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Study Title **A TEST OF MDMA-ASSISTED PSYCHOTHERAPY
IN SUBJECTS WITH CHRONIC POSTTRAUMATIC
STRESS DISORDER (PTSD)
2/07/03**

CONSENT FOR ASSISTING A HUMAN SUBJECT

This consent form describes a research study and your role as a spouse, partner, relative or friend of a research participant. Please read this form carefully. Do not hesitate to ask anything about the information provided; it should make you think of questions you might have. The investigator will describe the study and answer your questions.

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

INFORMATION ABOUT THE STUDY

PURPOSE AND BACKGROUND

This small and specific study is to learn if the drug MDMA is safe and helpful for subjects with PTSD given MDMA-assisted psychotherapy. The researchers plan to use the results of this study to design further studies

MDMA is a controlled (illegal) drug and is sometimes known as "Ecstasy". MDMA is investigational, which means it has not been approved by the US Food and Drug Administration (FDA) for medical use, except within research studies.

MDMA has been used legally in research as well as illegally in uncontrolled environments (like nightclubs). Although there are lots of stories about Ecstasy and there is much known about it and its problems, there remains much that is unknown. There is some suggestion that MDMA might be helpful as an adjunct to psychotherapy in people with PTSD (posttraumatic stress disorder).

This study will compare use of MDMA (125 mg) with a placebo (0 mg – a “sugar pill”).

Your spouse, partner, relative or friend is being asked to participate in this research study because he or she has been diagnosed with posttraumatic stress disorder (PTSD) and has not gotten better after having talk therapy (psychotherapy) and taking medication for PTSD. If he or she is in this study, your spouse, partner, relative or friend will need to be helped out during certain times in this study. If you agree to help out, you will be with your spouse, partner, relative or friend at the end of the session where they receive MDMA or placebo. You will help them get home and you will keep them company until 24 hours has passed since the time they took the MDMA or placebo.

Length:

As a spouse, partner, relative or friend helping the person in this study, you will be asked to stay with the person in the study on two occasions, with these occasions happening three to five weeks apart.

CONDUCT

If your spouse, partner, relative or friend is accepted into the study and he or she has asked you to be involved in the study, you will be asked to agree to the following:

1. Attend the last hour of session when the person in the study takes MDMA or placebo, and meet with the researchers running the study.
2. Give your spouse, partner, relative or friend taking part in the study a ride home after each time they have taken MDMA or placebo.
3. Be able to stay with your spouse, partner, relative or friend for at least 24 hours after they have taken MDMA or placebo.
4. Help your spouse, partner, relative or friend by making sure they are feeling alright, and calling the researcher running the study if there are any problems.

If you have problems doing any of these things, then please let us know and let the person taking part in this study know as well so that he or she can find someone who can do all the things listed

SELECTION OF DRUG – MDMA OR PLACEBO?

Each subject will be randomly assigned (by chance, as if by flipping a coin) to get either MDMA or placebo. Your spouse/relative or friend will have 60% of receiving MDMA and a 40% chance of receiving placebo.

To minimize bias, neither the subject nor the study researchers know who is getting MDMA or placebo. However, this information is available if needed in an emergency.

YOUR ROLE IN THE EXPERIMENTAL SESSION:

Before your spouse, partner, relative or friend will be in this study, you will meet with them and with the researchers to decide if you want to stay with the subject during the end of the session when he or she will be receiving MDMA or placebo. The subject has already found out that he or she is going to be in the study, and he or she will need to find one person who will stay with them and help them if they need help. All people helping out their spouse, partner, relative or friend will first agree to stay with and take care of the subject before the subject will be in the study.

There will be two MDMA/placebo sessions. The first will happen about three weeks after your spouse, partner, relative or friend has started the study, and the second session will happen three to five weeks after the first session.

During this session, the subject will be given either MDMA or placebo and have psychotherapy. This experimental session will begin at 9:00 AM and will end between 4:00 PM and 6:00 PM. You will arrive during the last hour of the MDMA or placebo session. You will meet with the researchers and the subject, and they will talk with you about your help in staying with the subject after the experimental sessions. You will be given a telephone number that will let you reach the researcher 24 hours a day, and you will learn to watch out for specific problems. You will also either provide the subject with a ride home or help him or her get a ride for both of you.

Once you and the subject have left the clinic, you will stay with him or her for at least 24 since your spouse, partner, relative or friend first took the MDMA or placebo. You and your spouse, partner, relative or friend can talk about specific times when he or she will want you to call the researchers. You and your spouse, partner, relative or friend can also arrange how you will stay with the subject for this period in time.

You will have a means to contact the study therapists, and you can contact them at any time. Dr. Mithoefer will be on call (reachable by telephone or pager) 24 hours a day throughout the research study, except on occasions when he is out of town. At those times another psychiatrist who knows about the study will be on call. Both you and the subject will have this telephone number. You can speak with the study researcher or other psychiatrist if both you and the subject have questions, or if you think then subject is very scared, upset or depressed and needs help right away. The subject may not be able to call the study researchers if he or she is having a very severe problem, and in this case you will call the study researchers at the same number given to the subject.

Twenty four hours after the start of each MDMA or placebo session, you will no longer have to stay with your spouse, partner, relative or friend. You and your spouse, partner, relative or friend may decide that you will still remain with the subject for some time longer than 24 hours.

You will be asked to arrive at the end of each MDMA or placebo session, and you can ask the study researchers any questions you have each time you meet with them. You will be asked to stay with the subject for 24 hours after each session. However, if for any reason your spouse, partner, relative or friend is not going to have the second MDMA or placebo session, then your role in helping the subject and the researchers is complete. In all other cases, your role in helping your spouse, partner, relative or friend will be done 24 hours after the second, and final, MDMA or placebo session.

POSSIBLE RISKS OR DISCOMFORTS

The following section describes risks of harm to you that might happen from helping the person who is in this study.

Risks of helping the subject after the MDMA or placebo session:

After having the MDMA or placebo session, and despite staying with the study investigators, the subject might continue to feel very upset after the MDMA or placebo session. He or she may feel very frightened or angry, or she or he may feel very depressed and helpless. This may make you also feel frightened, angry, depressed or helpless because of your spouse, partner, relative or friend's feelings. You may also feel especially upset when you cannot make your spouse, partner, relative or friend feel better, less frightened or angry, or happier.

It may also be the case that the person who is in the study will want to talk about his or her experience with you. The things that he or she says while you stay with him or her may be very frightening, sad or upsetting. You may want to contact or speak with the study researchers about how you feel. They can give you information about how to deal with the subjects' feelings and can help you find ways to share these feelings with the subject without becoming overwhelmed by them.

Risks of dealing with an emergency after the MDMA or placebo session

Some people may become very distressed after the MDMA or placebo session and may need to stay with the study researchers until they are less likely to hurt themselves or others. You may have to wait for them to feel better before you can go home with them. The study researchers will let you know when they think that your spouse, partner, relative or friend is ready to leave the clinic.

Your spouse, partner, relative or friend may seem alright at first and then become very upset, sad or frightened later. If they seem like they might hurt themselves or someone else, you should get help immediately and telephone the study researchers as well. Your spouse, partner, relative or friend may ask you to contact the study researchers for them.

POSSIBLE BENEFITS:

Neither you nor the person in this study will benefit directly from participating in this study. You will be helping someone you care for through what might be some hard parts of the study. This study might help find ways of treating people with PTSD in the future.

FINANCIAL ISSUES:

Costs:

If you must pay for travel or parking when coming to stay with and help your spouse, partner, relative or friend, the study therapists will pay you back the costs of travel or parking.

Payment for Participation:

You will not be paid any money for your role in helping out the subject in this study. Travel or parking costs will be paid for by the sponsor as needed.

Alternatives:

The person taking part in the study can contact another person to help him or her out and stay with him or her after each MDMA or placebo session. The subject can also decide that he or she does not want to be part of this study.

Confidentiality:

All information collected will be treated and handled as confidentially as possible. **Absolute confidentiality cannot be guaranteed.** Your role in helping out the subject will only be recorded on this consent form and in any contact information you provide to the study investigators. It will not be part of the study data.

When not in use, information will be stored in a locked office. While information about the subject may be shown to the researcher, the FDA or the sponsoring organization, your role in helping out the subject will probably not be viewed by anyone else.

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

Questions:

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

Dr. Michael Mithoefer,
208 Scott Street, Mt. Pleasant, SC, 29464,
(843) 849-6899 (24 hour pager)

If you have other questions about other effects of MDMA, you can contact MAPS. Their address is

MAPS
2105 Robinson Ave.,
Sarasota FL. 34232
Tel: 943-924-6277

If you have concerns you don't feel comfortable asking the investigator, you may contact:

Independent Review Consulting Inc.
P.O. Box 170
San Anselmo CA. 94979
Tel: 1-800-472-3241

This is a group of people who perform independent review of research.

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.

AGREEMENT OF SPOUSE/RELATIVE/FRIEND OF SUBJECT

Your role in supporting the person enrolled as a subject in this study should be voluntary. You may refuse to help support the subject or may stop assisting the subject in this study at any point in time. You should call the study doctor and the subject if you decide to do this. Your decision will not affect the ability of the subject to be in this study or his or her current or future medical care.

ASSERTIONS

I have read the information in this consent form and it has been read to me. All my questions about the study and my role in assisting the person who is a research subject in this study have been answered. I freely consent to being with the subject during the last hour of each MDMA or placebo session, to giving the subject a ride home and to being with the subject for 24 hours after each MDMA or placebo visit. I agree to reach the investigators if the subject needs help or if I need to ask questions about problems happening after each MDMA or placebo session.

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

	SELECTED COMPANION OF SUBJECT	INVESTIGATOR
Printed name		
Signature		
Date		
