



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 Brigham and Women's Hospital (BWH) 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 BWH.

- 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 BWH FWA (FWA00000484) is approved and on file with the Office for Human Research Protections (OHRP). The current expiration date for the BWH FWA is available from the [OHRP Assurances webpage](#).

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 Assurances webpage](#).

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

Membership

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