

Michael C. Mithoefer, MD

October 15, 2009

Re: **Study #MT-1.** "A Phase 1 Placebo-Controlled, Double-Blind Crossover Study to Assess Psychological Effects of MDMA when Administered to Healthy Volunteers"

Dear [REDACTED]

I am hereby submitting the following study for review by [REDACTED] IRB. The study is a Phase 1 study of the psychological effects of MDMA in healthy volunteers. It has been reviewed and cleared by FDA.

Please find along with this application

- Study protocol, Amendment 1, dated September 16, 2009
- Draft informed consent materials, dated September 15, 2009
- Investigator's brochure, dated December, 2007
- Current Curriculum vitae of principal investigator and co-investigator
- FDA form 1572, dated October 14, 2009
- Letter from FDA to Rick Doblin PhD saying study may proceed, dated Oct 1, 2009
- Medical License of Principal Investigator, dated October 12, 2009
- Copies of or information on measures to be used in the study
 - NEO Personality Inventory
 - Columbia Suicide Severity Rating Scale (Baseline and Since Last Visit)
 - Profile of Mood States (sample)
 - Brief Symptom Inventory (Information)
 - State Interpersonal Closeness Measure (sample)
 - Subjective Units of Distress
 - Participant wallet card
 - Instructions to Participants (Reminder of Study Rules)

█ forms for study initiation, including

Study Information and Commitment Form, dated October 5, 2009

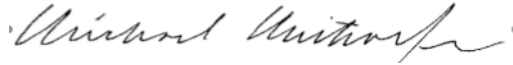
Investigator Site Questionnaire, dated October 14, 2009

Conflict of Interest Disclosure Form, dated October 14, 2009

Indemnification Form, dated October 5, 2009

Submission Letter to IRB, dated October 13, 2009

Sincerely,

A handwritten signature in cursive script, appearing to read "Michael Mithoefer".

Michael C. Mithoefer MD