

**Informed Consent Form Quiz****A Randomized, Triple-Blind, Phase 2 Pilot Study Comparing 3 Different Doses of MDMA and Psychotherapy in 16 Veterans with Chronic (PTSD)**

It is very important that subjects taking part in this study know what will happen to them during the study and be aware of the possible risks and problems involved as a result of their participation. We know there is a lot to read and keep track of in the informed consent form. We have created this quiz in order to make sure that you are not confused about the study and any problems related to it. Please answer these questions as best as you can. This will let us know if we did not explain a specific part of the study well enough, or if we need to talk more about a part of the study in more detail. Don't worry if you don't get all of the answers right. We will go over the quiz with you, with special attention on any questions that were answered incorrectly.

1. Can you keep taking medication for depression or anxiety while you are in this study?

Yes **No**

2. If you have high blood pressure that you can control with medication

- a. You cannot be in the study
- b. You will need to stop taking your blood pressure medication
- c. You may have to have some extra tests before you can be in the study**

3. What are the doses of MDMA you could receive in the first 3 MDMA sessions in this study?

- a. low dose one time, medium dose one time and high dose one time
- b. low, medium or high dose all three times**
- c. low or medium dose twice and high dose once

4. If I agree to be in this study, in Stage 1 I will come to the clinic:

12 times                      15 times                      **20 times**

5. In addition to the regular psychotherapy sessions, how many experimental sessions will there be in which you will receive MDMA in Stage 1?

One                      Two                      **Three**

6. A second (supplemental) dose will be given during a session if

- a. the therapists think it will help you
- b. you have been randomly chosen to receive a second dose
- c. the therapists agree that it is safe for you to do so and you have no objection to taking it.

7. How long will the experimental (MDMA-assisted) sessions last (not counting the overnight stay)?

About 4 hours   **About 8 hours**   About 24 hours

8. If someone taking part in this study becomes extremely upset or panics, the investigators can have him or her hospitalized.

**Yes**   No

9. How will you be assigned to receive a particular dose of MDMA?

- a. **It will happen at random, as by coin toss**
- b. It will be decided by the study doctors after thinking about your medical history
- c. The first people in the study will get the lowest dose, and the last people will get the highest dose

10. Right after the experimental session, your immune system will be less active than usual.

**Yes**   No

11. Is there a risk that the serotonin neurons in your brain might be hurt by being in this study?

No risk   **Some risk**   Definite risk

12. It is possible to become addicted to MDMA.

**Yes**   No

13. The FDA and some other governmental agencies can see my data if they request it.

**Yes**   No

14. When can you withdraw from the study?

**Anytime I want to**      Only after the first experimental session

15. Will you have to pay for any medication or treatment that you need to take to treat a problem caused by being in the study (such as medication to lower blood pressure or anti-anxiety medication, or hospitalization due to emotional or physical reasons)?

Yes      **No**

16. If I am in this study, the sponsor (MAPS) will pay for therapy with another psychotherapist.

Yes      **No**

17. If you have any complaints or concerns about being in the study, who can you contact?

- 1) Dr. Mithoefer (Principal Investigator)
- 2) MAPS (Sponsor of the study)
- 3) The Institutional Review Board (IRB)
- 4) The Food and Drug Administration (FDA)

1    2    3    4    **all of the above**