



1801 Tippah Avenue
Charlotte, NC 28205
Phone (704) 358-9830
FAX (704) 358-1650
Rick Doblin,
MAPS President

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Multidisciplinary Association for Psychedelic Studies, Inc.

Small Steps, Gradual Progress, New Opportunities

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AFTER A YEAR AND A HALF OF HARD WORK, a groundbreaking MDMA research protocol has been born. A collaborative effort of MAPS, several psychiatrists at the University of California at Irvine (UCI), and numerous expert consultants, the protocol seeks to explore the safety and efficacy of MDMA-assisted guided imagery and psychotherapy in the reduction of pain and distress in end-stage pancreatic cancer patients. If approved by all required authorities, the historic protocol will be the first human study using MDMA conducted in the United States since 1985, when MDMA was made illegal. A protocol approved by the FDA will have the added effect of catalyzing MDMA research around the world.

The MAPS strategy discussed in the last newsletter involved submitting the protocol first to the FDA around the beginning of this year and then submitting it to the UCI Institutional Review Board (IRB). Our strategy was modified as it became clear that the protocol was more well received at UCI than anticipated. Since FDA approval is much more likely if IRB approval is in hand, we decided to delay submission to the FDA and first seek IRB approval.

On February 28, 1992, UCI's Institutional Review Board formally approved the study! The protocol has now been submitted to the FDA for final review. The FDA can either approve the protocol, reject it or place it on hold pending further pre-clinical studies or advisory committee hearings. If the FDA approves the protocol, MAPS will begin a major fund-raising campaign to raise the estimated \$75,000 - \$100,000 needed for the experiment. Though this will require a great deal of work, raising the necessary funds for an approved experiment may be less difficult than raising funds for the process of seeking protocol approval, a struggle with an uncertain outcome and long odds. The current members of MAPS are the core group without whose support no progress would have been made. To all of you, I extend my deep appreciation. Because of your support for the long hard work that went into the protocol design, we have finally succeeded in submitting a well-designed protocol to the FDA. Now we wait and hope that Springtime has really arrived!

In addition to reports on psychedelic research in the US and Switzerland, this issue contains fascinating reports about psychedelic research in Russia. Of special importance is the proposal from Dr. Luchakova for funding for collaborative studies. Soviet state-funded science is in a crisis. It is now possible to assemble a world-class psychedelic research group for a fraction of the cost here in the US. This is a rare opportunity for MAPS and you will hear more about it in the future. — *Rick Doblin, MAPS President*