

December 14, 2009

Rick Doblin, PhD
Multidisciplinary Association for Psychedelic Studies
3 Francis Street
Belmont, MA 02478

RE: Protocol#: MT-1

“A Phase I Placebo-Controlled, Double-Blind Crossover Study to Assess Psychological Effects of MDMA when Administered to Healthy Volunteers”

Hi Ilsa and Rick,

The Board will re-review study MT-1 (IRB Tracking # [REDACTED]) at the meeting tomorrow, December 15th. Upon a preliminary review of the submission, the Board has asked me to forward the following questions:

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.”
2. What are the reporting duties to the subject’s state of residence, for a positive HIV screen?
3. Is the pregnancy testing urine or serum?

The Board will meet tomorrow at 1 p.m. EST. Any responses you could provide prior to that time would be very helpful.

If you have any questions, please feel free to contact me.

Thank you!

[The IRB]