

December 14, 2009

[REDACTED]

RE: Protocol MT-1 (IRB Tracking [REDACTED])

Dear [REDACTED]

What follows are our responses to the three additional questions that the Board asked us today to address. We're sending this in time for the Board meeting at 1 PM tomorrow. We'd be glad to respond to any additional questions the Board may have about Protocol MT-1 (IRB Tracking [REDACTED])

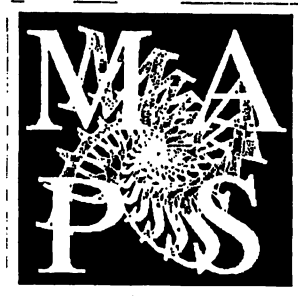
[REDACTED] Question 1: Please provide a written definition for "Healthy Volunteers" as noted in study title, ideally based on a recognized/accepted psychological standard.

If the primary objective is to collect psychological effects of MDMA in healthy volunteers, by assessing changes in mood state before, during and after the sessions, and to assess personality traits, please justify Inclusion criteria #s 3 and 5. Also, the protocol (pg 62) describes allowance for subjects to be engaged in an on-going therapeutic relationship with a psychotherapist or psychiatrist. This is not addressed in I/E criteria, and again raises the question of what defines a "healthy volunteer."

MAPS Reply to Question 1:

Psychiatry and clinical psychology have not formulated a measure of psychological health. There is no recognized standard for psychological health aside from absence of psychological conditions. In this study "healthy volunteers" will be defined as people who do not meet criteria for any current psychiatric diagnosis on the SCID administered by the independent rater at screening and who do not have any exclusionary medical condition as determined by screening history and physical exam and lab tests.

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Inclusion criteria #3 states, “may have a history of a mood disorder (except bipolar affective disorder type I, see exclusions) and/or an anxiety disorder or other non-excluded psychiatric disorder.” We do not believe that including people with a history of mood, anxiety or other non-excluded psychiatric disorder, in the absence of current disorder, is at odds with our goal of assessing psychological effects in healthy volunteers. We will have baseline measures to assure that there are no current disorders and we will be comparing the final scores with those baseline measures.

Inclusion criteria #5 states, “are willing to refrain from taking any psychiatric medications from study enrollment until up to seven days after the second experimental session, with the exception of gabapentin when prescribed for pain control.”

In response to Item 2 to the previous review, we noted that psychiatric medication can be administered to people for non-psychiatric conditions. Hence we do not expect that discontinuing psychiatric medication for a non-psychiatric condition will affect mood during the course of the study.

The statement on p. 62 refers to risk mitigation in response to serious psychological distress, if it should occur. It encourages involvement with a psychotherapist in treating this event if someone is already seeing a psychotherapist. We do not require people to be in psychotherapy, nor do we exclude people in psychotherapy.

People undergo psychotherapy for psychological problems that do not constitute a psychiatric diagnosis, as well as for personal growth or professional training and development. Undergoing psychotherapy is not an indicator of an absence of mental health. Since enrollment in this study is open to people who are in graduate therapist training programs, we anticipate that some applicants will be in psychotherapy as part of their training.

Question 2: “What are the reporting duties to the subject’s state of residence, for a positive HIV screen?”

MAPS Reply to Question 2:

All positive HIV screens will be reported by Dr. Mithoefer to the South Carolina Department of Health. Today, Dr. Mithoefer contacted the reporting division of the South Carolina Department of Health. He learned that if he reports a case of HIV to them, they automatically forward it to the person's home state if they don't live in South Carolina.

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Question 3: "Is the pregnancy testing urine or serum?"

MAPS Reply to Question 3:

The pregnancy testing is urine. That information is found in the protocol in sections 6.2.1 Prescreening and Screening, p. 31 of the copy of the protocol provided to the Board, and in 6.2.3 Experimental Session (Visits 2 and 4), on p. 33 of the protocol.

I will be available tomorrow afternoon during the time of the Board meeting should the Board have any additional questions that they would like addressed immediately.

Sincerely,

A handwritten signature in black ink that reads "Rick Doblin". The signature is written in a cursive, flowing style.

Rick Doblin, Ph.D.  
MAPS Executive Director

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