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APPROVAL OF RESEARCH

October 16, 2013

Charles Grob, M.D.
[redacted]

Dear Dr. Grob:

On 10/15/2013 the John F. Wolf, M.D. Human Subjects Committee (2) reviewed the following protocol:

Type of Review/Submission:	Expedited/Initial Review, Reference #037491
Project Title:	A Placebo-Controlled, Randomized, Blinded, Dose Finding Phase 2 Pilot Safety Study of MDMA-Assisted Therapy for Social Anxiety in Autistic Adults
Investigator:	Charles Grob, M.D.
LABioMed Project No.:	30026-01
Funding Agency:	Multidisciplinary Association for Psychedelic Studies
Grant ID:	MAA-1
IND:	63,384
Documents reviewed:	HRP-211: Submission Packet for Initial Review by IRB (Version 1.0) HRP-211: Application (Version 1.1) Submission Response Form/Modifications Required to Secure Approval (Version 1.0) Consent Form – Version 10/11/2013 (Version 1.0) & Consent Form – Version 9/25/2013 (Version 1.3) PHI Authorization – Version 8/1/2013 (Version 1.0) Research Advisory Panel of California - Approval Letter 9/30/2013 (Version 1.0) Research Advisory Panel of California - Outcome Letter dated 9/25/2013 (Version 1.0) RAP-C Receipt & Review Confirmation 8/29/2013 (Version 1.0) 2013 CV – A. Danforth (Version 1.0) Toronto Alexitymia Scale-20 (Version 1.0) The Awareness of Social Inference Test (TASIT) (Version 1.0) Rosenburg Self Esteem Scale (Version 1.0) Quality of Life Questionnaire (Version 1.0) Perceived Stress Scale (Version 1.0) Liebowitz Social Anxiety Scale (Version 1.0) Feedback Questionnaire 07/24/2013 (Version 1.0) Interpersonal Reactivity Index (Version 1.0) Emotion Regulation Questionnaire (Version 1.0) Columbia Suicide Severity Rating Scale (Since Last Visit) - Version 1/14/2009 (Version 1.0) Columbia Suicide Severity Rating Scale (Baseline), Version 1/14/2009

	(Version 1.0) Beck Depression Inventory-II (Version 1.0) Autism Diagnostic Observation Schedule (ADOS-2), Second Edition (Version 1.0) MAA-1 Walletcard - 31Jul2013 (Version 1.0) MAA-1 Study Rules Reminder - 31Jul2013 (Version 1.0) MAA-1 Phone Script - 31Jul2013 (Version 1.0) MAA-1 Memory Aid - 25Feb2013 (Version 1.0) Advertisement Text 7/31/2013 (Version 1.0) LA BioMed PRACC Form (Version 1.0) MAA1 Protocol Version 2, 21-May-2013 (Version 1.0) MAA1 Description of Case Report Forms 25Feb2013 (Version 1.0) Investigator IRB Protocol - 7/31/2013 (Version 1.0) Investigator Brochure MDMA, Edition 7, 01Aug2013 (Version 1.0) 2013 CV - Charles Grob, M.D. (Version 1.0)

The John F. Wolf, M.D. Human Subjects Committee (2) approved the protocol from 10/15/2013 to 09/24/2014 inclusive. Within 30 days prior to the protocol's scheduled Continuing Review (08/27/2014), you are to submit a completed "HRP-212: Continuing Review Progress Report" and required attachments to request continuing approval or "HRP-251: Final Report/Inactivation" to close the study.

Specific Condition of Approval:

- Human Subjects Bill of Rights – By California law a copy of the Human Subjects Bill of Rights, in a language in which the subject is fluent, must be given to all research subjects in this study as there is a real or foreseeable risk of biomedical harm. Numerous translations are available for download on the Compliance iRIS website at https://imedris.labiomed.org.
- All subjects must be able to consent for themselves to be enrolled in this study. This means that you cannot enroll incapable subjects who require enrollment by consent of a legally authorized representative.

Important Note: Approval by the IRB does not, in and of itself, constitute approval for the implementation of this research. Other LA BioMed clearance and approvals or other external agency or collaborating institutional approvals may be required before study activities and initiated. Research undertaken in conjunction with outside entities, such as drug or device companies, are typically contractual in nature and require an agreement between the institute and the entity.

If continuing review approval is not granted before the expiration date of 09/24/2014 approval of this research expires on that date.

Please see iRIS for the stamped approved consent documents. Use copies of these documents to document consent.

In conducting this research you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

Signature applied by Gina Fierro on 10/16/2013 04:10:05 PM PDT

Gina Fierro
Compliance Office

cc: Alicia Danforth
Office of Research Administration