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APPROVAL NOTICE

DATE:	11/13/2015
TO:	HELEN LAVRETSKY PSYCHIATRY/BIOBEHAVIORAL SCI
FROM:	JAMES MC GOUGH, MD Chair, MIRB3
RE:	IRB#12-001714-CR-00003 2015 Review for IRB#12-001714 Brain aging and treatment response in geriatric depression

The UCLA Institutional Review Board (UCLA IRB) has approved the above-referenced study. UCLA's Federalwide Assurance (FWA) with Department of Health and Human Services is FWA00004642.

Submission and Review Information

Type of Submission	Continuing Review
Type of Review	Full Board Review
Approval Date	11/12/2015
Expiration Date of the Study	11/11/2016
Funding Source(s)	1) NIH - MISCELLANEOUS AGENCIES AND DEPARTMENTS *Grant PI*: HELEN LAVRETSKY *Grant Title*: Brain aging and treatment response in geriatric depression *Grant Number*: R-01 MH097892 2) NAT'L ALLIANCE FOR RESEARCH ON SCHIZOPHRENIA AND DEPRESSION *Grant PI*: HONGYU YANG *Grant Title*: Magnetic Resonance Spectroscopy evaluating Memantine Augmentation of Escitalopram in Late Life Depression *Grant Number*: 22325

Specific Conditions for Approval

-- **Research Participants Bill of Rights** - By California law, a copy of the Research Participants Bill of Rights in a language in which the participant is fluent must be given to all research participants in this study as there is a real or foreseeable risk of biomedical harm. Numerous translations are available for download on the HRPP website at http://www.ohrpp.research.ucla.edu/pages/bill-of-rights.

Regulatory Determinations

-- **Waiver of Signed Informed Consent** - The UCLA IRB waived the requirement for signed informed consent for telephone screening under 45 CFR 46.117(c)(2) / 21 CFR 56.109(c)(1).

Documents Reviewed included, but were not limited to:

Document Name	Document Version #
12-001714_Namenda Aging Brain Telephone Screen 9-2-2014 clean.pdf.pdf	0.03
12-001714_Namenda Consent 11-21-2014.pdf.pdf	0.03
12-001714_Namenda Aging Brain Flyer 4-22-2013.pdf.pdf	0.04
12-001714_Namenda Aging Brain Ads 4-22-2013.pdf.pdf	0.04

Important Note: Approval by the Institutional Review Board does not, in and of itself, constitute approval for the implementation of this research. Other UCLA clearances and approvals or other external agency or collaborating institutional approvals may be required before study activities are 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 University and the entity.

General Conditions of Approval
As indicated in the PI Assurances as part of the IRB requirements for approval, the PI has ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the IRB.

The PI and study team will comply with all UCLA policies and procedures, as well as with all applicable Federal, State, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

- Ensuring that the personnel performing the project are qualified, appropriately trained, and will adhere to the provisions of the approved protocol,
- Implementing no changes in the approved protocol or consent process or documents without prior IRB approval (except in an emergency, if necessary to safeguard the well-being of human subjects and then notifying the IRB as soon as possible afterwards),
- Obtaining the legally effective informed consent from human subjects of their legally responsible representative, and using only the currently approved consent process and stamped consent documents, as appropriate, with human subjects,
- Reporting serious or unexpected adverse events as well as protocol violations or other incidents related to the protocol to the IRB according to the OHRPP reporting requirements.
- Assuring that adequate resources to protect research participants (i.e., personnel, funding, time, equipment and space) are in place before implementing the research project, and that the research will stop if adequate resources become unavailable.
- Arranging for a co-investigator to assume direct responsibility of the study if the PI will be unavailable to

direct this research personally, for example, when on sabbatical leave or vacation or other absences. Either this person is named as co-investigator in this application, or advising IRB via webIRB in advance of such arrangements.