



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: Brigham and Women's Hospital (BWH) IRB Statement of Compliance

The BWH 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 Brigham and Women's 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 BWH IORG is IORG0000046. The BWH FWA00000484 is approved and on file with the Office for Human Research Protections (OHRP). The current expiration date for the Brigham and Women's Hospital FWA is available from the OHRP IRBs and Assurance webpage <http://ohrp.cit.nih.gov/search/>.

IRB Registration

The BWH and MGH IRBs relied upon by the BWH 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 BWH FWA. The current expiration dates for the BWH and MGH IRBs' registrations are available from the OHRP IRBs and Assurance webpage <http://ohrp.cit.nih.gov/search/>.

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

Membership

The BWH and MGH 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, BWH 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 BWH 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 BWH 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.