

March 3, 2003

Rick Doblin, Ph.D.  
President, MAPS  
3 Francis Street  
Belmont, MA 02478-2218

**RE: MDMA Assisted Psychotherapy for the Treatment of Post Traumatic Stress Disorder**

Dear Dr. Doblin:

On February 25, you had a telephone conversation with Don Mayne of IRC. You asked him to request the IRB to clarify a few issues from their letter dated February 21. These issues were discussed again during the IRB meeting February 25.

The members reserve their right to hire an outside consultant to assist their review [45 CFR 56.107(f)]. It is customary practice to do this at the expense of the sponsor. You have indicated agreement with this plan, and we thank you for your cooperation. Efforts are underway to get estimates from qualified consultants, and—as we indicated in our February 21 letter—you will be provided these estimates before any additional expense is incurred.

The primary objective for hiring an outside consultant is to provide the IRB with impartial information relevant to the evaluation of risk vs. benefit in this trial. This evaluation is both paramount and all-inclusive. The outcome of the evaluation will affect how the IRB decides on most of the outstanding issues discussed in previous letters. In general, the higher the degree of risk, the more that risk must be managed. In particular, mitigation of what has been perceived to be a pervasive and unconscious bias will be a fundamental aspect of risk management. That was the reasoning behind the original stipulation to hire an outside CRO and second research site.

The majority of members consider your arguments for using Dr. Wagner and Ms. Emerson in lieu of a CRO to be compelling. Similarly, most are still willing to consider the use of just one site. However, these preliminary deliberations could change if the protocol is found to pose a higher degree of risk than we have been led to believe.

We feel compelled to remind you at this juncture that your original agreement with Erica Heath of IRC was that all members must feel comfortable with this study for full board approval to be possible. That, in effect, translates to a consensus—not just a majority. Naturally, a consensus takes longer to reach than a majority. Given that, and the controversial nature of this study, our circumspection should not be surprising. Your continued respect of our autonomy, and adherence to your original agreement with IRC will be very much appreciated.

We understand your anxiousness, and sympathize with the isolation of your present position. You have put a lifetime of work into this project, but to be fair, we have only known about it for little more than two months. We thank you for the courtesy of allowing us to perform the function for which we were hired.

Sincerely,

Penny Wells, Dr. P.H., IRB Chair  
(by) Erica J. Heath, CIP, IRC President