SUBJECT INFORMATION AND CONSENT FORM AND HIPAA AUTHORIZATION

Study Title: An Open-Label Proof-of-Principle Study Testing the Use of an Additional MDMA-Assisted Psychotherapy Session in People who Relapsed after Participating in a Phase 2 Clinical Trial of MDMA-Assisted Psychotherapy to Treat Chronic, Treatment-Resistant Posttraumatic Stress Disorder (PTSD)

Protocol #: MP1-E2

Study Sponsor: Multidisciplinary Association for Psychedelic Studies (MAPS)
309 Cedar Street, #2323
Santa Cruz, CA 95060

Principal Investigator Name: [redacted]

Research Site Address(es): [redacted]

Daytime telephone number(s): [redacted]

24-hour contact number(s): [redacted]

Cellular number: [redacted]

PURPOSE OF THE SUBJECT INFORMATION AND CONSENT FORM

This consent form describes a research study and your role as a subject. Please read this form carefully before you decide to take part in this study. You may ask the study therapists anything about the information provided. You are being asked to participate in this research study because you have been diagnosed with posttraumatic stress disorder (PTSD), and because your symptoms have relapsed after initial improvement you experienced during participating in a study testing the use of MDMA-assisted psychotherapy for people with chronic, treatment-resistant PTSD.

Please ask the study therapists to explain any words or information in this consent that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

PURPOSE AND BACKGROUND

This exploratory ("proof-of-principle") study is designed to provide information on whether an additional session of psychotherapy ("talk therapy") combined with the drug MDMA (methylenedioxymethamphetamine) is safe and helpful for people with posttraumatic stress disorder (PTSD) whose symptoms had improved after receiving MDMA-assisted therapy sessions, but relapsed over time. The researchers plan to use the results of this study to design further studies.

MDMA is an experimental drug, which means that it has not been approved by the United States Food and Drug Administration (FDA) for medical use except in research studies. MDMA is also a controlled drug (illegal to use outside of research) and is sometimes known as "Ecstasy" (which is supposed to contain MDMA but often contains other drugs instead of or in addition to MDMA). MDMA has already been used legally in research and illegally in uncontrolled environments, such as nightclubs. While much is known about MDMA and its risks, a lot still remains unknown about this drug.

The study is sponsored by a U.S.-based non-profit organization, the Multidisciplinary Association for Psychedelic Studies (MAPS, www.maps.org). You have participated in MAPS' first small study of MDMA-assisted psychotherapy in people with PTSD. MAPS has other MDMA/PTSD pilot studies underway in the U.S. and Switzerland and is planning new studies in Israel, Canada and Jordan.

Before it became illegal in 1985, some psychologists and psychiatrists combined MDMA with psychotherapy to help people with psychological problems, including PTSD. Though we do not know why it may help people with PTSD, we know that MDMA increases positive mood and changes the way we see and think about the world around us, making it easier to think about and recall things that happened to us that are upsetting. People say they feel caring and forgiving toward themselves and others during the MDMA experience. It is possible that these drug effects, when combined with psychotherapy, help people work through thoughts, memories and emotions related to PTSD.

This study will investigate whether an additional MDMA-assisted psychotherapy session with a full dose of MDMA, 125 mg, possibly followed by a second dose half the size of the first dose, can help with relapsed PTSD symptoms.

LENGTH OF STUDY

This study will take about 12.5 months after enrollment.

TYPE OF STUDY

This is an open-label study, meaning that both you and the study therapists will know that you have received MDMA and the dose of MDMA that you got. There will be up to three subjects in this study.

STUDY PROCEDURES/WHAT WILL HAPPEN TO YOU

SCREENING/EVALUATION AND BEGINNING OF STUDY

If you agree to take part in this study, you will first sign this Subject Information and Consent Form before any study-related procedures are performed. Before you can be in the study, the study therapists must first make sure that you qualify for the study and that you are generally physically healthy. The screening process will take approximately 1-1.5 hours. The study therapists will request to review your medical records and may ask your permission to contact your treating doctor or psychotherapist to get additional information about your medical history if necessary. They will need to do this so that they will know if you can participate in the study or not.

You will also need to complete the following:

- Two questionnaires about your PTSD symptoms and how you deal with them in your everyday life.
- Discussion with the study doctor about any changes that may have happened in your medical or psychiatric condition since your participation in the MP-1 study. The study doctor will rate how well you are doing in general.
- A questionnaire about feelings of depression or other symptoms or feelings you might experience.
- A questionnaire about thoughts or feelings you might have about hurting or killing yourself.
- A questionnaire about your quality of life.
- A urine test for drugs of abuse. Your urine drug screen must be negative to take part in the study.
- A urine pregnancy test if you are a woman and are able to get pregnant. Your urine pregnancy test must be negative for you to take part in the study.

Y**ou may need to have extra medical tests done to make sure you can be in the study.**
People who control their high blood pressure with medications may have to see a cardiologist (heart doctor) for more tests, and people with a liver disease called hepatitis C may have to visit a liver specialist. If you have hepatitis C, you will have to complete the treatment that the liver specialist or your doctor prescribes.

PREPARATORY SESSION

- You will have a preparatory psychotherapy session with the study therapists. During the session, you will talk about the traumatic incidents that led to your PTSD, how your PTSD symptoms have changed since your participation in MP-1 study, the ways PTSD symptoms are affecting your life, and what you would like to achieve during this study. This session will be recorded to audio and video, and you may request copies of these recordings. You will be asked questions about thoughts or feelings you might have about hurting or killing yourself.
- You will be introduced to the attendant who will remain with you during the overnight stay after the MDMA-assisted psychotherapy session.
- If you would like another individual present during or after the experimental session, a meeting between the study therapists and that individual will be scheduled prior to the experimental session. There must be mutual agreement between the subject and the study therapists concerning the presence of this support individual.
- You will be given the Subject Information Sheet, which includes instructions and restrictions for conduct 24 hours prior to the experimental session.

BEGINNING OF STUDY

If you were taking any psychiatric medicines before the study, including stimulants, you will have to gradually stop taking them. The study doctor (who is one of the two therapists), in consultation with your prescribing physician, will help you do this if necessary.

You will have to give the study therapists the name and contact information (such as home phone number, cell phone number or email) of a spouse, relative or close friend to contact in case of medical emergency; for example, when you might be at risk of hurting yourself or someone else, so they can reach that person to let them know what is going on.

SCHEDULE OF EVENTS

Below is the schedule of events from the screening until the final study visit, which is 12 months after the MDMA-assisted psychotherapy session.

	Screening	Preparation	MDMA and Non-Drug Therapy Sessions				2 Month Follow-up	12 Month Follow-up
Study Visit #		1	2	3	4	5	6	7
Screening	X							
Assessment of PTSD symptoms	X						X	X
Psychotherapy		X		X	X	X		
Psychotherapy With MDMA			X					

EXPERIMENTAL SESSION

There will be one day-long experimental session when you will receive MDMA (125 mg, possibly followed by 62.5 mg) and psychotherapy. The experimental session will occur after you enroll in the study.

One week before the experimental session you will need to avoid taking:

- any herbal supplements, except with prior permission from the study doctor;
- any nonprescription medications, unless you have permission from the study doctor (with the exception of non-steroidal anti-inflammatory drugs or acetaminophen [Tylenol]);
- any prescription medications, with the exception of birth control pills, thyroid hormones or other medications approved by the study doctor.

You must not eat or drink any alcohol after midnight on the night before the MDMA session, though you can drink non-alcoholic liquids during this time, such as water or juice. You cannot use any psychoactive drugs, with the exception of caffeine or nicotine, within 24 hours of the MDMA session. You cannot use nicotine or caffeine for two hours before and six hours after a dose of MDMA.

First, you and the study therapists will discuss your goals for the experimental session, and the study therapists will answer any questions you may have.

Immediately before the experimental session:

- Your urine will be tested for drugs of abuse, including stimulants, sedatives, opiates and cannabis.
- If you are a woman who can become pregnant, you will take a urine pregnancy test.

Throughout the experimental session:

- Your blood pressure and pulse will be measured periodically (every 30 minutes).
- Your temperature will be measured every 60 to 90 minutes.
- You will also complete a very brief, simple test of how comfortable or distressed you feel at that moment. You will complete it every 60 to 90 minutes throughout the experimental session.
- About an hour before receiving the drug and about six hours afterward, you will complete the questionnaire about thoughts you may have about hurting or killing yourself.
- The study therapists will check in on you every hour or so to see how you are doing.

The experimental session will be recorded to audio and video, so that the study therapists can have accurate records of the session and so that they can gather more information about drug-assisted psychotherapy sessions. The study therapists can give you copies of these recordings if you want.

After test results come back and if they are negative, you will receive a capsule containing 125 mg of MDMA. After taking the capsule, you will relax in an environment that is meant to bring out thoughts and feelings, including thoughts and feelings about the trauma. Both study therapists will remain with you, and they will help you if you need them to do so. There will be beverages available including water, juices and Gatorade or similar sports drinks, and you will be encouraged to drink an adequate amount of fluid. You can drink it whenever you wish to do so, within the limits of the amount that is safe for your body. Later on, food will also be provided.

Approximately one and a half to two and a half hours after you took the first capsule, you may receive the second dose of MDMA, unless the study doctor notices any problems after the first dose. The second dose will contain half the amount MDMA of the first dose.

The study therapists will measure your blood pressure, pulse and temperature, and will watch for any unwanted effects or health problems. If any do occur, they will be treated, and the study therapists will explain to you what they are going to do.

The therapists will stay with you until you have fully recovered. If the therapists think you are at risk of hurting yourself or others, they will either remain with you all night or have you admitted to a hospital until you are no longer at risk of hurting yourself or others. The therapists will ask

you about thoughts of killing or harming yourself before and after MDMA administration. You will also be asked to complete a questionnaire about what you experienced during the experimental session. You can complete this questionnaire at any time between the end of the experimental session and the time you leave the study site the next day.

If you request and the study therapists agree to it, you can have a person of your choice stay with you during some or all of the experimental session, starting at an agreed-upon time, or when you stay at the office of the study therapists after the session. When he or she arrives, this person will stay in the waiting room until he/she is brought into the session by one of the study therapists.

You will be spending the night in a room in the offices of [redacted] with an attendant who will be staying in another room nearby. If you need to talk with the therapists or are having any problems and need to contact the therapists, the attendant will contact them immediately.

On the next day, you will have a regular (non-drug) therapy session with the study therapists. You will need to have someone drive you to wherever you are staying (home, hotel or another location) from the non-drug therapy session on that day because we do not know how MDMA will affect your ability to drive, and because some people report feeling tired, less alert or having trouble concentrating the day after having taken MDMA. If you cannot find anyone to take you home, the study therapists will find someone to drive you.

Starting on the day you return from the non-drug therapy session, the therapists will telephone you every day for a week to inquire about how you are feeling and determine whether you should see them before your next visit. On the second and the seventh day of the phone contact, the therapists will ask you about thoughts or feelings you might have of killing or harming yourself. These telephone calls will take approximately 5 to 15 minutes, though they can be as long as you need them to be. You may schedule additional meetings or telephone calls with the study therapists besides those that are scheduled as part of the study. You can contact the study therapists at any time yourself, and they will be reachable by telephone 24 hours a day throughout the study, except on occasions when they are out of town. At those times, another psychiatrist familiar with the study will be on call and can be reached by his/her phone number, which will be given to you as well.

You will be given a card with telephone numbers for reaching [redacted] and the Copernicus Group Independent Review Board (IRB) that reviews the study. You can keep this card in your wallet to make it easier for you to make these contacts if you need to do so.

If you were taking any psychiatric medications before the start of the study, you can resume taking them 10 days after the MDMA session. However, you cannot start any new medications until two months after the experimental session. You agree to contact the study doctor if any of the following things happen: you have an increase in symptoms for which you previously took medicines, you need to contact your outside therapist other than for the usual appointments, and/or you start taking the prescribed psychiatric medicines earlier than 10 days after the MDMA session. You should also contact the study doctor if you have a strong and lasting negative reaction (unwanted effect or health problem) after the experimental session.

PSYCHOTHERAPY AFTER THE EXPERIMENTAL SESSION

You will have three regular (non-drug) psychotherapy sessions to help you express, understand, bring together and connect any thoughts or feelings you may be having about your symptoms and their causes and to think and talk about your experiences during the experimental session. You will have psychotherapy with the study therapists on the morning after the experimental session, followed by two more psychotherapy sessions. These visits will last 60 to 90 minutes. You and the study therapists will also discuss how to use what you learned to help you work on your PTSD, how to face and solve difficulties you may have faced during the experimental session, and how to gain maximum benefit and understanding from the experimental session. The study therapists will also ask you about thoughts of killing or harming yourself during each session. Each regular psychotherapy session will be recorded to audio and video, and you can ask for a copy of these recordings.

FOLLOW-UP 2 MONTHS AFTER THE EXPERIMENTAL SESSION

During this visit, you will meet with the study therapists and a study researcher who is not one of the study therapists. The study researcher will ask you questions about your PTSD symptoms. You will also complete one more PTSD questionnaire, a questionnaire on feelings of depression or other symptoms you might have, and a questionnaire on your quality of life. The study therapists will ask if you had any thoughts about hurting or killing yourself during that time and assess your general wellbeing. The tests will help the study therapists tell if your symptoms have changed or stayed the same over time. This visit should last up to two hours.

At the end of the visit, the therapists will give you a memory aid card. This card is to help you to remember any problems related to your mental health that can occur between this visit and your last visit, 12 months after the MDMA session. On this card you will record any new important mental health problems, hospitalizations related to you mental health problems and medications used to treat these problems. You will be asked about these problems during your last visit.

LONG-TERM FOLLOW-UP 12 MONTHS AFTER THE EXPERIMENTAL SESSION

This visit will take place either in person or over the telephone approximately 12 months after the MDMA-assisted psychotherapy session. The same study researcher who asked you about your PTSD symptoms at 2 month follow-up will do so again.

The study therapists will ask if you had any thoughts about hurting or killing yourself during the time since the previous visit and assess your general wellbeing. The therapists will ask you about any changes in medications or your psychiatric health, including any benefits or harms, during the follow-up period between your previous visit and the 12-month follow-up visit.

You will complete another PTSD questionnaire, a questionnaire about feelings of depression you may have and a questionnaire about your quality of life. You will also complete a questionnaire containing questions about the good and bad points of MDMA-assisted therapy, and any medications or therapy you needed since the last visit. There are no right or wrong answers to these questions. All these questionnaires will be mailed to you for you to fill out. They will come with an envelope that is already stamped and has only the researchers' address on it. Do not put your name on the questionnaire.

The researchers will use your answers to these questionnaires to see if there are any long-lasting effects on your PTSD symptoms or other life events from participating in this research study, and, specifically, if your PTSD symptoms have improved after receiving an additional MDMA-assisted psychotherapy session.

POSSIBLE RISKS OR DISCOMFORTS

MDMA has not been widely tested in humans, but as of 2011 approximately 540 people have received MDMA in clinical research settings without any serious problems happening.

There may be unknown side effects or risks from the use of MDMA. Possible known risks of MDMA include the following:

***Serious problems*:** There have been some serious problems, and even deaths, associated with the use of Ecstasy outside of controlled clinical or laboratory settings. These problems include high fever, brain swelling associated with drinking too much liquid, convulsions, and liver damage. Some recreational users of Ecstasy became severely anxious, depressed or paranoid (thinking that other people are out to get them). Since you will be receiving moderate amounts of uncontaminated MDMA in a controlled setting with trained therapists who will be closely monitoring your physical and psychological reactions, these problems are not expected to occur either during or after the experimental session. While this does not guarantee that they will not occur, it does mean that if they do occur, the study therapists are prepared to respond to these in a safe and professional manner.

***Changes in vision, hearing or other senses*:** In previous studies in which MDMA was given to volunteers (including a total of about 494 healthy people without emotional disorders and 46 with PTSD), most subjects reported experiencing temporary and minor changes in vision and hearing, such as sounds seeming closer or farther away than usual or objects seeming brighter than usual. These changes typically lasted 2 to 3 hours. Between 12% and 33% of people who took MDMA reported unusual feelings in their bodies, such as tingling or numbness.

***Blood pressure and heart rate*:** The effects of MDMA usually last 4 to 6 hours. With the dose used in this study, the increases in blood pressure and heart rate are likely to be moderate. Average increase in systolic blood pressure is 35 mmHg (measurement unit for blood pressure) and average diastolic blood pressure increase is 20 mmHg. Heart rate may increase by approximately 30 beats per minute (BPM).

In previous studies, blood pressure rose well above normal levels in a few subjects (a little less than 5% of subjects) after receiving MDMA, but these subjects did not report any discomfort and did not require any treatment. Although these increases in blood pressure are similar to what happens after heavy exercise, they could cause serious problems in individuals with pre-existing heart or vessel conditions. These serious problems could include heart attack or stroke. We will screen all potential subjects for preexisting heart problems before they are allowed to be in this study. While this does not guarantee that no heart problems will occur, it does reduce the risk of this happening.

Do not participate if you know you have pre-existing heart or blood vessel problems.

***Anxious or jittery feeling*:** Some subjects in previous studies (16%) reported feeling over-stimulated or anxious during the MDMA session. These feelings usually lasted less than 30 minutes. Letting yourself accept and feel these emotions deeply can be part of the psychotherapy. If you are not able to deal with these experiences in a way that helps you, the study therapists will work with you to deal with these feelings. It is possible that if such periods of heightened emotion do not clear up or grow weaker during the session, you could be at increased risk for suicide or other self-harm afterwards. You will be encouraged to ask the attendant, who will be staying with you after the experimental session, to call the study therapists immediately if you have any thoughts about hurting or killing yourself so they can help you resolve them safely. If necessary, they may prescribe an anti-anxiety medication or medication for sleep. If you are in immediate danger of hurting or killing yourself or hurting someone else, then the study doctor may require you to be admitted to a hospital.

***Insomnia & drowsiness*:** In previous studies, between 17% and 23% of subjects have reported insomnia (difficulty sleeping) or feeling tired, irritable, or drowsy for as long as 3 days after receiving MDMA. If you have difficulty sleeping, the study doctor may prescribe you a medication for sleep.

***Mood*:** Some after-effects of MDMA may be noticeable up to 2 or 3 days later. While some subjects felt that their mood was better during this period; other subjects (about 14%) felt that it was worse.

***Immune System*:** You may have a less active immune system for 2 or 3 days after receiving MDMA. This may make you more likely to become sick with a cold or other infection during this time. The study describing this finding did not report how many people in the study showed these changes.

***Addiction*:** There is a small chance that you will become dependent on (addicted to) MDMA. One study found that up to 6% of people using Ecstasy for recreational purposes were dependent on it. However, a study of people who received MDMA for the first time in a legal laboratory setting found that they did not want to try MDMA again outside of the laboratory.

People who have recently (in the last 6 months) had problems with drug abuse should not take part in this study.

Possible Brain Damage: Experiments in rats and monkeys show that high and repeated doses of MDMA can change certain brain cells that release a chemical called serotonin; in mice (though not in humans), the affected cells release dopamine. The changes include loss of the parts of the cells (called "axons") that connect different brain areas. Rodents given repeated, high doses of MDMA are less sensitive to a later dose of MDMA, are more likely to become overheated when placed in a warm room, and some studies found that they performed worse in difficult memory tests. Recent studies in monkeys and rodents suggest that the doses used in these studies are far higher than those typically taken by humans in either recreational or laboratory settings.

Many studies found that people who had used Ecstasy (which may or may not contain MDMA) many times in recreational contexts were not able to recall words, pictures or patterns as well as people who did not use Ecstasy, and performed less well on tests of planning and impulse control. These differences are not great, but they lasted for at least a year after people had

stopped taking Ecstasy. Not all studies have found Ecstasy users to have difficulty recalling words or pictures or to have impulse control problems. Studies comparing people before and after they had taken a few tablets of Ecstasy in a recreational setting with people who did not take them found less improvement in memory when tested about 18 months after they were tested the first time in the people who took Ecstasy, and no other changes in thinking or planning. When compared with people who do not use Ecstasy, studies found Ecstasy users were more likely to report feeling generally anxious or depressed. Many of these studies found that using alcohol or other drugs was also associated with feeling anxious or depressed. At least two studies found that people who are anxious, depressed or have psychological problems before taking any drugs are more likely to take Ecstasy than people without these problems, but there is no proof that MDMA might not cause these problems in some people. Studies of people receiving one or two doses of MDMA in a laboratory setting have not found any lasting changes in memory or planning. It is believed that the amount of MDMA you will receive will not produce any lasting changes in memory or planning, though this cannot be guaranteed.

Only one study has looked at brain scans of people before they got MDMA and then again after they have received one or two moderate doses of MDMA. This study did not show any changes in the brain following MDMA, though it is possible that there were changes that were too small to notice. Other studies looked at people before and after they had taken a few tablets of Ecstasy in a recreational setting, and found one small change in the amount of blood flow in a specific part of the brain, but did not show signs of brain injury. The decrease in blood volume might be from a temporary decrease in a type of brain receptor or it might be a sign of reduced function in this area. Findings from these studies suggest that the amount of MDMA you will receive in this study will not produce any lasting changes in your brain, though this is not guaranteed.

Other Risks:

You should not drive or use machinery after the experimental session (up to 24 hours afterwards). This is because the study drug may cause drowsiness, lack of co-ordination or slower reaction time.

If you are tested for drugs of abuse within three days of the experimental session, you may test positive. The study doctor will provide you with an information card in case you are tested for drugs of abuse, and if you are tested for drugs of abuse while you are in this study, you can have the person(s) testing you call the study doctor to verify that you are in this study.

The interviews you have during the study involve no specific risks or discomforts beyond those of a standard clinical interview situation. You may feel upset at the review of your emotional experiences, or you may feel boredom or fatigue. Answering questions about thoughts you might have of hurting or killing yourself may be upsetting.

It is possible that after you stop taking psychiatric medicine (as for depression or anxiety) as part of the study, you may start to have symptoms again. If this happens, you should talk with your outside therapist and [redacted]. If you have to start taking these medicines again before or within 10 days after the MDMA session, then the study doctor will have to take you out of the study.

REPRODUCTIVE RISKS

Effects of MDMA on the growth and development of an unborn baby are not known. Birth defects could include physical deformities, mental retardation and premature birth; therefore, you will not be allowed to enter the study if you are pregnant. If you incidentally become pregnant after you have had the experimental session, the study doctor and the Sponsor (MAPS) will ask you about and keep track of your pregnancy and will need to know about the outcome of the pregnancy.

Women who are able to become pregnant must use one of the allowed birth control methods, such as birth-control pills or shots, intrauterine devices (IUDs), or diaphragms used along with spermicide and with partner using condoms, or sexual abstinence during the first 2 months of the study. The study doctor will explain these methods to you and will help you decide which might be best for you, and they can suggest to you where you can get more information and advice about it.

If you are a woman of childbearing potential, you will be tested at the start of the study, and again before the MDMA session, to see if you are pregnant. If, at any time during the study, you think that you may be pregnant or are worried that you may become pregnant, you must inform [redacted] immediately. If you should become pregnant during the study, the study doctor will help you get proper advice and help you and your unborn baby get proper care while you are pregnant.

NEW FINDINGS

If any new information becomes available about MDMA while you are taking part in this study, the study therapists will tell you about it as soon as possible. You may contact the study doctor at any time after your participation ends to find out if any new information about this study has become available.

POSSIBLE BENEFITS

Your symptoms of PTSD may improve while participating in this study. There is no guarantee that you will benefit from taking part in this research study. However, information obtained from this study may help doctors and researchers to improve treatment for PTSD in future.

COSTS

The Sponsor of this study, Multidisciplinary Association for Psychedelic Studies (MAPS), will cover the costs that are directly related to this study. This includes the costs for all psychotherapy sessions that are a part of this study, for the psychological and laboratory testing, including any extra tests you might need to do solely to see if you can be in the study, and for the study drug. You, your private medical insurance (if any) or the public health insurance plan (if any) will not be charged for any procedures done solely for the purpose of the study. You or your insurance company will remain responsible for on-going treatment unrelated to the study.

PAYMENT FOR PARTICIPATION

The Sponsor, MAPS, will reimburse you for travel-related expenses as follows:

Subjects who drive to the study site:

If you must drive more than 50 miles round trip for visits, you will be reimbursed at a rate of $0.25 per mile. If you live far enough away that it is not practical or desirable to make the round trip in one day, MAPS will pay up to $150.00 a night for all motel bills and up to $50.00 per day for meals in advance.

Subjects who fly to the study site:
MAPS will pay for all travel expenses in advance. MAPS will pay up to $150.00 a night for all motel bills and up to $50.00 per day for meals.

If you must pay for parking, MAPS will pay for the costs of parking.

ALTERNATIVES

One alternative to being in this study is to decide not to participate. You may decide to try other treatments for PTSD. There are antidepressants, such as Paxil (paroxetine) or Zoloft (sertraline) and anti-anxiety medications such as Xanax (alprazolam) and other forms of psychotherapy that you can try. If you are currently having psychotherapy and/or taking medicines, you could continue with those for a longer period of time. The study doctor can discuss the alternatives and their potential risks and benefits with you.

CONFIDENTIALITY

To ensure confidentiality, only your subject number and initials will be provided to the study Sponsor. When not in use, your information will be stored in a locked office. Absolute confidentiality cannot be guaranteed.

Some people need access to the information to monitor the study. Medical records, including audiotapes and videotapes, which identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes. Before that any information that could directly identify you will be removed. Medical records may be looked at by:

- the Sponsor (MAPS);
- the FDA;
- the Department of Health and Human Services (DHHS) agencies; and/or
- the Copernicus Group Independent Review Board (IRB).

The results of this research study may be presented in meetings or in publications. Your identity will not be disclosed there.

All records in [redacted] are subject to subpoena by a court of law.

Audiotapes and videotapes: The study therapists will listen to or watch these recordings, as well as MAPS staff and other researchers seeking to better understand the principles of MDMA-assisted psychotherapy. No identifying information will be written on or otherwise attached to the tape recordings. You may listen to or watch these recordings if you wish, but you do not have to. You will not automatically receive a copy of the recordings, but if you request, you will get it.

You have the right to check your study records and ask for changes if the information is not correct.

By signing this Subject Information and Consent Form, you consent to the collection, access, use and disclosure of your information as described above.

TREATMENT AND COMPENSATION FOR INJURY

In the event of a study-related injury, the physician who treats you will bill your insurance company. If your insurance company denies coverage or if the insurance is not available, then MAPS will pay for any costs that arise from treating a study-related injury, including hospitalization. Neither the Sponsor nor the study doctor has a program in place to provide additional compensation in the event of an injury.

Your health insurance may not be willing to pay for the costs of treating a study-related emergency. The study Sponsor (MAPS) will pay for any study-related procedure that your insurance will not cover.

LEGAL RIGHTS

The above section does not restrict your right to seek legal assistance. You do not waive any legal rights by signing this Subject Information and Consent Form.

VOLUNTARY PARTICIPATION

Your decision to take part in this research study is completely voluntary. There will not be any penalty or loss of benefits to you if you decide not to take part.

In addition, you may withdraw from (leave, stop being in) the study at any time for any reason. There will be no penalty if you decide to withdraw from the research study. Before withdrawing from this study, notify your study doctor that you wish to withdraw. This notice will allow your study doctor to inform you if there are any potential medical risks of withdrawal. You may be asked to complete some final questionnaires. If you decide you do not want to continue in the study during the experimental session, you will still have to stay in the office until the study doctor thinks that you are well enough to leave and that all the effects of the drug have worn off.

WITHDRAWAL

Your study doctor, the sponsor company, or the FDA have the right to stop your participation in the study at any time, with or without your consent, for any of the following reasons: if you have an adverse effect from the study drug; if you need a treatment not allowed in this study or for a part of the study duration, such as restarting medication for depression or anxiety; if you do not keep appointments; if you do not take the study drug as instructed; if you become pregnant; or if the study is canceled by the FDA or the sponsor company. If the study doctor decides to take you out of the study, he will let you know that he is doing this and the reason for doing this. If you are taken out of the study, you may be asked you to complete some final questionnaires.

QUESTIONS

If you have any questions about this study, its procedures, risks, benefits or your alternatives or rights, or if at any time you feel you have experienced a research-related injury, please contact the study doctor:

Principal Investigator Name: [redacted]

Daytime telephone number(s): [redacted]

24-hour contact number(s): [redacted]

Cellular number: [redacted]

If you have any questions or concerns about your rights as a research subject or want to discuss a problem, get information or offer input, you may contact Copernicus Group Independent Review Board (IRB) at 1-888-303-2224 (toll free). An IRB is a group of scientific and non-scientific individuals who perform the initial and ongoing ethical review of the research study with the study subject's rights and welfare in mind. Copernicus Group IRB has reviewed and approved the research study described in this Subject Information and Consent Form. If you have study-related comments, complaints or concerns, you should first contact the study investigator. Please call the IRB if you want to talk to someone other than the study investigator or have difficulty reaching the study investigator. For further information regarding the clinical trials process and your role as a research subject, you may visit the Copernicus Group IRB website at www.cgirb.com.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

SUBJECT'S STATEMENT OF CONSENT

"An Open-Label Proof-of-Principle Study Testing the Use of an Additional MDMA-Assisted Psychotherapy Session in People who Relapsed after Participating in a Phase 2 Clinical Trial of MDMA-Assisted Psychotherapy to Treat Chronic, Treatment-Resistant Posttraumatic Stress Disorder (PTSD)"

My participation in this study is voluntary. I may refuse to take part in or I may stop taking part in this study at any time. I will contact the study doctor if I decide to do this. My decision will not affect my current or future regular medical care or any benefits to which I am entitled at this site. The study doctor and/or the Sponsor may stop my participation in this study at any time without my consent if he decides it is in my best interest or if I do not follow the study doctor's instructions.

I agree to have my sessions audio- and videotaped during this study.

I have read the information in this consent form and it has been discussed with me. I have been given sufficient opportunity to consider whether to participate in this study. All of my questions so far about the study and my participation in it have been answered. I freely consent to participate in this research study.

By signing this consent form, I have not waived any of the legal rights which I otherwise would have as a subject in a research study. I have been told that I will be given a copy of this consent form signed by me and the investigator.

	SUBJECT	**INVESTIGATOR:** I certify that the information provided was given in a language that was understandable to the subject.
Printed Name		
Signature		
Date		

HIPAA AUTHORIZATION

The United States government has issued a privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your personal health information. The document you are reading, called an "Authorization", describes your rights and explains how your health information will be used and disclosed (shared).

In working with the Sponsor, the study doctor, [redacted], will use and share personal health information about you. This is information about your health that also includes your name, address, telephone number or other facts that could identify the health information as yours. This includes information in your medical records and information created or collected during the study. This information may include your medical history and laboratory test results. Some of these tests may have been done as part of your regular care. The study doctor will use this information about you to complete this research.

In most cases, the study doctor will use your initials and assign a code number to your information that is shared with the Sponsor. The Sponsor and its representatives may review or copy your personal health information at the study site. Regulatory authorities and the Copernicus Group Independent Review Board may also review or copy your information to make sure that the study is done properly or for other purposes required by law.

By signing this Authorization, you allow the study doctor to use your personal health information to carry out and evaluate this study. You also allow the study doctor to share your personal health information with:

- the Sponsor and its representatives
- the Copernicus Group Independent Review Board
- the U.S. Food and Drug Administration (FDA)
- other regulatory agencies

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, these groups are committed to keeping your personal health information confidential.

You have the right to see and get a copy of your records related to the study for as long as the study doctor has this information. However, by signing this Authorization, you agree that you might not be able to review or receive some of your records related to the study until after the study has been completed.

You may choose to withdraw this Authorization at any time, but you must notify the study doctor in writing. Send your written withdrawal notice to:

[redacted]

If you withdraw from the study and withdraw your Authorization, no new information will be collected for the study purposes unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed. All information that has already been collected for the study purposes, and any new information about the adverse event related to the study, will be sent to the study Sponsor.

If you withdraw from the study but do not withdraw your Authorization, new personal health information may be collected until this study ends.

This Authorization does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. Your study doctor will keep this Authorization for at least 6 years.

If you do not sign this Authorization, you cannot participate in this research study or receive the study drug. If you withdraw this Authorization in the future, you will no longer be able to participate in this study. Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

AUTHORIZATION

I authorize the release of my medical records and personal health information related to this study to the Sponsor and its representatives, the Copernicus Group Independent Review Board, the FDA, and other regulatory agencies as described above. I have been told that I will receive a signed and dated copy of this Authorization for my records.

	SUBJECT	**INVESTIGATOR**
Printed Name		
Signature		
Date		