

October 22, 2009

[The IRB],

Hello from Rick. I just saw your email exchange with Ilsa and have one point to add about the selection of our medical monitor that I'm sending to you before your IRB committee meeting at 1 PM Thursday.

By the way, I'm writing you from Jerusalem where Michael Mithoefer and I are attending an international scientific conference on the treatment of PTSD. We also met with the therapist team on our ongoing Israeli MDMA/PTSD study. Yesterday, Tuesday, Michael and I were in Amman for meetings with Jordanian FDA staff and our Jordanian MDMA/PTSD research team. We have written a protocol that we'll be submitting to the Jordanian IRB in a few weeks.

Though your email didn't request it, Question #7 was unanswered, so I'll reply.

<7. Explain how the PI will dually serve as medical monitor and as PI for the study, and how the Sponsor designee as PhD will be medically qualified and objective, also given their conflict of interest>

I believe that Dr. Mithoefer and myself are fully qualified to serve as an objective medical monitor/ risk-analysis team.

Nevertheless, in view of your concerns about possible bias and/or appearance of bias, and my lack of medical qualifications, please remove both the PI and the Sponsor's designee (me) as co-medical monitors. The new medical monitor we'd like to work with, Dr. Julie Holland, worked for nine years as an emergency room psychiatrist at Bellevue and is an editor of the comprehensive reference book, Ecstasy- A Complete Guide. Dr. Holland has donated funds to MAPS but is not and has never been a consultant or employee. Would Dr. Holland's degree of connection to MAPS be acceptable for our medical monitor? If so, I'll offer her the responsibility and opportunity to be MAPS' Medical Monitor on our Protocol MT-1, and on subsequent studies conducted by Dr. Mithoefer. I'm writing to you now before knowing if Dr. Holland even wants this position because the main point I would like to communicate is that we will find another medical monitor other than Dr. Mithoefer or myself.

Rick