



Human Research Committee

Partners HealthCare System, Inc.
399 Revolution Drive, Suite 710
Somerville, MA 02145

Memorandum

TO: Collaborators and Sponsors

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

Date: January 1, 2017

Re: The McLean Hospital Corporation (McLean) Human Subjects Research Statement of Compliance

McLean operates in compliance with all applicable regulations and guidelines pertaining to human subjects research as listed below, and with the Federalwide Assurance (FWA) and Incorporated "Terms of the Federalwide Assurance for institutions within the United States" held by McLean.

- 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) guidance relating to Good Clinical Practice (GCP), section 3(3.1-3.4) unless ICH guidelines conflict with FDA Regulations.

Federalwide Assurance (FWA)

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

IRB Registration

McLean relies primarily on the Partners HealthCare System, Inc. (PHS IORG0009015) IRBs for review and continuing oversight of human-subjects research. The PHS IRBs are registered with the Department of Health and Human Services (DHHS) as required by OHRP and FDA, and are designated in the McLean FWA. The current expiration dates for the PHS IRBs' registrations are available from the OHRP IRBs and Assurance webpage <http://ohrp.cit.nih.gov/search/>.

PHS IRBs: #IRB00010756; #IRB00010757; #IRB00010758; #IRB00010759; #IRB00010760; #IRB00010761; IRB00010762

McLean may also rely on other external IRBs registered with OHRP/FDA under reliance agreements executed between McLean and the reviewing IRB's organization.

PHS IRB Membership

The PHS IRBs meet the IRB membership requirements in DHHS and FDA Code of Federal Regulations 45 CFR 46.107 and 21 CFR 56.107. As a matter of policy, PHS does not provide the IRB membership rosters to collaborators or sponsors. Any IRB Chair or member who has a conflict of interest with regard to a protocol under review will not participate in the deliberation or vote on that protocol except to provide information requested by the IRB.

PHS Approval Letters

The PHS IRBs do not require the IRB Chairs or any other member of the IRB to sign approval letters. There is no regulatory requirement for such signatures. The documents reviewed and approved by the IRB are included in the approved submission available in Insight.

AAHRPP Accreditation

McLean Hospital as part of the Partners HealthCare human research protection program has been fully accredited by the Association for Accreditation of Human Research Protection Programs (AAHRPP), and was most recently reaccredited for 5 years effective June 21, 2016.