SUBJECT INFORMATION AND CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION FOR RESEARCH

Study Title: A Phase 1 Placebo-Controlled, Double-Blind Crossover Study to Assess Psychological Effects of MDMA when Administered to Healthy Volunteers

Company and Funding: Multidisciplinary Association for Psychedelic Studies (MAPS)
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PURPOSE OF THE SUBJECT INFORMATION AND CONSENT FORM
This consent form describes a research study and your role as a participant. Please read this form carefully. If you have any questions at all about the information provided, do not hesitate to ask. The investigator will describe the study and answer your questions.

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

PURPOSE AND BACKGROUND
This study, sponsored by MAPS, is designed to measure the psychological effects of MDMA in an MDMA-assisted psychotherapy session in up to twenty healthy volunteers. These effects include personality traits, mood, feelings of closeness to the self or others, and psychological symptoms.

MDMA is an experimental drug, which means that it has not been approved by the US Food and Drug Administration (FDA) for medical use except in research studies. MDMA is also a controlled drug (illegal to use outside of research) and is sometimes known as "Ecstasy" (which is supposed to contain MDMA, but often contains other drugs instead of or in addition to MDMA). MDMA has already been used legally in research and illegally in uncontrolled

environments such as nightclubs. While much is known about MDMA and its risks, much remains unknown about this drug.

You are being asked to participate in this research study in order to provide important information on the effects of MDMA on mood and personality in healthy people. In addition, you completed a sponsor-designed training program to teach you how to provide a standardized form of MDMA-assisted psychotherapy research. However, completing the training program and participating in this research study does not guarantee that you will be selected to conduct MAPS research studies.

This study will compare the effects of MDMA with the effects of a placebo (an inactive substance) given during two separate day-long sessions. Safety will also be assessed.

Type of Study
This study is a randomized, double-blind cross-over study. This means that everyone in the study will get MDMA during one session and placebo on another session; that is, there is a 100% chance you will receive MDMA, and a100% chance that you will receive placebo. However, the study session when you get MDMA or placebo will be decided by chance, as with flipping a coin. You will have an equal chance of receiving either MDMA or placebo on the first experimental session. Neither you nor the researchers will know when you will get MDMA and when you will get placebo. However, this can be determined if medically necessary.

Study Length
Your participation in this study will last approximately two months from the time you are enrolled. You will initially visit the investigator's office for a screening visit, and after you are enrolled, approximately five more times, including two day-long sessions followed by an overnight stay after each experimental session. There will be one day with no experimental sessions between the first and second experimental session. You may have to give permission for the researchers to gather relevant information (such as past medical records) in order to be allowed to participate in the study. Additional time may be needed to obtain and consider this information. You may also need to stop taking certain medications in order to be allowed to participate. After the second experimental session, you will have one week of daily telephone calls with the investigators, and two more telephone calls with the investigators one and two months after the first of the two experimental sessions.

Conduct
If you agree to take part in this study, you will first sign this Subject Information and Consent Form before any study-related procedures are performed, including discontinuation of any disallowed medications.

If both you and the head researcher, Dr. Mithoefer, agree that you should be in the study, you will be asked to agree to the following:

You will have to participate in all study visits and procedures. You may have to stop taking psychiatric medications for a long enough time for none of the drugs to be in your body when you participate in the first experimental (MDMA or placebo) session (although the physician

monitoring the study (the "study doctor") may make a specific exception, such as giving you medication for sleep or anxiety if needed after the MDMA session). If you are currently taking psychiatric medication for a psychiatric condition, you cannot be in this study. If you are taking psychiatric medications for a non-psychiatric condition, then you will need to give Dr. Mithoefer permission to talk to your doctor about whether it is advisable for you to stop taking the medication and how best to do so.

For your safety, it is very important that you tell the study doctor about all medications you are taking, including herbal or natural remedies from the week before until seven days after the second experimental session, and to check with the study doctor before you begin taking a new medication any time from the week before until the second experimental session.

PROCEDURES/WHAT WILL HAPPEN TO YOU

Schedule of Events

Time is counted from the first study visit after you are selected to be in the study. Screening will be done within one month before you start the study.

		Must be at study site				
	Screening	Preparation	Experimental Session 1	Integration 1	Experimental Session 2	Integration
Visit	up to 1 month before visit 1	1	2	3	4	5
Screening	X					
Medical Exam and History	X					
Tests (labs and ECG)	X					
Preparation		X				
Questionnaires	X	X	X	X	X	X
MDMA			X		X	
Overnight stay			X		X	
Integration				X		x
Telephone Contact	X					

*= Questionnaire over telephone; + = Questionnaire sent in the mail

Before you can participate in the study, the researchers must first make sure that you qualify for the study and that you are physically healthy. This evaluation may be performed over several office visits.

This process will include the following:

- Answering questions about your medical and psychiatric history, including: which (if any) medications you are currently taking, what kinds of medical and psychiatric treatment you have received (if any).
- A physical examination that will include measures of your blood pressure, pulse, temperature, and body weight.
- A brief examination of your heart and lungs, as well as a brief overall checkup to make sure that you are in good health.
- An electrocardiogram (ECG) to measure the electrical activity of your heart.
- A brief neurological exam will take place.
- A blood sample (about 2 tablespoons) and a urine sample for routine laboratory tests of hematology and chemistry, including thyroid function.
- Urine pregnancy test for women of childbearing potential.
- If it appears you are eligible for the study and you are on medications that would require tapering, you may be asked to begin tapering off medications.
- An HIV test. State law requires that the results of positive tests for HIV be reported both to you and anonymously to a local health agency.

Beginning of Study –Preparatory Session (Visit 1):

During the preparatory session, you and the researchers will discuss your expectations or plans for the experimental sessions and you will review and discuss what will happen during the experimental sessions. You will be asked not to eat anything or drink any alcohol after midnight on the night before the first session. The preparatory session will be similar to the type of preparation for a person undergoing MDMA psychotherapy. The preparatory session is your opportunity to talk with the researchers about any specific goals, plans or worries you may have about the experimental sessions.

During this session it will be confirmed that you are on no exclusionary medications. In addition, you will complete about five questionnaires about your personality and that include brief psychological testing. The preparatory session will be recorded to audio and video, and the researchers will give you a copy of these recordings as soon as they are available.

If you would like another individual present during one or both of the experimental sessions, a meeting between the study doctor and staff and that individual will be scheduled during this introductory session. Permission must be granted by the study doctor for the presence of another individual during an experimental session.

If you do not have a person who will stay with you overnight, you will also meet the attendant who will work at the clinic on the evening after each experimental session until the follow-up ("integrative") session the morning after the experimental session.

The study doctor or staff will also give you a set of written instructions and restrictions for what 24 hours before the experimental sessions. You must agree to take nothing by mouth except alcohol-free liquids after 12:00 A.M. (midnight) the evening before an experimental session. You must also refrain from the use of any psychoactive drug, with the exception of caffeine or nicotine, within 24 hours of each experimental session. You must not use caffeine or nicotine for 2 hours before and 6 hours after study drug administration.

They will remind you of this information before the second experimental session.

Experimental (MDMA or Placebo) Sessions (Visits 2 and 4):

There will be two day-long experimental sessions. The second experimental session starts the day after the follow up (integrative) session for the first experimental session, so that there is 48 hours between the two sessions. Subjects will receive MDMA during one experimental session and placebo during the other session. Every subject has a 50% chance of getting MDMA first.

You will have been asked not to eat anything or drink any alcohol after midnight on the night before the session. You can drink non-alcoholic liquids during this time, such as water or juice.

At the beginning of the first experimental session, you will have a urine drug test and (for female participants) a pregnancy test. At the beginning of the second experimental session, you will have a urine pregnancy test (for female participants) but not a drug screen. If the drug screen is positive, the session may be delayed, rescheduled or cancelled. If the pregnancy test is positive, you will be withdrawn.

You will have some brief psychological tests before and during each session. Some of these tests are meant to make sure you can still be in the study and to identify potential problems that may arise during the experimental session, while others are to measure mood or changes in how you think or feel. The researchers will discuss your goals with you, so that it will be clear what you want to achieve during each experimental session. The researchers will also answer any other questions you have about each experimental session.

The session will last for six to eight hours, though the researchers will remain with you for a longer period of time if necessary. You will also spend the night in the clinic and remain until after the follow-up session the next morning.

Your temperature, blood pressure and pulse will be measured before your study drug dose and during each experimental session.

You will complete a brief, simple questionnaire of how comfortable or distressed you feel every 60 to 90 minutes throughout the experimental session. This will allow the researchers to know how you are feeling throughout the session and to see whether your feelings of comfort or distress change after receiving MDMA or placebo.

The attendant will arrive during the last hour of the experimental session. If you choose, a spouse, close friend or family member can also join you at this point in the session.
You will be asked to report any side effects you may feel.

Each experimental session will be audiotaped and videotaped, so that the researchers will have accurate records of the session and so that they can gather more information about drug-assisted psychotherapy sessions. You will receive copies of these recordings.

After the preliminary tests, around 10:00 A.M., you will receive a capsule that contains either the placebo (225 mg lactose) or MDMA (125 mg mixed with 100 mg lactose). This is so the two capsules will have the same weight and appearance. After taking the capsule, you will sit or lie down in a comfortable position. You can ask for an eye shade if you wish. You may listen to music during much of each experimental sessions, through headphones if you are comfortable with them. Periodically you will be asked to talk to the researchers. You may also request periods of silence. Lying or sitting in a comfortable position and listening to music are meant to bring out emotional thoughts and feelings. Both researchers will remain with you, and they will help you if you need them to help you. They will speak with you and ask you to talk to them at least once an hour, but you can talk to them whenever you wish. There may be periods of time when, after you have been talking, they will suggest that you stop talking for a while in order to pay attention to your inner experience (your inner thoughts and feelings). There will be beverages available, and you will be encouraged to drink an adequate amount of fluid. You can drink it whenever you wish to do so, within the limits of the amount that is safe for your body. Later on, food will also be provided.

Approximately one and a half to two and a half hours later, you and the researchers will talk about possibly giving you a second capsule that will contain placebo or MDMA (62.5 mg). If you and the researchers agree, then you will take the second dose. The second dose will always be the same drug as the first dose; MDMA if your first dose was MDMA, and placebo if the first dose was placebo. You may decline the second dose. If you or the researchers notice problems after you took the first capsule, then you will not receive the second capsule.

The researchers will continue to measure blood pressure and pulse at regular intervals. Temperature will also be measured, but slightly less often. You will be monitored for any side effects, which will be treated if they occur. If this should occur, the researchers will explain what they are doing at all times.

If you decide you do not want to continue in the study during either the first or the second experimental session, you will still have to stay in the clinic until the researchers think that you are well enough to go and that all the effects of the drug have worn off.

If you have a spouse, close friend or family member whom you would like to be with after your session, he/she can arrive during the experimental session.

The attendant will arrive during the last hour of the experimental session. If you have arranged for it ahead of time with the researchers, he or she may also stay as the attendant, or may stay in addition to an attendant arranged by the researchers.

If you are confused or upset eight or more hours after the start of an experimental session, the researchers will stay with you until you have recovered more fully. If the researchers think you

are at risk for hurting yourself or others, they will either remain with you all night or have you admitted to a hospital until you are no longer at risk of hurting yourself or others. The researchers will ask you about thoughts about killing or harming yourself before and after MDMA administration and throughout the follow up period.

If the researchers determine that the effects of the drug have worn off and that you are in an appropriate frame of mind, they will leave the clinic with the attendant in charge. If you or the attendant consider it necessary, the attendant will call Dr. Mithoefer and request that he return to the clinic, which should take him between 10 and 20 minutes.

You will be spending the night in a room in the offices of Dr. Mithoefer. The attendant will be staying in another room nearby. If you find you need to talk with the researchers or you are having other problems and need to contact the researchers, the attendant will contact them immediately.

Follow Up (Integrative) Sessions (Visits 3 and 5):

There will be two follow-up or integrative sessions, one on the day after the first experimental session and one on the day after the second experimental session.

On the morning after each experimental session, you will have a 90 minute non-drug, "integrative" therapy session with the researchers before leaving the office. You will undergo brief psychological testing, including completion of 4 questionnaires, before beginning the integrative session.

During this integrative session, you and the study doctor will discuss your experience during the experimental session, any new thoughts or insights the experience gave you about your goals or issues, and any new thoughts or insights you might have about MDMA-assisted psychotherapy in general. You may also discuss any goals or plans you have for the second experimental session during the first follow-up. This session will be recorded to audio and video, and you will receive a copy of the recordings. In addition you will be asked to create a narrative on your experiences. You will also be asked about medications you take.

You will need to arrange ahead of time to have someone take you back to wherever you are staying (home, hotel or other location near the study site) from this non-drug session because we do not know how or for how long MDMA will affect your ability to drive, and because some people report feeling tired, less alert or having trouble concentrating a day after having taken MDMA. If you cannot find anyone to take you home, the researchers will find someone to drive you.

If you had confronted unexpectedly intense or disturbing material during an experimental session, the study doctor will provide means of continued contact throughout this day as needed. The integrative telephone contact schedule will be reviewed and additional integrative sessions with you may be scheduled, if needed.

Daily Telephone Calls with Researchers after the Second Follow-Up (Integrative Session):

After you return home, the study doctor or study staff will telephone you every day for a week to inquire about how you are feeling and to see if you have any problems, either psychologically or medically, after the MDMA session. You will be asked about medications you are taking. If the study doctor determines you need it and you agree to it, additional meetings can be scheduled. If you have an additional meeting during this time, you will not have a telephone call that day.. These telephone calls usually last between 5 and 15 minutes but can last as long as is necessary. You will have some short psychological testing over the telephone on the first and last day of daily telephone contact.

You can contact the study doctor or staff at any time. Dr. Mithoefer will be on call (reachable by telephone or pager) 24 hours a day throughout the two month study, except on occasions when he is out of town, in which case another study doctor will be available. The contact information will remain the same.

One and Two Month Follow-Up:

The study doctor or study staff will call you on two additional days, approximately one and two months after the first experimental session, to inquire about how you are feeling and to see if you have any psychological or medical problems, and to discuss any good or bad experiences you had after experimental sessions. You will also have a short psychological test during each of the telephone calls. You will be asked about medications you are taking. The study doctor or study staff will ask you about ways in which the experimental sessions influenced your view or your thoughts on the practice of MDMA-assisted psychotherapy, as well as any long-term good or bad effects that arose from the experimental sessions. The telephone calls will probably last between 5 and 15 minutes but can last as long as is needed.

Approximately two months after the experimental sessions, the study doctor or study staff will send you one of the same psychological tests that you had completed at the start of the study, for you to complete and mail back using an envelope sent along with the measure. The return envelope will be pre-stamped and have the research office address as return address. The completed test should be returned within two (2) weeks of your receiving it.

POSSIBLE RISKS OR DISCOMFORTS

MDMA has not been widely tested in human subjects. Some of the effects that have been observed are listed below.

Side effects during the MDMA experience that are less severe but more frequently reported, are:

- lack of appetite (70%)
- teeth grinding or tight jaw muscles (63%)
- dry mouth (57%)
- difficulty balancing or walking (44%)
- decreased concentration (42%)
- neck or back pains (50%)

Between 40% and 70% of subjects in previous studies reported these side effects. Between 15% and 40% of subjects reported (from most to least common) feeling either hot or cold, feeling that

their heart was racing, sweating, dizziness, drowsiness, upset stomach, diarrhea, anxiety, tenseness, thirst, weakness, fatigue, shaking, headache, irritability, or feeling faint. 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.

Risks from MDMA

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 subjects without emotional disorders and 21 with PTSD) most subjects reported experiencing temporary and minor changes in vision and hearing, such as sounds seeming closer or farther away than usual or objects seeming brighter than usual. These changes typically lasted 2 to 3 hours. 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 35 mmHg (measurement unit for blood pressure) and average diastolic blood pressure increase is 20 mmHg. Heart rate may increase by approximately 30 beats per minute (BPM). The study doctor will be prepared to treat sustained or significantly elevated blood pressure.

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

Anxious or jittery feeling: Some subjects in previous studies (16%) reported feeling over-stimulated or anxious. 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 17% and 23% of subjects have reported insomnia (difficulty sleeping) or feeling tired, irritable, or drowsy for as long as 3 days after receiving MDMA.

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, 14% 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 6 months) had problems with drug abuse should not take part in this study.

Possible Brain Damage: Experiments in rats and monkeys show that high and repeated doses of MDMA can change certain brain cells that release a chemical called serotonin; in mice (though not in humans), the affected cells release dopamine. The changes include loss of the parts of the 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.

Other Risks:

You should be very careful when driving or using machinery immediately after the experimental sessions (up to 24 hours afterwards). This is because the study drug may cause drowsiness, lack of coordination or slower reaction time.

If you are tested for drugs of abuse within three days after the experimental session, you may test positive. You will receive a wallet with telephone numbers for reaching the researchers, and other people related to the study. The wallet card will include a sentence saying that you might test positive for drugs of abuse. You can show this to the person in charge if you are tested for drugs while you are in the study and they can call Dr. Mithoefer to verify that you are participating in this study.

The interviews and psychological tests you receive over the course of the study involve no specific risks or discomforts beyond those of a standard clinical interview situation. You may feel upset talking about some life experiences, or you may feel boredom or fatigue.

The medical evaluations involve some blood tests. The risks of blood drawing include temporary discomfort from the needle stick and bruising. In rare instances, fainting could also occur.

REPRODUCTIVE RISKS:

The 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 participate in the study if you are pregnant.

Women who are able to become pregnant must use one of the allowed birth control methods while they are in the study and for at least one month afterward. The researchers will explain these methods to you and will help you decide which might be best for you. The researchers can also suggest where you can get more information and advice.

You will be tested at the start of the study before the MDMA session to see if you are pregnant. If, at any time during the study, you suspect that you may be pregnant or are concerned that you may become pregnant, you must advise Dr. Mithoefer immediately. If you should become pregnant during the study, the researchers will help you with a referral if needed and will follow you through to the outcome of your pregnancy.

NEW FINDINGS

If any new information becomes available about MDMA while you are participating, the investigators will tell you about it. You may contact the study doctor at any time after your participation ends to find out if any new information about this study has become available.

POSSIBLE BENEFITS

There is no direct medical benefit to you.

Participating in this research may contribute to knowledge about the psychological effects of MDMA in healthy people. After you have completed the training program for learning MDMA-assisted psychotherapy, and have had both the MDMA and placebo experimental sessions in this study you may better appreciate and understand MDMA-assisted psychotherapy. This may give you a more accurate idea of what the experience is like for future patients with PTSD.

COSTS

The sponsor of this study, the Multidisciplinary Association for Psychedelic Studies (MAPS), will cover the costs that are directly related to this study. This includes the costs for all psychotherapy sessions, for the psychological and laboratory testing, for medical examinations, and for the experimental study drug. You will not be charged for any procedures done solely for the purpose of the study.

If you are currently conducting a MAPS-sponsored Phase 2 pilot study of MDMA-assisted psychotherapy, your travel expenses will be covered. If you are not currently conducting a MAPS-sponsored Phase 2 pilot study, you will need to pay your own travel expenses to and from the research location.

Other travel expenses (including lodging and meals) will not be reimbursed.

You or your insurance will remain responsible for on-going treatment unrelated to the study.

REIMBURSEMENT FOR PARTICIPATION

You will not be paid for taking part in this study.

ALTERNATIVES

Your alternative is to decline to participate. You do not have to participate in this study to be eligible to work in a MAPS-sponsored clinical trial.

CONFIDENTIALITY

All information collected will be treated and handled as confidentially as possible. However, absolute confidentiality cannot be guaranteed. When not in use, information will be stored in a locked office.

Some people need access to the information to monitor the study or for regulatory purposes so copies will be made of some documents. If documents are copied for this purpose, all information that could be used to identify you will be removed first.

Medical records and other study documents may be seen by:

- the sponsor, MAPS;
- the FDA and similar agencies in other countries;
- the Department of Health and Human Services (DHHS) agencies;
- governmental agencies in the US and in other countries;
- Copernicus Group Independent Review Board (IRB)

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

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

Audiotapes and videotapes: Only MAPS researchers and therapists, researchers participating in MAPS training programs, and regulatory agencies such as the Food and Drug Administration, will listen to or watch these recordings. No identifying information will be written or otherwise attached to the recordings. Any other use of recordings, such as presentation at scientific meetings or use in documentaries, will be done only with your specific additional written permission. You will receive a copy of the audio recording of your experimental sessions. This is to give you an opportunity to listen to what you and the researchers said during the session, and to think about what happened during the experimental session at a later date. You may listen to the tape if you wish, but you do not have to listen it. You will not automatically receive a copy of the video recording of your experimental session, but if you wish, you may also receive a copy of the video recording.

TREATMENT AND COMPENSATION FOR INJURY

In the event of a study-related injury, the physician who treats you will bill your insurance company. If your insurance company denies coverage or insurance is not available, then MAPS will pay for any costs that arise from treating a study-related injury, including hospitalization.

Neither the Sponsor nor the study doctor has a program in place to provide other compensation in the event of an injury.

LEGAL RIGHTS

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

VOLUNTARY PARTICIPATION

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

In addition, you may withdraw from the study at any time. There will be no penalty if you decide to withdraw from the research study. Before withdrawing from this study, notify your study doctor that you wish to withdraw. This notice will allow your study doctor to inform you if there are any potential medical risks of withdrawal. You may be asked to return to the clinic for tests.

WITHDRAWAL

Your doctor, the sponsor company, 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, if you do not keep appointments, if you do not take the study drug as instructed, if you become pregnant, or if the study is canceled by the FDA or the sponsor company.

QUESTIONS

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

Dr. Michael C. Mithoefer MD

If you have other questions about other effects of MDMA, you can contact Rick Doblin, Ph.D., President of MAPS, the organization sponsoring this study.
The address is:

Rick Doblin, Ph.D.

If you have concerns that you do not feel comfortable asking the investigator or sponsor, you may contact the Independent Review Board (IRB) that approved this study:

[redacted]

An Independent Review Board 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 safety and welfare in mind. Copernicus Group IRB has reviewed and approved the research study described in this Subject Information and Consent Form**.** If you have study-related comments, complaints or concerns, you should first contact the study investigator. Please call the IRB if you want to talk to someone other than the study investigator or have difficulty reaching the study investigator. For further information regarding the clinical trials process and your role as a research subject, you may visit the Copernicus Group IRB website at www.cgirb.com.

The study doctor or study staff will give you a wallet card containing contact information for the researchers, the sponsor and the 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

Protocol Title: *A Placebo-Controlled, Double-Blind Crossover Phase 1 Study to Assess The Psychological Effects of MDMA on Mood and Personality Traits when Administered to Healthy Volunteers*

My participation in this study is voluntary. I may refuse to take part in or you may stop taking part in this study at any time. I should 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 have read the information in this consent form and it has been discussed with me. All of my questions so far about the study and my participation in it have been answered. I freely consent to participate in this research study.

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

	SUBJECT		INVESTIGATOR
Printed name			

Signature			
Date			

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION FOR RESEARCH

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, «FirstName» «MiddleName» «LastName» «Suffix», 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 and the Copernicus Group Independent Review Board may also review or copy your information to make sure that the study is done properly or for other purposes required by law.

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

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

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

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

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

Dr. Michael C. Mithoefer MD
[redacted]

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

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

AUTHORIZATION

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

	SUBJECT		INVESTIGATOR
Printed name			
Signature			

Date			