (i.e. The MHS may not alter, deny, or make your legal entitlement to benefits a condition of your participation in this study or your decision to provide consent to use your protected health information).

By signing this consent, you are authorizing NMC Camp Lejeune to obtain and release the information as described in this consent form. You have the right to refuse to sign this permission form.

5. Disclosure. All information contained in this Consent Statement or derived from the medical research study described herein will be retained permanently at Naval Medical Center Camp Lejeune and salient portions thereof may be entered into your health record. You voluntarily agree to its disclosure to agencies or individuals identified in the preceding paragraph. You have been informed that failure to agree to such disclosure may negate the purposes for which the research study was conducted.

13. What If You Get Injured?

If you suffer any injury as a result of your participation in this study, medical treatment is available at Naval Medical Center Camp Lejeune. All medical care (*including medical treatment for injuries related to this study and medical care unrelated to this study)* will be evaluated and provided in keeping with the benefits to which you are entitled under applicable regulations.

14. Will You Get Paid for Participation?

You will not be compensated for your participation in this study. All treatments related to this study will be provided in accordance with applicable regulations.

15. What Are Your Rights as A Participant?

Your participation in this project is voluntary and your refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled under applicable regulations. If you are currently in the military, this study does not involve rank structure or chain of command; you are free to decline if you do not want to participate. If you choose to participate, you are free to ask questions or withdraw from the project at any time without prejudice to your future care. Any new significant findings developed during the course of the research, which may affect your willingness to participate further, will be explained to you. Please notify Dr. Nathan Butler at (910) 548-1272 or Catherine Christian at catherine.c.christian2.ctr@mail.mil or (910) 459-0760.

If you withdraw, you will no longer receive study drugs or treatments that are part of the study, unless these are also part of your normal drugs or treatments. Your withdrawal will involve no loss of benefits to which you are otherwise entitled. If you withdraw from this study, your data will be included in the data analysis for this project.

16. Can Your Participation in This Study Be Terminated?

The investigator may terminate your participation in this project for the following reasons:

- If your provider determines that any point that you are not eligible for the study.
- If you wish to be terminated from the study.

17. Who Can You Call If You Have Questions or Concerns About This Study?

If you have any questions regarding this research project, you may contact the Principal Investigator, Dr. Nathan Butler at (910) 548-1272 or by email at nathan.h.butler.mil@mail.mil or the study coordinator, Catherine Christian at Catherine.c.christian2.ctr@mail.mil or (910) 459-0760.

If you feel you have suffered an injury as a result your participation in this research project or if you have any questions regarding your rights as a research subject at Naval Medical Center Camp Lejeune, you can contact the Research Administration Officer at (910) 450-3460, the Chair, Institutional Review Board at Naval Medical Center Camp Lejeune at (910) 450-4048, or the Head, Clinical Investigation Department at (910) 450-3460.

SIGNATURES

Investigators must use the following steps in order to orient the potential subject to the purpose of the research and why they might wish to participate:

- **Step One:** The Investigator must explain the study to the potential subject verbally, providing all pertinent information (purpose, procedures, risks, benefits, alternatives to participation, etc.), and must allow the potential subject ample opportunity to ask questions.
- **Step Two:** Following this verbal explanation, the potential subject should be provided with a written consent form and afforded sufficient time to consider whether or not to participate in the research. "Sufficient time" can range from hours to days, depending on how long it reasonably takes to evaluate the procedures, risks, potential benefits, and alternative treatments.
- **Step Three:** After allowing the potential subject time to read the consent form, the Investigator should meet with the potential subject and answer any additional questions he or she may have.

PARTICIPANT STATEMENT

By signing below, you are indicating that you were given enough time to read this study consent form, all of your questions about this research project were adequately answered and a copy of this consent form was given to you for future reference. Most importantly, by signing this consent form, you are indicating that you voluntarily agree to participate in this research study.

Participant's Signature	Date (DD/MMM/YY)	Typed/Printed Name

Sponsor's Status

PARTICIPANT CONTACT INFORMATION

Home Phone: ( ) -

Cell Phone: ( ) -

Email Address: _____

INVESTIGATOR STATEMENT

You have explained to the above individual the nature and purpose of the study, the potential benefits and possible risks associated with the study, and the alternatives to participation in this study. You have answered any questions that were raised. You have explained the above to the subject on the date stated on this consent form. Consent was obtained prior to participation in the study.

Investigator performing consent process and obtaining written signature.

Investigator or Coordinator's Signature	Date (DD/MMM/YY)	Typed/Printed Name
		Grade or Rank

WITNESS STATEMENT

I confirm that the research study was thoroughly explained to the subject by the investigator or coordinator. The consent form was reviewed with the subject and the subject's questions were answered. The subject appeared to have understood the information.

Witness' Signature	Date (DD/MMM/YY)	Typed/Printed Name
		Grade or Rank