

**Research Compliance Standard Operating Procedure (SOP):
Coordination of External Audits and Other External Investigations of Research Projects
January 2022**

Overview

To assist hospitals in meeting external audit responsibilities for research, the Mass General Brigham Chief Research Compliance Officer is responsible for tracking and reporting external audits and working with the hospital and Mass General Brigham individuals listed below to facilitate research audits in accordance with the Mass General Brigham *Policy on Coordination of External Audits and Other External Investigations of Research Projects*.

- Hospital SVP for Research (or equivalent position), CFO, Research Administration Director, and Research Compliance or Corporate Compliance Officer; and
- Mass General Brigham Chief Academic Officer, Executive Vice President for Administration and Finance, Vice President for Human Research Affairs, Vice President for Research Management, and Research Controller.

The audit coordination policy identifies “Designated Officials” for the major research audit areas who serve as the liaison to the external auditor(s), in addition to assuming responsibility for:

- Informing and consulting Mass General Brigham and hospital senior leadership on the conduct of the audit;
- Gathering materials;
- Scheduling interviews; and
- Coordinating the management response and any necessary follow-up.

Although every audit is unique, the audit process is similar for most engagements and typically consists of the phases described in this SOP.

Roles and Responsibilities

Designated Official

- (1) Informs appropriate hospital and Mass General Brigham senior management; hospital and Mass General Brigham Research Compliance (or hospital Corporate Compliance Office if there is no Research Compliance Office); and, if necessary, the Office of General Counsel of the audit or review request; and communicates with them throughout the audit;
- (2) Notifies leadership of the affected operational team to ensure that the proper individuals are available to assist the auditors and, if necessary, appoint a functional liaison or point of contact within the department;
- (3) Gathers relevant records, determines their applicability to the audit or review, or provides guidance to the Principal Investigator, Department Administrator and/or other departmental or hospital staff in identifying the relevant records;
- (4) Schedules interviews; and
- (5) Coordinates the management response to the audit or review.

DESIGNATED OFFICIALS:

Animal Research:

BWH: BWH Director of Animal Welfare Assurance

MGH: MGH Director of Animal Welfare Assurance

McL: Sr. Director for Research Operations
MEE/Seri: MEE VP for Research Operations
SRH: MGH Director of Animal Welfare Assurance
IHP: MGH Director of Animal Welfare Assurance

Biosafety and Related Environmental Health Issues:

For audits related to the *NIH Guidelines* on Recombinant DNA and/or audits by the NIH Office for Biotechnology Activities at all Mass General Brigham facilities: MGB Director of Biosafety

For all other research/laboratory safety-related issues (e.g., OSHA, MWRA, etc.):

BWH: Director of Environmental Affairs/Environmental Health & Safety
MGH: Director of Environmental Affairs/Environmental Health & Safety
McL: Sr. Director of Facilities
SRH: Chief Compliance Officer
MEE: Research Safety Manager
IHP: Associate Provost for Research
MGB: Director of Biosafety

Radiation Safety:

BWH: Radiation Safety Officer
MGH: Assistant Director for Radiation Safety
MEE: Research Safety Manager
McL: Chief Compliance Officer
SRH: Chief Compliance Officer
IHP: Associate Provost for Research

Clinical Trials Billing:

BWH: Manager of Clinical Trials Billing Compliance
MGH: Director of Research Compliance
McL: Research Compliance Specialist
SRH: Director of Finance
MEE/Seri: VP, MGB Compliance, Audit & Business Integrity
NWH: Manager, Office of Research
Salem: Compliance Officer

Conflict of Interest:

BWFH, MGH, McL, SRN, IHP, NWH and Salem: MGB Director of the Office for Interactions with Industry

Food and Drug Administration (FDA) Audits/Reviews:

BWH: Principal Investigator
MGH: Principal Investigator
McL: Principal Investigator
SRH: Principal Investigator
MEE/Seri: Principal Investigator
NWH: Principal Investigator
Salem: Principal Investigator

Financial Audits (including UG Annual Audit):

BWH, MGH, McL, MEE, SRH, IHP, NWH and Salem: MGB Research Controller

Human Subjects Research:

BWH, MGH, McL, MEE, SRH, NWH, and Salem: MGB Director of IRB Operations

HHS Office of Research Integrity:

BWH: Research Integrity Officer

MGH: Research Integrity Officer

McL: Research Integrity Officer

MEE/Seri: Research Integrity Officer

IHP: Research Integrity Officer

SRH: Research Integrity Officer

NWH: Research Integrity Officer

Salem: Research Integrity Officer

MGB: Chief Research Compliance Officer

All Other Audits, Reviews, or Inspections (e.g., programmatic audits):

BWH: VP for Research Operations

MGH: Director of Research Compliance

McL: Corporate Compliance Officer

SRH: Chief Compliance Officer

IHP: Associate Provost for Research

MEE/Seri: VP for Research Operations

NWH: Director of Research

Salem: Compliance Officer

MGB: Chief Research Compliance Officer

MGB Chief Research Compliance Officer

- (1) Tracks and maintains statistics on all non-FDA and non-human subjects audits, reviews and investigations for each hospital and system-wide for periodic reporting to the Mass General Brigham Research Compliance Committee, Mass General Brigham Board of Directors Audit and Compliance Committee, and other hospital or Mass General Brigham senior management groups;
- (2) Provides subject matter expertise to the hospitals in responding to non-FDA and non-human subjects audits;
- (3) Provides oversight of the process to ensure hospital senior leadership (Sr. VP for Research, CFO), Compliance, OGC, etc. are involved appropriately; and
- (4) Works with hospital Research Compliance or Corporate Compliance staff following an audit to monitor compliance with corrective action plans and application of lessons learned across the Mass General Brigham system.

MGB Research Controller

- (1) Coordinates annual Uniform Guidance (UG) audit for all Mass General Brigham hospitals and affiliated institutes serving as liaison to external auditors and hospital and Mass General Brigham senior leadership;
- (2) Works closely with hospital CFO, SVP for Research, and Mass General Brigham Vice President for Research Management on sponsor, non-UG financial audits serving as the Designated Official or sharing this responsibility with hospital financial staff;

- (3) Communicates with hospital and Mass General Brigham senior leadership as necessary throughout the audit;
- (4) Provides subject matter expertise to the hospitals; and
- (5) Other audit follow-up duties as required.

MGB Vice President for Research Management

- (1) Works closely with Mass General Brigham Research Controller on responding to the UG audit;
- (2) Makes staff available to provide reasonable assistance to the audit team on financial and non-financial audits (with the exception of FDA and for-cause human subjects research audits);
- (3) Provides subject matter expertise to hospitals and Mass General Brigham senior leadership in responding to non-FDA audits; and
- (4) Other audit follow-up duties as required.

Hospital Research Compliance/Corporate Compliance Officer/Director

- (1) Provides training to research community and designated officials on audit policy and SOP;
- (2) Notifies Chief Research Compliance Officer of audit requests for tracking and reporting via email to PHSRC@partners.org;
- (3) Keeps senior management (SVP for Research, CFO, etc.) apprised of progress;
- (4) Provides subject matter expertise for non-FDA and non-human subjects audits;
- (5) Monitors corrective action plans; and
- (6) Once the audit has been settled, works with appropriate hospital or Mass General Brigham department to ensure documentation is maintained in departmental or grant and contract file.

Hospital Sr. Vice President for Research (or equivalent position) and Chief Financial Officer

- (1) Determines whether findings of non-compliance have merit;
- (2) If meritorious, directs remediation, implementation of corrective action plan, reporting to sponsor, and all other steps necessary to close the matter;
- (3) If findings are deemed to be without merit, works with the Office of the General Counsel and Mass General Brigham and hospital Research Compliance/Compliance Offices to take steps necessary to appeal the disallowances or otherwise defend the hospital's interest.

Audit Process - with the exception of FDA and for-cause Human Research Audits

(1) Pre-Audit Notification

- a. Notices received by managers or anyone other than the Designated Official (DO) should be forwarded to the DO immediately upon receipt.
- b. The DO is responsible for reporting the audit notification in accordance with the DO Communication Grid at the end of this document.
- c. Mass General Brigham Chief Research Compliance Officer informs the Mass General Brigham Chief Financial Officer and Treasurer and the Mass General Brigham Chief Academic Officer as necessary.

(2) Entrance Conference

The DO is responsible for coordinating an entrance conference with the appropriate Mass General Brigham or hospital personnel and the external auditors to establish the purpose, scope and time of the audit or review; determine the information required by the external auditor; and arrange facilities and equipment necessary to facilitate the audit. This may be done via phone or email prior to audit or in person. Minutes or other documentation of agreements reached should be prepared and made available to the external auditor and appropriate Mass General Brigham/hospital

personnel.

(3) Fieldwork

Auditor interviews staff, reviews procedure manuals and business processes, tests compliance and assesses adequacy of internal controls. DO responds to requests, questions, etc., consulting hospital or Mass General Brigham senior management, Research Compliance, and OGC as necessary. Provides periodic updates.

(4) Draft Report

After all fieldwork is completed, the auditor may prepare a draft report that documents objectives, procedures, conclusions, and recommendations.

(5) Responses to Audit Reports

Based on direction from senior management, the DO is responsible for coordinating and drafting a response.

(6) Audit Recommendation Follow-up

Every effort should be made to implement recommendations within six months of the issue date of the report.

FDA Audits and For-cause Human Research Audits

Notification of FDA or inspection audits should be reported promptly to the Mass General Brigham Director of the HRA Compliance and Education Office, and notification of a human subjects audit should be promptly reported to the IRB Director of Operations for their respective audits. These individuals will provide the study's Principal Investigator, as the Designated Official for the audit/inspection, with guidance on how to respond. They are also responsible for tracking the audits and reporting on a periodic basis to the Mass General Brigham Chief Research Compliance Officer for subsequent reporting to the Mass General Brigham Research Compliance Committee and Mass General Brigham Board of Directors Audit and Compliance Committee in addition to internal reporting to Institutional Officials and relevant compliance groups.

Designated Official Communication Grid (Non-FDA & HS Research Audits)

Audit Area	Hospital SVP for Research	Hospital CFO	Hospital Research Compliance	MGB Research Compliance phsrc@partners.org	MGB VP, Research Management	Other
Animal Research	✓		✓	✓		
Biosafety/Environmental Health & Safety (EHS)	✓		✓	✓		
Clinical Trials Billing	✓		✓	✓		BWH & MGH CTO Director
Conflicts of Interest	✓		✓	✓	✓	
Financial Audits	✓		✓	✓	✓	
Research Integrity			✓	✓		
All Other	✓			✓	✓	Chief and/or head of hospital department