[redacted]

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

Anyone asked to take part as a subject in a medical research study or asked to agree on behalf of someone else, has the right to understand the following:

1. What the study is about and why it is being done.

2. What you will have to do if you take part in the research study and what treatments, drugs or medical devices, if any, will be used.

3. Any pain or discomfort you may expect to feel and what risks you might run, if any, from taking part in the research study.

4. What benefit to your health, if any, you might get from taking part in the research study.

5. Other non-research treatments, drugs or medical devices that may be available to treat your illness and a comparison of the risks and benefits of these other treatments with the one you are being asked to agree to receive.

6. What medical treatment, if any, will be available to you after the research study, if medical complications arise as a result of the study.

7. You will be given a chance to ask questions about the research study, until you are satisfied that you understand what is involved. You should expect your questions to be answered clearly, fully and honestly.

8. If you agree to take part in the research study, you can later change your mind at any time without being penalized. Leaving the study will not affect your usual medical care.

9. You will not be pressured, forced, misled, given wrong facts, bribed or unfairly influenced to get you to agree to take part in the experiment.

10. You will be given a copy of any consent form you sign for the research study.

SUBJECT INFORMATION AND CONSENT FORM AND HIPAA AUTHORIZATION

Study Title: A Randomized, Double-Blind, Placebo-Controlled Phase 2 Pilot Study of MDMA-Assisted Psychotherapy for Anxiety Associated with a Life-Threatening Illness

Protocol #: MDA-1

Study Sponsor: Multidisciplinary Association for Psychedelic Studies (MAPS)
1115 Mission St.
Santa Cruz, CA 95060

Clinical Investigator Name: [redacted]

Research Site Address(es): [redacted]

Daytime Telephone Number(s): [redacted]

24-hour Contact Number(s): [redacted]

Why am I invited to take part in this research study?
You are being asked to participate in this research study because you have been diagnosed with a life-threatening cancer or neurological illness and because you are experiencing significant anxiety as a result of that illness.

What should I know about a research study?
- Someone will explain this research study to you.
- Research studies only include people who choose to take part.
- Whether or not you take part is up to you.
- You can choose not to take part in the research study.
- You can agree to take part now and later change your mind.
- Whatever you decide will not be held against you.
- Feel free to ask all the questions you want before you decide.

Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have questions, you can ask your study doctor to explain the study more.

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 any time.

Why is this study being done?
This small study is designed to provide information on whether MDMA-assisted psychotherapy is safe and helpful for subjects with anxiety related to a life-threatening cancer or neurological illness. We plan to use the results of this study to design future studies of MDMA-assisted psychotherapy.

The study is sponsored by a U.S.-based non-profit organization, the Multidisciplinary Association for Psychedelic Studies (MAPS, www.maps.org). MAPS has completed two previous studies of MDMA-assisted psychotherapy for a different condition – post-traumatic stress disorder (PTSD) – and is currently conducting several more studies for this condition. MAPS is also conducting studies of MDMA-assisted psychotherapy for social anxiety in people with autism.

MDMA is a chemical that is structurally similar to some stimulant chemicals, like methamphetamine, which is both a major drug of abuse and an FDA-approved treatment for Attention Deficit Disorder, and to some psychedelic (hallucinogenic) chemicals, like mescaline, which is found in peyote cactus. MDMA causes the release of serotonin, dopamine, and norepinephrine in the brain, and the hormones oxytocin and prolactin. The effects most people experience from MDMA are mostly due to serotonin release, and somewhat due to norepinephrine and dopamine release. The release of these chemicals in the brain can change people's emotions and feelings. It has some stimulant-like effects such as raising your heart rate or body temperature or making you feel more energetic. It also has some perceptual effects, like changing how you see yourself or how you see the world. MDMA's effects last between 4-6 hours in most healthy adults.

MDMA is experimental, which means it has not been approved by the FDA for medical use, except within research studies like this one. MDMA is illegal to use outside of research and is sometimes known as "Ecstasy" (which is supposed to contain MDMA, but can often contain other drugs instead of or in addition to MDMA).

MDMA operates differently from currently approved anti-anxiety drugs, in that it is not sedating and does not need to be taken daily. Before it became illegal, some psychotherapists combined MDMA with psychotherapy (“talk therapy”) to help people with psychological problems, sometimes including anxiety related to life-threatening illness and there are narrative reports of people being helped in this way. No studies have yet been conducted to evaluate whether MDMA-assisted psychotherapy can help people with this kind of anxiety. We know that MDMA increases positive mood and also changes the way we see and think about the world around us. This may make it easier to recall upsetting experiences and think about them differently. It may also enable people to handle fears about their future and to re-evaluate these with less anxiety.

Some people report that MDMA helps them to feel more caring, connected, and forgiving toward themselves and others after MDMA. MDMA can sometimes decrease fear, avoidance, and negativity and increase trust and connection between a patient and their therapist. When this occurs, MDMA may make the therapy more likely to work. It is possible that these MDMA-related positive effects, in combination with psychotherapy, will help some people with their anxiety about the recurrence or presence of a life-threatening illness.

Two scientific studies of MDMA-assisted psychotherapy reported reduction in symptoms from a different type of anxiety disorder, Posttraumatic Stress Disorder (PTSD). In addition, published scientific research has shown that psychedelic (hallucinogenic) drugs such as psilocybin and LSD, combined with a similar type of psychotherapy, reduced anxiety in people with a life-threatening illness

Are there potential conflicts of interest?
The study doctor inviting you to take part in this research study may also be your treating doctor. In such cases, your study/treating doctor has an interest in both your care and promoting the successful conduct of this research. Sometimes these two interests may cause conflict. You can choose not to take part in the study and still receive treatment from your doctor. If you do wish to consider taking part in the study,, you will need to speak about the study to an independent doctor who is not your personal doctor and is not a member of the treatment team a This independent doctor will answer your questions and conduct the informed consent process.

The study doctor conducting this research does not have any financial interest in the sponsor of this study, which is a non-profit organization, or in the study; this means that the study doctor will not be financially affected whether the results of the study are positive or not. However, the study doctor and his staff will be paid by the sponsor for the work that he and the study staff have to do as part of this study and for the use of the site’s facilities. The study doctor is contracted by the sponsor to conduct the study, and is not an employee of the sponsor.

MAPS, the non-profit company sponsoring the study, is seeking to develop MDMA into an FDA-approved prescription medication that it can market under highly regulated conditions, with the potential to generate income to further MAPS' mission.

How many people will take part in the study?
A total of 18 people will take part in this study. At this time, this site is the only site that is conducting this study.

Who can be in the study?
We are looking for men and women who are over 18 years old, and who have a life-threatening illness that is either cancer or a neurological illness that does not affect your ability to think clearly. You must also have significant anxiety because of your illness. You must not be currently receiving primary treatment for your illness in order to be in the study. This means you cannot be receiving treatments like chemotherapy or radiation at the same time that you are in the study. If you are receiving maintenance treatments for your illness, the study doctor will need to talk to your regular doctor to see if you can be in the study. There are also other requirements you must meet in order to be in the study. The study doctor will discuss these requirements with you.

What will happen if I take part in this research study?

<u>You must be aware of the following:</u>

- We may video-record all office visits and therapy sessions for research purposes, which include developing a treatment manual, and to possibly train future therapists in this type of therapy. You can ask to view these recordings at any time while you are taking part in this study. These videos are part of the study data and are kept in the same secure way as all information collected about your participation in the study. Only specific researchers can view these videos. If you ask to view them, you will be given a personal hard drive with your video data uploaded onto it. When we video record you, we will include your face. We will not label the video with your name, address, or any other identifying information. You will be given the option to not have these videos used for training or research presentations. We will discuss this with you before you enter the follow-up period if you complete the treatment period, or at the time you stop participating in the study if you do not complete the treatment period.

  If the Principal Investigator [redacted] is not one of the therapists on your therapy team, he will still monitor your study sessions by video.

- You will have to avoid taking any medicines for psychological problems from the time of enrollment in the study up until you complete the one-month follow-up after your final experimental session, unless the study doctor makes a specific exception, such as giving you medicine for sleep or anxiety temporarily and if needed. Decisions about which medications you can keep taking and which you will have to stop will be made by the investigator after talking to your doctor. If you are taking opiate medications for pain management, you can remain on

these medications, although we may ask you to reduce the dose or avoid taking them for at least 24 hours before the experimental sessions, because these medications may reduce the effectiveness of MDMA. If your pain becomes too severe to handle during this period, you will be allowed to take your medication. You will need to give the study doctor or a member of his study team permission to talk with your own doctor. They may discuss ways to help you safely stop or decrease your medication if necessary. We will help you do this. You may return to taking your medications during the follow-up period.

- You must let us know about any medical conditions or procedures, like surgery, within 48 hours of their occurrence.

- You will need to name a relative, spouse or close friend as your support partner during the study. This person will complete questionnaires about you, and may come to some study visits if you and your therapists agree that they can be there.

- We will ask you to name two other people who know you very well and see you regularly to answer questionnaires about you during the study. They do not need to come with you to any study visits.

- We will not allow you to drive after each experimental session in which you receive the study drug (MDMA or placebo). We will arrange for your transportation after experimental sessions.

- You will need to give us the name and contact information (telephone number, cell phone number, or email) of a relative, spouse, or close friend to contact in case of medical emergency.

- If you are currently seeing a psychotherapist, you may not begin any new psychotherapy or change the type, frequency, or length of visits with your psychotherapist until after your final session/visit. This is so any change in your anxiety symptoms are more likely to be from the experimental treatment rather than from any new psychotherapy treatments.

- For your safety, it is very important to tell us about all medicines you are taking, including herbal or “natural” remedies or supplements, and to check with us before you begin taking a new medicine while in this study.

- You will also need to tell us if you become pregnant anytime during the study. If you are a woman that can have children, you must not get pregnant while you are taking part in this research study. You must agree to practice two effective and acceptable forms of birth control (described later in this form).

- If you have an increase in symptoms for which you previously took medicine, if you need to contact your outside therapist other than for the usual appointments, and/or if you start or stop taking prescribed medicine, you should let us know as soon as possible.

- You should not be a part of any other clinical trial (research study) or take MDMA or Ecstasy outside of the study during the whole time you are in this study.

- If you must go the hospital or are in a life-threatening situation at any time during the study even if it doesn't have anything to do with the study, you will need to call us as soon as you can to let us know the details.

- We will ask you to allow us to obtain copies and review your medical records from your treating doctors. We will require a signed release form from you in order to do this.

How long will I be in the study?
This study may take up to 15 months or 18 visits if you receive MDMA in Stage 1 of this study. This time period includes active participation for up to 3.5 months and long-term follow-up visits 6 and 12 months after the last experimental session.

This study can take up to 18 months or 29 visits to complete both Stage 1 and 2 plus the long-term follow-up visit if you receive the placebo dose in Stage 1. If you are in this placebo group, you will have 12 visits in Stage 1 and you can choose to have an additional 15 visits in Stage 2, where you will receive the active dose of MDMA over an additional 3.5 months. This total time period includes 6 months of active participation plus long-term follow-up visits at 6 and 12 months after the last experimental session.

The timeline after enrollment for starting treatment can move fast or slow depending on availability of open appointments. You may start therapy as soon as one week after enrollment or be delayed by as long as two months. Depending on your group, you will visit the therapist's office approximately once a week for 3.5 (active dose groups) or 6 months (placebo group) during the active period. Experimental sessions last all day and require an overnight stay; they are approximately every two to four weeks for 3 or 6 months depending on the group you are assigned to. After these overnight stays, you will also have a brief daily phone call with the therapists for 7 days and you will have 3 psychotherapy sessions a week apart. You will have testing visits, which require interviews, 5-6 times during the study. After active participation is complete, you will have a follow up visit one month after your final experimental session and six months and one year later.

Types of visits and duration:

Psychotherapy sessions (90-minutes each): 3 introductory sessions at the start of participation and 3 sessions after each experimental session. These are approximately once a week.

Experimental sessions (8-hours long plus an overnight stay): 3 sessions for each person in the active dose arm and 2 sessions plus 3 optional sessions for each person in the placebo arm. These are every 2-4 weeks.

Evaluation and Testing Visits (2-4 hours): Testing and completing questionnaires 5-6 times, starting with the beginning of the study.

You will need to be flexible and take the appointments we offer most of the time because there is a limited time frame for each type of visit and there are many participants we need to accommodate.

Screening
If you agree to be in this study, you will sign this form before any study procedures are done. You will need to have the following exams, tests or procedures to find out if you can be in the study. Some of these tests will be performed by members of the research team who are not [redacted] or the study therapists. This is called screening and this process can take up to 2 months. You may see the study doctor ([redacted]) or a member of his study team on two or more occasions during this time. We will ask your permission to contact your doctor and psychotherapist to get information about your medical and psychiatric history. We will need to do this so that we will know if you can be in the study or not. If you feel that these evaluations are too much to deal with during a given office visit, please tell us so we can schedule a different office visit for you to complete them. This interview may be video recorded for research purposes.

The tests will include the following:

- A questionnaire about your anxiety symptoms. Your score on this questionnaire will be used to decide if you can be in the study.
- 2 questionnaires about feelings of depression or other symptoms or feelings you might experience.
- A questionnaire about your mental health.
- Questions about your medical history, including questions about your emotional and psychiatric history. This may include any previous medical or psychiatric problems or treatment and may include questions about difficult experiences you may have had during childhood or at other times of your life.
- Questions about thoughts and feelings you might have about suicide. This is a required questionnaire for many FDA drug trials, and you will be asked about this periodically throughout the study.
- A questionnaire about any pain you may be experiencing in your body.
- A physical examination that will include measures of your blood pressure, pulse, temperature, and body weight.
- An ECG (electrocardiogram) will also be taken, which is a recording of the electrical activity of your heart.
- A sample of your blood (about 2 tablespoons, or about 30 mL) and a urine sample for routine laboratory testing, including tests of metabolism and liver function. An HIV test will also be run. If you have positive test results for HIV, we will notify you. We are required to notify state health authorities of positive results. If you do not want to be tested, you should not take part in this research study.
- A urine drug screen. Your urine drug screen must be negative before experimental sessions.

- 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.

If you have decided that you want to be in the study and if we find that you are eligible, then you can be in the study and you will schedule your first preparatory psychotherapy session with one of the study therapist teams. You will see the same therapy team for the whole study. If you were taking psychiatric medicines when the therapists first checked to see if you could be in the study and it took time to taper off of them, you may have your anxiety and other symptoms measured again after you have stopped taking your medications. Your first experimental session will be between 3 and 8 weeks after your baseline anxiety symptoms are measured. The time will depend on scheduling and on the time it takes for any medication to clear from your body.

Preparatory Sessions and Baseline Measures:
Once screening is complete and you are enrolled in the study, you will meet with the study therapists three separate times before the first experimental session. These visits will last about 90 minutes. During each preparatory session, you will talk about the emotions and issues that you are dealing with as a result of your illness, the ways these issues are affecting your life, and what you would like to achieve during these sessions. You will also learn more about what to expect during experimental sessions. You will be asked questions about thoughts or feelings you might or might not have about suicide during one of these preparatory sessions. You will be asked about this at multiple visits, although you may not experience these thoughts or feelings at all.

You will also answer some more questionnaires about your symptoms during the preparatory sessions:

- During the first preparatory session, you will answer questionnaires about the quality of your sleep, personal growth since your diagnosis, and your attitudes or beliefs about death.
- During the second preparatory session, you will answer questionnaires about ways you pay attention to or are mindful of your experience, and how you treat yourself during difficult or painful experiences.
- During the third preparatory session, you will answer questionnaires about your anxiety and overall quality of life.

You may also be asked about any pain you may be experiencing in your body.

We will give you a card that says you are taking part in a research study involving the use of MDMA. This card will also include the telephone numbers to reach us (the researchers) and the Copernicus Group Independent Review Board. You can keep this card in your wallet to make it easier for you or anyone treating you in an emergency to contact us if you or they need to do so.

Stage 1 Experimental Sessions:
This study is double-blind, meaning that neither you nor the study researchers will know what drug you will receive. The drug you get will be decided at random, as if by tossing a coin. However, this information is available if needed in an emergency. Thirteen people will receive the full dose and five people will receive placebo. You will have a 72% chance of receiving full dose MDMA and a 28% chance of receiving the placebo. You will find out what you received about 1 month after your second experimental session is complete.

After you have completed three preparatory therapy sessions, you will have the first of two day-long experimental sessions combined with psychotherapy. During these sessions, you will receive either full dose MDMA or placebo. These sessions will happen two to four weeks apart. After each experimental session, there will be an integrative session and over the next two weeks, two additional integrative sessions. These integrative sessions are designed 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 experience during the experimental sessions. Each experimental session will last about eight hours, though one or both study therapists will remain with you for a longer time if needed. Afterwards, you will stay overnight in a comfortable setting at the study site.

Experimental sessions will take place in [redacted] home psychotherapy office, which is located 3.3 miles from the Marin General Hospital. The treatment room will be comfortably furnished, with a bed in which you will sit or lie on during the MDMA experience along with chairs for both co-therapists. The treatment room has a restroom nearby. The treatment room will be equipped with video cameras to record the sessions and stereo and speakers for music during the sessions. The treatment room has windows from which only trees, bushes and landscaping is visible and is in a quiet location. A nearby overnight room will also be used following experimental sessions, and there will be space for both the co-therapy team and a night attendant to remain on-site overnight if necessary. [redacted] will also remain on-site overnight.

The next morning, after each session, you will have an “Integrative Session” at which we will check to see how you are doing and discuss any concerns of yours that may have arisen. The details of these sessions are described below.

One week before each of the experimental sessions, you will need to avoid taking:

- Any herbal supplement (except with prior permission);
- Any non-prescription medications, unless you have permission (with the exception of non-steroidal anti-inflammatory drugs or acetaminophen [Tylenol]);
- Any prescription medications, unless you have permission (with the exception of birth control pills, thyroid hormones or other medications). You will need to talk to the study doctor about which medications are okay to keep taking.

You must not eat after midnight on the night before each session, but you can drink non-alcoholic liquids during this time, such as water or juice. You cannot use nicotine or caffeine for 2 hours before and 6 hours after receiving the capsule. If you are taking opiate medications for pain management, you may be asked to reduce the dose or avoid taking them for 24 hours prior to each session, although if your pain becomes too severe, you will be permitted to take these medications. We will give you a paper with these instructions before your first experimental session.

Before you receive the MDMA or placebo during each experimental session (about 9:00 am):

- We will collect a sample of your urine for a drug screen. If the drug screen is positive, the result may be reason for delaying or rescheduling the session, or for withdrawal from the study.
- If you are a woman who can have children, we will use your urine sample for a pregnancy test. You cannot take part in this study if you are pregnant.

After you receive either MDMA or placebo during each experimental session:

- Your therapy team will measure and record your blood pressure, temperature, and pulse every 60-90 minutes and as needed (at least 7 times).
- Your therapy team will ask you to rate the amount of distress you feel on a scale of 1 to 7 every 60-90 minutes and as needed (at least 7 times).
- Your therapy team will remain with you for six to eight hours after you take the study drug (MDMA or placebo).
- During each experimental session, you may sit or lie down in a comfortable position. You can ask for an eyeshade or headphones. Music will be a part of your sessions. Lying or sitting in a comfortable position and listening to music are meant to bring out thoughts and feelings, including thoughts and feelings relating to your illness or diagnosis. You will be able to move about and use the toilet, as needed for your comfort.
- Your therapy team will ask to talk to you at least every hour, but you can talk to us or remain silent whenever you wish.
- About one and a half to two and a half hours after receiving MDMA or placebo, you and the study therapists will talk about taking a second capsule. The second dose will be half the amount of the first dose. If you and the study therapists agree, then you will take the second dose. If you or the study therapists notice problems after the first capsule, then you will not get the second capsule.
- Your therapy team will give you food and drinks during each session at your request.
- If you request it and your therapy team agrees to it, your support partner may stay with you during some of the experimental session, starting at an agreed-upon time. When your support partner arrives, they will stay in the waiting room until there is a good time for them to come into the experimental session.

If you are still confused or very upset eight or more hours after the start of the experimental session, your therapy team will stay with you until you have recovered more fully. If your therapy team thinks you are at risk for hurting yourself or someone

else, they will either stay with you all night or have you stay in a nearby hospital until they are certain you are not at risk. If the study therapists decide that the effects of the drug have worn off and you are in a good frame of mind, they will leave the study site with the attendant in charge.

You will spend the night in a comfortably furnished room at the study site. If you request and the study doctor agrees, you may also have a companion stay with you at the study site during or after an experimental session. This can be the person who is completing questionnaires as part of the study or it can be another person. An attendant will stay in another room at the same location from the time after you are done with the experimental session until the integrative session the next morning. The attendant will offer dinner and breakfast, help you with any physical needs if requested, and contact the study therapists to speak with them or to have them return to the study site at your request, or if the attendant thinks it is needed.

If you find you need to talk with the study doctor or a member of his study team or you are having other problems and need to contact them, your support partner may contact them for help.

You will complete some questionnaires about feelings you might have experienced during or after the experimental session. You can complete these questionnaires at any time between the end of the experimental session and the start of the integrative session on the next day. During the time between the end of the experimental session and the start of the integrative session the next day, we ask that you use the time as a period of rest and reflection in our quiet setting.

Integrative Session – Therapy after Experimental Sessions
On the next morning, you will have a non-drug (integrative) therapy session 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 experience during the experimental sessions. Each integrative session will last about 60 to 90 minutes. You and the study therapists may discuss whether you would like your support partner present inside or outside these sessions.

Before starting integrative therapy on the day after each experimental session, we will ask you to guess whether you got MDMA or placebo. However, we will **not** tell you if your guess is correct.

Time between Each Experimental Session (2-5 weeks)
After the integrative sessions, your therapy team will telephone you every day for a week to see how you are feeling and whether you should return to see the study doctor or a member of his study team before your next scheduled psychotherapy session. These telephone calls will take about 5 to 15 minutes, although they can be longer if needed.

You may schedule additional meetings with the study doctor or a member of his study team besides those that are scheduled as part of the study. You can contact them at any time. You will be able to reach one of them by telephone 24 hours a day throughout this entire research study.

You will meet with your therapy team during two additional integrative sessions after each experimental session. During these sessions with the study therapists, you will have regular psychotherapy to help you express, understand, and integrate (bring together and connect to your life) any thoughts or feelings you may be having about your anxiety symptoms and their causes and about your experiences during experimental sessions. These sessions will last 60 to 90 minutes. You and the study therapists will also discuss ways to use what you learned to help you manage your anxiety, and to solve difficulties that may have arisen during the experimental sessions. This will enable you to gain maximum benefit and understanding from the experimental sessions.

If there are delays in following the usual study schedule, your therapy team will telephone you at least once a week to talk about how you're doing. These telephone calls will take approximately 5 to 15 minutes. You are requested to call the study therapists if any of the following things happens: you have an increase in symptoms for which you previously took medication, you need to contact your outside therapist other than for the usual appointments, you start or stop taking prescribed medication, and/or you go to the hospital for any reason.

Measuring Anxiety, Depression and Other Tests After Experimental Sessions
Approximately two to three months after the start of the study (one month after the second experimental session), a study researcher will ask you about your anxiety and other symptoms. This visit may last about two and a half hours. These tests are so that the study therapists can tell if your symptoms have changed or stayed the same over time. As before, some of the tests will be given by another researcher who is not one of the study therapists.

We will also ask the people you chose at the beginning of the study to fill out the same questionnaires about your mood and personal growth. These questionnaires can be done away from the study site and returned in the mail.

After you complete these tests, you will meet with the other study therapists. You and the study therapists will learn whether you received the placebo dose or the full dose of MDMA. The study researcher that measured your depression symptoms will not find out. The tests will help the study therapists tell if your symptoms have changed or stayed the same over time.

If you learn, after your second experimental session, that you received the placebo dose, then you will be given the option to go on to the next part of the study without finishing Stage 1, described below (Stage 2).

Open-label MDMA Session for People who received Full Dose
If you are one of the thirteen participants in the full dose group, you will have a third day-long experimental session with the same dose of MDMA that you had in your first two sessions. After learning that you were in the full dose condition, you will schedule and complete your last experimental session, which will be "open label," meaning you will receive MDMA, but this time you will know. You will have the same regular psychotherapy visits after this last experimental session.

Approximately five months after the start of the study (one month after the third experimental session), you will meet with the study researcher again. The researcher will ask about your symptoms and you will fill out the same questionnaires you filled out at the last assessment session. You will also be asked to participate in an interview with one of the study therapists, where they will ask you questions about your experiences while participating in the study. This visit may last about 3.5 hours, and can take place over more than one day.

We will also ask the people you chose at the beginning of the study to fill out the same questionnaires about your mood and personal growth. These questionnaires can be done away from the study site and returned in the mail.

At this time, approximately one month after your third experimental session, you will receive a memory aid card to help you keep track of your health in between your last visit and follow-up visits 6 and 12 months after the final experimental session. The card will help you to remember to tell the researchers about any new problems or medical conditions or changes in medication that happened during this time.

Stage 2 Experimental Sessions – Open-label MDMA
If you are one of the five subjects who received a placebo, you may take part in three open-label MDMA-assisted sessions scheduled two to four weeks apart as part of Stage 2. In this part of the study, you will receive an active dose of MDMA during each session. Signing this consent form means you agree to take part in the second part of the study. **The 13 people who receive a full dose of MDMA during Stage 1 cannot take part in Stage 2.**

If you decide to take part in Stage 2, you will have 12 more visits with your therapy team and three experimental sessions. These sessions will be conducted similarly to the experimental sessions you had during the first part of the study, except that you will know you are getting full dose MDMA with an optional supplemental dose that is half the initial dose. You will only have one preparatory session rather than three sessions before your first experimental session in Stage 2. The study timing and procedures will be similar to Stage 1.

You will be given the same tests for anxiety and other symptoms, well-being and attitudes about yourself and about death, about one month after the second and one month after the third open-label experimental session, and you will have an interview with one of the therapists about your experiences in the study one month after the third open-label session.

We will also ask the people you chose at the beginning of the study to fill out the same questionnaires about your mood and personal growth at these visits. These questionnaires can be done away from the study site and returned in the mail.

At the one-month follow-up after your third experimental session, you will receive a memory aid card to help you keep track of your health in between your last visit and follow up visits 6 and 12 months after the final experimental session. The card will help you to remember to tell the researchers about any new problems or medical conditions, or changes in medication that happened during this time. You may have your regular doctor fill out this card for you.

Long-term Follow-up 6 and 12 Months after Last Experimental Session
About 6 months and then 12 months after your last experimental session, you will complete measurements of your anxiety and other symptoms either over the phone or in person. If you only participated in Stage 1, then this will happen 6 and 12 months after your third experimental session, and if you were in Stage 2, then this will happen 6 and 12 months after the third experimental session in Stage 2.

The same study personnel who asked you about your anxiety and other symptoms will do so again, either in person or over the telephone. You will be asked about any thoughts you may have about the good and bad points of MDMA-assisted therapy, and your thoughts about taking MDMA. There are no right or wrong answers to these questions.

The questionnaires may be mailed to you for you to fill out. It will come with an envelope that is already stamped and has only the researcher's address on it. Do not put your name on the questionnaires.

We will also ask the people you chose at the beginning of the study to fill out the same questionnaires about your mood and personal growth. These questionnaires can be done away from the study site and returned in the mail.

A researcher who is part of the study may ask you about any changes in medication or your mental health, including any benefits or harms, during the follow-up period between your last visit and the 6-month and 12-month follow-up visit in person or over the phone.

The researchers will use your answers to these questionnaires to see if there are any long-lasting effects of being in the study, such as changes in anxiety and other symptoms and the study's impact on your and your support persons' lives.

Study Plan

Table 1. Schedule of Events – Stage 1

Stage 1	Screen-ing	Intro and Preparation			Therapy 1				Therapy 2				Evaluation	Therapy 3				Evaluation	Long Term Evaluation
	Both Groups													**Full Dose MDMA Group Only**					
Study Visit		1 Enroll	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	
Screening	X																		
Measure Symptoms	X	X	X	X				X				X	X				X	X	X
Questionnaire about suicidality	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Study Partner Answers Questionnaires	X												X					X	X
Psychotherapy		X	X	X		X	X	X		X	X	X			X	X	X		
Psychotherapy with Drug					X				X					X					
Medical Exam	X																		
Learn What You Received													X						

Table 2. Schedule of Events – Stage 2

Stage 2	Preparation	Therapy 1				Therapy 2				Evaluation	Therapy 3				Evaluation	Long Term Evaluation
	Placebo Group Only															
Study Visit #	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	
Measure Symptoms	X*				X				X	X				X	X	X
Questionnaire about suicidality	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Study Partner Answers Questionnaires										X					X	X
Psychotherapy	X		X	X	X		X	X	X			X	X	X		
Psychotherapy with MDMA		X				X					X					

* Symptoms may be measured again if more than 8 weeks passes between Visit 12 and 18.

What are my responsibilities if I take part in this research?
If you take part in this research study, you are responsible for coming to all study visits, following the study doctor's and his study team's instructions, informing the study team about any changes in your health, taking the study drug (MDMA or placebo) as agreed upon, and completing all therapy sessions, questionnaires, and interviews.

Can I stop being in the study?
Yes. You can decide to stop at any time. Please discuss your concerns with the study doctor if you are thinking about stopping or have decided to stop. If you decide to stop participation in the study, the study doctor will assist you with follow-up care and restarting your medications, if necessary.

It is important to tell the study doctor if you are thinking about stopping so any risks from the MDMA can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

Your doctor, the sponsor of the study (MAPS), the Copernicus Group IRB, or the FDA has 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 drugs,
- if you need a treatment not allowed in this study, such as restarting medication for psychological problems,
- if you do not keep appointments,
- if you have very high blood pressure,
- if you get significantly ill, or if your already-existing illness gets significantly worse,
- if you have an important and strong lasting reaction (unwanted effect or health problem) during or after an experimental session,
- 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 any of these things happen, you or the study doctor may decide that you should not take part in the next experimental session. You may make this decision to stop taking part in the study for any reason. If the study doctor decides to take you out of the study, he will let you know that he is doing this and tell you his reason for doing this. If you are taken out of the study or decide you do not want to receive treatment in the study, the study doctor will ask you to complete some final questionnaires about your mental status. If you decide you do not want to continue in the study during an experimental session, we will ask you 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. If this happens, we will also ask you to allow us to interview you about your thoughts on being in the study and for you to complete the same questionnaires you completed at the beginning of the study during the follow-up visit in 6 and then 12 months.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

If you stop being in the study, already collected data (information collected from and about you while you are in the study) may not be removed from the study database. We will ask whether we can collect data from your routine medical care. If you agree, we will handle this data the same as research data.

What treatments and/or procedures are experimental?
We are carrying out all of the procedures and/or treatments described above for research or experimental purposes. MDMA is an experimental drug, and has not been approved for use by the U.S. Food and Drug Administration (FDA) for medical use except in research studies.

What side effects or risks can I expect from being in the study?
You may have side effects while on the study. We will watch everyone taking part in the study carefully for any side effects. As of December 2015, more than 1185 people have received MDMA in clinical research settings without any serious unexpected problems happening. However, doctors don't know all the side effects that may happen. Side effects may be anything from mild to very serious. Your study doctor or his/her staff may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the MDMA. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to your study doctor about any side effects that you have while taking part in the study even if you think they may not be caused by the medicines.

Side effects that are most frequently reported by 25% or more of participants during the MDMA experience (100 to 125mg) are:

- Muscle tightness (jaw) (55%)
- Decreased appetite (42%)
- Muscle tightness (27%)
- Nausea (27%)
- Feeling Cold (27%)
- Sweating (25%)
- Restlessness (25%)

In these studies, participants (mostly with Posttraumatic Stress Disorder) also experienced anxiety, headache, and fatigue at a similar rate during MDMA or placebo. Less than 25% of participants receiving MDMA reported dizziness, insomnia, thirst, problems walking or with balance, dry mouth, difficulty concentrating, depressed mood, and nystagmus (eye wiggles), from most to least common. When these side effects occur, they usually last less than four hours. However, some effects have been reported to last for more than 24 hours and (rarely) for as long as four days.

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

Physical Risks:

Serious problems: There have been some serious problems, and even deaths, associated with the use of Ecstasy outside of controlled settings (outside of research studies). In research studies (clinical trials), none of these serious problems have happened. Outside of medical settings, these problems have included high fever, brain swelling associated with drinking too much liquid, convulsions (seizures), and liver damage. Since you will be receiving moderate amounts of uncontaminated MDMA in a controlled setting with trained and experienced researchers who will be closely monitoring your physical and psychological reactions, these problems are not expected to occur either during or after the experimental sessions. While this does not guarantee that they will not occur, it does mean that if they do occur, the researchers are prepared to respond 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 365 participants without emotional disorders and 21 with PTSD) most participants 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 12-33 out of every 100 people who took MDMA also 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. At the dose in this experiment, the increases in blood pressure and heart rate are likely to be moderate. Average increase in systolic blood pressure is 28 mmHg (measurement unit for blood pressure) and average diastolic blood pressure increase is 13 mmHg. Heart rate may increase by approximately 30 beats per minute (BPM) on average.

In previous studies, blood pressure rose well above normal levels in a few people (a little less than 1 out of every 20) after receiving MDMA, but they 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 ask you about and check you for heart problems during the screening for this study. While this doesn't guarantee that no heart problems will occur, it does reduce the risk of this happening.

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 may become dependent on (addicted to) MDMA. One study found that up to 6% (a little more than 1 out of every 20) of people using Ecstasy for recreational purposes were dependent on it. However, three studies of people who had received MDMA in a research study found that they did not want to try MDMA again outside of the study. People who have recently (in the last 2 months) had problems with drug abuse should not take part in this study.

Mental Risks:

Anxious or jittery feeling: Some participants in past studies with an anxiety disorder who received MDMA (48%, or about half) or placebo (58%, or about 6 out of 10 people) reported feeling over-stimulated or anxious at a similar rate. 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 doctors 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 your support person or attendant to call the study doctors immediately if you have any thoughts about hurting or killing yourself so they can help you resolve them safely. If necessary, they may prescribe anti-anxiety medication or medication for sleep.

The way MDMA affects the brain has the potential to cause mania in some people, although mania has not been reported in individuals receiving MDMA or ecstasy.

If you are in immediate danger of hurting or killing yourself or hurting someone else, then the researchers may require you to be admitted to a hospital. MDMA is not known to increase the risk of suicide.

Mood: Some after-effects of MDMA may be noticeable up to 2 or 3 days after receiving MDMA. While some people felt that their mood is better, 11%, or about 1 in 10; felt that it was worse after receiving MDMA in other research studies. Your mood may or may not change in the days following your treatment sessions.

Possible risks to brain function: One study conducted by the sponsor in 20 people with PTSD found that two doses of 125mg MDMA spaced a month apart did not lead to differences in how well their brain functioned from a placebo control. The dose you will receive in this study will be similar to this amount. Studies of people receiving one or two doses of MDMA in a laboratory setting have not found any lasting changes in memory or planning. Studies comparing people before and after they decided to take a few tablets of Ecstasy, which may or may not contain MDMA, in a recreational setting with people who did not take them found less improvement in memory in the people who took Ecstasy, and no other changes in thinking 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 decided to take 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 temporary lowering of 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.

Many studies found that people who had used Ecstasy many times in recreational contexts were not able to recall words, pictures or patterns as well as people who did not use Ecstasy. They also performed less well on tests of planning and impulse control. These differences are not great, but they have 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. 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.

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 cell (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 find they perform worse in difficult memory tests. Recent studies in monkeys and rodents suggest that the doses used in those studies were far higher than those typically taken by humans in either recreational or laboratory settings.

Worsening of symptoms: You may experience a worsening of your anxiety symptoms while taking part in this study. This may occur when you are stopping your current medications and if you receive placebo (no active medicine). This may also occur if you receive MDMA during this study.

Other Risks:

You should not drive or use machinery immediately after each experimental session (up to 24 hours afterwards). This is because the study drug (MDMA) may cause drowsiness, lack of co-ordination, or slower reaction time. If needed, the study doctor may prescribe medication for sleep.

If you complete a urine drug screen within three days of each experimental session, you may test positive. The researchers will provide you with an information card explaining this. If you are tested for drugs while you are taking part in this study, you can have the person(s) testing you call us to verify that you are taking part 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.

In order to be eligible for this study, you must complete a blood test. The risks of blood drawing include temporary discomfort from the needle stick, bruising, and rarely, infection at the site of the needle stick. Fainting could also happen. If you are not comfortable with giving blood for screening, please let us know because it is required to take part in this study.

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 the study doctor. If you have to start taking medicine again, then the study doctor will have to take you out of the study.

Reproductive Risks - Females: Effects of MDMA on the growth and development of an unborn baby are not known; therefore you will not be allowed to enter the study if you are pregnant. If you become pregnant after you have had at least one experimental session, the study doctor and the sponsor (MAPS) will ask you about and keep track of the pregnancy. If this happens, you will need to stop being in the study and they will need to know about the outcome of your pregnancy.

Women who are able to become pregnant must use one of the allowed birth control methods, such as birth control pills or shots, IUDs (intrauterine devices), and barrier method used along with spermicide for at least one month afterward your final study visit/session. We 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.

If you are a woman that can become pregnant, we will give you a pregnancy test at the start of the study and again before each experimental 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 notify us immediately. If you should become pregnant during the study, we will help you get proper advice and help you and your unborn baby get proper care while you are pregnant. However, you are responsible for the costs of the care for your pregnancy.

For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?
Your mental health may improve while taking part in this study, but there is no guarantee that you will benefit from taking part in this research study. Information obtained from this study may help doctors and researchers to improve treatment of anxiety and other symptoms in individuals with life-threatening illnesses in the future.

What other choices do I have if I do not take part in this study?
One alternative to being in this study is to decide not to take part in it. You may decide to try other treatments for anxiety. There are other medicines, such as anti-anxiety medications like Valium (diazepam) or Xanax (alprazolam) and other forms of psychotherapy that you could try. If you are currently having psychotherapy and/or taking medicine, you could continue with those for a longer period of time.

The researchers can discuss the alternatives and their potential risks and benefits with you. Talk to your doctor about your choices before you decide if you will take part in this study.

Will my personal and medical information be kept confidential?
To ensure confidentiality, your information will be stored in secure electronic systems or in a locked office. Absolute confidentiality and security cannot be guaranteed, but every effort will be made to maintain your confidentiality.

People outside of your treatment team will need access to your information to monitor the study and conduct further research and training. Any paperwork copied will have any information that could be used to identify you removed first, except for videos, which will still show your face. If records are copied, only your participant number and initials will identify you to the study sponsor unless you give specific permission, for example at a time when you sign a media release.

Medical records, including video, which identify you, and the consent form signed by you will be looked at and/or copied for research or regulatory purposes. These records may be looked at by:

- The sponsor, MAPS and the people they hire.
- Researchers who cooperate with MAPS to conduct further research, and people who conduct therapist trainings on behalf of MAPS.
- The FDA and similar agencies in other countries.
- Governmental agencies in other countries.
- The Copernicus Group Independent Review Board (CGIRB).

All records in California are subject to subpoena by a court of law.

The results of this research study may be presented in meetings, presentations, or in publications, where your identity will not be disclosed. Video of your sessions may be used in training sessions for research therapists or other researchers only in controlled settings as described below.

Video recordings: The study therapists will video record each visit. The purposes for this recording that you are agreeing to by signing this informed consent are:

- So that you will have access to review your own therapy sessions.
- So the study therapists will have accurate records of the session.
- So that trained raters working for the sponsor can verify that the therapy is being carried out according to the protocol and the methods described in the Treatment Manual, or for further development of the Treatment Manual.
- For further research on the therapy and how it is performed.
- For training other therapists and scientists to develop and work on additional research.

For the above purposes the adherence raters, researchers and therapists who may be viewing these recordings will be selected by the sponsor, and will sign confidentiality agreements to ensure they do not share the identifying information they may receive.

Information contained in recordings that could be used to identify you may include:

- Your physical appearance
- Your voice
- Your name (if it is spoken on the recording)
- Situations from your life that might be discussed

You may watch the recordings if you wish, but you do not have to. Due to processing time required, they will not be available immediately after your visit. Once the recordings are processed you may request access to your own recordings. Your name or other identifying information will not be used to label these recordings. Sometimes audio or transcripts from these video files will be processed separately and used for additional research.

With your permission, the investigators and/or sponsor may use portions of your videos to educate a broader audience at medical conferences or other settings. In these settings the audience will not be specifically screened and selected, and confidentiality agreements will not be obtained from the audiences. You are not required to agree to use of your video in these settings in order to participate in the study. Signing this consent form does not mean you have given permission for your videos to be used in this way. You will have the opportunity to sign an additional release for these situations if they arise and if you choose to allow this use. At the end of the treatment period when you have completed all of the questionnaires and measures, you can make a decision about whether or not you wish to grant this additional consent.

These recordings will be stored on hard drives stored in a locked and secure location when not in use. No personally identifying information will be used to label the video recordings. A copy will be transferred to the sponsor for electronic storage on the web to allow for viewing purposes described above. Electronic systems used will include measures to protect confidentiality of your identity and video data. Total security cannot be guaranteed, but the sponsor is consistently working to maintain and improve the

security of its data systems. Your videos may be viewed in online trainings or in-person trainings with pre-screened therapists. People viewing these videos will be required to sign a confidentiality agreement.

During your study sessions you may ask to stop the recording at any time, but your therapists will ask your permission to turn it back on when you are ready.

By signing this consent form, you consent to the collection, access, use and sharing of your information as described above. You have the right to check your study records and ask for changes if the information is not correct.

Will I be paid to take part?
You will not receive any payment for taking part in this research study.

What are the costs of taking part in this study?
The sponsor of this study, MAPS, will cover the costs that are directly related to this study. This includes the costs for all therapy sessions that are a part of this study (includes all experimental and integrative sessions), for the psychological and laboratory testing, for medical examinations, including any extra tests you might have solely to see if you can be in the study (if you are eligible), and for the study drug. You, your private medical insurance (if any), and the public health insurance plan 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.

The study sponsor will not pay for meals and lodgings or travel expenses that are incurred away from the study site. There is no expense incurred for meals or lodging at the study site.

What happens if I am injured because I took part in this study?
It is important that you tell your study doctor, [redacted] if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at [redacted]. If you cannot reach your study doctor, you may call the nearest hospital emergency department.

You will get medical treatment if you are injured as a result of taking part in this study. If you are injured as a direct result of the study medicines or procedures required by this study, we will provide you with appropriate medical care including treatment and hospitalization if necessary. The sponsor of this study agrees to pay for such medical care including treatments and hospitalizations that are not covered by your health insurance or other third party provider.

What are my rights if I take part in this study?
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

CONTACT FOR QUESTIONS
If you have any questions or concerns about your participation in this research study or if you feel that you have experienced a research-related injury or reaction to the study drug, or have a complaint about the research study, contact:

Investigator Name: [redacted]

Daytime telephone number(s): [redacted]

24-hour contact number(s): [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 the research study described in this 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.

The researchers will give you a wallet card containing contact information for the researchers, the sponsor and the Copernicus Group IRB.

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

"A Randomized, Double-Blind, Placebo-Controlled Phase 2 Pilot Study of MDMA-Assisted Psychotherapy for Anxiety Associated with a Life-Threatening Illness"

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 call the researchers 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 researchers and/or the sponsor may stop my participation in this study at any time without my consent if they decide it is in my best interest or if I do not follow the researchers' instructions.

I agree to have my sessions video-recorded 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 take part in this study. All of my questions so far about the study and my participation in it have been answered. I freely consent to take part 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 after it has been signed and dated and the Experimental Subject's Bill of Rights.

_____

Signature of Subject Date

_____

Printed Name of Subject

I certify that the information provided was given in language that was understandable to the subject.

_____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

Witness signature lines and attestation
The information in the consent form was accurately explained to, and appeared to be understood by the subject. Informed consent was freely given.

Signature of Witness	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 record and information created or collected during the study. This information may include your medical history, physical exam 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, such as the FDA 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.

Your records may also be inspected by the Research Advisory Panel of California (RAPC) or by State and Federal regulatory agencies.

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 the address below:

If you withdraw from the study and withdraw your Authorization, no new information will be collected for 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 study purposes, and any new information about an 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 will expire December 31, 2060, unless you withdraw it in writing before then.

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. 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.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date

_____

Printed Name of Person Obtaining Authorization

_____ _____

Signature of Person Obtaining Authorization Date