University of Maryland, Baltimore Institutional Review Board (IRB) Phone: (410) 706-5037

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New Study Approval Notification

Date: September 29, 2009

To: Teodor Postolache

From: IRB Chair/Vice Chair: Ann Zimrin

RE: HP-00043574

Risk designation: Greater Than Minimal Risk

Submission Date: 8/27/2009

Original Version #: N/A

**Approval for this project is valid from 9/17/2009 to 9/16/2010**

This is to certify that the University of Maryland, Baltimore (UMB) Institutional Review Board (IRB) met on

9/17/2009 and has fully approved the above referenced protocol entitled, “*Light treatment for Winter SAD:*

*metabolic effects and prediction of antidepressant response by immediate improvement*”

Please be aware that only valid IRB-approved informed consent forms may be used when written informed consent is required.

Investigators are reminded that the IRB must be notified of any changes in the study. In addition, the PI is responsible for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103(4)(iii)).

DHHS regulations at 45 CFR 46.109 (e) require that **continuing review** of research be conducted by the IRB at intervals appropriate to the degree of risk and **not less than once per year**. The regulations make **no provision for any grace period extending the conduct of the research beyond the expiration date of IRB approval.** You will receive continuing review email reminder notices prior to study expiration; however, it is your responsibility to submit your continuing review report in a timely manner to allow adequate time for substantive and meaningful IRB review and assure that this study is not conducted beyond the expiration date. Investigators should submit

continuing review reports in the electronic system at least six weeks prior to the IRB expiration date.

In addition, you must inform the IRB of any new and significant information that may impact a research participants' safety or willingness to continue in your study and any unanticipated problems involving risks to participants or others.

Research activity involving veterans or the Baltimore VA Maryland Healthcare System (BVAMHCS) as a site, must also be approved by the BVAMHCS Research and Development Committee prior to initiation. Contact the VA Research Office at 410-605-7131 for assistance.

The UMB IRB is organized and operated according to guidelines of the International Council on Harmonization, the United States Office for Human Research Protections and the United States Code of Federal Regulations and operates under Federal Wide Assurance No. FWA00007145.

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