PARTNERS

McLean Hospital Corporation

MEMORANDUM

To: Collaborators and Sponsors

From: Rosalyn A. Gray, Director
Human Research Review and Compliance

Date: January 28, 2014

Re: McLean Hospital Institutional Review Board (IRB)

The McLean Hospital IRB operates in compliance with all applicable regulations and guidelines pertaining to IRBs as listed below, and with the Federalwide Assurance (FWA) and incorporated "Terms of the Federalwide Assurance for institutions within the United States" held by the McLean Hospital Corporation.

- Department of Health and Human Services (DHHS) 45 CFR Parts 46 and 164
- Food and Drug Administration (FDA) 21 CFR Parts 50 and 56
- International Conference on Harmonization (ICH) guideline E6 relating to Good Clinical Practice (GCP), section 3(3.1-3.4) unless ICH guidelines conflict with FDA Regulations

Federal Wide Assurance

The McLean Hospital FWA00002744 is approved and on file with the Office for Human Research Protections (OHRP). The current expiration date for the McLean Hospital FWA is available from the OHRP IRBs and Assurances webpage **http://ohrp.cit.nih.gov/search/.**

IRB Registration

The McLean Hospital IRB00001123 is registered with the Department of Health and Human Services (DHHS), as required by OHRP and FDA, and is designated in the McLean FWA. The current expiration date for the McLean Hospital IRB registration is available from the OHRP IRBs and Assurances webpage **http://ohrp.cit.nih.gov/search/**.

Membership

The McLean Hospital IRB meets the IRB membership requirements in DHHS Code of Federal Regulations 45 CFR 46.107 and 21 CFR 56.107. As a matter of policy, McLean Hospital does not provide the IRB membership roster to collaborators or sponsors.