

Memorandum

TO: Collaborators and Sponsors

From: Martha Jones, Vice President, Human Research Affairs

Date: April 5, 2021

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:

MASS GENERAL BRIGHAM INCORPORATED - FWA #24920

BRIGHAM AND WOMEN'S FAULKNER HOSPITAL, INC. - FWA #116

THE BRIGHAM AND WOMEN'S HOSPITAL, INC. - FWA #484

THE GENERAL HOSPITAL CORPORATION d/b/a MASSACHUSETTS GENERAL HOSPITAL - FWA #3136

THE MCLEAN HOSPITAL CORPORATION - FWA #2744

MASSACHUSETTS EYE AND EAR INFIRMARY - FWA # 6221

THE MGH INSTITUTE OF HEALTH PROFESSIONS, INC. - FWA #5728

NANTUCKET COTTAGE HOSPITAL - FWA #22891

NEWTON-WELLESLEY HOSPITAL - FWA #799

NORTH SHORE MEDICAL CENTER, INC. - FWA #7262

THE SCHEPENS EYE RESEARCH INSTITUTE, INC. - FWA # 8093

THE SPAULDING REHABILITATION HOSPITAL CORPORATION - FWA #465

SPAULDING HOSPITAL-CAMBRIDGE, INC. d/b/a SPAULDING HOSPITAL FOR CONTINUING MEDICAL CARE CAMBRIDGE - FWA #25044

REHABILITATION HOSPITAL OF THE CAPE AND ISLANDS CORPORATION - FWA #25058