Official Title:	Optimizing the Use of Ketamine to Reduce Chronic Postsurgical Pain (KALPAS)
NCT Number:	NCT05037123
Study Number:	21-00715
Document Type:	Informed Consent Form
Date of the Document:	• March 13, 2024

Consent and Authorization Document

Study Title:	**OPTIMIZING THE USE OF KETAMINE TO REDUCE CHRONIC POSTSURGICAL PAIN**
Study Sponsor:	**New York University School of Medicine**
Funding Source:	**National Institutes of Health (NIH)**
Version Date:	**19 Jan 2023**

Part 1 of 2: MASTER CONSENT

SUMMARY

You are being invited to take part in a research study. This study is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study this consent form includes two parts. Part 1 of this consent form is the Master Consent and includes information that applies to all study sites. Part 2 of the consent form is the Study Site Information and includes information specific to the study site where you are being asked to enroll. Both parts together are the legal consent form and must be provided to you.

- The purpose of this study is to see if the drug ketamine reduces chronic (long-term) pain after mastectomy surgery.
- You will be asked to complete a series of questionnaires about your pain, function and mood etc., both before and after surgery. More details are discussed in this document.
- If you participate in the study, you may not get the drug ketamine. You will be randomized to either get ketamine or a placebo (saline that does not have drug).
- The study lasts about 12 months. If you choose to participate, you can still take yourself out of the study later.
- The drug ketamine does have some risks. The risks are explained later in this document.
- You might benefit from this study, but there is no guarantee of benefit.

- Joining this research study is voluntary. You do not have to be in this study

About volunteering for this research study

Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called "participants" or "research participants." These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for your records.

BACKGROUND

What is the purpose of this study? The purpose of this research study is to better understand whether a drug called ketamine reduces chronic (long-term) pain after surgery. We are also interested in studying how well ketamine reduces opioid use and whether it helps with mood, sleep, and function after surgery.

Ketamine is an FDA approved, non-opioid drug that has been safely used clinically over the last 50 years. Ketamine is commonly used as a general anesthetic (medication that helps you sleep during surgery) and, at low-doses (<1 mg/kg, similar to the doses in this study), is used as an analgesic (medication that helps reduce pain). Recently, ketamine has also been FDA-approved as a treatment for depression.

We are asking you to take part in this research study because you are scheduled to undergo mastectomy with your surgeon.

NUMBER OF PARTICIPANTS

We estimate that 750 patients will enroll in this study. Patients will be enrolling from different sites across the United States.

Your involvement in this study is expected to **last 12 months after surgery,** as this time corresponds with the timing of the follow-up questions.

However, there will be a small group of participants that will only need to complete up to **3 months of follow-ups.** If you are a part of this group, the research staff at your site will inform you prior to enrolling in the study.

STUDY PROCEDURES

PHASE I: BASELINE QUESTIONS

Once you have signed this consent form, if you choose to do so, you will be asked to complete a series of baseline questions that ask you to report on your pain, prior health status, sleep quality, etc. before surgery. You will be provided an electronic link to complete the questions on your smartphone, mobile device, or computer. If you prefer, you may also complete the questions on paper or with someone via telephone.

Below is the list of questionnaires and the estimated time it will take to complete them:

Baseline Questionnaires	Estimated Completion Time
Review of Inclusion/Exclusion Criteria	~ 2 minutes
Demographics	~ 3 minutes
Medical History and Medication History	~3 minutes
Tobacco, Alcohol, Medications Use (TAPS) – *Part 1 // Part 2**	~2 minutes / ~ 3 minutes*
Brief Pain Inventory (BPI)	~5 minutes
PROMIS depression and anxiety	~3 minutes
Pain Catastrophizing Scale (PCS)	~2 minutes
Patient Health Questionnaire (PHQ-2)	~1 minute
Generalized Anxiety Disorder (GAD-2)	~1 minute
PROMIS sleep disturbance and duration	~3 minute
PROMIS-physical function	~2 minutes
PROMIS fatigue	~2 minutes
Analgesic Use	~ 3 minutes
TOTAL:	**~32 minutes**

*This questionnaire is only to be completed if the participant scores a positive result from part 1 assessment. If so, the estimated time of completion for the Baseline visit is **33 minutes.**

PHASE II: RANDOMIZATION AND TREATMENT

Once you have completed all the baseline questionnaires and prior to your surgery, you will be randomly assigned (by chance, like flipping a coin) to one of three groups. You will have an equal chance of being in Group 1 or Group 2 or Group 3. You, your surgeon, your anesthesiologist, and the research team will not know which group you are assigned to.

Group #1: Continuous Infusion	Group #2: Single-Dose	Group #3: Placebo (No ketamine)
In Operating Room: (1) After you are sedated, you will first receive a **single dose of ketamine** at 0.35 mg/kg. (2) Next, you will receive an intravenous (IV) **infusion of ketamine** at 0.25 mg/kg during surgery. **In Recovery Room:** (3) After surgery, you will receive a single dose of saline. (4) You will continue to receive **ketamine infusion** which was started in the operating room at 0.25mg/kg/hr infusion for 2 hours after surgery.	***In Operating Room:*** No ketamine will be administered to you during the surgery. (1) Instead, after you are sedated, you will receive a **single dose of saline and IV saline infusion** throughout the surgery. **In Recovery Room:** (2) After surgery, you will receive a **single dose of ketamine** at 0.6 mg/kg in the post-anesthesia care unit (PACU or recovery room) (3) You will continue to receive **saline infusion** which was started in the operating room for 2 hours.	***In Operating Room:*** Saline infusion No ketamine will be administered to you during or immediately after surgery. (1) You will receive a **single dose of saline and IV saline infusion** throughout the surgery. **In Recovery Room:** (2) After surgery, you will receive a **single dose of saline**. (3) You will continue to receive **saline infusion** which was started in the operating room for 2 hours.

Saline Doses/Infusions:

Saline infusions/doses do not contain ketamine. Study participants are given saline so that the effects of the drug (ketamine) can be compared against no drug.

You will have IV lines for the mastectomy operation. In cases where additional IV lines are needed, the anesthesiologist or clinical care team taking care of you during the mastectomy may give you additional IV lines for the infusion of ketamine or saline, depending on your assigned group.

The rest of your procedure, including surgery, the medication that allows you to sleep during surgery, and all post operation care will follow normal procedures as determined by your doctors regardless of your participation in this study or what group you are assigned to.

PHASE III: FOLLOW UP QUESTIONS

After surgery, we will ask you to complete a series of questionnaires regarding your pain, mood, and function and to track your overall recovery progress at **six different time points over a 12-month period.**

The questionnaires will be available online and can be completed electronically through your smartphone, mobile device, or computer. We will provide you with the links and information to complete the questions. However, if you are unable to complete the questions electronically or are having any trouble, someone from our research team will contact you to help you complete them. If you prefer, you may also complete the questions on paper or with someone via telephone. If you prefer to complete questions on paper, we will mail you the packet of questions with a stamped return envelope. You can either return it using the stamped return envelope, or call our research staff to provide your responses.

On postoperative day (POD) 1, or 1 day after surgery, you will be asked to complete the **two** questionnaires listed below. If you are still in the hospital, someone from the research team will ask you to complete the questionnaires electronically or via paper. Some participants will go home on the same day of their surgery and will not stay in the hospital.

In this case, you will be provided with the links to complete the questions online.

POD 1	Estimated Completion Time
Brief Pain Inventory (BPI)	~5 minutes
Side Effects Questionnaire	~1 minute
*Analgesic Use**	*~ 3 minutes*
TOTAL	**~6 minutes**

*This questionnaire is only to be completed if you are discharged from the hospital on the same day as your procedure. If so, the estimated time of completion for this follow-up is **9 minutes** .

On POD 7 (or 7 days after surgery), you will be asked to complete the **nine** questionnaires below:

POD 7	Estimated Completion Time
Brief Pain Inventory (BPI)	~5 minutes
PROMIS-neuropathic pain	~1 minute
Breast cancer pain questionnaire (BCPQ)	~4 minutes
PROMIS depression and anxiety	~3 minutes
PROMIS sleep disturbance	~2 minutes
PROMIS fatigue	~2 minutes
PROMIS-physical function	~2 minutes
Side Effects Questionnaire	~1 minute
Analgesic Use	~3 minutes
TOTAL	**~23 minutes**

1, 3, 6, and 12 months after surgery, you will be asked to complete the **nine or twelve*** questionnaires below:

1, 3, 6, 12 months	Estimated Completion Time
Brief Pain Inventory (BPI)	~5 minutes
PROMIS-neuropathic pain	~1 minute
Breast cancer pain questionnaire (BCPQ)	~4 minutes
Patient Global Impression Change (PGIC)	~1 minute
PROMIS depression and anxiety	~3 minutes
PROMIS sleep disturbance and duration	~3 minutes
PROMIS fatigue	~2 minutes
PROMIS-physical function	~2 minutes
Analgesic Use	~3 minutes
*Pain Catastrophizing Scale (PCS)**	*~2 minutes*
*Patient Health Questionnaire (PHQ-2) **	*~1 minute*
*Generalized Anxiety Disorder (GAD-2) **	*~1 minute*
*Tobacco, Alcohol, Medications Use (TAPS) –Part 1 ** // Part 2 ****	*~2 minutes / ~3 minutes****
TOTAL	**~24 minutes**

*These three questionnaires are only completed at the 3-month follow-up, and so the estimated time of completion for the 3-month follow-up is **28 minutes** .

This questionnaire is only to be completed at the 6-month follow-up, and so the estimated time of completion for the 6-month follow-up is **26 minutes .

***This questionnaire is only to be completed if the participant scores a positive result from part 1 assessment. If so, the estimated time of completion for 6-month follow-up is **27 minutes** .

Specific questions on side effects from study drug will be asked after completion of study drug infusion and at 1 and 7 days after surgery.

Please note that it may take longer to complete each follow-up time point than the time estimated above if you choose to complete questionnaires via telephone instead of completing electronically online.

Please see the Comprehensive Schedule of Follow-Ups below:

Questionnaires	POD 1 *Time: 6 or 9 minutes*	POD 7 ***Time: 23** minutes*	1 month *Time: 24 minutes*	3 months *Time: 28 minutes*	6 months *Time: 24 minutes*	12 Months *Time: 24 minutes*
Pain Questionnaires:						
1. Brief Pain Inventory (BPI) *(5 minutes)*	X	X	X	X	X	X
2. PROMIS-neuropathic pain *(1 minute)*		X	X	X	X	X
3. Breast cancer pain questionnaire (BCPQ) *(4 minutes)*		X	X	X	X	X
4. Patient Global Impression of Change (PGIC) *(1 minute)*			X	X	X	X
Mood Questionnaires:						
5. PROMIS depression and anxiety *(3 minutes)*		X	X	X	X	X
6. Pain Catastrophizing Scale (PCS) (2 minutes)				X		
7. Patient Health Questionnaire (PHQ) – 2 *(1 minute)*				X		
8. Generalized Anxiety Disorder (GAD) – 2 *(1 minute)*				X		
Function Questionnaires:						
9. PROMIS sleep disturbance *(2 minutes)*		X	X	X	X	X
10. Sleep Duration *(<1 minute)*			X	X	X	X
11. PROMIS fatigue *(2 minutes)*		X	X	X	X	X
12. PROMIS-physical function *(2 minutes)*		X	X	X	X	X
13. TAPS – Part 1 **Part 2 – only completed if participant scores a positive result from part 1.*					X*	
Analgesic Use:						

Questionnaires	POD 1 *Time: 6 or 9 minutes*	POD 7 ***Time: 23** minutes*	1 month *Time: 24 minutes*	3 months *Time: 28 minutes*	6 months *Time: 24 minutes*	12 Months *Time: 24 minutes*
Opioid, non-opioid use and dosage assessment **only complete if discharged on same day of surgery and/or before POD1*	X*	X	X	X	X	X
Safety Monitoring:						
Side effects questionnaire	X	X				
Study Discharge						X

ALTERNATIVE PROCEDURES

What other choices do I have if I do not participate? Participation in this research study is **voluntary** and will NOT affect the care you receive for your surgery, or in the future.

RISKS

Risk of Study Drug

The potential risks associated with receiving ketamine include psychological, physiological and cardiovascular effects. However, because ketamine will be given in the operating room and/or recovery room, all participants will be closely monitored by the care team if any of these effects were to occur.

Psychological effects may include: decreased awareness, sedation, dream-like state, vivid dreams, disorientation, hallucinations, delirium, out-of-body experiences, and changes in perception about body, surroundings, time and sounds can occur.

Physiological effects may include: immobility, lack of coordination, amnesia (not remembering certain events), and slurred speech. Cardiovascular side effects may include elevated blood pressure and pulse rate. Also, respiratory depression may occur if given over a short duration of time. However, in our study, the single dose will be given approximately over a 60-minute period to minimize the chance these effects will happen.

Lastly, if side effects do occur, they are likely to end shortly after receiving ketamine and participants will be under the direct care of the post-anesthesia care unit (PACU) team. There are no expected side effects from receiving saline. The research may involve risks that are currently unforeseeable.

The surgeon and anesthesiologist will explain the risks associated with the anesthesia and mastectomy surgery since you will undergo these procedures regardless of your study participation. You will be asked to read and sign consents related to your surgery and your anesthesia plan. The risks associated with surgery and anesthesia will be discussed with you at that time.

There is also a *minimal* risk that you may receive a smaller or greater dose of study drug than intended due to clinical dosing error and/or equipment malfunction.

Discomfort related to placement of intravenous (IV) line

IV lines are routinely placed for the mastectomy operation. In cases where additional IV lines are needed, additional IV lines may be placed for the infusion of ketamine. There is a small risk of bleeding and pain at the site of insertion of IV lines.

Discomfort related to answering study questions

Answering questions about your pain, emotions, and recovery may cause discomfort or anxiety. There may be some mild level of fatigue associated with answering these questionnaires.

Risk of breach of confidentiality

As with any research, there is a risk of a breach of confidentiality. This means that it is possible that someone who isn't supposed to know your information could know it. However, the study team will make every effort to make sure this doesn't happen. We will do this by de-identifying your information, which means we will label the information we collect from you with a code so your name won't be known.

The personal health information collected about you will be kept confidential (which means it will not be given to people who are not authorized to use it), and it will not be made publicly available unless required by applicable law or a government authority. Also, your identity and contact details will not be given to anyone unless required by law. To protect your privacy, your

identity and contact details will be replaced by a code, such as a number that cannot identify you. Only the study doctor and his staff will have access to the key code.

BENEFITS

What are the possible benefits of the study? It is possible that some study participants who receive ketamine (single dose or infusion) may experience better pain control, improved mood, function, and decrease in the use of opioids and their potential side effects during the study. It is also possible that you may not get any benefit from being in this research study. Additionally, others may benefit in the future from what we learn in this study and standard pain prevention therapies for women undergoing mastectomy may also be changed based on the findings of this study.

RIGHT OF THE INVESTIGATOR TO WITHDRAW PARTICIPANTS

When is the study over? Can I leave the Study before it ends? This study is expected to end after all participants have completed all time points, and all information has been collected. This study may also be stopped or your participation ended at any time by your physician, the principal investigator, or study staff without your consent if:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The principal investigator or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time . Leaving the study will not interfere with your future care, payment for your health care, or your eligibility for health care benefits. You may be asked to continue with follow-ups for safety purposes.

NEW INFORMATION

What if new information becomes available? During the course of this study, we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

COSTS AND COMPENSATION TO PARTICIPANTS

Will I be paid for being in this study? You will receive $150** for the completion of all study follow-up time points. If you do not complete all study time points, you will not receive the full $150 but instead will be paid for the time points you do complete. The table below outlines the amount of payment you can expect for completing each study time point.

After enrolling in this study, on day of surgery or before discharge, you will receive an envelope with a debit card that will be reloaded after the completion of POD 7, 3 months and 12 months' time points.

**However, if you are a part of the small group of participants that only need to complete up to 3 months of follow ups - you will receive up to $90 for the completion of the study follow-up time points and the card will be reloaded after the completion of POD 7 and 3-months after surgery.

Follow-up Time Point	Payment
POD 1	$15
POD 7	$15
Card reloaded – up to $30, based on completed time points	
1 month	$30
3 months	$30
Card reloaded – up to $60, based on completed time points	
6 months	$30
12 months	$30
Card reloaded – up to $60, based on completed time points	

We ask all participants to provide their date of birth, current home address, email address (if applicable) and phone number, during the baseline time point (Demographics assessment). This information is needed to process and add the participation payments to your study debit card. This information will remain confidential in our study database and be removed from the final database once the study is completed.

Depending on your personal cellular data provider and plan, there may be additional costs to your data plan when using a personal smartphone or mobile device without Wi-Fi connectivity in order to complete the questionnaires electronically. The study is not responsible for costs of accessing or using the Internet for completing the study questionnaires electronically. If you foresee this being a problem, please let us know and we can work with you to find alternatives for you to complete your assessments (ie: over the phone with a research staff member).

Will I have to pay for anything? You or your insurance company will be charged or held responsible for the costs associated with your surgical procedure (mastectomy/ prophylactic mastectomy with or without lymph node dissection). However, you will not be charged, nor will your insurance company be charged, for any study treatment related costs. The costs of ketamine and saline will be covered by the study.

Your individual insurance or government health insurance program may not cover certain services, items or procedures. You may want to discuss this with your insurance carrier in advance. You will be responsible for any co-payments and/or deductibles for services rendered.

What if I am injured from being in the study? For medical emergencies, contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of part 2 of this consent form. If such complications arise, the principal investigators will assist you in obtaining appropriate medical treatment but this study does not provide financial assistance for medical or other injury-related costs.

SINGLE IRB CONTACT

Institutional Review Board: 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.

Consent and Authorization Document

Study Title:	**OPTIMIZING THE USE OF KETAMINE TO REDUCE CHRONIC POSTSURGICAL PAIN**
Principal Investigator:	**Jing Wang, MD, PhD, and Lisa Doan, MD** **NYU Langone Hospital - Tisch/Kimmel Hospital** **Department of Anesthesiology, Perioperative Care and Pain Medicine** **550 First Ave New York, NY 10016** **212-263-5072** **NYU Langone Hospital - Brooklyn** **Leroy Phillips, MD** **Department of Anesthesiology, Perioperative Care and Pain Medicine** **150 55th Street Brooklyn, NY 11220** **718-630-7535** **24 Hour Number: 646-501-2320**

Part 2 of 2: SITE SPECIFIC INFORMATION

This part of the consent form includes information about the site that is asking you to participate in this study and is specific to participation at your site only. Before making your decision, both the site-specific information and the general study information should be reviewed with you. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

AUTHORIZATION FOR USE OF PROTECTED HEALTH INFORMATION

HIPAA: How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of your medical chart within NYU Langone Health. An EMR is simply a computer version of a paper medical record.

If you are or have been a patient at NYU Langone Health in the past, you have an EMR at NYU Langone Health. Information from your research participation will be added to this EMR.

If you have never been a patient at NYU Langone Health, you may not have an EMR at NYU Langone Health. In connection with your participation in this study, an EMR will be created for you. The purpose of your EMR at NYU Langone Health will be to facilitate this research study and allow the researchers to maintain information arising from your participation in this research study. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility, for example, your name, the name of your primary doctor, the type of insurance you have, your date of birth and other health-related information.

What maybe placed in the EMR?

Information related to your participation in the research (e.g., laboratory tests, research-related notes, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by NYU Langone Health.

This information will be accessible to other members of the NYU Langone workforce that are not part of the research team. Information within your EMR may also be shared with others who NYU Langone Health has determined may appropriately have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Will I have access to research-related information within the Electronic Medical Record?

The 21st Century Cures Act allows patients increased access to their EMR. If you agree to participate in this study, this means that any research-related information placed in your EMR will be available to you immediately.

As a research participant, this means that you have immediate access to any research-related information that is placed in your EMR before the researchers have had an opportunity to review the information.

In this study, some research-related information in your EMR will not be available to you until the end of the study. This information will not be accessible in your EMR immediately in order to protect the integrity of the research trial results.

Results in the medical record that will not be immediately accessible: any progress and/or research notes that may notify you of your group assignment and/or whether you received ketamine or placebo).

The researchers will provide you access to this research-related information in your EMR when the study is over.

Certificate of Confidentiality

To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health. This means that your research information, including lab results, x-rays, MRIs, information about the investigational drug used in this study, may be included in your NYU Langone Health electronic medical record.

What information may be used or shared with others in connection with this study?

All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?

The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.

- Collaborating centers including:
  - University of Utah as the data coordinating center
  - Duke University as the clinical coordinating center
  - Vanderbilt University as the recruitment center
  - Johns Hopkins University as the statistical coordinating center
- The University of Utah Institutional Review Board (IRB) and local site IRBs, which review research involving people to make sure the study protects your rights
- Federal oversight agencies, i.e. the Food and Drug Administration, the National Institutes of Health.

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

Data Storage and Sharing Your study data will be stored securely at the University of Utah Data Coordinating Center. At the end of the study, the data will be stored indefinitely by the NIH or a data center selected by the NIH to enable future research use. Your name and other personally-identifying information will not be kept with the final research data. This study is part of the NIH HEAL Initiative focused on understanding and developing new treatments for addiction and pain. Research gives us the best information and progresses more quickly when data are available from many studies and many individuals, and when many researchers can work with the data and analyze them in different ways. Therefore, your data will be used for this and other NIH HEAL Initiative studies. Your stored data will also be made widely available to other researchers. The shared data may be used indefinitely for research not related to this study or the HEAL Initiative, without asking you for additional consent. If you withdraw from participating in this research study before it is done, we will keep and continue to use data that have already been collected unless you also withdraw your permission for us to use this information (see section below). A description of this clinical trial will be available on http://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.

WHO TO CONTACT

Who can I call with questions, or if I'm concerned about my rights as a research subject? 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 top of part 2 of 2: Site Specific Information of this consent form or contact Randy Cuevas, MPA, Research Project Manager at 212-263-1538.

If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

RESEARCH RELATED INJURY

Compensation for Injury For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of part 2 of 2: Site Specific Information of this consent form.

There are no plans for NYU Langone Health to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

NYU Site Requirements of Compensation

As is required by the laws that apply to NYU Langone, in order for you to receive a payment (i.e. check, Clincard or bank gift card), you need to give the study staff either your Social Security number or your Alien Registration number and will be asked to complete a IRS W9. If you do not have either of these numbers or are not willing to complete the IRS, you may be in the study but will not receive any payment.

You are required to track all payments made to you by NYU Langone for your participation in any research for this calendar year. You must let us know immediately if/when the total research payments presently equal or is likely to exceed $600.00 total (not including travel reimbursements) for this calendar year. If your total payments (for one or more studies) reach $600.00, please advise the Principal Investigator listed on top of part 2 of 2 or contact Randy Cuevas, MPA, Research Project Manager at 212-263-1538

In order to receive payments for your participation in research, you may need to provide your Social Security number. This is because NYU Langone is required to report to the Internal Revenue Service (IRS) any amounts that are paid to research participants that are equal to or greater than $600.00, and you may be taxed on these research payments above $600.00. If you will receive payments in any amount by a check, you will need to provide your Social Security number or Alien Registration number and will be asked to complete a IRS W9. If you do not have either of these numbers or are not willing to complete the IRS, you may be in the study but will not receive any payment.

Please note that this requirement is ONLY for participants who are expected to receive $600 or more in a calendar year (for example: participating in other studies etc.)

CONSENT:

I confirm that I have read this 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 this document.

_____
Participant's Name

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining
Authorization and Consent

_____ _____
Signature of Person Obtaining Date
Authorization and Consent