

Memorandum

TO: Collaborators and Sponsors

From: Martha Jones, Vice President, Human Research Affairs

Date: July 9, 2024

RE: Mass General Brigham and its Affiliates Human Subjects Research Statement of Compliance

Mass General Brigham Incorporated (formerly Partners HealthCare System, Inc.) and its Affiliates listed below (together, the “Mass General Brigham Institutions”) operate 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 each of the Mass General Brigham Institutions:

- 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 FWAs listed below for each of the Mass General Brigham Institutions are approved and on file with the Office for Human Research Protections (OHRP). The current expiration dates for the FWAs are available from the OHRP IRBs and Assurance webpage <http://ohrp.cit.nih.gov/search/>.

Mass General Brigham IRB Registration

The Mass General Brigham Institutions rely primarily on the Mass General Brigham Incorporated (IORG0009015) IRBs (Mass General Brigham IRBs) for review and continuing oversight of human-subjects research. The Mass General Brigham IRBs are registered with the Department of Health and Human Services (DHHS) as required by OHRP and FDA and are designated in the FWAs of each Mass General Brigham Institution FWA. The current expiration dates for the Mass General Brigham IRBs’ registrations are available from the OHRP IRBs and Assurance webpage <http://ohrp.cit.nih.gov/search/>.

Mass General Brigham IRBs: IRB00012706 and IRB00012707

The Mass General Brigham Institutions may also rely on other external IRBs registered with OHRP/FDA under reliance agreements executed between the Mass General Brigham Institution and the reviewing IRB’s organization.

The Mass General Brigham IRBs meet the IRB membership requirements in DHHS and FDA Code of Federal Regulations 45 CFR 46.107 and 21 CFR 56.107 respectively. As a matter of policy, Mass General Brigham 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.

The Mass General Brigham 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

The Mass General Brigham Human Research Protection Program is currently accredited by the Association for Accreditation of Human Research Protection Programs (AAHRPP) and has been since December 2004.

Mass General Brigham Institutions:

The Brigham and Women's Hospital, Inc – FWA #484
Brigham and Women's Faulkner Hospital, Inc. – FWA #116
Cooley Dickinson Healthcare, Corporation – FWA #4296
General Hospital Corp d/b/a Massachusetts General Hospital – FWA #3136
Mass General Brigham Incorporated – FWA #24920
Mass General Brigham Home Care – FWA #31990
Massachusetts Eye and Ear Infirmary (MEEI) – FWA #6221
McLean Hospital Corporation – FWA #2744
MGH Institute of Health Professionals, Inc – FWA #5728
Nantucket Cottage Hospital – FWA #22891
Newton-Wellesley Hospital – FWA #799
North Shore Medical Center, Inc – FWA #7262
Rehabilitation Hospital of the Cape and Islands Corporation – FWA #25058
Schepens Eye Research Institute, Inc – FWA #8093
Spaulding Hospital- Cambridge, Inc d/b/a Spaulding Hospital for Continuing Medical Care Cambridge – FWA #25044
Spaulding Nursing & Therapy Center Brighton, Inc – FWA #32562
Spaulding Rehabilitation Hospital Corporation – FWA #465
Wentworth-Douglass Hospital – FWA #1324