Study Title: Repeated Ketamine Treatment to Accelerate Efficacy of Prolonged Exposure in PTSD

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Principal Investigator: [REDACTED]	
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INTRODUCTION

You are being asked to participate in a research study. The box below highlights some key information that you should know about the project, and more detailed information is provided on the following pages. Before you decide whether to participate, please ask questions about any of the information you do not understand.

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. Whether or not you decide to participate, treatment at the VA for which you are eligible will not be affected. Refusal to participate does not involve any penalty or loss of benefits to which you're entitled.
- **Purpose**. The purpose of this research is to evaluate the efficacy of a known sedative drug, ketamine, to enhance Prolonged Exposure (PE) psychotherapy among veterans with Post Traumatic Stress Disorder (PTSD), compared to an control medication, midazolam. A control medication is a substance that has no therapeutic effect on the condition being treated but may produce side effects like those of the study drug being tested. Midazolam is also a sedative and the dose of midazolam infused will be lower than the sedative therapeutic dose. You will receive either ketamine or midazolam, while participating in PE. PE is a common "talk therapy" to treat PTSD. Ketamine is an anesthetic (used to temporarily put people to sleep) but at low dose, as it will be used in this study, may cause tiredness so you will stay awake during infusions.
- **Duration.** It is expected that your participation will last up to six months, approximately 24 visits.
- **Procedures and Activities.** You will be assigned to either the group of participants who will receive the study drug, ketamine, or to the group who will receive the control medication, midazolam. Regardless what group you will be assigned, the procedures are the same. You will receive the drug infusion 24-72 hours before your first PE session. This will be repeated for the following two weeks. Thus, you will receive a total of three drug infusions. You will then continue with the rest of PE therapy for about 7 more sessions, one session per week. Between study sessions, we will follow up with you to see how you are feeling and ask you to complete study forms either over the telephone, email, online, or in person. At the end of the PE therapy, we will follow up with you once a month, for three months, to see how you are feeling.
- **Risks.** Some of the likely risks or discomforts of your participation include side effects from the sedatives (ketamine or midazolam), placing of intravenous line, feeling uncomfortable responding to some questions related to your mental health, elevated anxiety while in PE therapy, and the time commitment for the assessments.
- **Benefits**. There may be no direct benefit to you from being in the study. The knowledge gained from this study may benefit others in the future.
- **Alternatives.** As an alternative to participation, you could seek medication and/or psychotherapy treatment available from a VA or other licensed clinician for PTSD.

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Detailed Information about this Research Study

What is research?
One purpose of this informed consent document is to provide clear information about the activities involved with this study. There are important differences between research and treatment plans:

- The goal of *clinical care* is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.
- The goal of *research* is to learn new things that may help groups of people in the future. Research teams learn things by following the same plan with many study participants, so they do not usually make changes to the plan for one person. You may or may not be helped by volunteering for a research study.

How many people will be studied?
We expect about 120 people to participate in the study at the Minneapolis VA Health Care System. All study activities will be completed at the Minneapolis VA Medical Center.

What happens if I say "*Yes, I want to be in this research*"?
The following information describes what will happen while you participate in this study.

Study eligibility determination (Baseline Visit):
To see if you are eligible for this study, you will have a personal interview about your mental health history with study staff. We will also ask you to complete questionnaires to learn about your current symptoms of PTSD, pain, anxiety, depression, suicidal risk, and your understanding about your participation in this study. We will check the dosage of all medications you are currently taking. We will also ask you to complete several assessments on a computer to test your memory and concentration. These assessments generally take about 90 minutes. A short physical examination, electrocardiogram (ECG – which is an electrical recording of the heart) and laboratory tests will be completed on this visit. A urine sample will be collected to test for certain drugs and/or pregnancy (if you are female). The drug test will identify any opiates, methadone, phencyclidine (PCP), buprenorphine, oxycodone, amphetamines, barbiturates, benzodiazepines, marijuana, cocaine, or alcohol that may be in your body. In addition, a urine sample will be collected before each infusion and one additional urine sample will be collected at some point throughout the study for a total of 4 samples during the treatment phase of the study. You will also be asked to take a breathalyzer test which involves blowing into a tube to estimate your blood alcohol level. If breathalyzer test shows evidence of alcohol use, we will not be able to do the testing and depending on the frequency of use, we may reschedule you for a later point in time or discontinue you from the study. If the results of these tests are positive and you are currently showing signs of intoxication, you may be evaluated by qualified clinical staff.

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Pregnancy: If you identify as female, and believe you are or may become pregnant, you should not participate in this study. Due to unknown risks and potential harm to an unborn fetus, you will not be permitted to participate if you are pregnant. Women of childbearing age will be asked to provide a urine or blood sample for a pregnancy test. Women participating in this study are asked to use a medically accepted contraceptive method including oral, intrauterine device, condoms, and/or spermicidal foam or gel for the duration of the study, if sexually active.

Study staff will make a notation in your VHA medical record of your study participation.

Experimental Study Drug Infusions:
If you are eligible and agree to participate in the study, you will be assigned by chance to receive ketamine or midazolam 24-72 hours prior to your first PE session. This will happen again two more times in the next two weeks. Prior to any infusion, study staff will ensure that you are picked up by a responsible adult to safely reach your home once infusion is complete.

The ketamine or midazolam you get will be chosen by chance like flipping a coin. You will have an equal chance of receiving either the experimental drug ketamine, or the midazolam. Neither you nor the study staff will know which one you are getting. Only the research pharmacist will know which drug you were assigned to take. If there is a medical reason that absolutely requires that your primary care physician know whether you are taking the active study drug or the control medication, the research pharmacist can "break the blind" and inform your doctor. If the blind has been broken, you will be withdrawn from the study, however.

Each infusion session can be scheduled Monday through Thursday. Each infusion including preparation for the infusion and discharge procedures will last approximately 4 hrs. We ask that you fast overnight, at least 8 hours, prior to each infusion. You should abstain from eating, drinking milk, or having solids at least 8 hours before your infusion appointment; and avoid clear liquids 2 hours before each infusion. You can have sips of water to take your scheduled prescribed medications. If your schedule prevents you from having an infusion in the morning, you may schedule the start of an infusion in the afternoon. However, you should still not eat anything for 8 hours nor drink any liquids for 2 hours prior to the start of each infusion, even if the infusion is in the afternoon.

After you arrive for your scheduled infusion at a location the study staff will inform you in advance, you will be checked-in by the reception desk. At the beginning of your session, a urine sample will be collected for a drug test and you will be administered a breathalyzer test and pregnancy test (female only), as well as asked to complete questionnaires for depression, suicide, and potential side effects of ketamine or midazolam. If breathalyzer test shows evidence of alcohol use, we may reschedule you for a later point in time. If breathalyzer tests continue showing evidence of alcohol use, we may discontinue you from the study. A catheter (IV) will be placed preferentially in your non-dominant arm for the drug administration. A non-

invasive monitor will also be connected to you to monitor heart rate, blood pressure, respiration, and concentration of oxygen in your blood every 10 minutes before and during the infusion.
You will be monitored after the infusion is complete for at least one hour or until all your vital signs are back to levels they were at before the infusion. We will also ask you to complete questionnaires to track possible side effects from the study drug. Before leaving, we will assess for any physical or mental discomfort, and to confirm that you are back to previous mental and physical state before infusion started. We will also confirm you have a competent adult to take you home. Twenty-four to 72 hours after the infusion and prior to your PE session, we will ask you to complete several questionnaires and repeat the computer testing.

ELECTROENCEPHALOGRAM (EEG) ***(this is optional):***
We also would like to measure electrical activity in the brain by using electroencephalogram (EEG). This part of the study is optional. An EEG uses electrodes (small metal discs or sensors) placed on the head with gel. The test does not hurt. The gel used to put the discs on your head is sometimes sticky and they discs may scratch a little bit. We plan to record data before, during, and at the end of each of the three infusions. Each time will last up to 15 minutes.
•I agree to have the electroencephalogram (EEG) procedure done during the infusions.

_____
(subject initials)

•I do not agree to have the electroencephalogram (EEG) procedure done during the infusions.

_____
(subject initials)

Prolonged Exposure (PE) Therapy:
PE is a commonly used talk therapy to help individuals confront fears. You will meet with a therapist to complete PE within 24-72 hours after your infusions, for the first three weeks or first three PE sessions. During PE, you will be asked to gradually approach traumatic memories, feelings, and/or situations. The first two PE sessions will evaluate your PTSD symptoms and explain how PE therapy is given. Starting on the third PE session, you will begin to describe a traumatic event you experienced with the guidance from a trained therapist. You, along with the therapist, will talk about any emotions that come up during the exposure session. You will be given homework to complete outside of the therapy sessions.

You will be asked to continue weekly PE therapy for a total of about 10 sessions. Your therapist and you will agree on the exact number of PE sessions you will need, as therapy is unique for each patient.

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On average 10 sessions are needed for therapy to be considered "complete." Then, after the last PE session you attend, there will be a once per month follow-up visit for three months. During the follow-up sessions, you will be asked to complete several questionnaires about PTSD, depression, and suicide risk.

AUDIO RECORDINGS (*this is optional*):

•I agree to have audio recorded of administered clinical measures/interviews/PE sessions for the purpose of rater training, and to help with quality of assessments or PE sessions. I understand these are audio recorded on a digital recording device and will be securely stored, encrypted, and password protected. I understand these will include only my study ID number, number of study visit, and date of the assessment.

_____
(subject initials)

•I do not agree to have my clinician administered clinical measures/interviews audio recorded for this initial screening visit or future study visits.

_____
(subject initials)

The following table shows the time frame and planned activities for the study:

	Baseline Assessment (includes consent, interview, questionnaires, computerized assessment, and physical exam/labs	**Infusion** of study drug	**Follow-up visit** (questionnaires and computerized tests)	**PE Therapy Session** (1-3 days post infusion)	Time Commitment (estimate)
Visit 1	X				4 hrs
Visit 2		X			4 hrs
Visit 3				X	1.5 hrs
Visit 4			X		1 hr
Visit 5		X			4 hrs
Visit 6			X		1 hr
Visit 7				X	1.5 hrs
Visit 8		X			4 hrs
Visit 9			X		1 hr
Visit 10				X	1.5 hrs

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Visit 11			X		1 hr
Visit 12				X	1.5 hrs
Visit 13				X	1.5 hrs
Visit 14			X		1 hr
Visit 15				X	1.5 hrs
Visit 16				X	1.5 hrs
Visit 17			X		1 hr
Visit 18				X	1.5 hrs
Visit 19				X	1.5 hrs
Visit 20			X		1 hr
Visit 21				X	1.5 hrs
Visit 22			X		2 hrs
Visit 23			X		1 hr
Visit 24			X		2 hrs

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for communicating with study staff on time, arranging transportation, complying with study schedule for infusions, PE sessions, and follow-up visits. You will also be responsible to follow recommendations made to you by study staff and inform the study staff of any side-effects you may experience from the study drug.

What happens if I say "Yes" but change my mind later?

You can end your study participation at any time without penalty or loss of VA benefits or other benefits to which you are entitled.

If you decide to leave the research study, you may do so at any time. However, if you chose to withdraw from the study during an infusion, you will be monitored after the infusion is complete for at least one hour or until all your vital signs are back to levels they were at before the infusion. Study staff will also ensure you have a ride home. If you withdraw from the study, you will be referred to your mental health treatment coordinator to follow up with you. Nevertheless, even after your withdrawal from the study, study staff will be available to answer any questions and provide any additional referrals you may need.

What are the risks of being in this study?

Discomfort or inconvenience from study procedures

Some people report anxiety, boredom, frustration, or fatigue while participating in the study. You may take breaks as often as needed, and you may decline to answer questions or tests that make you uncomfortable. We will also do our best to schedule your appointments so that they are most convenient for you.

Although precautions will be taken to minimize risks of participants, some risks involved with this study include those associated with: (a) ketamine or midazolam drug administration, (b) phlebotomy and

intravenous line placement, (c) psychiatric evaluation, clinical, and cognitive assessment (d) delay in treatment, (e) increased levels of anxiety or clinical deterioration associated with Prolonged Exposure therapy, (f) pregnancy and breast-feeding.

Ketamine or midazolam administration: Ketamine is a medication approved by the Food and Drug Administration to be used as an anesthetic (medication used to sedate people during surgery). The dose of ketamine used in this study is lower than the dose typically used for surgery, so it is unlikely that you will fall asleep because of ketamine. In the same way, the dose of midazolam infused will be lower than the dose to cause sedation. In this study we expect that the side effects of ketamine and midazolam would last for the time of administration and begin to decrease within 10-15 minutes after the infusion is stopped. Generally, noticeable ketamine as well as midazolam side effects are gone within 30-60 minutes of completing the infusion.

The most common side effects of ketamine or midazolam during infusion may include change in blood pressure, reduced concentration, dream-like feelings, changes in the way you think, or increased anxiety. Others include: feeling detached from your surroundings or as if you are in a dream; colors or sounds seeming brighter or duller than usual; feeling that you are floating; having blurred vision; or feeling mildly sedated.

Less common side-effects can include feeling of paranoia, euphoria (feeling high or extreme happiness), dysphoria (unease or general dissatisfaction with life), confusion, and hallucinations (hearing or seeing things that are not really there), flashbacks, brief memory loss, and difficulty thinking. If any of these feelings make you uncomfortable you can ask us to stop the study procedure at any time.

Physical possible effects could also be decreased pain, sweating, headaches, rash, gastrointestinal (GI) disturbances including nausea, vomiting, diarrhea, and constipation. The risks of vomiting are minimized by asking you to refrain from eating anything 8 hours prior of the infusion session. You may take your regularly prescribed medication with water. There may be other unknown side-effects that could occur.

Some people have also reported mild decreased concentration, residual drug effect, or a "hangover" on the day after their infusion. The exposure to ketamine or midazolam carries a low risk of abuse or use in the future. If you are concerned about this possibility, you should not participate in this study. Also, if at any point after completing this study you become aware of a desire to use or abuse ketamine or midazolam, you should contact study staff immediately. We will refer you to an appropriate treatment, if necessary.

You will be evaluated by a clinical member of the research staff prior to discharge from the infusion visit to ensure that all clinically significant effects have resolved and that it is safe for you to leave the testing site. Prior to study procedures transportation arrangements should be made for you to get back home and avoid difficulties driving with any drowsiness.

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We take precautions to help reduce the chance of having an unpleasant response to ketamine or midazolam or to reduce the severity of any lingering medication effects. You should know that unexpected, potentially harmful effects occasionally occur with administration of any type of drug and cannot be predicted with certainty so please call the study staff at any time if you are concerned about side effects related to the study drug. Also, study personnel for this study can stop the medication if we feel that your symptoms have worsened to the point that is unsafe for you.
We will monitor you before, during, and after the infusion to be sure all side effects of the study drug are tolerable and worn off before you leave.

1) We will ask you to contact study staff at any time if any unpleasant effects occur.
2) If your symptoms worsen or you develop other psychiatric or physical symptoms, treatment may be required, including hospitalization.
3) We will also schedule follow-up visits for evaluation of treatment response and side effects. We will also ask whether you have developed any significant cravings for illicit drugs or have started to abuse illicit drugs; if so, we will offer you a referral to receive appropriate treatment.

Are there other reasons why I might stop being in the study?

Your participation might be terminated by the investigator without regard to your consent under the following circumstances:

- Your health changes and the study is no longer in your best interest.
- New information becomes available, and the study is no longer in your best interest.
- You do not follow the study rules.
- The study is stopped by the Institutional Review Board at Minneapolis VA Health Care System or by the study funder, the United States Department of Veterans Affairs. The study funder is the organization providing money to conduct the study. The study sponsor is the organization who oversees the study.

To safely terminate your participation, we will ask you about any adverse events related to the study, possible suicidal ideations and/or behaviors, and your current mood symptoms including PTSD and/or depression. We will also notify your mental health treatment coordinator that your participation in the study has ended and confirmed appropriate follow up of clinical care is in place.

Questionnaires, Interviews, and Study Surveys
Some questions that are asked during the study may make you feel uncomfortable. Some people may feel distressed while being interviewed about their mood and mental health history. If this occurs, you do not have to answer any question that makes you feel uncomfortable and you can stop the interview at any time. You may also become fatigued or anxious during some of the study procedures. You may take breaks at any

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time or decline in participating. There is a social risk of stigma for PTSD if you are evaluated to have PTSD. You may be asked to complete self-reported measures via email, phone, mail, or in person which will NOT contain Identifiable Private Information. Identifiable Private Information will only be collected over phone or in person.

Cognitive testing
Inconveniences and side effects of these tests may include a sense of frustration, fatigue, or emotional distress. If you are upset by any part of the testing, you can stop your participation at any time, and a trained clinical staff member will be available to help you. You will be given breaks during testing as you need them if you feel tired. You may stop the cognitive assessment at any time. Completing the cognitive testing will be done in person or remotely and will NOT contain Identifiable Private Information. If you chose to complete the cognitive testing remotely, a link will be sent to you to complete.

Prolonged Exposure Therapy
Some patients report an increased level of anxiety while participating in PE. The therapist working with you will help you prepare for a potential increase in anxiety as part of PE procedures and standard practice. If you become too anxious, you can withdraw from PE therapy at any time, for any reason.

Blood Draws / Infusions
Having your blood drawn may cause discomfort. You will have a small amount blood drawn, approximately 1-2 tablespoons (10-30ml) for a routine laboratory test. The risks of drawing blood from a vein and IV catheter placement are bruising, bleeding at the puncture site, slight pain, and uncommonly, fainting, and inflammation of the vein. There is also a slight possibility, although rare, of infection due to a blood draw or an infusion. To minimize these risks, sterile procedures are used, pressure is applied at the site after the IV is removed, and you may recline during the blood draw and/or infusion.

Fasting
You will need to fast overnight for at least 8 hours prior to your infusion. This is to avoid possible nausea and vomiting during and after the infusion. Thus, you may become hungry the morning of your infusion. You will need to fast from clear liquids 2 hours prior to your infusion. Thus, you may become thirsty the morning of your infusion. You will be offered food and beverage immediately after your drug infusion and you can drink and eat as tolerated.

Will being in this study help me in any way?
There may be no direct benefit to you from being in the study. The knowledge gained from this study may benefit others in the future.

What if my test results show something unexpected?
There is a possibility that the study tests/procedures may discover that you have a potential abnormality that we did not expect to see. This is what is called an "incidental finding." Study procedure blood draw is

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done for research purposes only. They are designed to answer research questions, not to medically examine you or provide a clinical diagnosis. If we see something unusual, we will inform you so you can obtain appropriate follow-up evaluation by your physician. The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

Will I be paid for being in the study?
If you agree to take part in this research study, we will pay you up to $480 for your time and effort. All payments will be paid via EFT (electronic funds transfer). Participants will be compensated for completing the assessment sessions throughout the study. Assessment or follow-up sessions involve individual clinical interviews, self-report, and questionnaires. Participants will be paid $80 for screening and initial assessment (baseline visit, approximately 4 hours); $20 for each assessment during the infusions (total of 3 visits over three weeks; approximately 2 hours); $80 for PE therapy sessions 4 and 6; $60 for PE therapy session 8; and $50 for PE therapy session 10 (total of 4 paid sessions over 2.5 months; approximately 1.5 hours each); and $30 for follow-up assessment months 1 and 3 and $10 for month 2 following the last PE session (total of 3 over three months; approximately 2 hours). Participants who prematurely withdraw from the study will be compensated for only the sessions they completed. Compensation for participation in research is considered taxable income. If you receive $600 or more in any one calendar year, the VA is required to report this information to the Internal Revenue Service (IRS). FORM 1099 (Miscellaneous Income) will be issued to you and a copy will be sent to the IRS.

Are other procedures or treatments available if I don't participate in this study?
If you have not been evaluated for PTSD through your primary care provider, please contact your mental health coordinator to schedule an appointment with a clinician for evaluation and available treatments. For PTSD that does not completely improve after treatment or therapy, your primary care provider or psychiatrist may consider increasing current psychotropic medications, switching medication, or adding another. Different forms of psychosocial counseling (psychotherapy) could also be recommended. If medications and psychotherapy are not working, there are other evidence-based treatments for PTSD that you should talk with your psychiatrist or therapist about.

Will it cost me anything to participate in this research study?
There will be no charge to participants for any aspects of this study including services, testing, evaluation, or medications. Participant's insurance will not be charged. **Veterans who must make a co-payment for their usual medications or treatments will continue to be required to make such a co-payment for non-study related drugs.** There should be no additional medical costs to you for taking part in this study. However, frequent clinic visits may result in transportation costs and possible wages lost due to time missed from work.

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Use of Identifiable Private Information or Identifiable Specimens

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us permission to use your information, including health information in your medical records that can identify you. Information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all identifying information has been removed. Any private information will be stored securely on the VA Network, only accessible to pertinent research staff.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information to people who have a need to review this information. The results of this study may be published or presented, but your identity and records will not be revealed unless required by Federal Law. Organizations that are required by law to provide oversight of research projects may review your records. This includes several federal agencies, the VA's Research & Development Committee, and the Institutional Review Board. The Food and Drug Administration (FDA) as a federal agency required by law to provide oversight of this research and may review participant records. The sponsor or sponsors of the research project will also be allowed to review your medical records. Because of the need for these inspections, absolute confidentiality cannot be guaranteed.

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

Employees as Research Subjects

If you are a VA employee, you are considered a class of research subjects with special protections. Your decision to participate in this study should be free from pressure or coercion to participate. The research team will secure your information according to VA data security and privacy policies. Every effort will be made to prevent access by your supervisor and co-workers, but accidental disclosure or release of your private information could potentially occur.

Will I receive research test results?

Most tests done in research studies are only for research and have no clear meaning for health care. The investigator(s) will not contact you or share your individual test results unless there is an "incidental finding" that pertain to your physical health or may be helpful for your primary care physician to know about. If we see something unusual, we will inform you and/or your physician so you can obtain appropriate follow-up evaluation by your physician.

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What happens if I am injured while participating in this research?
If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution. In the event you cannot reach a VA facility, the VA will pay for necessary medical care for any injury or illness directly related to your participation in this research study.

You should immediately report any injuries resulting from your participation in this study to [REDACTED] during the day. During the evenings or weekends call the VA operator at [REDACTED] and ask to have the psychiatrist on call paged. Tell the operator that you are in a research study. If you do not live in the metropolitan area, you may call the toll-free number: [REDACTED]

The study sponsor **will** cover reasonable medical expenses for necessary treatment if you are injured by the study drug or properly performed study procedures and have not caused the injury by failing to follow the directions of the study doctor or study staff. No compensation is available should an injury occur, and the participant does not give up any legal rights or release the VA from any liability by signing the form.

Whom do I contact if I have questions, concerns or feedback about my experience?
You are encouraged to contact the Patient Representative at [REDACTED]if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

If you wish to verify the validity of the study and its authorized contacts, call the Patient Representative or contact the IRB office at [REDACTED].

I have reviewed the information provided in this document. My questions have been answered and I voluntarily consent to participate in this study. I understand that I have not given away any of my legal rights by signing this form.

Subject's Signature: _____ Date: _____

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