To whom it may concern:

Please accept this request from your patient to participate in a program using ketamine-assisted therapy paired with a twelve-week community of practice for individuals experiencing mental distress.

Traditional treatment modalities addressing PTSD and treatment resistant depression have not been as successful as hoped. Ketamine-assisted therapy (KAT) is a safe and research-informed treatment option that shows promise in effectively treating a variety of mental health conditions. Ketamine is already used within the health system to treat a variety of ailments including pain management, anesthesia and treatment resistant depression, however, there is nothing available to patients that allows them to integrate their experiences through group sessions.

Each patient experience will be different, but it is generally thought that low dose psycholytic therapies, such as KAT, reduce ego defenses, promote insights and empathogen-like (heart-opening) responses, while higher (but still sub-anesthetic) doses create dissociative, psychedelic, out-of-body, ego-dissolving peak responses. Based on research and expert opinion, the RTT KAT medical protocol to support KAT will use:

- Intramuscular injection (IM), given in the shoulder or hip, which delivers a highly bioavailable amount of medicine with a rapid onset.

Program information: Over 20 medical professionals are collaborating to run this program. It is 3 months in duration and includes:

- Intramuscular injection (IM), given in the shoulder or hip, which delivers a highly bioavailable amount of medicine with a rapid onset.
- 3 Ketamine Assisted Therapy sessions (4 hours each) administered at the Snuneymuxw Hulit Lelum Health Centre.
- Holistic medical and psychological intake assessment overseen by our lead psychiatrist.
- Optional one to one sessions with a licensed therapist.

PLEASE NOTE: If the patient has a mental health diagnosis, refer based on that diagnosis (if it aligns with the eligibility criteria). If the patient has not received a diagnosis, please use a provisional or transient diagnosis, which will be then assessed by a psychiatrist prior to entering the program.

If you have any questions, please email kate@rootstothrive.com or julia@rootstothrive.com with 3 specific days and times we can call you and one of our clinicians will follow up on one of those specified days. We will email you in response to let you know which day and time. **When the form is completed, please fax to 250-244-8426 (confidential).**

Name: _____ Gender: ☐ M ☐ F ☐ U ☐ O

Surname First name

Address: _____

Street City Postal Code

DOB: _____ Preferred Phone: _____ Email: _____

(MM/DD/YYYY)

PHN: _____ Alternate Contact: _____ Phone: _____

Health Care Provider (HCP): _____ Phone: _____ Fax: _____

Referring HCP: _____ Phone: _____ Fax: _____

HCP Signature: _____ HCP's Billing #: _____ Date: _____ Referring Dr's office stamp

Provisional Diagnoses: past or present (check all that apply):

- ☐ Treatment Resistant Depression
- ☐ Obsessive Compulsive Disorder
- ☐ Post-Traumatic Stress Disorder
- ☐ Generalized Anxiety Disorder
- ☐ Adjustment Disorder
- ☐ Substance Use Disorder

AND/OR

Concurrent Challenges (separate from a formal/ongoing mental health diagnosis)

- ☐ Unresolved Grief
- ☐ Suicidal Ideation
- ☐ _____
- ☐ _____

Treatments tried (psychotherapy and pharmaceutical) for mental health condition:

_____
_____
_____

Exclusion Criteria:

- Presence of active psychotic symptoms
- Diagnosis of dementia or delirium
- Recent changes in medication related to mood disorders

Personal Mental Health/Substance Use History:

_____
_____
_____

Family Mental Health and Substance Use History:

_____
_____
_____

Allergies: _____

Current Medications - Noting (but not limited to):

- ❑ psychostimulants (including ADHD medications) _____
- ❑ MAOIs (Phenelzine, Selegiline) _____
- ❑ antidepressants (venlafaxine, bupropion, desipramine) _____
- ❑ calcineurin inhibitors (cyclosporine, tacrolimus) _____
- ❑ corticosteroids_____
- ❑ estrogens _____
- ❑ midodrine_____
- ❑ NSAIDs (ASA, ibuprofen, naproxen, diclofenac, celecoxib, etc.) _____
- ❑ testosterone_____
- ❑ triptans_____
- ❑ other_____

Relevant Abnormal Lab/ECG Results: _____

Baseline Vitals/Weight:

Date: _____ BP_____ Respiratory Rate _____ Pulse _____ Weight: _____

I (therapist/health care provider) _____ confirm that I have an ongoing therapeutic relationship with the patient I am referring and I will continue this relationship following their completion of the Roots to Thrive program.

Name:_____

Designation:_____

Signature:_____

Date:_____

ALL RTT-KAT PARTICIPANTS MUST REVIEW PRIOR TO RTT AND SIGN PRIOR TO KAT

CLINICAL TREATMENT PROGRAM CONSENT FORM

Roots to Thrive (RTT) & Ketamine-assisted Therapy (KAT)

You have expressed interest in ketamine-assisted therapy (KAT), a new and evidence-informed option that uses the medicine ketamine in partnership with therapeutic activities and relationships. For those who fit the inclusion criteria, it is a safe and effective treatment for psychological difficulties such as depression, and post-traumatic stress. The following information is to help you decide if KAT is right for you, describing how KAT works, the potential benefits and risks of participation, and how you will be supported throughout the program. If you choose to participate, you can decide to withdraw at any time during the program. In this case, please let both the KAT team and the physician who referred you know.

Please make sure all your questions have been answered by the KAT team before signing this document. Signing this consent is required to enter the RTT-KAT program, but it does not guarantee your entry. A fulsome intake process (medical and psychiatric) to ensure your safety and suitability for the program is required prior to participating in RTT-KAT. In the RTT-KAT psychiatric intake process, you will be screened for suicide risk. This is done through iterative conversation with the program's psychiatrist. For example, by asking: "1. Do you feel that life is worth living? 2. Do you wish you were dead? 3. Do you have thoughts of self-harm? 4. Do you have a plan?" If suicidality is a concern, the RTT-KAT psychiatry team will determine the best course of action, based on the unique situation.

Information About Ketamine

Ketamine was initially labelled for use as an anesthetic. In RTT-KAT, ketamine is used "off-label" to treat mental health conditions. This means that ketamine is being used for a purpose that is not listed on the official label (for what it was initially approved to be used for). At higher doses, it's mode of action mimics a psychedelic, which can work very quickly to significantly reduce anxiety and depression and create a sense of space or detachment from emotions and sensations. It can also bring about different states of conscious, including what might be described as spiritual or mystical awareness. These effects can support new insights; greater access to and / or a reorientation to memories and thought patterns; a different sense of self and reality. In a safe environment with therapeutic support, working with ketamine can help individuals heal and transform, finding greater peace and compassion.

How Ketamine Works

The current theory of ketamine's mode of action is as an NMDA antagonist working through the glutamate neurotransmitter system. This is a different pathway than that of other psychiatric drugs such as the SSRIs, SNRIS, lamotrigine, anti-psychotics, benzodiazepines, etc.

Ketamine is classified as a dissociative anesthetic, dissociation meaning a sense of disconnection from one's ordinary reality and usual self. At the much lower dosage level administered in KAP, one will most likely experience mild anesthetic, anxiolytic, antidepressant and, potentially, psychedelic effects.

No matter the route of administration, ketamine tends to produce dissociative effects in a broad range—almost none occurring in a session to strongly present– depending on dosage and one's

susceptibility. The evidence supports that the 'dissociative' experiences may well be instrumental in providing a more robust effect. In the Trance state, these effects are deliberately reduced in intensity to enable therapy and direct communication.

At higher but still sub-anesthetic doses, the dissociative effect predominates for a time, usually about a half hour to an hour. Both methods tend to produce a positive change in outlook and character and relieve symptoms of depression, PTSD, anxiety, and other difficult states of mind and heart. We employ sublingual for the first session and intramuscular methods for subsequent sessions.

Essential to both methods are time-outs from our ordinary state of mind, this period being of varying duration, usually 30 to 90 minutes, though it will seem timeless. Characteristically, there is a relaxation from ordinary concerns and usual mind, while maintaining conscious awareness of the flow of mind under the influence of ketamine. This tends to lead to a disruption of negative feelings and obsessional preoccupations. This relief and the exploration and experience of other possible states of consciousness are uniquely impactful. As your Roots to Thrive Team, we act as guides to the experience, preparing you for it and facilitating your process. For most people, KAT is singularly beneficial.

How a KAT Session Works

The ketamine-assisted therapy (KAT) component of the program consists of a series of three sessions, beginning with a lower dose and then progressing to a higher dose (up to 1.5mg/kg taken intramuscularly) with subsequent sessions. This calibrated process enables you to gain comfort and confidence in the process. During your KAT treatment sessions, you and your group will be accompanied by a medical clinician and a KAT trained therapeutic sitter. Once ketamine is taken, the vast majority of effects will last between one to two hours.

Unlike other forms of therapy, KAT is largely an inner journey. You will not be talking through your experience while the medicine effects are unfolding. A clinician and therapist will be present and available to provide you with support at any time. There will be an opportunity to share and process your experience once the effects of the medicine have worn off and, in the days, following. To support an inward focus and minimize external distraction, instrumental music will be played, and we encourage the use of eye shades. Before, during, and after your session, we will monitor your physical vital signs, and will be available to answer any questions you have. As the medicine begins to wear off, we will encourage you to continue exploring your inner world, and to work with stress regulation and loving-kindness practices that resonate with you, as you transition back to your ordinary state of consciousness. Part of your KAT preparation work (with your therapist or community of practice) will be to explore such regulation and loving-kindness practices, for use at any time. To continue assessing your needs and progress and to improve the quality of our program, we will also ask you to complete feedback surveys at various points as you move through the RTT-KAT program. These quality improvement results that speak to program impact will be shared with others, but no personal information will be shared.

Roots to Thrive (RTT) Group KAT Sessions

The Roots to Thrive (RTT) community of practice (CoP) program is the primary support and development vehicle in the RTT-KAT program. You will meet virtually every week for two hours during the 3-month RTT-KAT program. Within your 3-month treatment period, you will also participate in three group KAT

sessions with the same group you are meeting with weekly. These CoPs aim to mirror unconditional positive regard and to cultivate greater resiliency individually and collectively. You will be participating in KAT with your CoP members. The RTT communities of practice have shown improvements in cognitive control and many other personal and social benefits (gaining a sense of belonging in community and ultimately, resiliency).

Please acknowledge your understanding and consent in the statement below.

You will receive ketamine in a group format, with participants who are also part of your community of practice.

- Mirroring unconditional positive regard is a primary principle in the group format. As such, people may come into the program who have a history where they may have acted out in ways that resulted in harm to themselves or others. These acts may be of a physical, emotional, or sexual nature. As a program, we understand that other people's past transgressions may result in trauma being activating in others. We see these events as opportunities, as long as well supported and managed in a safe relational environment. Please reach out to a team member if you need more support or accommodations. We, as a team, are committed to ensuring that all participants can relax into a co-created environment that feels physically, emotionally, and spiritually safe for all. As your team members, we will do our best to minimize and manage any risks. We are in this together!
- All participants are required to keep other's experience and sharing confidential within the group, and to protect group agreements for creating and maintaining a safe and supportive environment.
- Within the group, participants must agree to open sharing: no one will ask another to hold a secret.
- If a group member shares privately with you a concern for their health or wellbeing, this must be reported to a facilitator right away, for everyone's safety, trust and comfort.
- You will remain onsite for the duration of your treatment (4 hours or longer) to enable adequate time to transition home. Prior to leaving, you will participate in a group debrief, have a set of vital signs taken, walk to the bathroom, tidy your space, and when you feel ready, you will be walked to your ride home.

Please initial here that you understand and consent to these statements: _____.

Risks

Ketamine is an FDA-approved drug that we are using "off-label" for ketamine-assisted therapy. It has an extensive record of safety and has been used at much higher doses for surgical anesthesia, without respiratory depression. As with any other medication, there are also some potential risks and side effects to be informed of and to consider.

The most common physical side effect is a short-term rise in blood pressure or heart rate, which may be a risk to those with heart disease and can be misinterpreted as a symptom of anxiety. Other possibilities for side effects include dizziness/light-headedness, sedation, impaired balance, mental confusion, excitability, diminished ability to see things that are actually present, diminished ability to hear or to feel

objects accurately including one's own body, headache, anxiety, nausea, vomiting, and diminished awareness of physical functions such as respiration. These effects are transient and resolve as the active phase of the medication ends (generally within 2-4 hours).

Repeated, high dose, chronic use of ketamine has caused urinary tract symptoms and even permanent bladder dysfunction or cystitis. These adverse effects are much less likely in medically supervised ketamine treatment populations, but might include more frequent, painful, or difficult urination. Please inform your providers immediately if you notice any of these side effects.

In terms of psychological risk, ketamine has been shown to worsen certain psychotic symptoms in people who suffer from schizophrenia or other serious mental disorders. It may also worsen underlying psychological problems in people with severe personality disorders and dissociative disorders.

To mitigate potential risks, the following conditions will make you ineligible to receive Ketamine-assisted Therapy.

- *Hypersensitivity to ketamine,*
- *Presence of active psychotic symptoms,*
- *Diagnosis of dementia/delirium, high risk for coronary artery disease, uncontrolled cardiopulmonary disease/ cardiovascular disease/hypertension, aneurysm, history of intracerebral hemorrhage, hepatic cirrhosis, hepatorenal disease,*
- *Pregnancy*
- *If breastfeeding, must agree to refrain within 11 hours of ketamine administration.*

Additionally, you should plan for a 4-hour time period to be on site during KAT session days. This allows time for a multi-step check in and assessment process. The medical portion of the KAT session will unfold within a 90-minute period. You will then have additional transition time before transitioning home. Lingering side effects are generally not debilitating, but they can cause drowsiness for up to 6 hours.

Benefits

The benefits are described in previous sections of this document. It must be recognized that you may or may not receive any benefit from your participation.

Participation

Your participation is voluntary. You can choose not to participate, or you may withdraw at any time.

Managing Dual Roles

When practitioners investigate their own professional practices for quality improvement or research purposes, and there are patients for which they have a previously established relationship (I.e. as a teacher, colleague, employee, spouse, dependent), it's called a dual role. Dual roles can also exist between team members, between a team member and a patient, or between two patients. While dual roles are not necessary problematic, they do need to be articulated and managed, especially when involving positions of authority (power over) and when patient confidentiality/privacy is a concern. To

manage dual roles, all patients and team members will be asked to disclose dual roles. If such roles exist the team will work with you to determine how best to manage, mitigating any potential risks.

Cost

The RTT-KAT program is based on a cost-recovery model. These costs are regularly assessed based on program needs.

Questions

If you suffer any concerning effects from your treatment or if you have any general questions, please report to the clinician overseeing your care.

Confidentiality

All medical and other personal information and records are collected and used under the authority of the section 26(c) of the B.C. *Freedom of Information and Protection of Privacy Act*, and will be kept confidential to ensure your privacy, as per the *Health Professions Act* and the regulations of each of the professional governing bodies for the attending professionals and applicable law. They will be maintained with the same precautions as all medical records. Your personal information will only be shared with third party health professionals for the purpose of conducting and monitoring your treatment (i.e. sending a discharge note to your referring physician).

Please note, legal and professional ethical responsibilities do require disclosure of confidential personal information in very limited circumstances, such as where you threaten the bodily harm or death of yourself (i.e. suicidality) or others, or you report abuse regarding a child or vulnerable adult. If you have questions or concerns regarding the collection and use of your personal information, please email Shannon Dames at Shannon.dames@viu.ca, who is the Vancouver Island University program lead.

You also have the legal right to access your personal information and, if need be, an opportunity to correct any errors in this information.

The Use of Your Personal Information for Treatment and Research Purposes

To better understand the impact of this program and to continue improving the quality of our program, we will also ask you to complete various mental health and feedback questionnaires at various points in the program. These results will not include personal or otherwise identifiable information. **No** information or record that discloses your identity will be released without your consent unless it is medically necessary or required by law.

To share our learnings from your feedback and your progress in the program, your de-identified data will be pooled with the other participant's data and used for research purposes. We plan to publish the results in a peer-reviewed journal.

Please initial *each* statement, which signifies that you agree with each of the below statements:

___ I understand that my treatment data will be de-identified, and then used for research purposes.

___ I understand all information stated in the above statements regarding confidentiality.

___ I understand that the email address I provide to the program will be used to receive and send communications and health and wellness measures between myself and the team.

___I understand that the facilitators and treatment team will handle any and all personal

information about me in accord with the confidentiality, privacy and ethical standards of his/her

professional association. Within those standards I give permission to share my clinical information with collaborating members of the clinical team as necessary.

Medical Informed Consent:

Please initial each statement, which signifies that you agree with each of the below statements:

___ I have read and understood the verbal and written patient information provided to me. This includes information on how ketamine works, indications for use, contraindications, side effects, dosing, route of administration and how I can prepare for ketamine-assisted therapy sessions.

___ I am aware that ketamine for this protocol is being used "off label," i.e. it has not been approved by Health Canada for this purpose. I have tried other treatments which I have not tolerated or have not been effective and have considered other alternatives prior to ketamine-assisted therapy.

____I am aware of that while research suggests there are potential benefits of this treatment, it is still being studied.

___ I understand the medical risks and benefits, and I freely give my consent to participate in ketamine-assisted therapy as outlined in this form, and under the conditions indicated in it.

___ I have had the opportunity to raise questions and have received satisfactory answers. Before I make my decision about participating in ketamine-assisted therapy, I have the right to ask and will be encouraged to ask any questions I may have about the process.

___ My decision to undertake ketamine assisted therapy is completely voluntary.

___ No oral or written statements have been made to pressure me to undertake ketamine-assisted therapy.

___ I understand that I may withdraw from ketamine-assisted therapy at any time, up until the actual injection has been given.

___ I fully understand that the ketamine-assisted therapy session(s) can result in a profound change in mental state and may result in unusual psychological and physiological effects.

___ I understand that I need to have someone drive me home from the sessions, and not operate heavy machinery or engage in any driving or hazardous activity for at least 6 hours or more, depending on the continued presence of effects after my session has concluded. The ketamine-assisted therapy team may

release me to alternative forms of transportation (i.e. Local Transit or Taxi) based on their assessment of my condition after the session has concluded.

___ I understand that I am to have no food or drink 4 hours prior to my ketamine-assisted therapy session.

___ I understand that if I show up intoxicated or under the influence of other substances, I will not be able to undertake ketamine-assisted therapy.

___ I understand that I may be offered lorazepam if deemed necessary for anxiety, ondansetron for nausea, and captopril or clonidine for high blood pressure.

___ I understand that I can keep a copy of this RTT-KAT Consent form (please prompt the team for a signed version if you do not receive).

By signing this Consent, you indicate that you understand the information provided and that you give your consent to participate in ketamine-assisted therapy and the collection of your personal data and program improvement suggestions. In addition, you have had the opportunity to discuss our therapeutic methods and medical procedures and your questions have been answered to your satisfaction. By signing below, you are consenting to take part in this treatment with the understanding that you may withdraw at any time without affecting the availability of continued medical care (outside of this therapy). Upon request, you will be provided with a signed copy of this consent form.

_____

Printed Name of Patient **Signature** **Date**

I confirm that I have explained the nature and purpose of the treatment to the individual named above. I have answered all questions.

_____

Printed Name of Physician **Signature** **Date**