Human Research Committee
Brigham and Women's Hospital
Massachusetts General Hospital
116 Huntington Avenue, Suite 1002
Boston, MA 02116

Memorandum

TO: Collaborators and Sponsors

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

Date: July 2, 2014

RE: Massachusetts General Hospital (MGH) IRB Statement of Compliance

The MGH 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 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.

IRB Organization (IORG) and Federalwide Assurance (FWA)
The MGH IORG is IORG0000257. 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/.

IRB Registration
The MGH and BWH IRBs relied upon by the MGH for review and continuing oversight of human-subjects research 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 MGH and BWH IRBs' registrations are available from the OHRP IRBs and Assurance webpage http://ohrp.cit.nih.gov/search/.

- MGH IRBs: #IRB00000433; #IRB00000931; #IRB00002610
- BWH IRBs: #IRB00000064; #IRB00000065; #IRB00003985; #IRB00006354

Membership
The MGH and BWH 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, MGH 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.

Accreditation
The MGH human research protection program is fully accredited by the Association for Accreditation of Human Research Protection Programs (AAHRPP) as part of Partners HealthCare.

Approval Letters
The MGH IRB does 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.