Washington University in St. Louis

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INFORMED CONSENT DOCUMENT

Project Title: Medication-assisted psychotherapy: Using ketamine-enhanced RODBT to target neural and behavioral mechanisms of action in emerging adults with moderate to severe treatment-resistant depression (TRD).

Principal Investigator: Kirsten Gilbert

Research Team Contact: Kirstyn Tan at (314) 273-7493 or psych-ket-ro@email.wustl.edu

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

KEY INFORMATION

The first section of this document contains some key points that the research team thought you would find important. The research study is described in more detail after this section.

This is a research study conducted by Dr. Kirsten Gilbert having to do with investigation brain differences in adults who differ on a characteristic of overcontrol. Be sure you understand why you might want to participate, or why you might not want to participate. You should carefully consider the information in this consent document and discuss it with the research team. You may choose to participate or not. Before you decide whether to be in this study, you may wish to consider other options that are available to you. Instead of being in this study, you could seek RODBT without being in this study.

If you agree and sign this consent, you will be volunteering to participate in the research study. All of the information below will be explained and is listed in more detail in the consent document below. The research team must give you a copy of this signed consent document.

If you agree to participate you will be asked to complete a screening, or initial, assessment. The screening interview is designed to assess your eligibility to safely participate in the study. We will ask you questions about your medical history, medications, psychiatric history, and mood and emotions. We will collect your vital signs and conduct an ECG and blood chemistry tests. We will conduct tests to assess your memory and problem-solving abilities, including computerized tests using a tablet. These procedures will take place at the research facility and will take approximately 4.5 hours.

How will this study affect me?

- The purpose of this study is to look at the effectiveness of and ability of a type of therapy to work successfully, called ketamine-enhanced Radically Open Dialectical Behavior Therapy (RODBT).
- As a voluntary participant, you will be asked to spend approximately 6 hours (on three separate visits across 5 months) of in-person assessments in addition to 1 hour long weekly individual

therapy session, 2 hour long weekly skills group therapy and twice weekly (for 4 weeks) 2-hour ketamine infusions.

- You were selected because you have moderate to severe and/or treatment-resistant depression (TRD).
- You will be in this study for approximately 22 weeks.
- You will need to come to the Washington University School of Medicine (WUSM) Department of Psychiatry for in-person assessments and therapy appointments and the Clinical Trials Research Unit (CTRU), on the 5th floor of the WUSM Center for Outpatient Health (COH) for ketamine infusions.
- The psychotherapy and in-person sessions will take place 4444 Forest Park Avenue in the Department of Psychiatry on the 2nd floor.
- The main risks to you during ketamine sessions are perceptual changes or hallucinations, floating sensations, and feeling nauseated. More detail about risks is provided below.
- You may benefit from volunteering because you will be contributing to better understanding of this therapy which will hopefully be put into clinical practice in the future. In the ketamine/therapy portion of this project, you may experience lessening of your symptoms and increases in your functioning.
- You will be paid up to $175 for completing the behavioral sessions and online questionnaires for participating in this study. You will not/will have costs for participating in this study.
- If you withdraw from the study, the research team may continue to use information already collected about you in this study.
- You may be contacted at the end of the study to give a brief interview about your experiences during the study. You will be paid $15 for your time. This interview will be audio or video recorded in order to be transcribed by a study team member at a later date. The video for this interview will be destroyed after transcription is complete.

The rest of this document provides more details about the study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you have moderate to severe and/or treatment resistant depression (TRD). This means that you have successfully tried at least two antidepressant medications or therapies that were unsuccessful at treating your depression.

The purpose of this research study is to look at the effectiveness and ability to work successfully of a type of medication assisted psychotherapy. This type of therapy is called ketamine-enhanced Radically Open Dialectical Behavior Therapy (RODBT). RODBT alone has not made enough rewiring in the brain, and we are looking to see if ketamine may improve to help this type of treatment. This could create a more fast-acting and durable treatment for TRD. Ketamine is known to cause side effects such as confusion and hallucinations. While these are temporary, they can be quite uncomfortable. Therefore, along with ketamine, we will give you an oral medication called clonidine, to prevent or reduce the

uncomfortable side effects of ketamine during the infusion and follow-up injections.

Ketamine is approved by the U.S. Food and Drug Administration for anesthesia and pain relief. However, the use of ketamine is considered investigational in this study.

Clonidine is approved by the U.S. Food and Drug Administration to for treatment of high blood pressure, attention deficit disorder, neuropathic pain, seizure disorder, mood disorder and migraine headaches. However, the use of clonidine is considered investigational in this study.

WHAT WILL HAPPEN DURING THIS STUDY?

- **What is going to happen to the participant as part of this study?**

Week	Description
Beginning of the study (week 0)	Baseline/pre-treatment in-person visit assessments • Blood draw • Vitals • EKG
Week 1	• 1 individual RODBT therapy visit per week (to get used to therapy and ketamine protocols)
Week 2	• 1 individual RODBT therapy visit per week (to get used to therapy and ketamine protocols)
Week 3	• 2 ketamine infusion visits • 1 individual therapy visit • 1 group session EXAMPLE: • Monday – ketamine infusion • Tuesday – group session • Wednesday – ketamine infusion • Thursday – individual therapy
Week 4	• 2 ketamine infusion visits • 1 individual therapy visit • 1 group session
Week 5	• 2 ketamine infusion visits • 1 individual therapy visit • 1 group session
Week 6	• 2 ketamine infusion visits • 1 individual therapy visit • 1 group session
Week 7 – 21	• 1 individual therapy visit • 1 group session

Week 22	• 1 individual therapy visit • 1 group session • Post – treatment in-person session

- **What is going to happen during the first study visit?**

At the initial session we will collect your vital signs and conduct an EKG and blood chemistry tests. Then a trained interviewer will ask you detailed questions about your lifetime history of depression, anxiety and other psychological symptoms, as well as your functioning at home, in school or work, and in social settings. We will audio record your responses to these questions and input your responses into Washington University's secure data collection website (REDCap). The interview portion will take approximately 1 hour to complete. Next, you will have an electroencephalogram (EEG) where we will put a cap on your head and small dots of non-toxic gel in your hair which washes out with water. You will complete three tasks while wearing the cap. The first will involve determining the direction arrows are pointing, the second will involve earning points by guessing doors, and the third will involve measuring brain activity with eyes open and closed. The EEG portion of the task will take approximately 1.5 hours to complete. After we remove the cap and you complete the EEG portion, you will fill out some surveys in the EEDP office about how you usually feel, think, and act. Filling out the surveys should take about 30 minutes and will generate protected health information (PHI) about your mental and physical health. The PHI generated from these questionnaires will be stored on Washington University's secure data collection website (REDCap) and will only be accessible by the research team. You are free to skip any questions you do not want to answer. The entire assessment should take approximately 3 hours.

- **What is going to happen during ketamine infusions?**

If you are a female participant, you will complete a urine pregnancy test immediately prior to your first ketamine infusion and will be informed that it is not advised to have unprotected sex throughout the ketamine infusion period (1 month). You will receive IV infusions of ketamine two times a week for four weeks. The IV infusion will take approximately 40 minutes, and we will monitor you for an additional 50 minutes. This means that infusion visits will take approximately 90 minutes. During that time, we will periodically measure your vital signs and assess for any psychiatric side effects. You may be asked to take a medication called clonidine to help manage side effects from the ketamine infusion.

- **What is going to happen during the RODBT treatment?**

RODBT is a type of therapy that has been shown to work with individuals who show behaviors of overcontrol, such as perfectionism, anxious apprehension, inflexibility and concern with making mistakes. RODBT helps individuals who are controlled relax rigid self-control, be receptive and open to new experiences and feedback, and increase social connectedness by helping activate the social-safety system. RODBT has been tested and shown to be effective with adults who are depressed. You will receive RODBT for 22 weeks. Participating in RODBT includes weekly 1-hour individual sessions and weekly 1.5-hour skills classes. These sessions will be provided by therapists who have been highly trained in using RODBT. You will work with the clinicians to schedule a therapy time that works for

both of your schedules. Clinicians will keep notes, which will generate PHI (Protected Health Information), from your sessions in a locked file cabinet in a locked office and your name will not be linked with these notes, only your assigned ID number. Participating in RODBT therapy will be at no cost to you.

- **What is going to happen during the follow-up sessions?**

You will complete two follow-up sessions, one mid-treatment and one after treatment has finished. The mid-treatment assessment will consist of similar EEG tasks and questionnaires to the initial visit and will take approximately 2 hours. The post-treatment session will include a similar interview, EEG tasks, and questionnaires to the first visit and will take approximately 3 hours.

- **Do I have to answer every question on the surveys or questionnaires?**
  - No, you are free to skip any question that you would prefer not to answer for any reason.

If you are eligible based on your phone screen, you will come to the Department of Psychiatry at 4444 Forest Park Avenue at Washington University School of Medicine to participate in the in-person research study.

You will need to drive or commute to the assessments that are done at Washington University School of Medicine. For the RODBT therapy, you will need to drive or commute to weekly individual and skills class therapy sessions. Parking will be free at all sessions.

If you tell us that you are thinking about hurting yourself or others, the research staff may give you referrals for treatment or work with you to contact your personal doctor or therapist to discuss your thoughts of harming yourself. We may need to work with you on a plan that might include getting you to a medical facility for safety. We also want to provide you with contact information for available resources, should you decide you need assistance at any time. You can call the toll-free 24-hour National Suicide Prevention Lifeline at 1-800-273-TALK (1-800-273-8255) or St. Louis Behavioral Health Response at 1-800-811-4760 (https://bhrstl.org/crisis-hotline/).

Google voice will be used to text you for appointment reminders and survey links. No PHI will be shared over Google voice messages and your phone number will not be saved.

Will you save my research information to use in future research studies?

The data and blood we are obtaining in this study may be made available for studies going on right now as well as studies that are conducted in the future. These studies may be done by researchers at Washington University, other research centers and institutions, or private companies involved in research.

We may also share your research data and blood with large data repositories (a repository is a database of information) for use by others, such as the research community, institutions, private companies and the general public. If your individual research data or blood is placed in one of these repositories, your name and other identifying information will be removed. All reasonable precautions will be taken to

protect your privacy and confidentiality. Necessary approvals will be obtained to use the data. Certain summary information may be available to the general public.

These future studies may provide additional information that will be helpful in understanding depression, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. Should this occur, there are no plans to provide financial compensation to you. There are no plans to provide financial compensation to you should use of your data and blood occur. It is unlikely that what we learn from these studies will have a direct benefit to you. By allowing us to use your data and blood, you give up any property rights you may have in the data and blood. We will protect the confidentiality of your information to the extent possible.

If you change your mind and do not want us to store and use your blood and data for future research, you should contact the research team member identified at the top of this document. The blood and data will no longer be used for research purposes. However, if some research with your blood and data has already been completed, the information from that research may still be used. Also, if the blood and data has been shared with other researchers it might not be possible to withdraw the blood and data to the extent it has been shared.

It is your choice whether to let researchers share your blood and data for research in the future. If you say "yes," you can change your mind later. If you say "no," you can still fully participate in this study.

Please place a mark next to your choice:

_____Yes, use my data and biospecimens in other research studies.
Initials

_____No, do NOT use my data and biospecimens in other research studies**.**

<u>Audio/Video Recording or Photographs</u>

One aspect of this study involves making video recordings of you when you participate in the free RODBT therapy portion of the study. The individual and skills class sessions will be video recorded so they can be supervised by the principal investigator and clinicians on this research study to ensure adherent therapy. Only the principal investigator, study clinicians and study staff have access to these videos and photographs. Videos will be destroyed immediately following your completion in the study and the photograph will be deleted at the end of the task.

While all video recordings are stored in a confidential manner, please be aware that the recording will likely contain information that would identify you.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 15 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately 22 weeks:

- In-person assessments (prior to starting treatment, mid-treatment and following completion of treatment)
    - There will be 3 in-person assessments, each lasting approximately 2 hours (range of 1.5-3 hours). The visits will be spaced at baseline (week 0), mid-treatment (week 6) and following treatment (week 22).
- Ketamine assessments
    - Will start in the 3rd week of participation and will occur twice weekly, for approximately 2 hours, for a total of 4 weeks.
- RO DBT therapy assessments
    - Will start the first week with individual therapy (1 hour long) and will span the entire 22 weeks.
    - Skills group therapy will start the 3rd week (2 hours long) and will continue until the end of 22 weeks.

WHAT ARE THE RISKS OF THIS STUDY?

Direct physical or psychological risks are low for this research study. You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Risks of individual and group therapy:

- Therapy may cause psychological distress, or social anxiety (during group sessions).
- Behavioral tasks can cause some form of concern of how well you are doing.
- Boredom may occur during the experimental sessions.
- Some mild discomfort may happen with the application of the mini surface electrodes because we put a non-toxic, water-soluble gel in your hair to record your brain waves.
    - We wash the gel out with water afterwards, but some people do like having gel in their hair.
- Five stickers will attach the electrodes to your forehead, temples, and cheeks, and removing them can feel like taking off a very small bandage.
    - You may notice some red spots on your face afterwards, but these will soon go away.
- Attending the weekly RODBT therapy sessions and ketamine infusions could result in a loss of time or wages.

Risks of Blood Draws and IV infusions:

The blood draw and IV infusions (or IM injections) may cause bleeding, bruising, or pain. Some

people become dizzy or feel faint. There is also a rare risk of infection.

Risks of an EKG:

For the EKG, adhesive patches (like Band-Aids®) will be placed on your chest, arms, and legs. In some areas, it may be necessary to shave a small spot of body hair so the adhesive patches can be attached. Wires from the machine are then attached to the adhesive patches. These wires record your heart's electrical activity. After an EKG, you may have mild irritation, slight redness, and itching at the places on your skin where the recording patches are placed.

Risks of Ketamine infusion:

Likely	• Feeling light-headed, "high," exhilarated, and/or happy • Having perceptual changes or hallucinations, floating sensations • Difficulty concentrating, paying attention, or remembering as many items as usual from a list (like items on a grocery list). • Mild and temporary increases in blood pressure • Feeling nauseated.
Less Likely	• Feeling dizzy, sleepy, anxious, and suspicious.
Rare	• Feeling sad, scared, confused, and/or disoriented. • Moderate and temporary increases in blood pressure. • Future abuse of ketamine. • Prolonged psychosis in individuals with a pre-existing psychiatric condition.

Risks of Clonidine:

Likely
- Dry mouth
- Constipation, nausea, or vomiting
- Mild abnormalities in liver function blood tests.
- Salivary gland pain.
- Leg cramps pain or musculoskeletal pain or joint pain.
- Feeling weak.

Less Likely
- Dry throat
- Low blood pressure.
- Dizziness.
- Tremor.
- Feeling nervous or irritable.
- Having trouble sleeping or feeling drowsy, tired, or sedated.
- Dry or blurred eyes or feeling tearful.

Rare
- Lack of appetite or abdominal pain.
- Transient elevation of blood glucose or blood serum creatinine tests.
- Fluid retention.
- Sexual dysfunction, genitourinary effects.
- Headache.
- Change in taste.
- Unpleasant dreams.

- ECG abnormalities, and palpitations.

Breach of Confidentiality
One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT OTHER OPTIONS ARE THERE?

Taking part in this research study is voluntary. You may choose not to take part in this research study or may withdraw your consent at any time.

Instead of being in this research study, you have other options including:
- Seeking RODBT treatment from clinicians in the community
- Seeking other forms of treatment in the community
- Seeking other forms of treatment involving ketamine infusions in the community

A list of clinicians in the St. Louis region that provide RODBT and other forms of psychological treatments can be provided to you.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. Payment will be given by a Forte debit card or with a check.

Each behavioral session you will be paid $50 for completion, and you will also be paid $25 for completion of repeated online questionnaires. Thus, you can make up to $175 for completing the three behavioral in-person assessments and questionnaires. If you complete over 70% of all the online questionnaires, you will also be entered into a drawing in which one person will win an additional $100. If you participate in the follow up interview you will be paid an additional $15.

You will be asked to provide your social security number (SSN) in order for us to pay you. You may also need to provide your address if a check will be mailed to you. If we mail a check, it can take up to 4 weeks to arrive at your noted address.

WHO IS FUNDING THIS STUDY?

The National Institutes of Health (NIH) is funding this research study. This means that Washington University is receiving payments from NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIH for conducting this study.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those listed below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- The National Institutes of Health (NIH)
- University representatives to complete University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.
The funding source for this research may require that we share the data from this study with others to make sure the results are correct and to use for future research. Your information will be shared in a way that cannot directly identify you.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as 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 the results. You can search this Web site at any time.

To help protect your confidentiality, we will remove identifying information from all data. We will assign you a study ID and store all data using this ID. We will keep the master list linking the code number and your identity separate from the research data. Only the PI, clinicians and people helping will be able to see the list. This list will be kept on a password-protected with two-factor authentication at Washington University School of Medicine.

- For paper/hard copy records:
    - Paper/hard copy records will be stored in locked filing cabinets at 4444 Forest Park Avenue, St Louis, MO 63108, Washington University School of Medicine (WUSM) or in locked filing cabinets in clinician offices.
    - All data collected from study procedures will be coded using the ID number, and will not include your identifying information.
    - Each participant will have study data or the participants ID#.
        - This folder will contain, for example, consent forms and contact information for

the participant. Only approved research team members will have access to the filing cabinets.

- For electronic records:
    - Most electronic records will be created and stored using REDCap, WUSM's secure data management system.
        - REDCap will be used to collect and store data from study procedures, which will be identified by your ID#.
        - A separate REDCap database will be used to store your identifying information, including (but not limited to) names, phone numbers, addresses, SSN's, and dates of birth.
        - Only approved research team members will have access to the REDCap projects.
    - Electronic records not created and stored through REDCap, will be stored on secure Washington University St. Louis Box servers on password protected computers.
        - Such files will be coded with an ID#.
        - Only approved research team members will have access to the Box documents and password protected computers.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others
- you give permission to disclose your information, including as described in this consent form
- it is used for other scientific research allowed by federal law.

This Certificate may not be effective for information held in foreign countries.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to

you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter found in the Participant section of the Human Research Protection Office website at hrpo.wustl.edu or you may request that the investigator send you a copy of the letter.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
            - You will not be allowed to continue to participate in the study.

Can we contact you by email and/or text?

We would like to contact you by email and/or text using Google voice for the purposes listed below. Some of these messages may contain health information that identifies you.

- Scheduling appointments
- Appointment Reminders
- Sending Surveys
- Survey Reminders

Only the research team will have access to your email and/or text communications. We will only communicate in this method to send you the information listed above. If you have any questions, wish us to stop sending these messages or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email and/or text using Google voice.

- Text messaging is not a secure communication method.
- There is always a risk that the message could be intercepted or sent to the wrong email address and/or phone number. To avoid this, we will send a test message to ensure we have the correct email address and/or telephone number.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer or cell phone with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any messages sent or received on any electronic devices used for work or through a work server.
- If you lose your phone, others may be able to access the messages that we send.

Do you agree to allow us to send your health information via email?

_____ **Yes** _____ **No**
Initials **Initials**

Do you agree to allow us to send your health information via text using Google voice?

_____ **Yes** _____ **No**
Initials **Initials**

If you have a MyChart account, we may use this as a way to communicate with you about the treatment and/or medical care you are receiving as part of this study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found in the Participant section of the Human Research Protection Office website at hrpo.wustl.edu. If you decide to leave the study early, we will ask you to attend a close out visit with your clinician if you are part of the therapy portion of the study. The close out visit with the clinician will involve closing out your treatment and ensuring you have referrals and a plan for future treatment, if applicable.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because we do not think you can complete the EEG procedures and/or ketamine infusions, because in our judgement it would not be safe for you to continue, or because funding for the study has ended. This might also happen if it would not be safe for you to continue with the ketamine RODBT therapy and you need a higher level of clinical care if your symptoms, condition, or impairment worsens.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Kirstyn Tan at (314) 273-7493 or psych-ket-ro@email.wustl.edu. If you experience a research-related injury, please contact: Kirsten Gilbert at 314-747-0001.

If you have questions, concerns, or complaints about your rights as a research participant please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy

of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 12/10/26.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)