Memorandum

TO: Collaborators and Sponsors

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

Date: January 1, 2017

RE: Massachusetts General Hospital (MGH) Human Subjects Research Statement of Compliance

The MGH 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 the Massachusetts General Hospital.

- 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 MGH FWA00003136 is approved and on file with the Office for Human Research Protections (OHRP). The current expiration date for the Massachusetts General Hospital FWA is available from the OHRP IRBs and Assurance webpage http://ohrp.cit.nih.gov/search/.

PHS IRB Registration
The MGH 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 MGH 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 IRB 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
MGH 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) since December 2004, and was most recently reaccredited for 5 years effective June 21, 2016.