CONSENT FORM

Title of this Research Study
Sufentanil Infusion vs Sufentanil Bolus and Time to Extubation during Routine Cardiac Surgery

Invitation and Summary

You are invited to be in this research study. Taking part in this research is voluntary. You do not have to take part. For the purposes of this document: "You" can refer to:

- Yourself
- The person for whom you are the Legally Authorized Representative (LAR)
- Your child under the age of 19.

"Organization" can refer to: University of Nebraska Medical Center (UNMC), Nebraska Medicine (NM), University of Nebraska at Omaha (UNO) or Children's Hospital & Medical Center (CH&MC).

Here is a summary of the purpose, methods, risks, benefits, and alternatives, to help you decide whether or not to take part in the research.

The purpose of the study is to compare the way we give an opioid pain medication (Sufentanil).

We typically give you this pain medication in the form of multiple larger doses pushed through your blood, and we are wanting to see if by giving this pain medication (Sufentanil) in a slow trickle fashion, through your blood, you would be able to have the breathing tube removed faster.

We aren't sure if one way of giving the medication will allow us to remove your breathing tube faster, this is why we are doing the study.

In this study, we will also draw your blood, but this will be done from an existing small tube that will be placed before surgery. This is similar to an IV, commonly used to draw your blood.

We will be drawing your blood 8 times in order to look at how much of the pain medication (Sufentanil) you have in your blood. The total amount of blood we will be collecting is 48mLs, which is about three Tablespoons. For your surgery, three tablespoons of blood taken is a common amount. We will then monitor how fast your breathing tube is removed, how long you stay in the intensive care unit (ICU) and

how long you stay in the hospital.

The possible risks of this study are loss of confidentiality, loss of blood and risks with the pain medication given. Each risk is full explained in the 'What are the Possible Risks of Being in this Study' section.

Potential benefits to you may be less pain and faster time to having the breathing tube removed, which may lead to less time spent in the intensive care unit and less time spent in the hospital.

Instead of being in this research study, you can choose not to take part.

Why are you being asked to be in this research study?
You are being asked to participate in this study because you are between the ages of 19 and 80 years old, and you are scheduled to have a surgery to correct an issue with your heart. Up to 150 people may participate in this study.

What is the reason for doing this research study?
We are doing this study because we want to see if changing the way we give pain medication makes a difference in the quickness of recovery.

What will be done during this research study?
In this study, you will be assigned to one of two groups. One group will receive the medication in scheduled doses (bolus). The other group will receive the medication in a slow trickle fashion in your vein (infusion). This will happen like a flip of a coin, 50/50 chance of which group you will be assigned. We will not know ahead of time which group you will be in. You will also have your blood drawn so that we can evaluation how much of the medication is in your body. The sample(s) we collect will not be used for other research studies by us, or by any other investigator after this research is over. If you decide to participate, you are agreeing to having your blood drawn an additional eight times, collected about three tablespoons of blood, throughout your hospital stay, for research only. By participating in the research study, you are also agreeing to having the pain medication you receiving during your surgery, while you are asleep, given to you in either a scheduled push of medication or in a slow trickle fashion. We will also be drawing your blood 8 times in order to look at how much of the pain medication (Sufentanil) you have in your blood. The total amount of blood we will be collecting is 48mLs, which is about three Tablespoons.

What are the possible risks of being in this research study?

The risks of the study include someone finding out who you are and the loss of blood. Only people directly involved in your care are listed on the study, in order to minimize the risk of someone finding out you are in a research study. We will take as small amount of blood as needed. There are additional risks of the pain medication you will be given during your surgery, whether or not you participate in the study. The potential risks of this pain medication are nausea, slow breathing, missing a breath, slow heart beat, and low blood pressure. Rarely, your heart may start to beat out of order, your chest muscles may become tight making it hard to breath. You may also experience of feeling of uneasy, sweating, shaking, fast heart rate, fever, vomiting or diarrhea. You will be monitored by an Anesthesiologist doctor throughout your entire procedure for any of these risks. Possible risks of being assigned to infusion group, versus standard medical care, could include prolonged sedation effect or delayed wakening from anesthesia, more pain after surgery, lower blood pressure and heart rate during surgery with increased need of supportive medications for blood pressure and heart rate.

What are the possible benefits to you?
Potential benefits to you include: faster time to have the breathing tube removed, which often leads to less time spent in the intensive care unit and less time spent in the hospital. You may also experience less pain.

What are the possible benefits to other people?
The same benefits that are possible to you may be possible to other people in the future. Future patients may experience less pain, less time with the breathing tube and less time spent in the hospital after their surgery.

What are the alternatives to being in this research study?
Instead of being in this research study, you can choose not to take part.

What will being in this research study cost you?
You will have to pay any insurance deductibles and co-payments. If you want to speak with someone about your insurance, just tell us.

Will you be paid for being in this research study?
You will not be paid to be in this research study.

Who is paying for this research?
This research is being paid for by the Department of Anesthesiology, of the University of Nebraska Medical Center.

What should you do if you are injured or have a medical problem during this research study?
Your health and safety is our main concern. If you are injured or have a medical problem because of this study call someone listed at the end of this consent form. You can get emergency medical treatment at Nebraska Medicine. You can also go to your doctor, the nearest emergency room or call 9-1-1.

We have no plans to pay for your treatment or give you any other money or compensation. Your insurance may pay. If they do not you will have to pay.

Signing this consent form does not mean you have given up any of your legal rights.

How will information about you be protected?
In the course of this research we may collect information about you. This can be things that could be used to find out who you are (like your name, phone number, birthdate, address). We call this "identifiable private information". We will keep this information as confidential as possible.
The information will not be used for other research by us, or by any other researcher.

Who can see information about you?
We also will get medical information about you (like medical record number, medical history, or the results of physical exams, blood tests, x-rays or other medical or research procedures). We call this "protected health information" or PHI. PHI is protected by a law called the HIPAA Privacy Rule. We will collect the smallest amount of PHI that we can. We will keep your PHI as confidential as possible.

By signing this consent form, you are letting us (the researchers listed on this consent form and other people involved in this research at the Organization) have access to your PHI. Your PHI will be used only for the purposes described in the section "What is the reason for doing this research study?"

You can change your mind and tell us to stop collecting your PHI for use in this research at any time by writing to the principal investigator. We can still use the PHI we have already collected. If you tell us to stop collecting your PHI, you will have to stop being in this research.

We may share your PHI with other groups listed below:
- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- The HHS Office for Human Research Protections (OHRP)

You are letting us use and share your PHI for as long as the research is going on.

How will results of the research be made available to you during and after the study is finished?
In most cases, the results of the research can be made available to you when the study is completed, and all the results are analyzed by the investigator or the sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address:
Jeffrey Songster, MD
University of Nebraska Medical Center
42nd & Emile St
Omaha, NE. 68198

A description of the clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What will happen if you decide not to be in this research study?
You can decide not to be in this research study. Deciding not to be in this research will not affect your medical care or your relationship with the investigator or the organization. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?
You can stop being in this research (withdraw) at any time. Just call the researcher or any research staff. If you stop being in the research study it will not affect your care or your relationship with the investigator or the organization. You will not lose any benefits to which you are entitled.

You may be taken off the study if you do not follow instructions of the investigator or the research team. You may also be taken off the study if the investigator does not feel it is safe for you to continue with the study. Any research data we have already collected can still be used in the research.

Will you be given any important information during the study?
We will tell you right away if we get any new information that might make you change your mind about being in the study.

What should you do if you have any questions about the study?
We gave you a copy of *"What Do I Need to Know Before Being in a Research Study?"*

If you ever have any questions about this study, call the Principal Investigator or anyone else listed on this consent form.

What are your rights as a research participant?
You have rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning your rights, or want to discuss problems, concerns, obtain information or offer input, or make a complaint about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB)
    - Telephone: (402) 559-6463
    - Email: IRBORA@unmc.edu
    - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
    - Telephone: (402) 559-6941
    - Email: unmcrsa@unmc.edu

Documentation of informed consent
You are deciding whether to be in this research study. Signing means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to be in the research study.
- You have been told you can talk to one of the researchers listed below on this consent form if you have any questions during the study.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Subject_____Date_____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate

Signature of Person Obtaining Consent_____
Date_____

Authorized Study Personnel
Principal
* Songster, Jeffrey
phone: 402-559-4081
alt #: 402-559-4081
degree: MD

Secondary
* Adams, Austin
phone: 402-559-4081
alt #: 402-559-4081
degree: MD

* Alex, Brandon
phone: 402-559-7405
alt #: 402-559-4081
degree: MD

* Aron, Rebecca
phone: 402-559-4081
alt #: 402-559-4081
degree: MD

* Bartels, Karsten
phone: 402-559-4081
alt #: 402-559-4081
degree: MD PhD MBA

* Brakke, Tara
phone: 402-559-4081
alt #: 402-559-4081
degree: MD

* Brannan, Stephen
phone: 402-559-4081
alt #: 402-449-4081
degree: MD

* Chacon, Martha (Megan)
phone: 402-559-4081
alt #: 402-559-4081
degree: MD

* Duhachek-Stapelman, Amy
phone: 402-559-5782
alt #: 402-559-4081
degree: MD

* Ghaly, Tammer
phone: 402-559-7370
alt #: 402-559-4081
degree: MD

* Goergen, Katie
phone: 402-559-4081
alt #: 402-559-4081
degree: MD

* Koch, Kristina
phone: 402-559-7370
alt #: 402-559-4081
degree: MD

* Lorenzen, Kristi
phone: 402-559-4081
alt #: 402-559-4081
degree: MD

* Maresch, Andrew
phone: 402-559-4081
alt #: 402-559-4081
degree: MD

* Markin, Nicholas (Nick)
phone: 402-559-4081
alt #: 402-559-4081
degree: MD

* Roberts, Ellen
phone: 402-559-4081
alt #: 402-559-4081
degree: MD

* Schulte, Thomas
phone: 402-559-4081
alt #: 402-559-4081
degree: MD

* Shillcutt, Sasha
phone: 402-559-3685
alt #: 402-559-4081
degree: MD

What Do I Need To Know Before Being In A Research Study?

You have been invited to be in a **research study**. Research studies are also called "clinical trials" or "protocols." **Research** is an organized plan designed to get new knowledge about a disease or the normal function of the body. The people who are in the research are called **research subjects**. The **investigator** is the person who is running the research study. You will get information from the investigator and the research team, and then you will be asked to give your **consent** to be in the research.

This sheet will help you think of questions to ask the investigator or his/her staff. You should know all these answers before you decide about being in the research.

What is the **purpose** of the research? Why is the investigator doing the research?

What are the **risks** of the research? What bad things could happen?

What are the possible **benefits** of the research? How might this help me?

How is this research different than the care or treatment I would get if I wasn t in the research? Are there other treatments I could get?

Does **everyone** in this research study get the same treatment?

Will being in the research **cost** me anything extra?

Do I have to be in this research study? Will the doctor still take care of me if I say **no**?

Can I **stop** being in the research once I ve started? How?

Who will look at my **records**?

How do I reach the investigator if I have more **questions**?

Who do I call if I have questions about being a **research subject**?

Make sure all your questions are answered before you decide whether or not to be in this research.

Academic Research & Services Building 3000 / 987830 Nebraska Medical Center / Omaha NE 68198-7830
402-559-6463 / FAX 402-559-3300 / Email: irbora@unmc.edu / http://www.unmc.edu/irb

THE RIGHTS OF RESEARCH SUBJECTS
AS A RESEARCH SUBJECT YOU HAVE THE RIGHT

to be told everything you need to know about the research before you are asked to decide whether or not to take part in the research study. The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

to freely decide whether or not to take part in the research.

to decide not to be in the research, or to stop participating in the research at any time. This will not affect your medical care or your relationship with the investigator or the Nebraska Medical Center. Your doctor will still take care of you.

to ask questions about the research at any time. The investigator will answer your questions honestly and completely.

to know that your safety and welfare will always come first. The investigator will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

to privacy and confidentiality. The investigator will treat information about you carefully, and will respect your privacy.

... to keep all the legal rights you have now. You are not giving up any of your legal rights by taking part in this research study.

to be treated with dignity and respect at all times

The Institutional Review Board is responsible for assuring that your rights and welfare are protected. If you have any questions about your rights, contact the Institutional Review Board at (402) 559-6463.