**SUMMARY STATEMENT**

**Farris Tuma**
**301-443-5944**
**ftuma@nih.gov**

**( Privileged Communication )** ***Release Date:*** **11/28/2005**

***Application Number:*** **1 R03 MH076817-01**

**MITHOEFER, MICHAEL C MD**
**208 SCOTT STREET**
**MT PLEASANT, SC 29464**

***Review Group:*** **ITV**
**Interventions Research Review Committee**

***Meeting Date:*** **10/18/2005** ***RFA/PA:*** **PA03-108**
***Council:*** **JAN 2006** ***PCC:*** **AD-TS**
***Requested Start:*** **01/01/2006**

***Project Title:*** **Treatment Manual Development for MDMA-Assisted Therapy**

***SRG Action:*** ******
***Human Subjects:*** **44-Human subjects involved - SRG concerns**
***Animal Subjects:*** **10-No live vertebrate animals involved for competing appl.**

| Project Year | Direct Costs Requested |
|---|---|
| 1 | 50,000 |
| 2 | 50,000 |
| TOTAL | 100,000 |

****NOTE TO APPLICANT: As part of the initial scientific merit review process, reviewers were asked to identify those applications with the highest scientific merit, generally the top half of applications that they customarily review. At the study section meeting, those applications were discussed and assigned a priority score. All other applications, including this application, did not receive a score. Provided is a compilation of reviewers' comments prepared prior to the meeting, without significant modification or editing by NIH staff.**

**NEW INVESTIGATOR**

**DESCRIPTION (provided by applicant):** The aims of this project are to develop and standardize 3, 4-methylenedioxymethamphetamine (MDMA) assisted psychotherapy as a novel treatment for posttraumatic stress disorder (PTSD). PTSD affects up to 20% of crime victims and veterans, reducing quality of life and productivity. The investigators plan to develop a treatment manual describing standardized therapy procedures in order to train therapists to perform MDMA-assisted therapy in larger Phase II and Phase III studies. When completed, the manual will include evaluative guidelines and associated measures of therapist adherence and competence. The investigators will develop the manual through the use of previous anecdotal accounts of MDMA-assisted therapy, and by observing and reviewing audio and video recordings of psychotherapy sessions. When appropriate, the manual will also be informed by findings from Phase I studies of MDMA in humans. Session recordings are from a randomized, placebo-controlled, double-blind study of MDMA-assisted psychotherapy in people with PTSD and an open-label study continuation for any participants who received placebo during the double blind study. The principal investigator and two co-investigators will observe, review and examine session recordings and develop a manual for each stage of MDMA-assisted psychotherapy. All investigators will assist in reviewing and editing successive manual, guideline and measure drafts. During manual development or immediately afterwards, the investigators will create evaluative guidelines for each stage of MDMA assisted therapy. Once they have produced a treatment manual, the investigators will create brief measures of therapist adherence and competence for assessing therapists trained in MDMA-assisted therapy with the manual, with measures at an appropriate level of detail for a novel intervention. The production of the treatment manual and attendant measures will permit further research into an innovative and potentially promising means of treating PTSD. If data from pilot studies and other Phase II studies provide evidence of safety and efficacy, standardized procedures for conducting the therapy will lead to rapid development of this intervention.

**CRITIQUE 1:**

Significance: Because PTSD represents a debilitating disorder, potentially effective interventions, particularly if found to be efficacious for current treatment-resistant patients, might be significant. This project represents one small step towards that goal.

Approach: The treatment manual, evaluative guidelines, and associated integrity protocol will be based on tapes of psychotherapy sessions to be conducted by the PI. The included patients have already begun therapy and agreed to be videotaped. However, it is unclear as to how this project specifically interfaces with the ongoing clinical trial. Although this project is seeking funding for the manual development aspect, and not the clinical trial itself, the trial is currently being conducted. Insufficient information is provided as to how patients are diagnosed, recruited, treated, and so forth.

In addition, little information is provided as to what the MDMA-assisted psychotherapy actually entails. There remains conceptual confusion, especially from a research perspective, regarding the difference between MDMA-assisted therapy, MDMA alone, and psychotherapy alone.

Insufficient information is also provided regarding the actual patients who participated previously and who will be recruited for this phase of the study. It is difficult to determine the validity of any treatment manual in the absence of such a context.

Insufficient detail is provided regarding the development of evaluative guidelines and the measures of treatment integrity. Whereas these are laudable goals, it is difficult to discern how the PI plans to achieve such goals in any detail.

Last, it appears that all MDMA-assisted therapy has been (and will be) conducted by the PI. This confounds both roles, especially if these psychotherapy session are to be the basis for standardization. In other words, it is unclear how much of the treatment will be based on clear theory and previous evidence and how much on the personal opinions of the PI. Having such roles confounded allows for bias.

Innovation: The project is viewed as innovative given the uniqueness of the psychotherapy approach.

Investigator: Although the PI appears to have clinical experience related to this project, there is limited background conducting similar types of projects or studies. The proposed research team also appears to have limited experience in psychotherapy treatment development and execution.

Environment: The environment in which this project is planned to take place appears limited (i.e., private clinical offices of the PI and select members of the research team).

Human Subjects: The plan with regard to the actual videotaping of psychotherapy sessions is adequate, but is not adequate overall, as little information is provided regarding the actual conduct of the therapy itself. Data and Safety Monitoring Plan for the overall endeavor (i.e., clinical trial plus videotaping of sessions) is viewed as inadequate.

Women/Minorities/Children Inclusion: The sample composition cannot be known from the application. Little information is provided about the recruitment strategies overall, even though the PI states that women would be eligible to participate (i.e., no plan is provided about targeting recruitment strategies to ensure such participation). As such, the plan is unacceptable. Even though the PI states that minority groups would be eligible to participate (i.e., no plan is provided about targeting recruitment strategies to ensure such participation). As such, the plan is unacceptable. Little information is provided about the recruitment strategies overall, even though the PI states that children between 18 and 21 would be eligible to participate (i.e., no plan is provided about targeting recruitment strategies to ensure such participation). As such, the plan is unacceptable.

Overall Evaluation: Whereas this project represents an innovative approach to the treatment of PTSD, little information is provided to adequately evaluate the validity of the proposed method of developing and standardizing the treatment protocol.

**CRITIQUE 2:**

Overall Evaluation: The application is to prepare a treatment manual for the standardization of procedures employing MDMA to assist in psychotherapy for treatment of PTSD with the intent to be used for future phase II and III clinical studies with this drug. It is unclear that this type of activity is typically not part of the NIMH mission.

The listed investigators do not appear to be the most appropriate to prepare such a manual. The application does not indicate that any of the participants are experienced in organizing such documents even though they may have some experience conducting clinical trials. In addition, because of the nature of these trials, it is particularly important to have unbiased evaluators who are not vested in the study to determine the significance of outcomes in order to achieve a practical and objective manual. A manual prepared by those who organized and implemented the study and who have much to be gained if the study results were positive, may be viewed with some degree of reservation and suspicion.

It might appear that preparation of a treatment manual for standardized procedures for MDMA-assisted psychopathology as a treatment for PTSD is premature, especially when it has not even been established that MDMA can be an effective or desirable part of PTSD treatment. The applicants acknowledge the possibility that the MDMA treatment may not be efficacious and in that case the exercise might become a record of the procedures for future study. This seems to be a weak argument for the project. It is not clear what research would be conducted on a failed study and it also seems that the identified team might not be ideally qualified to prepare such a document as none of the listed investigators have a particularly strong background in conducting peer-reviewed research and thus are likely not to be the best qualified team to organize a record that might be of research value or interest.

**CRITIQUE 3:**

Significance: The goals of this small-research grant application are to develop and standardize 3, 4-methylenedioxymethamphetamine (MDMA) assisted psychotherapy as a novel treatment for posttraumatic stress disorder (PTSD). PTSD is a severe and potentially disabling anxiety disorder for which practical and efficacious treatments are few. The applicants have identified a significant public health problem and offer a novel treatment strategy. As MDMA-assisted psychotherapy is not a currently accepted treatment for PTSD, development of a standardized treatment manual that can be used by researchers to test treatment safety and efficacy is essential.

Approach: In brief, the investigators will develop a treatment manual through the use of previous anecdotal accounts of MDMA-assisted therapy, and by observing and reviewing audio and video recordings of psychotherapy sessions from an ongoing Phase I trial of MDMA-assisted psychotherapy for the treatment of PTSD. Initial drafts will be written by the PI and two co-investigators. These drafts will be reviewed, discussed and edited by all investigators. Following development of a treatment manual that describes each stage of MDMA-assisted psychotherapy, the investigators will develop measures of therapist adherence and competence that can be used to assess the skills of therapists who are interested in employing MDMA-assisted therapy. If time permits, efforts will be made to develop a training program for therapists who plan to engage in MDMA-assisted therapy.

Importantly, three drafts of a treatment manual have already been written, and the most recent version is available for review on-line. As such, development of a treatment manual will actually be revision of the currently available manual. The first phase of this revision process will begin when the investigators begin to videotape sessions (both with and without drug/placebo) from the ongoing 12-session study of MDMA-assisted psychotherapy of PTSD (12 subjects will receive MDMA and 8 will receive placebo and, if desired, those who receive placebo can enroll in MDMA-assisted therapy in follow-up). The two psychotherapists who conduct these sessions, along with Dr. Ruse, a clinical psychologist, will review as many tapes as practically possible, and will make efforts to extract the salient features of each type of session (initial, pre-drug assisted, post-drug assisted, termination).

Strengths of the application include the fact that, without a standardized (and reproducible) treatment method, it will be difficult to determine in a controlled manner whether MDMA is efficacious as a psychotherapeutic adjunct in the treatment of PTSD or, in contrast, whether one of many potential confounds is responsible for the effects of therapy in this population. Indeed, as noted by the applicant, the therapy that is being employed in the ongoing clinical trial employs a number of well-established treatments for PTSD (e.g., CBT methods).

Weaknesses of the application include the fact that it is not at all clear how, exactly, the investigators decide what to include and exclude in the manual. It is implied that procedures and methods that are currently being employed by the investigators are desirable and might be emulated as the standard of care. If so, it is unclear why the investigators need to review the tapes, since they are the ones who are setting the standard and how it will be determined which features should be included in the manual, and which should be excluded. While the videotapes, no doubt, will include valuable research material, it seems odd that the therapists who performed the therapy will need to review these tapes to determine what it is that they themselves are doing. While there may be a good explanation, it is not included in this application. In general, as reviewed in the excellent paper by Dr. Carroll included in the Appendices to this application, the initial goals of a psychotherapy treatment manual should be to specify treatment techniques goals and formats (and how they differ from other treatments) as well as to specify theoretical active ingredients. It is not sufficiently clear how review of video and audiotapes might facilitate this process given that three versions of the manual have already been written.

A review of the current version of the treatment manual again raises the question of what, exactly, will be done to revise and improve the manual and how it will be determined that the manual is “complete.”

A more detailed and systematic description of the methods to be employed in the manual development might be useful in this regard. It is difficult to evaluate the merit of this application because of insufficient detail. While it is clear that the investigators will review videotapes and discuss edits to the manual, the nature of the reviews and criteria for including versus excluding materials in the manual are not clear.

Innovation: The proposed research is highly innovative. No other research group has developed a treatment manual for MDMA-assisted psychotherapy.

Investigator: The PI is the first psychiatrist to conduct a Phase I trial of MDMA-assisted psychotherapy for the treatment of PTSD and, therefore, is an excellent candidate to lead the development of a treatment manual.

Environment: Adequate.

Human Subjects: No problems noted, with regard to treatment-manual development.

Women/Minorities/Children Inclusion: Acceptable.

Budget: Acceptable.

**CRITIQUE 4:**

Significance: This is an initial R03 application to complete a treatment manual for MDMA assisted psychotherapy for PTSD. MDMA assisted psychotherapy may be an important advance and standardized procedures will be necessary of future research.

Approach: The investigators propose modifying their existing draft manual to include evaluative guidelines and measures of therapist competence and adherence. The application might be strengthened by providing greater detail regarding the methods to be used.

While manual development is not original, it is necessary and MDMA assisted psychotherapy is novel.

Investigator: The investigator cites extensive clinical experience and he is Principal Investigator for a MDMA-assisted psychotherapy study sponsored by the Multidisciplinary Association of Psychedelic Studies. However, there is no evidence that he has training or experience in research or psychotherapy manual development. There is a similar lack of research training and experience among the other co-investigators, with the exception of one consultant.

Environment: The study environment appears to be the clinical offices of the investigators.

**CRITIQUE 5:**

Dr Michael Mithoefer and colleagues propose preparing a treatment manual to be used with MDMA assisted psychotherapy for Post Traumatic Stress Disorder (PTSD). A small 20-subject pilot clinical trial evaluating this therapy is being supported by a private, non-profit foundation (MAPS). The aim of this project is to develop and standardize MDMA-assisted psychotherapy as a novel treatment for PTSD. To accomplish this aim the PI and two co-PIs will observe, review and examine video and audiotapes of non-drug (60-90 minute) and drug (8 hour) therapy sessions from the ongoing clinical trial.

Significance: PTSD remains a prevalent and disabling disorder with few effective pharmacotherapies. There is a compelling need for new treatments and MDMA may have some utility in treating this disorder. Data from the MAPS supported placebo-controlled trial will help in deciding if MDMA has any

efficacy in the treatment of PTSD. The significance and importance of the proposed treatment manual is less clear. The manual will be constructed from data obtained in a single-site pilot study, possibly limiting the ability to generalize procedures to multiple sites. Although the preliminary data appear promising efficacy has not yet been demonstrated in the pilot study. Thus, development of a treatment manual appears premature.

Approach: Dr. Mithoefer will use video and audiotapes of MDMA and placebo therapy sessions to construct the treatment manual. Although the investigators have done an admirable job in launching the current pilot study there are several methodological deficiencies that need to be addressed for this to become an outstanding project. Most importantly, specific methodologies for analyzing tapes are not presented. Apparently, there are earlier draft versions of the manual but these were neither included for review nor summarized in the application. Without some detail about the current therapeutic procedure it is hard to understand exactly what will be done in the proposed work. Apparently, the PI and his research associates will view the tapes, think and then empirically decide which therapeutic features might become “standard”. Although this may be the best way to attack the relatively small data set from 20 patients a more structured approach is likely to yield results applicable to a larger cohort of therapists. It is quite possible that the proposed method will yield a treatment manual only applicable to Dr. Mithoefer or psychiatrists with similar treatment styles. Although there is not much published in the area of manual development the investigators have cited only a single reference (Carroll 2002). Perhaps the work of Rounsaville might be explored and incorporated into future applications. Additionally, because MDMA is a drug more attention needs to be given to methods assessing pharmacotherapeutic efficacy. Although a single reference on guidelines for investigating pharmacological interventions in PTSD is cited (Montgomery) adequate details are not given.

The team has listed a consultant with experience in constructing treatment manuals (Sherry Falsetti PhD). She will read manual drafts, consult on questions that might arise and assist in the development of adherence and competence measures. Because the authors have no experience in developing treatment manuals the availability of an experienced consultant is important. She apparently will attend the two 3-day sessions but otherwise her specific role is not described and her talents are not well incorporated into the application. Additionally, the 2003 citation for Dr Falsetti listed in the references is not indexed – perhaps her 2005 citation might be more germane to this project: Falsetti et al, Multiple channel exposure therapy: combining cognitive-behavioral therapies for the treatment of posttraumatic stress disorder with panic attacks. Behavior Modification. 2005 Jan; 29 (1):70-94. In this paper Dr Falsetti describes a process used to develop a non-pharmacologic treatment for PTSD. However, because MDMA is a drug treatment simply addressing psychological components of treatment is not adequate, standardized procedures for dosing and following drug associated adverse events need to developed and presented.

The authors propose developing “standardized methods, procedures and evaluative guidelines” for use in multi-site studies of MDMA assisted therapy in people with PTSD. Because this treatment method has not been validated a larger, appropriately powered and designed clinical trial might be done before developing a treatment manual. The current 20-subject single site study is too small to reliably represent the large and diverse population of PTSD patient who might be candidates for MDMA assisted therapy. Although many of the features proposed – standard methods, procedures and outcome measures – would be used in manual development these are also key features of a clinical trial. Assuming MDMA shows benefit in the pilot study perhaps the investigators might be encouraged to design and conduct a valid multi-center study. Accordingly, evaluating a study protocol where the “treatment manual” was one component of a larger trial might be more useful. If a pharmaceutical company were developing MDMA as a treatment for PTSD the next study might be the pivotal efficacy trial and much more than a treatment manual might be needed to demonstrate efficacy.

Innovation: Studies of MDMA assisted therapy are clearly innovative and merit support and recognition. There have been several reports from relatively uncontrolled trials of MDMA assisted

psychotherapy and the intent of the investigators is laudable. The methods for developing the manual are not innovative. Notably, the investigators appear eager to scientifically demonstrate the efficacy of MDMA in PTSD and have invested the time and resources to initiate a valid clinical trial of a controversial drug for a clinically important condition.

Investigators: Dr Mithoefer is a practicing psychiatrist with limited research experience. Despite his lack of academic support and research training he has successfully launched a complex human trial with a DEA schedule I drug - MDMA. He is clearly an exceptionally talented physician with great energy and enthusiasm and he has great potential but his qualifications to lead the next phase – design of a multi-site study and development of a “treatment” (really an experimental) protocol - is less clear. The co-investigators, although talented, have little experience in designing the studies logically needed after the pilot trial. The consultant has some of the experience necessary to assist protocol development but no experience designing a multi-center study.

Environment: The environment is supportive and appropriate. The collaboration between MAPS and the investigators is excellent.

Human Subjects**:** Unacceptable**.** Reviewers expressed concern that additional detail regarding provisions for monitoring the safety of subjects during the ongoing trial, e.g., blood pressure, body temperature, etc. is needed.

Overall Evaluation: This application has many admirable features but is premature for this stage of treatment standardization. The application lacks many important details –appropriate literature based procedures for manual development and details on the integration of psychological and pharmacological efficacy assessments need to be provided. Before any funds are committed to future research the investigators should complete the pilot trial and demonstrate efficacy without significant toxicity. A larger randomized trial incorporating safety measures and valid outcomes might be performed before codifying the treatment process. The investigators might consider partnering with experienced trialists to develop research procedures that incorporate what has been learned in the pilot study. Although this application does not generate much enthusiasm the investigators might be encouraged to return with an application for treatment research. New clinical with MDMA trials might be supportable if justified by efficacy and safety data from the pilot study.

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**MEETING ROSTER**

**Interventions Research Review Committee**
**National Institute of Mental Health Initial Review Group**
**NATIONAL INSTITUTE OF MENTAL HEALTH**
**ITV**
**October 18, 2005 - October 19, 2005**

## CHAIRPERSON

PHILLIPS, KATHARINE A, MD
PROFESSOR
DEPARTMENT OF PSYCHIATRY & HUMAN BEHAVIOR
SCHOOL OF MEDICINE
BROWN UNIVERSITY
PROVIDENCE, RI 02906

## MEMBERS

BARTELS, STEPHEN J, MD
PROFESSOR/DIRECTOR OF AGING
DEPARTMENT OF PSYCHIATRY
DARTMOUTH MEDICAL SCHOOL
NEW HAMPSHIRE-DARTMOUTH PSYCHIATRIC RESEARCH
CENTER
LEBANON, NH 03766

BRANDT, HARRY A, MD *
HEAD OF PSYCHIATRY
ST JOSEPH MEDICAL CENTER
DEPARTMENT OF PSYCHIATRY
TOWSON, MD 21204

BRODY, DAVID S, MD *
CHIEF OF GENERAL INTERNAL MEDICINE
DREXEL UNIVERSITY
SCHOOL OF MEDICINE
PHILADELPHIA, PA 191021192

BURGESS, HELEN JULIA, PHD *
ASSISTANT PROFESSOR
RUSH UNIVERSITY
BIOLOGICAL RHYTHMS LAB
CHICAGO, IL 60612

DELGADO, PEDRO L., MD
PROFESSOR AND CHAIR/RESEARCH CHAIR
DEPARTMENT OF PSYCHIATRY
UNIVERSITY OF TEXAS HLTH. SCI. CTR. AT SAN ANTONIO
HSC-MED 710L-2
SAN ANTONIO, TX 78229-390

DIAZ, ESPERANZA , MD *
ASSOCIATE PROFESSOR
DEPARTMENT OF PSYCHIATRY
YALE UNIVERSITY SCHOOL OF MEDICINE
NEW HAVEN, CT 06519

DOUGHERTY, DARIN D, MD *
ASSISTANT PROFESSOR
MASSACHUSETTS GENERAL HOSPITAL
DEPT OF PSYCHIATRY
CHARLESTOWN, MA 02129

GATZ, MARGARET J, PHD *
PROFESSOR
DEPARTMENT OF PSYCHOLOGY
UNIVERSITY OF SOUTHERN CALIFORNIA
LOS ANGELES, CA 90089

GOODMAN, WAYNE K, MD
PROFESSOR AND CHAIRMAN
DEPARTMENT OF PSYCHIATRY
COLLEGE OF MEDICINE
UNIVERSITY OF FLORIDA
GAINESVILLE, FL 32610

GREENMAN, LISA , JD *
STAFF ATTORNEY
FEDERAL PUBLIC DEFENDER ORGANIZATION OF MARYLAND
WASHINGTON, DC 20015

GUTHRIE, DONALD , PHD
PROFESSOR EMERITUS OF PSYCHIATRY
DEPARTMENT OF BIOSTATISTICS
UNIVERSITY OF CALIFORNIA, LOS ANGELES
LOS ANGELES, CA 90024

GYULAI, LASZLO , MD *
ASSOCIATE PROFESSOR
UNIVERSITY OF PENNSYLVANIA
DEPT OF PSYCHIATRY
PHILADELPHIA, PA 19104

HAAGA, DAVID A, PHD *
PROFESSOR
DEPARTMENT OF PSYCHOLOGY
AMERICAN UNIVERSITY
WASHINGTON, DC 20016

HAMER, ROBERT M., PHD
PROFESSOR
DEPARTMENT OF PSYCHIATRY AND BIOSTATISTICS
UNIVERSITY OF NORTH CAROLINA SCHOOL OF MEDICINE
CHAPEL HILL, NC 275997160

HILSENROTH, MARK J, PHD *
ASSOCIATE PROFESSOR
THE DERNER INSTITUTE OF
ADVANCED PSYCHOLOGICAL STUDIES
GARDEN CITY, NY 11530

HOFMANN, STEFAN G, PHD *
ASSOCIATE PROFESSOR
BOSTON UNIVERSITY
DEPT OF PSYCHOLOGY
BOSTON, MA 02215

HOPE, DEBRA A., PHD *
PROFESSOR
DEPARTMENT OF PSYCHOLOGY
UNIVERSITY OF NEBRASKA
LINCOLN, NE 685880308

JAYCOX, LISA H, PHD
SENIOR BEHAVIORAL SCIENTIST
RAND CORPORATION
HEALTH PROGRAM
ARLINGTON, VA 222025050

KLINKMAN, MICHAEL S., MD
ASSOCIATE PROFESSOR
DEPARTMENT OF FAMILY MEDICINE AND
DEPARTMENT OF PSYCHIATRY
UNIVERSITY OF MICHIGAN MEDICAL SCHOOL
ANN ARBOR, MI 481090708

LACHENBRUCH, PETER , PHD *
CONSULTANT
ASHTON, MD 20861

LAWSON, WILLIAM B, MD, PHD *
PROFESSOR
DEPARTMENT OF PSYCHIATRY
HOWARD UNIVERSITY HOSPITAL
WASHINGTON, DC 20060

LEE, BRENDA E, BA
EXECUTIVE DIRECTOR
MENTAL HEALTH ASSOCIATION OF ALLEGHENY COUNTY
PITTSBURGH, PA 15219

LINEHAN, MARSHA M, PHD *
PROFESSOR
DEPARTMENT OF PSYCHOLOGY
UNIVERSITY OF WASHINGTON
SEATTLE, WA 981951525

LUDMAN, EVETTE J, PHD *
RESEARCH ASSOCIATE
CENTER FOR HEALTH STUDIES
GROUP HEALTH COOPERATIVE
SEATTLE, WA 981011448

MARANGELL, LAUREN B, MD *
ASSOCIATE PROFESSOR/DIRECTOR
DEPARTMENT OF PSYCHOLOGY
BAYLOR COLLEGE OF MEDICINE
HOUSTON, TX 77030

MCCANN, UNA D, MD *
ASSOCIATE PROFESSOR OF PYSCHIATRY
JOHNS HOPKINS UNIVERSITY
SCHOOL OF MEDICINE
DEPARTMENT OF PSYCHIATRY
BALTIMORE, MD 212246823

MOLINE, MARGARET L., PHD *
DIRECTOR
EISAI MEDICAL RESEARCH
RIDGEFIELD PARK, NJ 07660

NEMEROFF, CHARLES B., MD, PHD *
REUNETTE W. HARRIS PROFESSOR AND CHAIR
DEPARTMENT OF PSYCHIATRY AND BEHAVIORAL
SCIENCES
SCHOOL OF MEDICINE
EMORY UNIVERSITY
ATLANTA, GA 30322

NEZU, ARTHUR M, PHD
PROFESSOR
DEPTS OF MEDICINE, PSYCHOLOGY, & PUBLIC HEALTH
DIRECTOR, CENTER FOR BEHAVIORAL MEDICINE AND
MIND/BODY STUDIES
DREXEL UNIVERSITY
PHILADELPHIA, PA 19102

O'BRIEN, RALPH , PHD *
DIRECTOR, COLLABORATIVE BIOSTATISTICS CENTER
DEPARTMENT OF BIOSTATISTICS & EPIDEMIOLOGY
CLEVELAND CLINIC FOUNDATION
CLEVELAND, OH 44195

O'HARA, MICHAEL WILLIAM, PHD
PROFESSOR
DEPARTMENT OF PSYCHOLOGY
UNIVERSITY OF IOWA
IOWA CITY, IA 52242

OQUENDO, MARIA A, MD
PROFESSOR
DEPARTMENT OF PSYCHIATRY
NEW YORK STATE PSYCHIATRIC INSTITUTE
COLLEGE OF PHYSICIANS AND SURGEONS
COLUMBIA UNIVERSITY
NEW YORK, NY 10032

PERSONS, JACQUELINE B, PHD *
DIRECTOR
SAN FRANCISCO BAY AREA CENTER FOR
COGNITIVE THERAPY
OAKLAND, CA 94618

RITTERBAND, LEE M, PHD *
ASSOCIATE PROFESSOR
UNIVERSITY OF VIRGINIA HEALTH SYSTEM
DEPARTMENT OF PSYCHIATRIC MEDICINE
CHARLOTTESVILLE, VA 22908

ROBERTS-BROWN, GLORIA
PROGRAM COORDINATOR
HISTORICALLY BLACK COLLEGES & UNIVERSITIES
(HBCU)
FACULTY DEVELOPMENT NETWORK
TOUGALOO COLLEGE, CCESR
ADMIN SECTY, HINDS COUNTY MENTAL HEALTH
COMMISSION
TOUGALOO, MS 39174

ROY, MICHAEL J LTC, MD *
PROFESSOR
DIVISION OF MILITARY INTERNAL MEDICINE
UNITED STATES ARMY
BETHESDA, MD 20814

SALKEVER, DAVID S., PHD
PROFESSOR
DEPARTMENT OF HEALTH POLICY AND MANAGEMENT
SCHOOL OF HYGIENE AND PUBLIC HEALTH
THE JOHNS HOPKINS UNIVERSITY
BALTIMORE, MD 21205

SCOGIN, FORREST R, PHD *
PROFESSOR
DEPARTMENT OF PSYCHOLOGY
COLLEGE OF ARTS AND SCIENCES
UNIVERSITY OF ALABAMA AT TUSCALOOSA
TUSCALOOSA, AL 354870348

SHEAR, M KATHERINE, MD
PROFESSOR
DEPARTMENT OF PSYCHIATRY
WESTERN PSYCHIATRIC INSTITUTE AND CLINIC
UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE
PITTSBURGH, PA 15213

STEIN, MURRAY B, MD, MPH
PROFESSOR
DEPARTMENT OF PSYCHIATRY
ANXIETY AND TRAUMATIC STRESS DISORDERS PROGRAM
UNIVERSITY OF CALIFORNIA SAN DIEGO
LA JOLLA, CA 92037

STEKETEE, GAIL S, PHD
PROFESSOR
SCHOOL OF SOCIAL WORK
BOSTON UNIVERSITY
BOSTON, MA 02215

STRAKOWSKI, STEPHEN M, MD, PHD *
PROFESSOR
DEPT. OF PSYCHIATRY, PSYCHOLOGY AND NEUROSCIENCE
COLLEGE OF MEDICINE
UNIVERSITY OF CINCINNATI
CINCINNATI, OH 452670559

STRIEGEL-MOORE, RUTH H, DIPL, PHD *
PROFESSOR
DEPARTMENT OF PSYCHOLOGY
WESLEYAN UNIVERSITY
MIDDLETOWN, CT 06459

TARIOT, PIERRE N., MD
PROFESSOR
DEPARTMENT OF PSYCHIATRY
UNIVERSITY OF ROCHESTER MEDICAL SCHOOL
ROCHESTER, NY 14620

TAYLOR, STEVEN , PHD *
PROFESSOR
DEPARTMENT OF PSYCHIATRY
UNIVERSITY OF BRITIST COLUMBIA
WESBROOK MALL
VANCOUVER, BC V6T2A1
CANADA

TRIVEDI, MADHUKAR H., MD
DIRECTOR AND PROFESSOR
MOOD DISORDERS RESEARCH PROGRAM AND CLINIC
DEPARTMENT OF PSYCHIATRY
UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL SCHOOL
DALLAS, TX 752359101

WILFLEY, DENISE E, PHD *
PROFESSOR
DEPARTMENT OF PSYCHIATRY
SCHOOL OF MEDICINE
WASHINGTON UNIVERSITY
ST. LOUIS, MO 63114

## MAIL REVIEWER(S)

HANSON, GLEN R, DDS, PHD
DIRECTOR, UTAH ADDICTION CENTER AND SENIOR ADVISOR, NATIONAL INSTITUTE ON DRUG ABUSE
DEPARTMENT OF PHARMACOLOGY AND TOXICOLOGY
UNIVERSITY OF UTAH
SKAGGS HALL
SALT LAKE CITY, UT 84112

MENDELSON, JOHN E., MD
SENIOR SCIENTIST
DRUG DEPENDENCE RESEARCH CENTER
LANGLEY PORTER INSTITUTE
UNIVERSITY OF CALIFORNIA AT SAN FRANCISCO
SAN FRANCISCO, CA 94143

## SCIENTIFIC REVIEW ADMINISTRATOR

SOMMERS, DAVID I., PHD
SCIENTIFIC REVIEW ADMINISTRATOR
DIVISION OF EXTRAMURAL ACTIVITIES
NATIONAL INSTITUTE OF MENTAL HEALTH
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MD 208929606

## GRANTS TECHNICAL ASSISTANT

DAWKINS, SHEILA LAVITA, BA
EXTRAMURAL SUPPORT ASSISTANT
DIVISION OF EXTRAMURAL ACTIVITIES
NATIONAL INSTITUTE OF MENTAL HEALTH
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MD 208929609

* Temporary Member. For grant applications, temporary members may participate in the entire meeting or may review only selected applications as needed.

Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.

**NOTIFICATION OF SCIENTIFIC REVIEW ACTION**

Release Date: 11/28/2005

MITHOEFER, MICHAEL C MD
208 SCOTT STREET
MT PLEASANT, SC 29464

Our Reference: 1 R03 MH076817-01 ITV

The scientific merit review of your application, referenced above, is complete. As part of this initial review, reviewers were asked to provide written evaluations of each application and to identify those with the highest scientific merit, generally the top half of applications they customarily review, for discussion at the meeting and assignment of a priority score. Your application did not receive a score. Unscored applications are neither routinely reviewed at a second level by a national advisory council or board nor considered for funding.

Enclosed is your summary statement containing the reviewers' comments. You should call the program official listed below to discuss your options and obtain advice.

Farris Tuma
301-443-5944
ftuma@nih.gov

If you choose to resubmit, it is important to respond specifically to comments in the summary statement, as outlined in the instructions in the PHS 398 application kit (http://grants1.nih.gov/grants/funding/phs398/phs398.html).

Enclosure

cc: Business or institutional official of applicant organization

PRESIDENT
MAPS
3 FRANCIS STREET
BELMONT, MA 02478