

To: Prospective Applicants

From: Berra Yazar-Klosinski, Ph.D., Lead Clinical Research Associate, Multidisciplinary Association for Psychedelic Studies (MAPS)

Date: October 14, 2011

Request for Proposals Description

Background

Autism spectrum disorders (ASD) are complex neurodevelopmental disorders with early childhood onset. The prevalence of ASD may be increasing, and ASD is more common than previously thought. These disorders, for which there is presently no cure and only limited treatments, generally have lifelong effects.

Anecdotal reports suggest that 3,4-methylenedioxyamphetamine (MDMA) may be a suitable pharmacologic agent for the treatment of ASD. MDMA may influence how certain types of empathy are experienced by adults on the spectrum. Pilot studies suggest that MDMA-assisted psychotherapy can help people overcome posttraumatic stress disorder (PTSD), which is an anxiety-related disorder that includes symptoms such as avoidance that are also found in people with ASD.

Purpose

The purpose of this Request for Proposals (RFP) is to catalyze a clinical study into the use of MDMA-assisted psychotherapy of some kind in adult subjects with ASD, when at the moment we have funding sufficient only to pay for protocol development expenses. This RFP is seeking the submission of proposals to support the development of a protocol designed to elucidate the treatment of ASD with the first ever study of MDMA in this subject population. MAPS will award \$10,000 as seed money to one research team for protocol development costs with the goal of completing a protocol within 6 months after the awarding of the grant. Only one protocol development grant will be awarded. Once the protocol is designed, MAPS will assist the research team in trying to raise the funds to actually conduct the study.

Scope

Potential types of studies that may be funded include, but are not limited to:

Pilot studies, including exploratory clinical trials, aimed to generate data that inform a decision whether to continue further clinical development of the proposed intervention

Identification of individual characteristics that predict response to a combination of the

proposed intervention with behavioral treatments
Clinical trials to identify moderators and effective ingredients (e.g. dose, intensity, mode of delivery) of the proposed intervention
Innovative and newly developed intervention strategies using MDMA to improve outcomes in school and community settings throughout the lifespan (e.g., academic functioning, social and adaptive behavior, family functioning, employment, community integration)
Developing a method to teach social skills using parents as therapists
Examining the cognitive and mood-based effects of MDMA in order to refine its use in treating autism
Identification of biological signatures for autism and their relevance to prediction of treatment response to MDMA and outcomes

Eligibility

Grant will be awarded to a team who has adequate time and credentials to design and conduct a clinical trial. Ideally, the team would also be eligible for grant monies through the NIH or other funding agencies. With guidance and support from MAPS, the team must also be able to navigate local regulatory agencies in order to conduct trial in compliance with all applicable regulations. Team must be willing to keep all data in the public domain and seek publication of results. A history of peer-reviewed publications is preferred.

How to Apply

Submit electronic copies (PDFs) of the following in a single email to Berra@maps.org

A. Protocol Synopsis (Not more than 10 pages) with the following sections included:

0. COVER PAGE - Name/Address of Institution where research will be conducted, Names and Credentials of Investigators and all sub-investigators/independent raters that are currently known.
1. STUDY AIMS, BACKGROUND AND DESIGN – Brief description of the proposed study with relevant research studies referenced.
2. SUBJECT POPULATION, INCLUSION/EXCLUSION CRITERIA – Include eligibility criteria, number of subjects to be enrolled and recruitment procedures.
3. RESEARCH METHODS OR PROCEDURES – Include primary and secondary outcome measures and assessment schedule
4. RISKS – Any risk to study subjects is of particular concern to the committee. Please describe any possible psychological or physical risk and methods to minimize them. For the purposes of this RFP, a review of MDMA neurotoxicity is not needed.
5. BENEFITS – Any benefit to study subjects is also of concern to the committee. Please describe any possible psychological or physical benefit.

B. Proposed Budget: The clinical study described in the protocol to be developed can have any expected cost. Please estimate direct and indirect costs associated with conducting the proposed study and a plan for generating research funds. MAPS will actively assist in

fundraising for the approval process for the completed protocol and the funds to conduct the study.

B. Documentation of Qualifications: Please submit CVs of all Investigators and relevant core study staff (i.e. independent rater, nurses, doctors, therapists, or other attendants who will have direct contact with subjects)

Minimal Data Collection requirements

The following measures will be required in proposals submitted to MAPS. These measures are based on the requirements of the National Institute of Health (NIH), a major source of grant monies for autism research.

- Autism Diagnostic Interview-Revised (ADI-R) and the Autism Diagnostic Observation Schedule (ADOS), for use according to their published manuals
- Vineland Adaptive Behavior Scales, Second Edition
- An IQ or developmental assessment measure, that includes both nonverbal and verbal components and results in standardized scores for both.

The NIH National Database for Autism Research (NDAR) houses research data of all types (genetic, imaging, clinical assessment, etc.) from human subjects involved in ASD studies, and is currently on track to receive data from tens of thousands of such subjects. NDAR's first data release occurred in November 2010, making mostly clinical assessment data from over 10,000 research subjects available to qualified investigators. It is expected that in the next several years, ASD data from more than 90% of new investigations will be available in or through NDAR.

One goal of this study is to contribute data to NDAR. Central clinical coordination and local data management for data cleaning and entry and bio-statistical consulting will be the responsibility of MAPS. For more information on NDAR, please visit <http://ndar.nih.gov/ndarpublicweb/>.

Request for Proposals Submission and Review Process

All proposals are due on December 16, 2011 at 5:00pm Pacific Standard Time. Please do not fax proposals. A decision will be made and all parties notified by January 13, 2012.

The grant will be awarded by a committee consisting of a team of reviewers from MAPS. The following factors will be taken into consideration when evaluating proposals (not in order of priority):

- Sophistication of research design
- Safety plan – both medical and psychological
- Credentials of team members and prior experience conducting clinical trials
- Plan for fundraising and demonstrated ability to raise some funds

- Demonstrated ability of team members to navigate regulatory agencies
- Location of proposed study (Only U.S. sites will be considered)

Contact

For questions and to submit proposals, please contact Berra Yazar-Klosinski, Ph.D. Lead Clinical Research Associate, MAPS via email at Berra@maps.org or 831-429-6362 ext. 104.

About MAPS

Founded in 1986, the Multidisciplinary Association for Psychedelic Studies (MAPS) is a 501(c)(3) non-profit research and educational organization. MAPS' mission is (1) to treat conditions for which conventional medicines provide limited relief—such as posttraumatic stress disorder (PTSD), pain, drug dependence, anxiety and depression associated with end-of-life issues—by developing psychedelics and marijuana into prescription medicines; (2) to treat many thousands of people by building a network of clinics where treatments can be provided; and (3) to educate the public honestly about the risks and benefits of psychedelics and marijuana.

MAPS helps scientists fund, design, and conduct clinical trials under the guidelines set forth by the United States Food and Drug Administration (FDA), the European Medicines Agency (EMA), the International Council on Harmonization (ICH), and other government regulatory bodies.