

**LCF FOUNDATION, INC.
DIVISION OF RESEARCH
RESEARCH CONSENT FORM
DR-2**

Protocol ID: 2004-092

Research Account: _____

Principal Investigator: Todd Shuster, M.D.

Project Title: SCREENING FOR A TEST OF MDMA ASSISTED PSYCHOTHERAPY IN SUBJECTS WITH ADVANCED-STAGE CANCER AND CANCER-RELATED ANXIETY

INTRODUCTION

Dr. Todd Shuster and colleagues are conducting a small, pilot study in 12 people with advanced-stage cancer who are either not helped enough or are not helped at all from anti-anxiety medications or who have declined to take anti-anxiety medications. The study explores the use of an experimental drug, MDMA (3,4-methylenedioxymethamphetamine), taken during two special psychotherapy sessions. The study will examine whether this intervention will be safe and reduce anxiety and improve quality of life.

This consent form is only for the initial screening process to be conducted by Dr. Todd Shuster. If Dr. Shuster's screening process indicates that you may qualify to be in the study, another member of the research team, Dr. John Halpern, will conduct additional evaluations at McLean Hospital, Belmont, MA, and will discuss the study with you in more detail. If you do qualify for the study and would like to participate, you will need to read and sign a second, longer informed consent for the entire study.

Being screened for and participation in this study is voluntary and refusal to participate will involve no penalty nor affect any future medical care or benefit to which you would otherwise be entitled. You are free to withdraw your consent and discontinue participation at any time. The Multidisciplinary Association for Psychedelic Studies (MAPS) is providing funding for this study.

WHY IS THIS SCREENING BEING DONE?

The screening tests and measures are being done to see if you might be able to take part in this study. After the researchers do these tests, they will know if you are a potential candidate for participation in this study. Having these tests done does not guarantee that you will be accepted into the study, and you are not required to accept an offer to participate in the study if you choose not to do so. If the initial screening tests show you may be able to be in the study, more medical and psychological tests will have to be performed to make sure you are eligible to be in the study.

HOW LONG WILL IT TAKE TO BE SCREENED FOR THE STUDY?

The length of pre-screening to be in the study should take about thirty minutes including a medical examination and the measure of anxiety.

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Date: _____

**Time: _____ a.m.
_____ p.m.**

WHAT IS INVOLVED IN BEING SCREENED TO BE IN THE STUDY?

People who are screened for this study will have a medical examination and will fill out a questionnaire on their anxiety level. The medical examination will be done during an office visit at the Medical Oncology Department of the Lahey Clinic Medical Center with Dr. Todd Shuster, a medical oncologist and investigator in this study, and the questionnaire on anxiety will be completed during the same visit. The exam and test will take up to thirty minutes.

The exam and test 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. Information will also be gathered regarding the type of malignancy of your cancer, sites of disease spread, prior treatment, and expected prognosis. Your ease in performing and doing various activities will also be assessed.
- A physical examination that will include measures of your blood pressure, pulse, temperature, and body weight.

WHAT ARE THE FORESEEABLE RISKS AND SIDE -EFFECTS OF THE SCREENING PROCESS?

Participation in this screening may involve some added risks or discomforts.

- Having a medical examination can take up a lot of time, and some parts of the examination may be uncomfortable.
- Completing a questionnaire about your anxiety might make you slightly more anxious, or you might find filling out the questionnaire boring.
- You may be disappointed or upset if the examination and anxiety questionnaire show that you cannot be in the study.

ARE THERE BENEFITS TO TAKING PART IN THIS SCREENING?

There are no direct benefits to you. While there is no guarantee, you may be eligible to take part in the study as a result of the screening.

WHAT OTHER OPTIONS ARE THERE?

The alternative to being screened for study is to choose not to be screened.

WHAT ARE MY RIGHTS AS A STUDY PARTICIPANT?

You may choose not to be screened for the study, or, if you agree to be in the screened, you may withdraw from the screening process at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concerns an adverse event (a bad side effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data 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.

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Your decision not to be screened for the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Lahey Clinic.

You have the right to review and copy your health information.

EXPLANATION AND OFFER TO ANSWER QUESTIONS

Dr. Shuster has explained the screening to be in this study to you and has answered your questions. If you have other questions or research related problems, you may reach Dr. Shuster at (781) 744-8410. Should you experience any problems arising from being screened for this study, you may contact the research administration department of the Lahey Clinic Office of Research Administration at (781) 744-8027.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Lahey Clinic. For records disclosed outside of Lahey Clinic, you will be assigned a unique code number. The key to the code will be kept in a secured area.

The results of this research project may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

The Lahey Clinic complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. Every reasonable effort will be made to protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected. Our Notice of Privacy Practices (a separate document) provides more information on how we protect your information. A copy of the notice will be provided to you.

You should be aware that under certain circumstances, information that you report will not be kept confidential. Pursuant to Massachusetts law, health professionals are mandated to report to the respective agency whenever in their professional capacity they have reasonable cause to believe a child under 18, or an elderly or disabled person is suffering from abuse or neglect. In addition to the above, mental health professionals are mandated to report or protect patients who pose a serious threat of physical harm to themselves or others

HOW LONG ARE SCREENING RESULTS KEPT?

The screening results will be retained in your research record for at least six years or until after the study is completed, whichever is longer. At that time, either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at Lahey Clinic. Any research information in your medical record will be kept indefinitely. If disclosed by the sponsor, the information is no longer covered by the federal privacy regulations.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

You will be informed of any significant new information that may affect your safety or your willingness to be screened for the study. If you have any questions concerning this study, the availability of

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medical care, or if you have experienced a research-related illness, injury, or emergency, contact Dr. John Halpern or Dr. Todd Shuster. This study has been reviewed and approved by the Lahey Clinic Institutional Review Board and the McLean Hospital Institutional Review Board. If you have any questions about your rights as a research subject, you may contact the Lahey Clinic Office of Research Administration, Research Administration Department of McLean Hospital, or the McLean Hospital Research Privacy Office at for assistance between 8:30 a.m. and 5:00 p.m., Monday through Friday.

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SUBJECT'S STATEMENT OF CONSENT

“PRE-SCREENING AND SCREENING FOR A TEST OF MDMA-ASSISTED PSYCHOTHERAPY IN PEOPLE WITH ADVANCED-STAGE CANCER AND CANCER-RELATED ANXIETY”

You have received a copy of this consent document to keep.

This research will be conducted and administered in compliance with all state and federal laws.

You have read this consent form and had the opportunity to ask questions. Dr. Shuster and his colleagues have answered all your questions to your satisfaction. You voluntarily agree to participate in this SCREENING PROCESS. You may refuse to take part in or you may stop taking part in this SCREENING PROCESS at any time. Your decision will not affect your current or future regular medical care or any benefits to which you are entitled at this site.

Subject:

Signature Printed name Date

Principal Investigator:

Signature Printed name Date

Witness:

Signature Printed name Date

PATIENT: Please initial and date this page after reading

Initials: _____ **Date:** _____ **Time:** _____ a.m.
_____ p.m.