PARTICIPANT INFORMATION AND CONSENT FORM AND HIPAA AUTHORIZATION

TITLE: Long-Term Safety and Persistence of Effectiveness of Manualized MDMA-Assisted Therapy for the Treatment of Posttraumatic Stress Disorder

PROTOCOL NO.: MPLONG
WCG IRB Protocol # 20191561

SPONSOR: Multidisciplinary Association for Psychedelic Studies (MAPS)
3141 Stevens Creek Blvd #40547
San Jose, CA 95117

<<CF-Main Header Block - Investigator>>
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.

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

(a) Be informed of the nature and purpose of the experiment.
(b) Be given an explanation of the procedures to be followed in the medical experiment and any drug or device to be used.
(c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment, if applicable.
(d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment if applicable.
(e) Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
(f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment or if complications should arise.
(g) Be given an opportunity to ask any questions concerning the experiment or other procedures involved.
(h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue in the medical experiment without prejudice.
(i) Be given a copy of a signed and dated written informed consent form when one is required.
(j) Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

INVITATION
You are being invited to participate in this long-term follow-up research study because you previously participated in a MDMA-assisted therapy study for treatment of posttraumatic stress disorder (PTSD). There will be approximately 400 participants involved in the study.

Your participation is completely voluntary. You do not have to join any research study and have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to either your medical care or any other services to which you are otherwise entitled or are currently receiving.

The sponsor is paying for this research study. Your study doctor will be paid by the sponsor. <<CF-Main Financial Disclosure>>

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. If you sign it, you agree to participate. 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 part of the 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 are doing our job explaining to you what this part of 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 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.

If you would like to review the information for this study, or a summary of the results, ask the study team for the ClinicalTrials.gov study registration number.

BACKGROUND

This long-term follow-up study will happen at least 6 months after your last Study Drug Session (8-hour therapy session) in the main study. The researchers plan to use the results of this long-term follow-up study to see if participants' PTSD symptoms improve, stay the same, or worsen over time after the study. The results of this study may also help researchers design more studies.

WHO CAN PARTICIPATE IN THE STUDY
You will be able to participate in the study if you participated in a previous study of MDMA-assisted therapy.

LENGTH OF STUDY
Participation in this study will take approximately 150 to 360 minutes (about 2.5 to 6 hours) total on 4 days, scheduled at least 6 months after your last Study Drug Session. The total length of participation in this study will be 7 to 60 days.

STUDY REQUIREMENTS
If you agree to take part in this study, you must provide a telephone number, postal address, and email address where the researchers can reach you at least 6 months after completing your last Study Drug Session.

You must be willing to answer questions about your PTSD symptoms. You must also be willing to provide a release for your medical records and answer questions about your health, use of the healthcare system, and medications you have taken. You must be willing to answer questions about how you are feeling, including questions about thoughts of hurting or killing yourself.

You will need to give the MPLONG site staff the name and contact information (phone number or email) of a relative, spouse, or close friend. The study team will contact this person only if you have a medical emergency, if you are at risk of hurting yourself or someone else, or if the study team cannot get in touch with you and need to know you are okay.

You may continue going to any therapy and taking any medications as usual during this study.

PROCEDURES/WHAT WILL HAPPEN TO YOU
The meetings and conversations during this study may be conducted remotely (from your home or other private place) or at the clinic location. The study consists of three parts.

1. **Meeting with the Study Team:** After you have signed this form, you will meet with a therapist or study staff member to discuss your medical history,

medications, and therapy. You will speak to a study team member, who will ask you questions about thoughts of killing or harming yourself. You may be asked to sign a health release so the study team can obtain medical records since you completed the main study. You may also provide these records yourself.

2. **Online Meeting with a Researcher:** An Independent Rater (someone you have never met before) will meet with you online to discuss your PTSD symptoms. The Independent Rater will also ask you questions about thoughts of killing or harming yourself. For this meeting, you must be in a quiet place with stable internet connection. Your device can be a phone, computer, or tablet. Your device must have a camera and you must be in a location in which you feel comfortable to discuss personal information. This meeting will be recorded.

3. **Questionnaires:** You will be asked to complete several questionnaires in a secure online database. You will speak to a study team member, who will ask you questions about thoughts of killing or harming yourself. You may go to the clinic to answer these questionnaires, or you may do so at home. You may be familiar with some of these questionnaires from the previous study. The questions will ask you how you feel and behave. There are no right or wrong answers to these questions. You will also speak to a study researcher to answer some of these questions.

The researchers will use your answers to these questions to see if there are any long-lasting effects of being in the study, such as changes in PTSD symptoms or other life events.

POSSIBLE RISKS OR DISCOMFORTS
No drugs or therapy are given in this study.

The interviews and questionnaires you will complete during the long-term follow-up visit involve no specific risks or discomforts beyond those of a standard clinical interview situation. You may feel upset talking about your emotional experiences, or you may feel boredom or fatigue. Answering questions about thoughts you might have of hurting or killing yourself may be upsetting. You have the right to skip any questions which you do not feel comfortable answering.

You will be asked questions regarding your emotional state; however, you will not be offered any additional services based on your responses. If you have difficulties with your emotions (e.g., feeling depressed or anxious) and would like help managing those difficulties, please talk with your family doctor or therapist about treatment.

There is the potential risk of the loss of confidentiality, though the study team and Sponsor work hard to keep your information private.

REPRODUCTIVE RISKS
There are no risks to taking part in the long-term follow-up visits for those who are able to become pregnant, are pregnant, or are lactating. No drugs or therapy are begin given in this study. If you are pregnant or lactating, you can take part in this study.

NEW FINDINGS
No drugs or therapy are given in this study. You may contact the study team 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 guarantee that you will benefit from taking part in the long-term follow-up. Information obtained from this study may help doctors and researchers to improve treatment for PTSD and design better research studies in the future.

COSTS
The sponsor of this study, MAPS, will cover the costs that are directly related to this study. You or your insurance will remain responsible for on-going treatment unrelated to the study. You may talk to the study staff and your insurance company about what is covered.

PAYMENT FOR PARTICIPATION
In order to remove some financial barriers to participation, you may be reimbursed for your time completing the study. If you do not complete all study visits, you may not be reimbursed. As a nonprofit organization, MAPS has limited funds to reimburse participants for financial assistance, and you have the option to decline funds if they are not needed. Reimbursement will be offered as outlined below:

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

ALTERNATIVES
The alternative to the long-term follow up is to decide not to take part in this study.

CONFIDENTIALITY
To ensure confidentiality, your information will be stored in secure electronic systems at the participating sites until securely transferred to a remote storage facility. These records will be stored after the end of the study in keeping with the regulatory and ethics board regulations governing your study site. Absolute confidentiality and security cannot be guaranteed, but every effort will be made to maintain your confidentiality.

People outside of your study 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 audio visual recordings, 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 at a time when 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, the people they hire, and the scientists they work with
- The U.S. Food and Drug Administration (FDA), Health Canada, and similar agencies in other countries;
- The Institutional /Independent Review Board (IRB) or Ethics Committee (EC) that reviewed this research. The Independent Review Board (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.<<CF-Main SMO Company 1>><<CF-Main Affiliated IN Language 1>>
- Members of the study team
- (For CA sites only) Your records may also be inspected by the Research Advisory Panel of California (RAPC) or by State and Federal regulatory agencies.

These people may look at your records to make sure the study has been done the right way. They also want to make sure that your health information has been collected the right way, or for other reasons that are allowed under the law.

The results of this research study may be presented in meetings, presentations, or in publications, where your identity will not be disclosed. To help make scientific knowledge accessible, the data collected in this study will be shared with other researchers.

If you are eligible and choose to participate in the MAPPUSX study after completing MPLONG, some of your MPLONG records will be shared with researchers at the MAPPUSX site. The medical history, concomitant medication, interim psychotherapy, and Columbia-Suicide Severity Rating Scale records that were collected during MPLONG will be reviewed by the MAPPUSX researchers. They will use this information during screening and data collection in MAPPUSX.

Audio visual recordings: By signing this informed consent you are agreeing to the audio and video recording of the online meeting with the Independent Rater. The reasons for recording the visits are:

- To maintain accurate records of the study visits and online evaluations
- To verify that the, assessments, and evaluations are carried out properly, according to the protocol
- To conduct further research on MDMA and MDMA-assisted therapy

For the above purposes the raters and researchers who may be viewing these recordings (or reviewing transcriptions of the recordings) will be selected by the sponsor and will sign confidentiality agreements to ensure they do not share the identifying information they may receive.

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

- Your physical appearance
- Your voice
- Your name (if it is spoken on the recording)
- Your address and phone number (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 audio visual recordings. A copy will be securely 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 audio visual data. Total security cannot be guaranteed, but the sponsor is consistently working to maintain and improve the security of its data systems.

After the study is complete at all locations, you may request access to view the video recordings from your study visits. You may contact the study site with any questions about video recording, or to request access to your records.

TREATMENT AND COMPENSATION FOR INJURY

If you are injured or get sick because of being in this research, call the study doctor immediately. Some study-related injuries or sickness can be treated by the study doctor. If the study doctor cannot treat a study-related emergency, they will arrange to transport you to the nearest hospital.

Treatment of a study-related injuries, sickness, or emergency would first be billed to your health insurance provider, if you have health insurance. If your health insurance

plan does not cover clinical trial-related claims that occurred during the course of the study, or you do not have health insurance, then the sponsor will cover any treatment costs directly related to the study. To cover those costs, the sponsor carries third-party insurance.

The sponsor will not cover costs of ongoing treatment unrelated to the study due to pre-existing conditions, or the cost of your time spent getting treatment for pre-existing conditions before receiving treatment in the study.

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 long-term follow-up is completely voluntary. There will not be any penalty or loss of benefits to which you are otherwise entitled 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 to which you are otherwise entitled if you decide to withdraw from the research study. Before withdrawing from this study, notify the study staff that you wish to withdraw. This notice will allow your study doctor to inform you if there are any potential medical risks of withdrawal.

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. Your video recordings will be retained.

WITHDRAWAL
Your study team, the sponsor, or government in your country has the right to stop your participation in this long-term follow-up study at any time, with or without your consent, for any of the following reasons:

- if you do not keep appointments or follow study procedures,
- if the study is canceled by the IRB, the FDA, Health Canada, Israeli Ministry of Health, or the sponsor.

The sponsor, the FDA or the IRB/EC may decide to stop the study at any time.

Note that if you decide to stop being in the study, or are removed from the study, or the study is stopped, the data collected about you up to the point will remain part of the study and may 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 staff 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"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (855)-818-2289 or, researchquestions@wcgirb.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

- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive. I will call the researchers if I decide to do this.
- 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 assessment audio and video-recorded during this study.
- I have read and understood the information in this consent form and it has been discussed with me.
- I have been given sufficient opportunity to consider whether to participate.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I freely consent to take part in this research study.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.

I will receive a signed and dated copy of this consent form for my own records<<CF-Main California Bill of Rights>>.

I consent to participate in this study.

_____

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 Therapist Obtaining Consent Date

_____

Printed Name of Therapist Obtaining Consent Date

HIPAA AUTHORIZATION

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

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

In most cases, the study doctor will use your initials and assign a code number to your information that is shared with the sponsor. The sponsor and its representatives may review or copy your personal health information at the study site. Regulatory authorities such as the FDA, other government agencies and the IRB 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
- Independent/Institutional Review Board (IRB) <<CF-Main SMO Company 2>><<CF-Main Affiliated IN Language 2>>

- The U.S. Food and Drug Administration (FDA) and other government agencies
- 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.

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.

For IL Sites Only: [You have the right to review any mental health information collected about you and shared with others.] <<CF-Main User Defined #7>>

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.

You do not have to sign this form. 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 otherwise 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, the FDA, and/or 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