Ms. Erica Heath
Independent Review Consulting, Inc.
100 Tamal Plaza # 158
Corte Madera, CA 94925

February 7, 2003

Dear Chairperson,

Drs. Doblin and Mithoefer have recently been in touch with me regarding the February 4, 2003 letter expressing the concerns of the IRB stemming from the review of the study protocol, MDMA-Assisted Psychotherapy for the Treatment of Posttraumatic Stress Disorder. I have been asked to write a letter to the Board regarding my role in this study.

With regard to the Board's concerns, my involvement in this proposed project is without any particular conflict of interest. I have been hired as an outside consultant. Prior to becoming involved in this study I had never heard of MAPS, nor had I ever met Drs. Doblin or Mithoefer. Actually, I have yet to met either in person to date. Likewise other than what I hear in the popular press, I know very little about MDMA and have no particular interest. Because I follow the general scientific neuropsychological literature, especially as it relates to any research on memory, I was aware of some scant uncontrolled studies that have raised some concerns about MDMA affecting memory.

After some detailed discussion and thought, I became involved in this proposed project as a consultant after being contacted by Dr. Mithoefer. He is a former psychiatry resident at the Medical University of South Carolina (MUSC) and had sought me out because of my reputation as being an expert in the field of neuropsychology. I am a scientist/clinician and am extremely knowledgeable about the measurement of cognitive and psychological constructs in both neurological and psychiatric populations. As an Associate Professor in Neurology in the clinician/researcher academic track at MUSC, I frequently serve in a role similar to this proposed project to help my colleagues execute neurobehavioral research. In addition, I also conduct my own independent clinical projects.

The services that I have provided thus far in this proposed project have been related to the science. I have contributed to the study design and have identified the dependent outcome measures. I will supervise the data collection in a blinded manner and will perform the data analysis.

As can be seen in my attached curriculum vita, I have an extensive clinical research background. I have been involved in funded, unfunded, and pharmaceutical funded projects. I have numerous published peer-reviewed empirical studies. I also frequently review manuscripts for publications in scientific journals.

In response to the Board's question of conflict of interest, I think that it is clear that my involvement in this project provides independent objectivity. Further, the nature of the outcome measures that I selected for this study are inherently objective and were chosen to eliminate confounding factors. Lastly, in response to the Board's concern for scientific rigor, it is my understanding that MAPS will work with Ms. Amy Emerson who will serve as a separate study monitor. I welcome that addition as it further strengthens this project's rigor. I have spoken to Ms. Amy Emerson earlier today and am confident that she will provide important help in the development of case report forms, in monitoring the project for standard operating procedures, etc.

In closing, I share the concerns of the Board that scientific rigor is critical, particularly given the controversial nature of this study. I hope my letter is helpful to the Board in further evaluating this proposal. Please feel free to contact me if there are any additional questions.

Sincerely,

Mark Wagner, Ph.D.
Associate Professor of Neurology
Medical University of South Carolina