Hi Rick,

The justification has been reviewed and is accepted. We will move forward with unconditional approval of the study as of 12/21/09.

We will still require one item for Dr. Mithoefer's submission. We received the signed page for the 1572 with the updated protocol, but we are missing the updated first page reflecting our new address.
Please submit the updated 1572 at your earliest convenience.

Thank you!

[The IRB]

-----Original Message-----
From: Rick Doblin [mailto:rick@maps.org]
Sent: Monday, December 21, 2009 12:22 PM
To: [The IRB]
Cc: Ilsa Jerome; Michael Mithoefer; Valerie Mojeiko
Subject: Re: Protocol MT-1

[The IRB],

<I have forwarded the justification to the reviewer for consideration. I will let you know as soon as I receive her response.>

Thanks, we look forward to hearing from you.
In the next few days, we're submitting a new MDMA/PTSD protocol to FDA, to enroll only veterans with PTSD. We anticipate obtaining FDA approval in the next 4-6 weeks. Then we'll submit the protocol to [The IRB] for your review. This protocol uses a dose-response design that may be the design for possible Phase 3 studies. We're gradually moving forward, thanks in large part to the willingness of [The IRB] to take a close but scientific and objective look at our protocol designs.

gratefully,

Rick