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Informed Consent Form for Participation in a Clinical Trial in Human Beings

I the undersigned:

First and surname:	
ID number:	
Address:	Zip code:

a) Declare hereby that I consent to take part in the clinical trial, as specified in this document.
b) Declare hereby that I am not taking part, at the time of signing this document, in another clinical trial that involves the use of any investigational product, and that I undertake not to participate in any other clinical trial that involves the use of an investigational product throughout the course of this trial.
c) Declare hereby that it has been explained to me by:

Name of investigator / sub-investigator providing explanations:

1. That the principal investigator: [redacted] has received approval from the director of the medical institute, where the trial will be conducted, to conduct the clinical trial in human beings, as laid out in the Public Health Regulations (Clinical Trials in Human Beings) 1980 (hereinafter the clinical trial).

2. That the principal investigator and sub-investigators do not have affinity [1] with the sponsor of the trial[2].

3. That the clinical trial is being conducted on the subject of: MDMA-Assisted Psychotherapy in People with Post-Traumatic Stress Disorder (PTSD).

4. That I am free to choose not to participate in this clinical trial and that I am free to discontinue my participation in the trial at any time, all this without prejudice to my right to receive the standard treatment.

5. That in case of completing a questionnaire, I am entitled not to answer all or part of the questions in the questionnaire.

6. That I am guaranteed that my personal identity will be kept confidential by all those involved and concerned with the study and will not be published in any publication, including scientific publications.

7. That the medical institute has acted to arrange for appropriate insurance coverage for the investigators, doctors and medical staff involved in the clinical trial, against claims submitted by participants in the clinical trial and/or third party claims related

[1] Affiliation - a relationship of paid employment, or a business or commercial relationship, or a familial or personal relationship, and any other relationship, including a relationship of subordination at work, which may raise suspicion of conflict of interests or dependence, with the exception of reimbursement or payment for participation in committees according to this Procedure.
[2] If the principle investigator is also the sponsor of the trial, this should be indicated explicitly.

to the clinical trial, either during the course of the trial or thereafter. This is without prejudice to my rights under any law.

8. That I am guaranteed willingness from those conducting the study to answer questions raised by me as well as the possibility of consulting with others (e.g. family doctor, relatives, etc.) in regard to making the decision to participate in the clinical trial and/or to continue in it.

9. That in clinical trials in which women of childbearing age participate, in case of pregnancy during the clinical trial, the woman will receive counseling (from the investigator) concerning the potential effects on the fetus and the fate of the pregnancy, including the possibility of terminating the pregnancy.

10. That with any problem related to the clinical trial, I may contact [redacted] at telephone number/answering machine: [redacted] at any time of day.

d) I declare that I have received detailed information regarding this clinical trial, according to the subjects listed below:

Protocol Number: MP-9

Study title: A Randomized, Double-Blind, Active Placebo-Controlled Phase 2 Pilot Study of MDMA-Assisted Psychotherapy in People with Chronic, Treatment-Resistant Post-Traumatic Stress Disorder (PTSD).

Objectives and background:
You have been invited to participate in this clinical study because you have been diagnosed with posttraumatic stress disorder (PTSD) and because your symptoms have not gone away following treatment with psychotherapy ("talk therapy") or medications. Your participation is voluntary, and you have the right to refuse to participate or withdraw from the study at any time. Please read this form carefully before you decide to participate in this study. You can take home an unsigned copy of this consent form to think it over or discuss it with family or friends before you reach a decision.
A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
The Be'er Ya'akov Medical Center and the Multidisciplinary Association for Psychedelic Studies (MAPS) are carrying out this study together. MAPS is an American non-profit organization that helps fund and support research into medical uses of psychedelic substances.
This study was designed to provide information about the safety and efficacy of psychotherapy in combination with MDMA in subjects with PTSD.
MDMA is an investigational drug that has not been approved yet for clinical use, except in studies like this. MDMA is illegal for use outside the study and is sometimes known as Ecstasy, although Ecstasy may or may not contain MDMA.
A similar study in the USA compared MDMA-assisted psychotherapy with inactive placebo in 21 participants, and achieved promising results. Additional preliminary studies of MDMA/PTSD have been conducted in Switzerland, the USA, and Canada, also with promising results. Although we do not know why MDMA may help people with PTSD,

we know that MDMA increases positive mood. When combined with psychotherapy, MDMA may help people organize and process thoughts, memories and emotions related to PTSD.
The first two subjects entering this study will receive the full dose of 125 mg MDMA. This is called "open-label", meaning the subjects and the study therapists will all know they are getting this dose of MDMA. The remainder of the study consists of three parts; Stage 1, Stage 2 and the long-term follow-up.

After the two open-label subjects, eight subjects in Stage 1 will be randomly assigned (as in the flip of a coin) to receive low or full dose of MDMA. Five out of eight (62.5%) of the patients will receive the full dose of 125 and 62.5 mg, and three out of eight (37.5%) will receive the low dose of 25 and 12.5 mg of MDMA.
The low dose will cause some, but not all of the effects of the full dose of MDMA.
You, the person measuring your PTSD symptoms, and the therapists in the study will not know who receives the full dose of MDMA and who receives the low dose until after Stage 1 ends. However, this information is available if necessary in case of emergency. If you receive the low dose in Stage 1 and choose to participate in Stage 2, you will receive the full dose of open-label MDMA, according to a similar procedure.

Study duration
The study will continue for a total of 14-16 months, including psychotherapy treatment and a follow up period. The psychotherapy treatment part of the study consists of Stage 1, which will last four months, and Stage 2, which will last another two and a half (2.5) months.

Number of participants in the study
Ten participants will take part in this study.

Subject responsibilities
If you and the study therapists agree that you can and want to be in the study, you will have to arrive for all study visits and be available for phone contacts for 7 days after each MDMA psychotherapy session You will have to avoid taking any medications for psychological disorders (for instance, insomnia, anxiety, etc.) from the time you start the study until the end of the psychotherapy treatment part of the study, unless the study therapists prescribe the medication. If you are taking this type of medication, you will have to grant the study therapists permission to discuss with your doctor the best way to stop taking your medication. If you are using cannabis, you must stop using it for at least 14 days before receiving MDMA-assisted psychotherapy.
If you are currently seeing a psychotherapist, you may not start a new psychiatric treatment or increase the number or length of the visits with your psychotherapist during the study.
For your safety, it is extremely important to tell the study therapists about all the medications you are taking, including any herbal or "natural" preparations, and to check with the study therapists before you start taking a new medication while you are in the study.

Study procedure / what will happen to you?

During the screening and study eligibility assessment period, the study researchers will ask you about your medical and psychiatric history, and will complete a physical examination, including taking your blood pressure, temperature, pulse and EKG

(recording of heart's activity). You may be asked to undergo additional tests. You will be asked questions about your PTSD symptoms, and you will also be asked to complete questionnaires about your PTSD symptoms, depression symptoms, and sleep quality. You will be asked questions about suicidal thoughts you may have. Blood samples will be collected (about two soup spoonfuls) and urine for routine laboratory tests, as well as a urine test to detect drugs and/or pregnancy.

Stage 1: Blinded MDMA-assisted psychotherapy sessions

Preparatory psychotherapy
You will meet with the study therapist for three preliminary psychotherapy sessions before the first experimental session. These visits will take between 60 to 90 minutes. During these sessions you will be asked questions and will talk about your PTSD symptoms. During the second or third preparatory session, you will answer questions about thoughts you might have about hurting or killing yourself. You will also learn more about the things you can expect during the experimental sessions. Each preparatory session will be recorded to audio and video. You can receive a copy of the recordings if you wish.
MDMA-Assisted Psychotherapy:
During Stage 1 you will have two experimental sessions of psychotherapy combined with a low or full dose of MDMA. These two experimental sessions will take place 3 to 5 weeks apart. Each experimental session of MDMA-assisted psychotherapy will take about eight hours. Two therapists will stay with you and help you throughout the entire treatment, and they will stay with you for even longer if necessary. After the experimental sessions you will need to stay overnight at the clinic.
You must not eat or drink alcohol after midnight on the night before each treatment, but you will be encouraged to drink liquids such as water or juice during the treatment. Afterwards, food will also be provided. You cannot use nicotine or caffeine for 1 hour before and 3 hours after receiving MDMA.
First, you and the study therapists will discuss your plans and goals for the experimental session, and the study therapists will answer any questions you may have. Before the treatment, a urine test will be collected to detect drugs of abuse and/or pregnancy. In addition, you will be asked to answer questions about suicidal thoughts before and after the treatment. During the treatment, your blood pressure, pulse and temperature will be measured, as well as your level of distress.
The experimental session will be recorded on audio and video format so the study therapists can have an accurate documentation of the session. You can receive a copy of the recordings if you like. If the results of the urine test are negative, you will receive a capsule of 25 or 125 mg of MDMA. Afterwards you will sit or lie comfortably, and listen to music. You will be asked to talk with the study therapists once in a while. Lying or sitting comfortably is designed to bring out thoughts and feelings including thoughts and feelings about the trauma.
About 2.5 hours after taking the first capsule, you and the study therapists will discuss taking the second dose of MDMA. The second dose will be equal to half of the first dose. If you and the study therapists agree to it, you can take the second dose. If you or the study therapists notice any problems after the first dose of MDMA, you will not receive the second dose of MDMA.
If the study therapists decide that the effects of the drug have passed and that you are in an appropriate mental state, they will leave the hospital and leave you under the observation of an attendant. If necessary, they will stay.

If you ask and the study therapists agree to it, you can choose someone to stay with you during part or all of the experimental session for support, including afterwards if you wish. If it is necessary during your overnight stay, the Be'er Ya'akov staff will contact the study therapists to talk to them or to ask them to return to the hospital.
Prior to starting the experimental session, you will have to arrange for someone to take you home after this session. If you cannot find anyone to take you home, the study therapists will arrange for an escort.
*Follow up phone call*s: After you return home, the study therapists will call you every day for a week to ask how you are feeling and to reach decisions about how well you are doing based on what you say during phone calls. Calls can last from five to fifteen minutes but can last as long as needed.
Integrative Psychotherapy after the experimental sessions:
After each experimental session you will have phone calls and integrative psychotherapy sessions. You will see at least one of two therapists during integrative psychotherapy, The integrative psychotherapy sessions will begin on the day after each experimental session. You will also receive two more psychotherapy sessions after this session. These sessions will take 60 to 90 minutes. You will also be asked about any thoughts you have about hurting or killing yourself during each experimental session, each integrative therapy session, and on the phone conversation with the study therapists on the second and seventh day. Each integrative session will be recorded to audio and video. You may receive a copy of the recording if you like.

When you arrive for the follow-up visit 2 months after receiving the second experimental session, you will have a meeting with the person measuring PTSD symptoms, depression symptoms and sleep quality. You will have a second meeting with the study therapists. If you are one of the 8 people who did not know the dose MDMA you received, you will find out whether you received the low or full dose of MDMA. If you received the low dose of MDMA, you can choose to enroll in Stage 2, the "open-label" portion of the study described below. People who had open-label experimental sessions will have both meetings, but they will not need to find out what dose of MDMA they had.

The people who have received the full dose of MDMA during Stage 1 cannot participate in Stage 2, but will be asked to complete the follow up visit 10 months later. If you will not go on to Stage 2, the researchers will give you a memory aid card. This is for you to keep track of your health during the months in between your last visit with the researchers and the 12-month follow up visit, described below. 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.

Stage 2: Open-label MDMA-assisted psychotherapy for low dose MDMA subjects

If you begin Stage 2 more than one month after completing Stage 1, you will answer questions about PTSD symptoms and complete the same questionnaires of symptoms of PTSD, depression, sleep quality and suicidal thoughts that you completed at the end of Stage 1. If you participate in Stage 2, you will receive two more experimental sessions. The two open-label experimental sessions will consist of psychotherapy assisted with the full dose of MDMA. There will be an interval of 3-5 weeks between each experimental session. During this interval, you will get phone calls and integrative therapy sessions, and complete another follow-up visit 2 months after your last experimental session.

At the end of Stage 2, you will receive a memory aid card to help you keep track of your health in between your last visit and the follow up visit 12 months after the last open-label session.

Follow up period

Twelve months after your last experimental session in Stage 1 or Stage 2, you will be expected to participate in a follow up visit that will take about 2 to 2.5 hours. During this visit you will answer the same kind of questions as you did in the beginning of the study, and you will be asked to complete questionnaires about PTSD symptoms, depression and sleep quality.

Possible risks and discomforts

MDMA has not been widely tested in humans, but as of December 2015, more than 1185 people have received MDMA in clinical research settings without any serious unexpected problems happening. There may be unknown side effects or risks from the use of MDMA. Some of the effects that have been observed are listed below.

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 PTSD) 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:

***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 have included high fever, brain swelling associated with drinking too much liquid, convulsions, and liver damage. Some recreational users of Ecstasy have become 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 doctors 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. People also reported unusual feelings in their bodies, such as tingling or numbness (between 12% and 33%).

***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 subjects (a little less than 5%) 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 doesn't guarantee that no heart problems will occur, it does reduce the risk of this happening.

***Anxious or jittery feeling*:** Some participants in past studies with an anxiety disorder who received MDMA (48%) or placebo (58%) 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.

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.

***Insomnia & drowsiness*:** In previous studies, between 7% 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 needed, the study doctor may prescribe medication for sleep.

***Mood*:** Some after-effects of MDMA may be noticeable up to 2 or 3 days later. While some subjects feel that their mood is better, 11% feel that it is 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 had 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 2 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 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 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 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 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.

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.

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 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.

If you are in immediate danger of hurting or killing yourself or hurting someone else, then the study therapists may require you to stay in a hospital.

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 become pregnant after you have had at least one experimental session, the study doctors and the sponsor (MAPS) will ask you about and keep track of the pregnancy and 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, and diaphragms used along with spermicide and with partner use of condoms, or sexual abstinence while they are in the study and for at least one month afterward. The study therapists 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 of childbearing potential, you will be tested at the start of the study and again before each 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 contact Dr. Michael C Mithoefer MD immediately. If you should become pregnant during the study, the study doctors will help you get proper advice and help you and your unborn baby get proper care while you are pregnant.

Other risks: The interviews you will have during the study do not involve any risks or discomfort except for those which exist during a regular situation of a medical interview. You may feel **upset, bored or tired**. Answering questions about thoughts you might have of hurting or killing yourself may be upsetting.
The medical evaluation involves a number of blood tests. **The risks of blood collection** include temporary discomfort from the needle puncture, bruising, and rarely an infection at the needle puncture site. Fainting may also occur.
It is possible that after you stop taking your regular psychiatric medication (for depression or anxiety) due to your participation in the study, symptoms will reappear. There is also a risk that you may have thoughts of hurting or killing yourself when you stop taking medicine and are in psychotherapy, especially if you have had these thoughts before. If this happens, you have to talk with your external therapist and the study therapists. If you go back to taking the medication, the study therapists will have to take you out of the study,

You must not drive or operate machinery immediately after each experimental session (until 24 hours following it). This because the study drug may cause drowsiness, loss of coordination or slower reaction time.

Drug detection test
If you undergo a drug detection test during the three days after each experimental session, a positive result may be received. The study therapists will give you an information card in case you are tested for drug use, and if you are tested for drug use while you are in the

study, you can ask the person testing you to contact one of the study therapists in order to confirm that you are in this study.

Potential benefit
There is no guarantee that you will benefit from participation in this study. However, information obtained from this study may help doctors and investigators improve the treatment for PTSD in the future.

Alternative treatments
One alternative to participation in the study is to decide not to participate. You have the right to decide to try other treatments for PTSD. Other medications exist, such as Paxil (Paroxetine) or Zoloft (Sertraline) and anti-anxiety medications such as Xanax (alprazolam), and there are other forms of psychotherapy you can try. If you are currently receiving psychotherapeutic treatment and /or taking a medication, you can continue receiving them for a longer period.

Costs
The sponsor of this study, the Multidisciplinary Association for Psychedelic Studies (MAPS) will pay expenses related directly to this study. These include all the expenses for psychotherapeutic treatments, psychological tests and the laboratory tests, physical examinations for the study, and the study drug. You, your private medical insurance (if exists) and your HMO will not be charged for any procedure carried out for the purpose of the study. You or insurance company/HMO will stay responsible for ongoing treatment that is unrelated to the study.

Treatment of injuries and compensation for injuries
In case of a study related injury, the sponsor (MAPS) will pay any costs resulting from the treatment of the injury. The sponsor (MAPS) has an insurance policy to cover the participants in case of any disabilities resulting from the drug or procedures used in the study. The insurance certificate protects the sponsor, the institution, the investigators and sub-investigators from legal actions against them.

Payment for participation
You will not be paid for participating in this study. You can be reimbursed for travel expense from your place of residence to the Be'er Ya'akov Medical Center.

Confidentiality
Any information collected will be handled and processed as confidentially as possible, except for when the delivery of information is required by law. **Complete confidentiality cannot be guaranteed. This does not limit the obligation of the study therapists and of other people to protect your privacy.**
Israeli law demands the Be'er Ya'akov Mental Health Center and hospitals affiliated with it, the investigators, sub-investigators, health care professionals and doctors maintain the confidentiality of your identifying information concerning your physical and mental state in the past, present or future ("confidential medical information").

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 Institutional Review Board for Beer Yaakov Mental Health Center

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.

Legal rights
The aforementioned section does not limit your right to seek legal aid. By signing this subject information and consent form you do not waive any legal rights.

Voluntary participation
Your decision to participate in this study is completely voluntary. There will be no penalty or loss of privileges if you decide not to participate.
In addition, you have the right to withdraw from the study at any time. There will be no penalty if you decide to withdraw from the study. Before withdrawing from this study, inform your study therapists that you want to withdraw. Your notification will allow your study therapists to inform you if there are any possible medical risks involved in withdrawing. You may be asked to return to the clinic for tests.

Removal from the study
The principal investigator, the sponsor (MAPS), the Israeli Ministry of Health, the American Food and Drug Administration (FDA) have the right to discontinue the study at any time, with or without your consent, for any of the following reasons: if you have any undesired effect or health problems from the study drugs or if the study therapists think

for any other reason that continuing to participate in the study does not serve your best interest, if you require a treatment not approved in this study, such as starting an anti-depression or anxiety medication, if you do not arrive to sessions and do not follow the rules of the study, if you do not want to take the study drug according to instructions, if you become pregnant, or if the study is cancelled by the FDA, the Be'er Ya'akov Medical Center, the Israeli FDA, or the sponsoring company.

New information

If any information is discovered about MDMA while you are in this study, the study therapists will inform you about it as soon as possible.

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, contact:

[redacted]

In case of an emergency, please contact Dr. _____ at tel. _____
OR go to the nearest hospital emergency department.

If you have concerns that you don't feel comfortable asking the study therapists or sponsor, you may contact the local ethics board.

e) I hereby declare that my aforementioned consent has been given voluntarily and that I have understood all of the above. In addition, I have received a signed copy of this informed consent form, legally dated and signed.

f) By signing this consent form, I allow the clinical trial sponsor, the institutional Helsinki Committee, the auditing entity of the medical institute and the Ministry of Health direct access to my medical file in order to verify the methods of the clinical trial and the clinical data. This access to my medical information will be performed while maintaining confidentiality, in accordance with the laws and procedures of maintaining confidentiality.

g) In cases where the clinical trial involves the provision of services: performing medical tests or supplying equipment, preparations or implants, I declare that I know and agree to have the information on my participation in the clinical trial forwarded to my attending physician at the HMO / health services[1] with which I am insured.

I know that the HMO / health services will not use this information for purposes other than medical treatment and follow up.

Name of clinical trial participant	Signature of participant	Date

If necessary[2]:

Name of independent witness	ID number	Signature of witness	Date

Statement of the investigator / sub-investigator:

This consent was obtained by me after explaining to the clinical trial participant all the aforementioned and after making sure that all my explanations were understood by him/her.

Name of investigator / sub-investigator providing explanations	Signature of investigator	Date

[2]In case the participant in the trial or his legal representative is unable to read the informed consent form, an independent witness must be present throughout the explanation about the nature of the clinical trial. After the participant or legal representative thereof has expressed their oral consent to participate in the trial, the witness shall sign the consent form while stating the date of signature.