

February 21, 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:

During the IRB meeting February 18, the members reviewed your latest response, which was dated February 10. They voted unanimously to table the discussion until a future meeting.

The members have mixed feelings, but are willing to consider your arguments against using an outside CRO and a second site for this study. They were encouraged by the qualifications of Dr. Wagner and Ms. Emerson, and could see them possibly filling the roles that the IRB wanted to be entrusted to outside monitors. More information may be needed *at a future time* to determine if this will be acceptable. For now, we have received everything we think we need from you for our review.

The IRB continues to be concerned about the issues of unconscious bias and the safety of human subjects in this proposed trial. They want to solicit the opinion of two qualified, objective psychiatric consultants to assess these issues, including the prospect of taking PTSD patients off of prescribed medications. There will be other assessments requested as well, including information relevant to the CAPS test.

The cost for these consultants would be passed on to MAPS. We cannot predict how many hours it would take for them to make the assessments that the IRB will require to enable continued consideration of this proposal. With your agreement, we will obtain estimates from the consultants, and send them for your approval before we proceed.

We thank you for your continued patience with this critical review process. We know that you have been working towards this review for a long time. We are also aware that Dr. Mithoefer feels a sense of urgency on behalf of his patients. With all this taken into consideration, we trust that you are confident enough with this project to allow us to be appropriately circumspect, and arrange for qualified, objective consultants to provide important safety information for the IRB.

Sincerely,

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