



# KALPAS

Ketamine Analgesia for Long-lasting  
Pain relief After Surgery (KALPAS)

## **(19JAN2023) KALPAS Consent and Authorization**

Dear Potential Research Participant,

Thank you for your interest in the KALPAS study for Optimizing the Use of Ketamine to Reduce Chronic Postsurgical Pain. Please review the electronic informed consent and authorization form below.

If you have any questions or concerns regarding participation in this study please contact your local study staff.

Thank you,

The KALPAS Team

## OPTIMIZING THE USE OF KETAMINE TO REDUCE CHRONIC POSTSURGICAL PAIN

Consent Version: 19JAN2023

We have summarized key information about this research study. More complete details have been provided by study staff including a full consent document for your review and a call or visit. Please be sure to read the entire consent document, and ask us any questions you might have.

You are being invited to take part in a research study. We want you to understand the research before deciding whether or not to participate.

Your participation is voluntary. That means you can choose whether or not you want to take part in this study. You do not have to be in this study. You can get standard care for your surgery even if you decide not to be in this study.

# Purpose and Procedures

The purpose of this study is see if the drug ketamine reduces chronic (long-term) pain after mastectomy surgery. You have been invited to participate in this research because you are scheduled to have mastectomy surgery.

- You will be asked to complete a series of questionnaires about your pain, function and mood etc., both before and after surgery
- If you participate in the study, you may or may not get the drug ketamine. You will be randomized to either get ketamine or a placebo (saline that does not have drug). Randomization means what group you are in will be decided by chance, like flipping a coin
- The study lasts about 12 months. If you choose to participate, you can still take yourself out of the study later

## Risks and Benefits

Ketamine is an FDA-approved drug that has been safely used for more than 50 years. There are some side effects that could occur with the drug ketamine. The side effects range from very common to rare, and vary in seriousness.

You might benefit from being in the study, but there is no guarantee of benefits. You might help others in the future by being in this research study.

### CONTACT

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on the full consent document you received or contact the research project manager, Randy Cuevas, at (212) 263-1538.

The University of Utah Institutional Review Board (IRB) is serving as the single IRB (SIRB) for this study. Contact the SIRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at [irb@hsc.utah.edu](mailto:irb@hsc.utah.edu).

I confirm that I have read the consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to participate in this research study and authorize you to use and disclose health information about me for this study, as you have explained in the consent document.

\* must provide value

Yes

No

Name of participant:

Please click to add your signature:

Date of Birth

M-D-Y

Used to confirm your identity for consent.

Month-Day-Year

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