[FOR CALIFORNIA SITES ONLY]

California Experimental Subject's Bill of Rights

Any person who is requested to consent to participate in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Learn the nature and purpose of the study (also called "experiment", "clinical trial" or "research").
2. Receive an explanation of the procedures to be followed in the medical study, and a description of any drug or device to be used.
3. Be informed of any related discomforts and risks that can reasonably be expected from participating in the study.
4. Learn about any benefits you might expect from the study, if applicable.
5. Be told about any other procedures, drugs or services that might be helpful to you and the relative risks and benefits of these alternatives.
6. Be informed of the medical treatment, if any, available to you if you are injured because of the study.
7. Ask any questions about the study.
8. Stop the study at any time without any effect on your healthcare benefits or medical care, even if you stop the study.
9. Receive a copy of the signed and dated consent form when one is required.
10. Decide to consent or not to consent to a medical study without feeling forced to participate.

_____

Printed Name of Subject

_____

Signature of Subject

_____

Date

<<CF-Main User Defined #2>>

**PARTICIPANT INFORMATION AND CONSENT FORM
AND HIPAA AUTHORIZATION**

TITLE: A Randomized, Double-Blind, Placebo-Controlled, Multi-Site Phase 3 Study of the Efficacy and Safety of Manualized MDMA-Assisted Psychotherapy for the Treatment of Severe Posttraumatic Stress Disorder

PROTOCOL NO.: MAPP1
IRB Protocol # 20180587

SPONSOR: Multidisciplinary Association for Psychedelic Studies (MAPS)
1115 Mission Street
Santa Cruz, CA 95060

CLINICAL INVESTIGATOR NAME: <<CF-Main Investigator Name>>

<<CF-Main Header Block - Sites>>
STUDY RELATED PHONE NUMBER(S): <<CF-Main User Defined #1>>

You should keep a copy of this form. If you have any questions or problems during the study, call the phone number(s) above.

PURPOSE OF THE PARTICIPANT INFORMATION AND CONSENT FORM
This consent form describes a research study and your role as a participant. This consent form may have words in it you do not clearly understand. Please read this form carefully before you decide to be in this study. You may ask the study staff any questions about the information provided.

The purpose of this form is to give you information about the study and, if signed, the form gives us your permission to participate. Signing this form does not guarantee that you will be enrolled in the study. The form describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. You should participate only if you want to. You may refuse to take part or withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. Signing this form will not result in you losing any of your rights. The main purpose of this form is to make sure that we clearly explain to you what the study is about.

You may take home an unsigned copy of this consent form to think about or discuss with family or friends before deciding whether or not to participate.

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.

Your study doctor, research and therapy team will be paid for their time to conduct this research study. <<CF-Main Financial Disclosure>>

This document uses words such as treatment, drug, medication, and participant. Please remember this is a research study and the use of these terms does not mean the use of the drug has been found to be safe or effective for your condition.

Before you decide whether to participate, you should think about how the tests and study visits will affect your time away from work and your schedule.

BACKGROUND
You are being asked to participate because you have reported symptoms of posttraumatic stress disorder (PTSD) lasting for at least six months or longer.

This multi-center study is designed to provide information on whether the drug MDMA combined with psychotherapy is safe and helpful for people who have PTSD.

MDMA is an experimental drug, which means that it has not been approved by the Food and Drug Administration (FDA) for sale for medical use in the United States (U.S.). MDMA is also a controlled drug (illegal to use outside of research) and is sometimes

known as “Ecstasy” or “Molly” (which is supposed to contain MDMA, but often contains other drugs instead of or in addition to MDMA). 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 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.

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 eight studies of MDMA-assisted psychotherapy in the U.S., Canada and Israel.

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

This study will test the safety of MDMA-assisted psychotherapy and whether it works. During MDMA-assisted psychotherapy sessions, you will receive a dose of MDMA or placebo and possibly a second dose equal to half the size of the first dose about two hours later. You will have either the same dose or a slightly higher dose for the second and third sessions, which will happen roughly one month apart.

TYPE OF STUDY

This study is double-blind, meaning neither you nor the study researchers will know if you get MDMA or placebo. You may get MDMA, or you may get a placebo (pills that do not contain MDMA). The drug you get will be decided at random, as if by tossing a coin. However, this information will be available if needed in case of an emergency. You will have a 50% chance of receiving MDMA and a 50% chance of receiving the placebo. Once the entire study is completed and all participants at all study centers have finished, you will find out what you received. There will be a total of at least 100 people in the study across multiple locations. Whether you receive MDMA or placebo, you will receive psychotherapy as well.

LENGTH OF STUDY

The length of active participation in the study will be about 19 to 38 weeks, depending on the length of screening and the time in between your study visits. Participation in the

study requires a large time commitment from you over the active study period. To confirm that you are eligible for the study, there will be multiple in-person visits to the study location, lab, and doctor's office, at least one online meeting with an evaluator, and phone calls from the study team. Then, there will be three preparatory visits, three day-long visits with overnight stays, and nine integrative (talk therapy) visits for you in a 13 to 26-week period (depending on visit scheduling). The audio and video of these visits will be recorded. There will be two evaluation days where you will complete many questionnaires. There will also be four online meetings with an evaluator who will ask you questions about your PTSD symptoms. You will meet also with the staff and therapy team about two months after your last Overnight Test Session.

The timeline for starting treatment after enrollment is variable depending on availability of appointments and if you need to discontinue any medications. You may have your first Overnight Test Session as soon as 2 weeks, or as long as 11 weeks after your first visit. Overnight Test Sessions last all day and require an overnight stay at the clinic afterwards. After these overnight stays, you will have eight brief phone calls with the therapy team during the 14 days after the visit.

You will be invited to enroll in a 12-month follow-up study at the end of your participation. This will be explained in another informed consent form.

When the study is complete, if we learn that you received placebo and if you still meet all study criteria, you will be invited to enroll in another study where you will get MDMA-assisted psychotherapy. This study would not start until all participants have completed this current study. This would be at a minimum a year and a half from the start of this study.

TYPES OF VISITS AND DURATION:

Screening Visits: Multiple visits at the study location, lab, and/or doctor's office, an online meeting with an evaluator, and phone calls from the study team.

Preparatory Visits (~90 minutes each): Three introductory sessions at the start of participation in the study, spaced about one week apart.

Integration Sessions (~90 minutes each): Three sessions after each Overnight Test Session. These are approximately one to three weeks apart and will involve you talking to your therapists about your thoughts and feelings. Some of these visits may be done remotely.

Telephone Calls after Integration Visits (~15-20 minutes each): Eight phone check-ins will take place on days 2, 4, 6, 7, 8, 10, 12, 14 after each Overnight Test Session.

Overnight Test Sessions (~8 hours long plus an overnight stay): Three visits about a month apart. You will be given either MDMA or placebo during these visits along with psychotherapy.

Online Meetings (60-90 minutes each): Four online video meetings where you will be interviewed about your PTSD symptoms. You will need to come to the study site for these meetings unless your research team tells you otherwise.

Evaluation and Testing Visits (90 to 120 minutes): Psychological testing and completing questionnaires two times, starting with the beginning of the study.

You will need to be flexible about taking the appointments offered most of the time because there is a limited time frame for each type of visit.

Please note that because of the COVID-19 pandemic, it may be necessary to delay some study activities, including the Experimental and Integrative sessions.

PROCEDURES/WHAT WILL HAPPEN

Screening/Evaluation and Beginning of Study
If you agree to be in this study, you will first sign this form before any study-related procedures are done.

Before you can be in the study, the study doctor must first make sure that you qualify for the study and that you are generally physically healthy. This screening process can take up to six weeks, and there will be one or more office visits and online meetings with an evaluator during this time. The online meeting will be recorded, and you will need to come to the study site. The study doctor may ask you for written permission to contact your doctors or psychotherapists to get information about your medical history. They may need to do this so that they will know whether you can be in the study or not.

If there are other medical concerns during screening, you may be asked to do additional testing with your primary care physician or another doctor. The study doctors will explain any tests they are asking you to do.

Psychological and medical screening will be done by staff, doctors, or your therapy team. The tests will include the following:

- 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.

- An interview about any psychological or psychiatric issues you may be experiencing, or that you have experienced in the past.
- A brief interview about thoughts you might have about hurting or killing yourself.
- Psychological questionnaires you fill out yourself.
- A physical examination that will include measures of your blood pressure, pulse, temperature, and body weight. This information will also be used to calculate your Body Mass Index (BMI).
- An ECG (electrocardiogram) and rhythm strip will also be taken, which are recordings of the electrical activity of your heart.
- A sample of your blood (about 2 tablespoons) and a urine sample for routine laboratory testing, including tests of metabolism, liver function, and alcohol use. We will also test for the human immunodeficiency virus (HIV) and Hepatitis C virus (HCV).

    - If you have positive test results for HIV or Hepatitis C, we will notify you. If the state we are practicing in requires that we notify state health authorities of positive results, we will do so. If you test positive for Hepatitis C, you will only be able to participate if you currently don't have symptoms of Hepatitis C (asymptomatic) and have been previously treated for it. If you do not want to be tested, you should not take part in this research study.

- A urine test for drugs of abuse. Urine drug screen will be reviewed in order for you to take part in the study. We will not report findings of drugs to any authorities.
- A urine pregnancy test if you are able to get pregnant. Your urine pregnancy test must be negative for you to take part in the study.

If you pass the initial screening and choose to participate, you will be enrolled in the study. However, this does not mean you are guaranteed to be able to participate in Overnight Test Sessions. The screening process continues until Visit 4, when the therapists will let you know whether or not you are fully eligible to participate in the study.

Beginning of Study

Once you pass the initial screening, we will schedule your first preparatory psychotherapy session with the therapy team.

If you are taking certain medications, you may need to stop taking them before you have your first online meeting to discuss your PTSD or your first Overnight Test Session. Your study doctor will discuss the medication plan with the doctor who prescribed the medications. Only stop medications if the study doctor gives you specific instructions for how to stop. Some PTSD medications can cause thoughts about wanting to kill yourself if you stop taking them too quickly and without the care of a

doctor. **This is very important. Do not stop taking any medications before you are supposed to.**

You must let the therapy team know about any change in medicines or medical conditions or procedures, like surgery, within 48 hours of it happening.

You will need to give the therapy team 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, should you become at risk of hurting yourself or someone else, or if the study team cannot get in touch with you, so they can reach that person to let them know what is going on or find out if you are okay.

Schedule of Events

The tables below show the type of in-person visits and online sessions you will have if you are selected to be in the study. All in-person visits and online sessions will be audio recorded to and video so that the therapy team will have accurate records of the sessions, and so that they can gather more information about these sessions.

Table 1: Schedule of Events

	Screening (2-6 weeks)	Screening, Intro, Preparation (1-11 weeks)				Treatment 1 (about 4 weeks)					Treatment 2 (about 4 weeks)					Treatment 3 (about 4 weeks)				Evaluation	Study Termination
																				(about 6 weeks)	
Visit #		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Informed Consent	✓																				
Medical Screening	✓																				
Bloodwork, ECG, rhythm strip	✓																				
Drug and Pregnancy Test	✓				✓	✓					✓					✓					
Measure PTSD Symptoms				✓					✓					✓						✓	
Other Psychological Testing	✓				✓					✓					✓				✓		✓
Psychotherapy		✓	✓		✓		✓	✓		✓		✓	✓		✓		✓	✓	✓		
Overnight Test Session						✓					✓					✓					
Phone Calls over 2 weeks							✓					✓					✓				

Preparatory Sessions

The first two preparatory sessions will last approximately 90 minutes and the last preparatory session will last about 2.5hours. These visits will be recorded. During each preparatory session, you will talk about the traumatic incidents that led to your PTSD, the ways PTSD symptoms are affecting your life, and what you would like to achieve during the study. You will be asked questions about thoughts or feelings you might have about hurting or killing yourself and complete psychological questionnaires in the third preparatory session. There will be four visits total during this period. You will need to come to the study site for all four visits: Three therapy visits and an online meeting with a researcher who will ask you questions about your PTSD symptoms. This information will be used to learn how you are doing after the study treatment.

At the third preparatory session, the staff will let you know whether you will continue on to the treatment part of the study. There are many reasons why you may not be eligible to continue in the study after the preparatory sessions. The study has very specific criteria. If you do not qualify for the study, this does not mean the study staff think you are not suffering from PTSD or that the treatment would not work for you in the future. If the study staff believe there is anything medically wrong with you, they will notify you so you can get follow-up care.

Overnight Test Sessions

If you qualify for the study after the preparatory sessions, you will be fully enrolled in the study. There will be three day-long Overnight Test Sessions. These visits will happen 3 to 5 weeks apart. These visits will be recorded. The first Overnight Test Session will occur after you have had three preparatory sessions. During the Overnight Test Session, you will receive a dose of either MDMA or placebo (pills that do not contain MDMA) followed 1.5 to 2 hours later by a dose of half the first dose of MDMA or placebo. During the second and third Overnight Test Sessions, you and your therapy team can decide if you would like to take the same dose you took in your first Overnight Test Session, or if you would like to try a higher dose. Your therapy team will discuss the optimal dose of MDMA with you for the second Overnight Test Session. The goal will be to decide on the optimal dose for you.

You must not eat any food or drink any alcohol after midnight on the night before each visit, though you can drink non-alcoholic liquids during this time, such as water or juice. You cannot use any psychoactive drug, with the exception of caffeine or nicotine, within 24 hours of each Overnight Test Session (or longer depending on the specific drug – this should be discussed with the therapy team). You cannot use caffeine or nicotine for 2 hours before and 6 hours after you take the first dose during the Overnight Test Session. For 1 week before each Overnight Test Session, you cannot take any herbal supplements, nonprescription medications, or prescription medications that have not been discussed and approved with the therapy team and study doctor.

If you are taking certain opioid medications for pain management, you can stay on these medications during treatment, although we will ask you to reduce the dose before each Overnight Test Session and stop taking them for 12 hours before and at least 24 hours after the first dose in each Overnight Test Session. If your pain becomes too severe to handle during this period, you will be allowed to take your medication.

First, you and the therapy team will discuss your goals for the Overnight Test Sessions and the therapy team will answer any other questions you may have.

Before an Overnight Test Session:

- Your urine will be tested for drugs of abuse, including stimulants, sedatives, opioids, and cannabis.
- If you can become pregnant, you will take a urine pregnancy test.
- Answer questions about thoughts you might have about hurting or killing yourself.

After urine testing, you will receive a dose containing either MDMA or placebo. After taking the dose, you will then sit or lie down in a comfortable position. You can ask for eyeshades if you wish. You will listen to music during much of each Overnight Test Session, either through headphones or room speakers. During the session there will be times when you will be asked to talk to the therapy team. If you are wearing headphones, you may remove them yourself if you want to talk to the therapy team or have times of silence. Lying or sitting in a comfortable position and listening to music are meant to bring out thoughts and feelings, including thoughts and feelings about past traumatic experiences. The therapy team will remain with you, and they will help you if you need them to. 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 times when the therapy team will suggest that you stop talking for a while in order to pay attention to your thoughts and feelings. There will be beverages available, including juices or Gatorade® or similar sports drinks, and you will be encouraged to drink an adequate amount of fluid. You can drink it whenever you wish to do so, within the limits of the amount that is safe for your body. In the afternoon, food will also be provided.

Approximately 2 hours after you take the first dose, you may take a second dose, after discussion with the study doctor. The second dose will contain half the amount of the first dose. The second dose may make the effects last longer. If you or the therapy team notice you have problems after the first dose, then you will not get the second dose.

The therapy team will watch for any side effects (unwanted effects or health problems), which will be treated if necessary. If this happens, the therapy team will keep you fully informed about any concerns or treatment. Your blood pressure, temperature, and pulse will be measured before taking the first and second doses and at the end of the session. If you have any symptoms including confusion, light-headedness, dizziness, chest pain,

shortness of breath, tell your therapy team. More frequent measurements may be needed if this happens.

If you are confused or upset 8 or more hours after the start of an Overnight Test Session, the therapy team will stay with you until you have fully recovered. If the therapy team thinks you are at risk of hurting yourself or others, they will either remain with you all night or admit you to a hospital until you are no longer at risk. The therapy team will ask you how you feel at the beginning and end of the Overnight Test Session and on several occasions during the phone follow-up period.

You will be spending the night in a room at the office of the therapy team with an attendant who will be staying in another room nearby. You can use the kitchen if you want. If you find you need to talk with the therapy team or you are having other problems and need to contact the therapy team, the attendant will contact them immediately.

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

After you return home from the therapy session, the therapy team will talk to you by phone on Days 2, 4, 6, 7, 8, 10, 12, and 14 after each Experimental Session to ask how you are feeling and see whether you should see the therapy team before your next scheduled non-drug therapy session. You and your therapy team can decide which days would be best to speak on the phone. The phone calls will take approximately 15 minutes, though they can be as long as you need them to be. The therapy team will ask you about thoughts about killing or harming yourself during the second and seventh day of phone contact. You can call the therapy team at any time; except for a few times when they may be unavailable. At those times the study doctor will be on call and can be called at the 24-hour number provided on this consent form.

The therapy team will give you a card with phone numbers for calling the emergency number and the IRB, which is an independent committee that protects the rights and welfare of study participants. You can keep this card in your wallet to make it easier for you to contact the therapy team if you need to.

If there are delays in following the usual study schedule, the therapy team will call you at least once a week to talk about how you're doing. These calls will take about 15 minutes. You need to agree to call the study doctors if any of the following things happen:

- you have an increase in symptoms that you have taken medication for in the past
- you have a new symptom or medical issue
- you need to contact your outside therapist other than for the usual appointments
- you start or stop taking a prescription medicine or an over-the-counter medicine that you have not previously cleared with the therapy team
- you go to the hospital for any reason

If you have very high blood pressure, get sick, or have an uncomfortable and strong lasting negative reaction (unwanted effect or health problem) during or after an Overnight Test Session, you or the therapy team may decide that you should not have the next Overnight Test Session. You may also make the decision to stop treatment in the study for any reason.

If the therapy team decides to take you out of the study for medical reasons after you have taken the study drug, they will let you know that they are doing this and their reason for doing it. They will help you find a therapist who can continue to help you with your PTSD, if needed. If you are taken out of the study or decide you do not want to receive treatment in the study, the study researchers will ask you to complete some final questionnaires about your PTSD symptoms. This is optional. If you decide you do not want to continue in the study during an Overnight Test Session, you will still have to stay in the office until the therapy team thinks that you are stable enough to leave and that all the acute effects of the drug have worn off. If this happens, you will also be asked to take part in some of the same interviews and questionnaires you completed at the beginning of the study. This is optional.

Integration Visits

The day after each Overnight Test Session, and 2 to4 weeks afterward, you will have therapy visits 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 Overnight Test Session. There will be three of these visits after every Overnight Test Session visit. These visits will be recorded. Some of these visits may happen remotely via telemedicine. These visits will last about 90 minutes. The therapy team will ask you questions about thoughts about killing or harming yourself at these sessions. At the last integration therapy visit you will also complete a psychological questionnaire.

Measuring PTSD After Sessions

Within one month after the first two Overnight Test Sessions and two months after the last Overnight Test Session, you will meet with an evaluator online, which will be recorded. These meetings will happen at the study site unless the study team tells you otherwise. The researcher will ask about your PTSD symptoms. You will also meet with your therapy team about 2 months after your last Overnight Test Sessions to fill out the same questionnaires from the start of the study. You will also be asked if you have had

any thoughts about hurting or killing yourself. The researchers will measure your blood pressure and weight. The tests will help the therapy team tell if your symptoms have changed or stayed the same over time.

At or after this visit you will also be invited to participate in a long-term follow-up study for an additional visit 12 months from the last time you had an Overnight Test Session to see if the changes in people's PTSD symptoms continue to improve, stay the same, or worsen over time after the study. There will be a separate consent form for this study.

You and the therapy team will discuss how you will be notified of whether you received MDMA or placebo once the study concludes. At that point, if you received placebo, you will be invited to participate in an extension study where all participants will receive MDMA. This may happen up to 2 years after you finish this study. There will be a separate consent form for that study if you wish to participate.

POSSIBLE RISKS OR DISCOMFORTS
MDMA has not been widely tested in humans, but as of October 2019, 1,600 people have been given MDMA in clinical research settings. Some of the effects that have been observed are listed below.

Side effects that are typically not severe but are more frequently reported at active doses of MDMA include:

- Anxiety (about four-fifths – 80%)
- Teeth grinding or tight jaw muscles (about two thirds - 66%)
- Lack of appetite (about half - 50%)
- Headache (about half – 50%)
- Fatigue (about half – 50%)
- Dizziness (about half – 50%)
- Nausea (about half – 50%)
- Sensitivity to cold (about two-fifths – 40%)
- Muscle tension (about one-third – 33%)
- Sweating (about one-third – 33%)
- Insomnia (about one-third – 33%)
- Restlessness (about one-third – 33%)
- Thirst (about one-third – 33%)
- Difficulty balancing or walking (about one-fourth – 25%)
- Dry mouth (about one-fourth – 25%)

One-fifth of participants or less reported (from most to least common) the following effects: low mood, difficulty concentrating, private worries, eye wiggling, heavy legs, tingling of hands or feet, drowsiness, irritability, weakness, need for more sleep. 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 research 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 research grade MDMA in a controlled setting with a trained therapy team who will be closely monitoring your physical and psychological reactions, these problems are not expected to occur either during or after the Overnight Test 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, 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 two to three hours. People also reported unusual feelings in their bodies, such as tingling or numbness.

Blood pressure and heart rate: The effects of MDMA usually last 6 to 8 hours with the first and second dose. 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 27.5 mmHg (measurement unit for blood pressure) and average diastolic blood pressure increase is 13.1 mmHg. Heart rate may increase by approximately 28.4 beats per minute (bpm) on average.

In past studies supported by MAPS, blood pressure rose well above normal levels in about one-third participants after taking MDMA, but these participants 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 blood vessel conditions. These serious problems could include an irregular heartbeat, heart attack or stroke. We will screen all potential participants 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: A little less than four-fifths (80%) of participants with PTSD in past studies who received MDMA reported feeling 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 therapy team will work with you to deal with these feelings. It is possible that if such periods of heightened emotion do not clear up or grow weaker during the session, you could be at increased risk for suicide or other self-harm afterwards. You will be encouraged to ask the attendant to call the therapy team immediately if you have any thoughts about hurting or killing yourself so they can safely help you. If needed, 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.

Your PTSD symptoms may get worse during the study.

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 and drowsiness: In previous studies, participants have reported insomnia (difficulty sleeping) or feeling tired, irritable, or drowsy for as long as 3 days after taking MDMA. If needed, the study doctor may prescribe medication for sleep. ***You should not drive or use machinery immediately after Overnight Test Sessions (up to 24 hours afterwards)****.* This is because the study drug may cause drowsiness, lack of coordination or slower reaction time.

Mood: Some after-effects of MDMA may be noticed up to two or three days later. While some participants feel that their mood is better, about one-fifth (20%) feel that it is worse.

Immune system: You may have a less active immune system for two or three days after taking 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 had problems with drug abuse should not be 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.

Emotional openness: MDMA is considered an "empathogenic" drug. This means people who use it may experience increased empathy and sociability. After taking the study drug, you may feel more emotionally open, friendly, extroverted, or talkative. You may also feel closer to your therapists or more trusting of them, or you may even feel love and sexual feelings toward your therapist(s). This can happen with any psychotherapy but may be heightened by MDMA. Your therapists are aware of the effects of the drug. They have been through training on how to appropriately care for someone who has taken MDMA and on a code of ethics that prohibits any sexual relations between therapists and participants, including after participation in the study has ended. All of your therapy sessions are recorded. One of the reasons for this is to ensure your safety. Videos are randomly reviewed by a group of trained researchers. Your therapists also have supervisors who continue to oversee and train them throughout the study.

RISKS OF BEING IN THE STUDY

If you are tested for drugs of abuse within 3 days of each Overnight Test Session, you may test positive. The therapy team will provide you with an information card in case you are tested for drugs of abuse, and if you are tested for drugs of abuse while you are in this study, you can have the person(s) testing you call your therapy team to verify that you are in this study. This card may not protect you from discipline at work or loss of employment. The study doctors will discuss when and how to present the information card. The card will not prevent you from being stopped or cited if you are driving erratically or poorly, so you should not operate machinery or drive a car until you feel normal again.

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

There is a risk of loss of privacy related to the conduct of audiovisual sessions during the study.

The medical evaluation involves some blood tests. 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.

It is possible that after you stop taking certain psychiatric medicines (as for depression or anxiety) as part of the study, you may start to have symptoms again. There is also a risk that you may have thoughts of hurting or killing yourself when you stop taking medicine, especially if you have had these thoughts before. If this happens, you should talk with your outside therapist and your therapy team. If you have to start taking medicine again,

then the study doctors will have to take you out of the study. There are some allowable medicines on study; your doctors will discuss these with you.

REPRODUCTIVE RISKS
Effects of MDMA on the growth and development of an unborn baby are not known; therefore, you will not be allowed to be in the study if you are pregnant. If you get pregnant after you have had at least one Overnight Test Session, the study doctors and the sponsor, MAPS, will ask you about and keep track of your pregnancy and will need to know about the outcome of your pregnancy. If you become pregnant, you will be withdrawn from receiving additional study drug, but you will be able to continue in the talk therapy sessions if you want to.

Those who are at risk of becoming pregnant must use one of the allowed birth control methods: intrauterine device (IUD), intrauterine hormone-releasing system (IUS), non-oral hormonal methods (including injected, intravaginal, implanted, or transdermal), abstinence, oral hormones plus a barrier contraception or double barrier contraception , or a vasectomized sole partner, during the study and for 10 days after the last Overnight Test Session. Two forms of contraception are required with any barrier method or oral hormones (i.e. condom + diaphragm, condom or diaphragm + spermicide, oral hormonal contraceptives + spermicide or condom). If you plan to be abstinent for the study, you will need to let the therapy team know what your back-up method will be. Not being of childbearing potential is defined as permanent sterilization or postmenopausal or assigned male at birth. The therapy team 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 of childbearing potential, you will be tested at the start of the study and again before each Overnight Test 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 tell your therapy team immediately. If you should become pregnant during the study, the study doctors will help you get proper advice and guide you to get proper care while you are pregnant. If you become pregnant, you will discontinue treatment but remain in the study for follow-up purposes.

NEW FINDINGS
If any new information becomes available about MDMA while you are in this study, the therapy team will tell you about it as soon as possible. You may be asked to sign a new consent form if this occurs. You may contact the therapy team at any time after your participation ends to find out if any new information about this study has become available.

POSSIBLE BENEFITS
Your symptoms of PTSD may improve while taking part in this study. 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 for PTSD and relationships in the future.

PAYMENT FOR PARTICIPATION
In order to remove some financial barriers to participation, you may be reimbursed for direct costs of participation (travel or dependent care costs, for example) for certain study visits as they are completed. If you do not complete a visit, you may not be reimbursed for costs associated with it. As a nonprofit organization, MAPS has limited funds to reimburse participants for financial assistance, and you will have the option to decline funds if they aren't needed. Options for reimbursement will be offered as outlined in the table below.

Visit	**Payment**
Overnight Test Session 1	Up to $70
Overnight Test Session 2	Up to $70
Overnight Test Session 3	Up to $70
Visit 3 Psychological Testing	Up to $70
Visit 19 Psychological Testing	Up to $70
TOTAL	**Up to $350**

<<CF-Main Payment for Part. Paragraph>>

COSTS
The Sponsor of this study, MAPS, will cover the costs that are directly related to the research. This includes the costs for all psychotherapy sessions that are a part of this study, 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), or 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 not included in the study.

ALTERNATIVES
One alternative to being in this study is to decide not to take part. You may decide to try other treatments for PTSD. There are approved medicines that may help treat your symptoms of PTSD and other forms of psychotherapy that you could try. Approved medications for PTSD are those called selective serotonin reuptake inhibitors (SSRIs named paroxetine (Paxil) and sertraline (Zoloft). If you are currently having psychotherapy and/or taking medicine, you could continue with those for a longer period

of time. The therapy team can discuss the alternatives and their potential risks and benefits with you.

CONFIDENTIALITY
To ensure confidentiality, your information will be stored in secure electronic systems or in a locked office at the participating sites until securely transferred to a remote storage facility. These records will be stored for at least 25 years after the end of the study. Absolute confidentiality and security cannot be guaranteed, but every effort will be made to maintain your confidentiality.

People outside of your therapy 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 and retain recordings of your voice. If records are copied, only your participant number and initials will identify you to the study Sponsor unless you give specific permission, (for example, if you sign a media release.

Medical records, including audiovisual, which could 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.
- The FDA, Health Canada, the Israeli Ministry of Health, and similar agencies in other countries.
- Copernicus Group Independent Review Board (CGIRB). The IRB is a group of scientists and non-scientists who review the ethics of research. The goal of the IRB is to protect the rights and welfare of study participants
- Members of the study team.

<<CF-Main User Defined #4>> Your records may also be inspected by the Research Advisory Panel of California (RAPC) or by State and Federal regulatory agencies.
****FOR CA SITES ONLY****

You have the right to review any medical records related to this study, including lab results and cardiac testing. At the end of the study, your therapist team or study doctor will provide a summary of study procedures, side effects or other health issues on study, and medications taken.

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

Audiovisual recordings: By signing this informed consent you are agreeing to the therapy team and evaluators audiovisual recording each visit. The reasons for recording the visits are:

- So that the therapy team will have accurate records of the session.
- So that trained raters working for the Sponsor can verify that the therapy and assessments are being carried out properly
- For further research on the therapy and how it is performed.
- For training other therapy teams to conduct MDMA-assisted psychotherapy and scientists to develop and work on additional research.

For the above purposes, the trained 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. If you ever want to withdraw consent from having your videos used at future trainings, you can let your study therapists know or send an email to video@mapsbcorp.com requesting this. Note: if you email video@mapsbcorp.com, you will be sending identifying information to MAPS (the sponsor of this study), including your name and email address. You will need to tell MAPS what study you were in, your initials or participant identification number, your therapists' names, and where you took part in the study. To avoid sharing this information, you can have your study therapists contact MAPS on your behalf without sharing your name or email address.

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

These recordings will be stored in remote data storage centers. No personally identifying information will be used to label the audiovisual recordings. A copy will be transferred to the Sponsor for secure 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 protection of this audiovisual data. Total security cannot be guaranteed, but the Sponsor is consistently working to maintain and improve the security of its data systems.

During your study sessions you may ask to stop the recording at any time, but your therapy team 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.

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

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

LEGAL RIGHTS
The above section does not restrict your right to seek legal assistance. You do not waive any legal rights by signing this form.

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

In addition, you may withdraw from (leave, stop being in) the study at any time. There will be no penalty or loss of benefits 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 if you would be willing to return to the office for final tests.

If you decide to stop being in the study or are removed from the study, the data collected about you up to that point will remain part of the study and will not be removed from the study database.

WITHDRAWAL
Your therapy team, the Sponsor, or the medicine agency in your country 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 depression or anxiety,
- if you do not keep appointments or follow study procedures,
- if you do not take the study drug as instructed,
- if you become pregnant, or

- if the study is canceled by the FDA, Health Canada, Israeli Ministry of Health, IRB, or the Sponsor.

The Sponsor, the FDA, Health Canada, Israeli Ministry of Health, or the IRB may decide to stop the study at any time.

If the study is stopped, the data collected about you up to that point will remain part of the study and will not be removed from the study database.

CONTACT FOR QUESTIONS
If you have any questions, concerns, or complaints about your participation in this study or if you feel that you have experienced a study-related injury or reaction to the study drug, or have a complaint about the research study, contact the study doctor using the information found on page 1 of this form.

You should contact the study doctor first if you have questions, complaints, or concerns about the study.

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to them at 888-303-2224, irb@cgirb.com, if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research participant.

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.

PARTICIPANT'S STATEMENT OF CONSENT

"A Randomized, Double-Blind, Placebo-Controlled, Multi-Site Phase 3 Study of the Efficacy and Safety of Manualized MDMA-Assisted Psychotherapy for the Treatment of Severe Posttraumatic Stress Disorder"

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 staff 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 their instructions.

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

I understand that this is a very demanding study that will take considerable time and attention between sessions. I agree to not take on any major activities or travel while I am in the study without discussion with the therapists.

I have read the information in this consent form and it has been discussed with me. I have been given sufficient opportunity to consider whether to participate. 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 participant in a research study. I have been told that I will be given a copy of this consent form<<CF-Main California Bill of Rights>>.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

I certify that the information provided was given in language that was understandable to the participant. I attest to adhering to informed consent procedures.

Signature of Person Obtaining Consent _____ Date _____

Printed Name of Person Obtaining Consent _____

ADDITIONAL CARDIAC TESTING

You may need additional testing by a cardiologist if you have hypertension, diabetes, or another medical condition. The cardiologist will explain these tests in detail. They may include a nuclear exercise stress test and/or carotid ultrasound. These extra tests may occur over one or two visits to a cardiologist's office. The visits will take between 1-3 hours each.

The study doctors will use the results of these tests to assess whether your heart is healthy enough to take MDMA in the study.

In addition to the risks or discomforts listed here, there may be other risks that are currently not known. Also, the risks or discomforts described may occur more often or be more severe than has been seen before.

Nuclear Exercise Stress Test

Exercise testing is a way of learning how your heart responds to strenuous exercise. For this test, you will go to a doctor's office that is specifically prepared for this kind of procedure. There are two parts to this test. The first you will receive a radiotracer followed by imaging (pictures) of your heart. You will then exercise on the treadmill or a stationary bicycle. About 2 minutes before stopping (or until signs of difficulty, such as shortness of breath or tension in your chest appear), you will receive a second radioactive tracer. Another set of imaging will be procured about 60 minutes later. The whole procedure will therefore take about 3 hours to complete. The exposure to radiation is very low. There are no known side effects to receiving the radioactive tracers.

The cardiac tracer is introduced via a needle placed in an arm. This is a fine, small gauge needle; it could cause brief minor pain where it is inserted, possible bruising, and rarely, infection or fainting.

The nuclear exercise testing may cause discomfort, fatigue, and shortness of breath. Rarely, more serious problems such as fainting, falling, or irregular heartbeat have been reported. In less than one in 10,000 cases, heart attacks have occurred. The doctor performing these testing procedures will monitor you continuously during the test and will stop the test if it appears that you are having problems or if you ask to stop the test.

The radiotracer contains a small amount of radiation. This is not necessary for your medical care, is for research purposes only, and is necessary to obtain the desired information. The "effective" radiation dose you will receive during the rest portion of this scan is approximately 2.552 mSv. The "effective" dose from the stress portion is approximately 7.656 mSv. Therefore, your total "effective" dose is 10.208 mSv. "Effective" dose is a quantity that is used to relate the different doses received by each

organ to a single value and can be compared to environmental radiation. The organ receiving the highest dose in this test is the gallbladder wall. Both portions of this test will be carried out on the same day. The total “effective” dose you will receive is comparable to 3.3 times the yearly dose from environmental radiation in the US (3.1 mSv), is allowed by the FDA for individuals participating in basic research studies and has not been shown to involve a risk of cancer

Carotid Ultrasound

A carotid ultrasound is a painless test that uses high-frequency sound waves to create pictures of the insides of your carotid arteries, which are inside your neck. The ultrasound will show the doctor if there is any buildup of plaque inside your carotid arteries. If there is too much plaque, it can cause blood clots, which can cause a stroke.

There are no known risks associated with the carotid ultrasound procedure, because it uses harmless sound waves, similar to how doctors record pictures of fetuses in pregnant people.

PARTICIPANT'S STATEMENT OF CONSENT

I consent to take part in this additional cardiovascular testing if it is required of me to screen for the study. The testing and the information in this consent form have been explained to me. I have read all pages of this form. I have had an opportunity to ask questions and they have been answered to my satisfaction. I have been told that I have not given up any legal rights. I will receive a copy of this signed and dated consent form.

Signature of Participant	Date
Printed Name of Participant	
Signature of Person Obtaining Authorization	Date
Printed Name of Person Obtaining Authorization	

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 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 U.S. FDA and the Copernicus Group Independent Review Board (CGIRB) 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
- Copernicus Group Independent Review Board (CGIRB)
- The U.S. Food and Drug Administration (FDA)
- Other regulatory agencies

<<CF-Main User Defined #5>> Your records may also be inspected by the Research Advisory Panel of California (RAPC) or by State and Federal regulatory agencies. ****FOR CA SITES ONLY****

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 study doctor using the contact information found on page 1 of this form.

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.

If you do not withdraw this Authorization, it will remain in effect.

If the research site is located in California, Delaware, Illinois, Indiana, Washington, or Wisconsin, this authorization will expire on 31Dec2060.

There is no expiration of this authorization except for research conducted in the states listed above.

<<CF-Main User Defined #3>> ***For IL Sites Only***You have the right to review any mental health information collected about you and shared with others.

You have the right to review and copy your health information. However, your access to this information may be delayed until the study is complete.

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 IRB <<CF-Main User Defined #6>>, Research Advisory Panel of California (RAPC) ****FOR CA SITES ONLY****, 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.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

Signature of Person Obtaining Authorization Date

Printed Name of Person Obtaining Authorization