



FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL
AND MASSACHUSETTS GENERAL HOSPITAL

Partners Human Research Committee

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

MEMORANDUM

To:

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

Date:

Re:

The Massachusetts General Hospital (MGH) IRBs operate in compliance with all applicable regulations and guidelines pertaining to IRBs as listed below, and with the Federal Wide Assurance (FWA) and incorporated "Terms of the Federalwide Assurance for Institutions within the United States" held by MGH.

- 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 MGH FWA (FWA00003136) is approved and on file with the Office for Human Research Protections (OHRP). The current expiration date for the MGH FWA is available from the [OHRP Assurances webpage](#).

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 Assurances webpage](#).

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

Membership

The MGH and BWH IRBs meet the IRB membership requirements in DHHS Code of Federal Regulations 45 CFR 46.107 and 21 CFR 56.107.