Mass General Brigham

Title:	Institutional Review Board Policy and Governance
Department:	Human Research Affairs
Policy Type:	Mass General Brigham System-wide
Applies to:	Employees, Professional Staff or Other Agents of Mass General Brigham
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Contact Person:	Director, Human Research Office

I. NAME, PURPOSE, AND RESPONSIBILITIES

The Institutional Review Boards of Mass General Brigham Incorporated are known collectively as the Mass General Brigham Institutional Review Boards (IRB). The IRB provides oversight for Mass General Brigham entities identified in Appendix I as well as entities that enter into reliance agreements documenting the Mass General Brigham as the entity's IRB of record for specified research.

The IRB provides review and continuing oversight of human subjects research to protect the rights and welfare of the research participants. The IRB is committed to following the letter and spirit of the human subject protection regulations, guidance, Mass General Brigham policies and accreditation standards to ensure the integrity of the IRB decision-making process.

The IRB operates in full compliance with all applicable federal, state, and local laws and regulations, and with the Federalwide Assurances (FWAs) and incorporated "Terms of the Federalwide Assurance for Institutions within the United States" held by the Mass General Brigham Institutions. This assurance applies to all non-exempt research involving human subjects funded by federal agencies subscribing to the Common Rule. The responsibility for the protection of the rights and welfare of human subjects is shared by both the institutions and the investigators conducting the research.

II. ETHICAL PRINCIPLES

The IRB is guided by the *Ethical Principles and Guidelines for the Protection of Human Subjects of* Research, generally known as the "Belmont Report."

III. AUTHORITY AND INDEPENDENCE

1.0 Authority

The IRB is authorized to review and oversee human subject research that is conducted by employees or agents of Mass General Brigham in connection with their institutional responsibilities, regardless of the location of the research or source of funding, in accordance with federal, state, and local laws and regulations.

Except for research exempted under 45 CFR 46.104 and 21 CFR 56.104 or waived in accordance with 45 CFR 46.101(i) or 21 CFR 56.105, all human research will be reviewed, approved, and subject to continuing oversight and review as required in 45 CFR 46.109 and 21 CFR 56.109. The IRB has the authority to:

1. approve, require modifications, or disapprove all research activities that fall within its jurisdiction;
2. suspend, place restrictions, or terminate approval of research activities that fall within its jurisdiction that are not being conducted in accordance with IRB requirements or that have been associated with unanticipated problems;
3. observe or have a third party observe the consent process and/or the conduct of the research if the IRB determines it to be indicated.
4. place restrictions on a research activity;
5. request a directed audit by the Mass General Brigham Human Research Affairs Compliance & Education Office;
6. otherwise investigate, address, remedy and, when required or appropriate, report on incidences of noncompliance with legal, regulatory, or IRB requirements or determinations;
7. conduct reviews and inquiries regarding human subject research as needed to obtain information necessary for the fulfillment of human research protection responsibilities and, for federally funded research, the institutional responsibilities outlined in the institutions' Office for Human Research Protections (OHRP)-approved Federalwide Assurance (FWAs); and
8. act as the HIPAA Privacy Board for research activities.

These fundamental authorities of the IRB are recognized by the Institutional Officials (IOs) for Mass General Brigham.

The IRB also has the authority within the institutions for determining:

- whether a research activity involves human subjects within the meaning of the DHHS, FDA, or other applicable federal regulations

- whether the institution(s) is engaged in human subject research within the meaning of DHHS regulations; and
- whether a research activity involving human subjects is exempt from 45 CFR 46 and 21 CFR 56.

Investigators or others within the organization may not independently make exemption determinations.

When any research overseen by the IRB takes place in a foreign country, the procedures prescribed by the international organization, if any, will afford protections that are at least equivalent to those provided by the IRB and the research design will consider the local research context where research procedures will occur.

In exercising their authority, the IRB communicates its decisions regarding human subject research to investigators and to the organization through the Mass General Brigham Human Research Office (HRO).

2.0 Independence

The IRB acts as an independent authority in the review and oversight of human subject research for Mass General Brigham. Consistent with federal regulations at 45 CFR 46.112 and 21 CFR 56.112, no one within Mass General Brigham may approve human subject research that has not been approved by the IRB or one of its designated external IRBs operating under a reliance agreement. However, research approved by the IRB may be subject to further institutional review and approval. Investigators may appeal the decision of the IRB in writing as described in section X: Review of Research.

3.0 Undue Influence

In the event of undue influence (e.g., someone outside of the IRB seeks to influence the outcome of IRB review of a research activity), the Vice President, Human Research Affairs (VP HRA) will work with institutional leadership and the IRB as necessary, to remedy any concern. The VP HRA will preserve the IRB's review independence in all such instances. Measures may include, for example, discussion between the VP HRA and the person causing the undue influence and, when appropriate, discussion with the appropriate department or division chair or supervisor; reassignment of the protocol to another IRB review; and/or recusal of the IRB member upon whom undue influence was exerted.

IV. SCOPE OF RESPONSIBILITY

The IRB is responsible for the review and oversight of all human subject research and clinical investigations that are conducted by employees or agents of Mass General Brigham in connection with their institutional responsibilities, regardless of the location of the research or source of

funding, except research reviewed by another institution or entity on behalf of Mass General Brigham through a written reliance agreement executed by the relying and reviewing institution or entity. Mass General Brigham routinely relies on the following entities for specified research:

- The Dana Farber/Harvard Cancer Center IRB for oncology research reportable under the NCI Comprehensive Cancer Center grant except for Phase I research conducted at the Mass General Hospital Cancer Center with an industry protocol and industry sponsored.
- The Harvard School of Public Health IRB for research involving prisoners.

V. SPECIFIC FUNCTIONS OF THE IRB

The IRB follows written policies and procedures for:

1. Determining whether a research activity submitted for IRB review is human subject research or a clinical investigation within the meaning of DHHS, FDA or other applicable federal regulations;
2. Determining exemptions from 45 CFR 46 and 21 CFR 56;
3. Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and to the institution;
4. Determining which projects require review more often than annually;
5. Determining which projects need verification from sources other than the investigators that no material changes have occurred since the last review;
6. Ensuring prompt reporting of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject;
7. Ensuring prompt reporting to the IRB, appropriate institutional officials and, when required or appropriate, to the department or agency head (regulatory agencies) of any unanticipated problems involving risks to subjects or others;
8. Ensuring prompt reporting to the IRB, appropriate institutional officials and, when required or appropriate, to the department or agency head (regulatory agencies) of any serious or continuing noncompliance with federal regulations or the requirements or determinations of the IRB;
9. Ensuring prompt reporting to the IRB, appropriate institutional officials and, when required or appropriate, to the department or agency head (regulatory agencies) of any suspension or termination of IRB approval; and
10. Except when an expedited review procedure is used, reviewing proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present and eligible to vote when the research activity is reviewed at a convened meeting.

VI. MEMBERSHIP

The IRB is composed of at least five (5) members with varying backgrounds to promote complete and adequate review of human subject research commonly conducted at the institutions. The membership includes individuals with the necessary experience and scientific or scholarly expertise

and knowledge of the local research context to review the scope of biomedical and behavioral research conducted at Mass General Brigham. The membership does not include individuals who have responsibilities for negotiating grants or contracts with sponsors, or for business development of the research enterprise through research ventures and licensing.

Members include both men and women and members of minority groups. Each member has one vote and may have one or more designated alternates with similar scientific or scholarly expertise. Should both the primary voting member and alternate voting member attend the same meeting and be present for review of the same research activity, only one member may vote on the specific research activity under review. The other is recorded in the minutes as attending, but not voting on the research activity.

The membership of each IRB panel includes:

- physicians;
- scientists;
- at least one member who is unaffiliated with Mass General Brigham or component of Harvard University (HU) and who is not part of the immediate family of a person who is affiliated with Mass General Brigham or HU component; and
- at least one member whose primary concerns are in nonscientific areas, such as community members, ethicists, and clergy
- at least one member who represents the perspective of research participants.

1. Diversity, Equity, and Inclusion

The IRB is committed to supporting diversity, equity and inclusion across its membership and includes individuals who represent the perspective of the community from which individuals are recruited to participate in research. No qualified individual will be rejected from the membership on the basis of race, gender, creed, religion, color, national origin, age, disability, or sexual orientation.

2. Appointment and Responsibilities

The VP HRA appoints members to the IRB. Appointment is based on the IRB membership needs with regard to representative capacity and scientific expertise and recommendation from the IRB Executive Committee. The HRO prepares and distributes letters of appointment to the individual and when applicable, copies the relevant Department Chair, Chief or supervisor. If an individual's application for membership is not accepted, the VP HRA will provide notice in writing and include the basis for the decision.

Members are appointed for two-year renewable terms. The VP HRA has authority to make an exception to the appointment term for an individual member.

All members are expected to fulfill the responsibilities described in *IRB Member Responsibilities*.

3. Designations

Members are designated by the VP HRA at time of appointment as:

1. Physician Scientists, Other Scientists, or Nonscientists
    a. Physician Scientists are members who have a medical degree
    b. Other Scientists are members whose training, background and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline or who have training or experience in scientific methods (e.g. PhD, MS, BSN, MSN)
    c. Nonscientists are members whose training, background and occupation would not incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline or does not have training or experience in scientific methods.

2. Affiliated or Unaffiliated
    a. Affiliated members include members or whose immediate family members have an affiliated role with Mass General Brigham or any component of HU. *"Immediate family member"* is defined as spouse, domestic partner, child, parent, or sibling. *"Affiliated"* includes, but is not limited to, employees including part-time employees; current students; members of any governing panel or board of the institution; paid or unpaid consultants; healthcare providers holding credentials to practice at the institution; and volunteers working at the institution on business unrelated to the IRB.
    b. Unaffiliated members are those members who do not meet the definition of an Affiliated member.

3. Primary Member or Alternate Member
    a. Primary Members have responsibility to vote, abstain from voting, or recuse themselves from voting as applicable on each research activity considered by the IRB when they are present for the discussion and vote unless the primary member's alternate is present and is voting on the research activity.
    b. Alternate members have responsibility to vote, abstain from voting, or recuse themselves from voting as applicable on each research activity considered by the IRB panel when they are present for the discussion and vote and the primary member for whom they are a designated alternate member is not present or is not voting.

4. Recruitment and Selection of New Members

Affiliated members are recruited through the Chairs/Chiefs/Heads of the hospital departments, divisions or units, through direct outreach, or through current IRB members. Unaffiliated members may be recruited through current IRB members, direct outreach, or various community agencies or groups. Additionally, individuals who are affiliated or Unaffiliated may self-refer.

New members are recruited on an ongoing basis as needed to ensure that the membership of the IRB continues to include individuals with varying backgrounds and the necessary experience and scientific or scholarly expertise to review the scope of biomedical and behavioral research conducted at Mass General Brigham and to represent the community from which subjects are recruited. In addition, new members are recruited on an as needed basis to replace members who resign, whose term is ending, and, when needed, to provide additional scientific or scholarly expertise to review new research programs.

5. Review of Membership

The IRB Executive Committee reviews the membership of the IRB at least annually to determine if the membership continues to include individuals with varying backgrounds and the experience and scientific or scholarly expertise needed to review the scope of biomedical and behavioral research conducted at Mass General Brigham. The HRO compiles information about member areas of expertise and representative capacity as well as the scientific areas covered by protocols reviewed at convened meetings. The IRB Executive Committee conducts a review of these data and provides a report to the VP HRA with recommendations for changes in IRB membership.

6. New Member Onboarding

Prospective members provide information about themselves pertinent to their role on the IRB and participate in education prior to appointment including, but not limited to:

1. Providing a copy of their current curriculum vitae, resume, or personal statement summarizing their applicable background.
2. Completing the *IRB Member Information Sheet*.
3. Attending at least one meeting of the IRB.
4. Completing the Collaborative Institutional Training Initiative (CITI) program basic biomedical research course.
5. Completing the IRB Member Orientation Program.

7. Use of Consultants

The IRB has the authority to use consultants, when needed, to supplement or provide scientific or scholarly expertise not available on the IRB.

The IRB Chairs(s) in collaboration with the HRO staff are responsible for determining when a consultant is needed to ensure appropriate review expertise for research scheduled to be reviewed at a convened meeting. The IRB Chair or designee is responsible for identifying the consultant and for requesting the consultation. The consultation may be provided in writing prior to the meeting or the consultant may be invited to provide consultation orally at the convened meeting. Consultants are not considered members and do not vote on human subject research reviewed by the convened board. However, consultants are subject to the Mass General Brigham policy on *IRB Member Conflicts of Interest*. Consultants are reminded that the discussions that take place at the meeting are confidential and may not be disclosed to others.

Expedited Reviewers are responsible for determining when a consultant is needed to ensure appropriate review expertise for research reviewed through an expedited process. The Expedited Reviewer is responsible for identifying the consultant and requesting the consultation. The consultation may be provided in writing or the consultation may occur orally. Consultants are subject to the Mass General Brigham policy on *IRB Member Conflicts of Interest*. Consultants are reminded that the discussions that take place are confidential and may not be disclosed to others.

8. IRB Member Continuing Education

Ongoing education is provided to IRB members through presentations at meetings, distribution of educational materials, and opportunities to participate in webinars or online workshops. Additionally, members have access to additional CITI human research courses, such as basic good clinical practice (GCP) or social and behavioral research courses, or the related refresher courses. The IRB Executive Committee or its designee(s) is responsible for educating members about new policies, procedures, or guidance from Mass General Brigham, the FDA, OHRP, or other governing or expert groups. Members are encouraged to attend local, regional, or national conferences each year. The cost of attending conferences is covered by Mass General Brigham HRA when funds are available in the budget.

9. IRB Member Evaluation

Members are evaluated and provided feedback on a continual basis by the IRB Chairs and senior HRO staff based on fulfillment of their responsibilities designated in *IRB Member Responsibilities*. Concerns are provided to the Executive Committee for consideration and remedy. Members are also surveyed annually to provide a self-assessment of their knowledge of regulations and ethical principles, their participation at meetings, and to provide feedback on the IRB Chairs and HRO staff. Members receive feedback from these surveys and are also provided with records of attendance and primary/secondary reviews.

10. Resignation and End of Term

A member may resign from the IRB prior to the end of their term by a written resignation submitted to the VP HRA. For members designated by their departments, the resignation must be with agreement from their Chair, Chief or supervisor.

The Chair, Chief or supervisor of members they have designated who resign from the IRB or whose term is ending, is responsible for identifying an appropriate replacement with similar scientific or scholarly expertise. The VP HRA will notify the departments, divisions and supervisors of members whose terms are expiring at least 3 months prior to expiration to allow time for identification and onboarding of new members.

11. Suspension or Removal of Members

The VP HRA may suspend or remove any IRB member on recommendation from the IRB Executive Committee who fails to fulfill any of the responsibilities as defined in the *IRB Member Responsibilities.* The IRB Executive Committee or its designee is responsible for providing reasonable notice of the grounds for the suspension or removal and an opportunity to be heard.

12. Membership Records

The HRO maintains a roster of members that includes the following:

1. Name
2. Earned degrees
3. Scientific status (physician scientist, other scientist, or nonscientist)
4. Experience and expertise, such as board certifications, licenses;

5. Representative capacity (e.g., children, pregnant women, ss, economically disadvantaged, educationally disadvantaged, or cognitively impaired adults)
6. Affiliation, if any, with any Mass General Brigham entity or with any component of HU

The HRO is responsible for updating the membership roster and IRB registration information as needed when membership changes and submitting the updated information to OHRP on behalf of Mass General Brigham. IRB rosters are retained for at least seven (7) years and are made available upon request, to authorized representatives of DHHS, FDA and other federal agencies when applicable, for inspection and copying onsite during normal business hours. Individual membership records are retained by the HRO for at least seven (7) years from date of last service.

VII. MEMBER CONFLICTS OF INTEREST

All members of the IRB are required to disclose conflicts of interest and recuse themselves from participating in the discussion and vote on human subject research with which they have a conflict of interest as defined in the Mass General Brigham policy on *IRB Member Conflicts of Interest.* In preparation for each meeting, the HRO reminds members that they must recuse themselves from the discussion and vote on protocols if they are involved in the conduct or evaluation of the research or have significant financial interests (i) that would reasonably be affected by the research for which IRB approval is sought, and/or (ii) in entities whose financial interests would reasonably appear to be affected by the research.

Members with a conflict of interest may provide information at the IRB's request, but they must leave the room prior to the discussion and vote on the research. Recusals are documented in the minutes of the meeting as not present for the discussion and vote with the reason for the recusal. Recusals do not count towards the quorum requirement for the review.

VIII. IRB LEADERSHIP

The VP HRA appoints a Senior IRB Chair, IRB Chairs and Vice Chairs. The Senior IRB Chair and IRB Chairs report to the VP HRA with respect to their IRB responsibilities. The Vice Chairs report to the Senior IRB Chair with respect to their IRB responsibilities. Chairs are selected based on their commitment to the mission and values of Mass General Brigham and to the field of human subject protections, their knowledge of research and regulatory affairs, personal integrity and collaborative approach, and ability to conduct an effective and efficient meeting. All chairs are expected to embody the highest standards of ethical and professional conduct and to comply with applicable federal regulations, state laws, and Mass General Brigham policies and procedures.

1.0 Senior IRB Chair

The Senior IRB Chair is responsible for the overall conduct of the IRB and for reviews conducted by the designated expedited reviewers to ensure compliance with federal, state, and local laws and regulations, Mass General Brigham policies and procedures, and the ethical principles described in the Belmont Report. The Senior IRB Chair designates IRB members to conduct expedited reviews. This position acts as the primary liaison to HRA leadership and federal regulatory authorities on behalf of the IRB and involves regular interaction with Principal Investigators and research team members. The Senior IRB Chair is the chair of the IRB Executive Committee. The VP HRA evaluates and provides feedback to the Senior IRB Chair annually.

2.0 IRB Chairs

The IRB Chairs act as primary liaisons with researchers at their respective hospitals and assume the responsibilities of the Senior IRB Chair when that person is temporarily unavailable. The IRB Chairs are responsible for chairing convened IRB meetings on a regular basis and conducting expedited reviews as needed in compliance with federal, state, and local laws and regulations, Mass General Brigham Policies and Procedures, and the ethical principles described in the Belmont Report. The IRB Chair leads meetings in an organized and collaborative manner engaging and respecting the perspectives of both the scientists and community board members. IRB Chairs regularly interact with Principal Investigators and research team members to discuss their IRB applications and facilitate a collaborative review process. The IRB Chairs are members of the IRB Executive Committee and participate in meetings with the IRB and HRA leadership to contribute to the development of policies and ethical approaches to the protection of human subject research. The VP HRA evaluates and provides feedback to the IRB Chairs annually.

3.0 IRB Vice Chairs

The Vice Chairs are responsible for chairing convened IRB meetings on a regular basis and conducting expedited reviews as needed in compliance with federal, state, and local laws and regulations, Mass General Brigham Policies and Procedures, and the ethical principles described in the Belmont Report. The Vice Chair leads meetings in an organized and collaborative manner engaging and respecting the perspectives of both the scientists and community board members. Depending on their contributed FTE, this position may also regularly conduct expedited reviews as designated by the IRB Chair. This position involves regular interaction with Principal Investigators and research team members to discuss their IRB applications and facilitate a collaborative review process as well as meetings with the IRB and HRA leadership to contribute to the development of policies and ethical approaches to the protection of human subject research. The Senior IRB Chair evaluates and provides feedback to the Vice Chairs annually.

4.0 Meeting Responsibilities

When acting as the chair of an IRB convened meeting, the chair or vice-chair is a voting member and has the following responsibilities:

1. Serve as a voting member of the IRB
2. Serve as a Primary or Secondary reviewer as appropriate for their expertise.
3. Preside at convened meetings during which the IRB conducts: (i) initial and continuing review of research activities involving human subjects; (ii) review of proposed changes in approved research during the period of approval that are not minor; (iii) review of

unanticipated problems involving risks to subjects or others, including adverse events that are serious, unexpected and related to the research; and (iv) review of reports of possible serious or continuing noncompliance.

4. Review modifications in research required by the IRB at convened meetings to secure approval and confirm that modifications have been made as required by the IRB.
5. Conduct review of unanticipated problems involving risks to subjects or others.
6. Review and make determinations of serious or continuing noncompliance.

IX. IRB STAFF

IRB staff must complete initial and continuing training regarding human subjects protections via the Collaborative Institute Training Initiative (CITI). Additionally, IRB staff receive ongoing training via various mechanisms, including participating in webinars, attending seminars/meetings and as provided by their supervisors or other Mass General Brigham HRPP leadership.

X. REVIEW OF RESEARCH

The IRB has the authority to determine whether a research activity is human subjects research as defined in 45 CFR 46 or a clinical investigation as defined in 21 CFR 50, 56, 312 and 812, or other applicable federal regulations. When the research activity is human subjects research, the IRB determines whether regulated research is exempt in accordance with 45 CFR 46.104 or 21 CFR.46.104. When providing ethical review of exempt research, the IRB will be guided by the *Belmont Report.* The IRB acts as the HIPAA Privacy Board for Mass General Brigham and as such reviews exempt research with regard to the requirements of the Health Insurance Portability and Accountability Act (HIPAA).

The IRB and relevant ancillary committees or departments approve all human subject research prior to initiation of the research. Human subject research cannot be approved by any other institutional body or individual(s) if the research has not been approved by the IRB. Investigators may appeal the decision of the IRB to disapprove human subject research in writing directly to the IRB. The appeal will be reviewed at a convened meeting of the IRB that disapproved the research initially. The investigator may appeal the decision of the IRB in person at the convened meeting.

The IRB conducts initial and continuing ethical and scientific review of non- exempt human subject research at intervals appropriate to the degree of risk and, when required by regulations, not less than once per year and reviews proposed changes in approved research during the period of IRB approval either at a convened meeting of the IRB or, when applicable, by use of the expedited review procedure authorized in 45 CFR 46.110 and, when applicable, 21 CFR 56.110. The IRB relies on the scientific review conducted as part of review by a federal funding agency, by the FDA, by a cancer center Scientific Review Committee or other organizational scientific review process. When a prior scientific review has not occurred or when the research is regulated by the Department of Defense, the IRB conducts a scientific review in conjunction with its ethical and regulatory review. When conducting initial and continuing review or review of proposed changes in approved research, the IRB determines that all of the requirements for approval of human subject research in 45 CFR 46.111 and, when applicable, 21 CFR 56.111, are satisfied.

When conducting review using the expedited review procedure, IRB chairs or designated expedited reviewers are responsible for determining whether the research is minimal risk and the applicability of the expedited review categories. The IRB chairs or designated expedited reviewers have the authority to approve or require modifications in the research to secure approval, however they may not disapprove the research. Research may be disapproved only after review by the IRB at a convened meeting.

XI. CONVENED MEETINGS

The IRB meets regularly to accommodate timely review of research.

1.0 Agenda

The agenda is finalized by the HRO staff taking into consideration the nature and complexity of the human subject research activities on the agenda and members attending the meeting. The agenda will be limited as needed to allow sufficient time for discussion of each research activity.

The agenda and materials related to the human subject research scheduled for review at the meeting are provided to members at least five (5) days in advance of the meeting to allow sufficient time for review. In emergent situations where it is necessary to review research in an accelerated time window, materials may be provide less than 5 business days prior to the meeting when HRO staff confirm in consultation with the meeting Chair that members will have sufficient time to review prior to the meeting.

2.0 Review Assignments

The HRO staff make preliminary assignment of Primary and Secondary reviewers. When making review assignments, the HRO staff take into consideration the experience and scientific or scholarly expertise and, when applicable, knowledge of and experience in working with individuals with impaired decision- making capacity, children, pregnant women and fetuses, or neonates, or other vulnerable subjects required to review the research.

3.0 Primary and Secondary Reviewers

The Primary Reviewer performs an in-depth review of all materials provided in the research application(s) relevant to the research they are assigned to review including, when applicable, any investigational drug brochure or investigational device information. The Secondary Reviewer conducts a review of the IRB application and materials consistent with the reviewer's representative capacity. The Primary and Secondary Reviewer are responsible for notifying the HRO staff at the time of review assignment if they have a conflict of interest as defined in the Mass General Brigham policy *IRB Member Conflicts of Interest*. In such cases, HRO staff will reassign review of the research activity to another member.

4.0 Members Not Assigned as Primary or Secondary Reviewers

Members who are not assigned as the Primary or Secondary Reviewer perform review of materials in sufficient depth to vote on the research activity at the convened meeting.

5.0 Quorum

Human subject research that cannot be reviewed using the expedited review procedure is reviewed at a convened meeting of the IRB where a quorum is present including at least one physician scientist and at least one member whose primary concerns are in nonscientific areas. At least one Unaffiliated member should also be in attendance.

Quorum is maintained for the discussion and vote on each research activity on the agenda. Members not present for or recused due to a conflict of interest from the discussion and vote on a research activity do not count towards the quorum. When the primary member and alternate member are both present for the discussion and vote on a research activity, only one member is counted towards quorum for the specific research activity under review. The IRB does not vote on any research activity when a quorum of the membership is not present for the vote. The IRB chair and/ or designee at the meeting is responsible for ensuring that at least one nonscientist member is in attendance and that quorum is achieved before the meeting begins and that these requirements are maintained throughout the meeting. The HRO staff are responsible for recording attendance and vote on each research activity.

6.0 Guests

Guests are not allowed at IRB meetings with the exception of individuals invited by the IRB to provide information pertinent to the review of research activities under consideration (e.g. consultants, study PI). In such cases, guests are reminded that the discussions that take place at the meeting are confidential and should not be disclosed to others. Guests are not members of the IRB by virtue of their attendance, do not participate in discussion or deliberations, and are not eligible to vote.

7.0 Discussion and Vote

The Primary and Secondary Reviewers present their reviews and the IRB chair at the meeting opens the review for discussion by the members. At the end of the discussion, the Primary Reviewer or chair of the meeting makes a motion to approve, requires modifications (to secure approval), defers action for more information, or disapprove the research. When the motion is to approve or require modifications, the motion includes the period of approval (one year or less). A vote on the motion is taken by show of hands, voice vote, or electronic ballot, and the number of votes for, against, and abstentions from voting are recorded in the minutes. All motions are decided by majority vote of the members present for the review and eligible to vote on the research activity.

8.0 Meeting Minutes

The minutes include the following:

- Primary voting members (or alternate voting members) present;
- Primary voting members absent;

- Staff, guests and consultants, present; and

For each human subject research activity reviewed at the meeting:

- Action taken by the IRB;
- Separate deliberations for each action;
- Number of votes on each research activity as number for, against, or abstaining from voting (documentation of quorum);
- Members attending the meeting but not present for the discussion and vote;
- Recusals of voting members with indication of those recused due to conflicts of interest;
- Period of IRB approval, (one year or less);
- When applicable, summary of information provided by consultant(s);
- Required regulatory determinations of the IRB and protocol-specific findings justifying those determinations including, when applicable, waiver or alteration of the consent process, additional protections for pregnant women, fetuses and neonates, additional protections for children; and additional protections for participants with diminished capacity;
- When applicable, rationale for significant versus nonsignificant risk device study determinations;
- Summary of the discussion of controverted issues and their resolution, if any;
- When applicable, justification of deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document;
- Modifications required and/or additional information requested by the IRB; and
- Basis for requiring changes or disapproving the research.

Minutes are drafted and made available to the IRB chairs for review for errors requiring correction, and are not to be altered once finalized. Minutes are retained by the HRO for at least seven (7) years and are maintained in a secure area within the HRO or in a secure area or application on the Mass General Brigham network.

9.0 Access to Meeting Minutes

Minutes of meetings are made available on request to the IOs of Mass General Brigham and to IOs of other institutions who, by appropriate IRB reliance agreement, rely on the IRB. Minutes are also available upon request to authorized representatives of DHHS, FDA and other federal agencies for inspection within a reasonable time frame, and for copying onsite during normal business hours.

XII. RECORDS OF REVIEW ACTIVITIES

The HRO maintains records of research activity reviewed by the IRB, whether at a convened meeting, through the use of the expedited review procedure, or for exempt research, to include:

- Minutes of convened meetings;

- All of the documents submitted with the research proposal for initial review and subsequently including, but not limited to, the application form, protocol summary, detailed protocol or research plan, recruitment materials (letters, flyers, advertisements, etc.), consent form(s), drug/device brochures, package inserts, or other information, NIH cooperative group protocol, NIH cooperative group sample consent form, ancillary committee/department review, scientific evaluations, if any;
- The application for funding (e.g., NIH or other federal grant), in the secure Agreements application on the Mass General Brigham network when applicable;
- Written reports from consultants when applicable;
- Checklists and forms documenting, when applicable, justification for expedited review, exemption determination, and findings required by applicable regulations;
- IRB-approved recruitment materials;
- IRB-approved consent forms;
- Progress reports, interim analyses, safety reports, DSMB/DMC reports;
- Reports of injuries to subjects and/or adverse events;
- Reports of unanticipated problems involving risk to subjects or others;
- Reports of protocol deviations and noncompliance;
- Proposed changes to the protocol and revised documents (amendments);
- Copies of all correspondence between the IRB and investigator;
- Continuing review activities and all documents submitted for continuing review including, but not limited to the application form, protocol summary, detailed protocol, recruitment materials;
- Statements of significant new findings provided to subjects; and
- Administrative information on research for which the IRB relies on an external IRB for review

Records of research activities are retained by HRO for at least seven (7) years from completion of the research or closure of the file. Files are maintained in paper format in a secure area within the HRO or sent to an external vendor for long-term storage as needed, or in electronic format in the secure Insight system on the Mass General Brigham network. Access to records is provided to the relevant IOs of Mass General Brigham and to IRB chairs, IRB members, and HRO staff to carry out their human research protection responsibilities.

Investigators have access to electronic records pertaining to their own research activities through the Mass General Brigham Insight system. Other institutional access to records is limited to those with a legitimate need for access, such as other institutional offices or departments within the Mass General Brigham Human Research Protection Program. Access to records are available upon request to authorized representatives of the sponsor and, when applicable, to authorized representatives of DHHS, FDA and other federal agencies for inspection and copying onsite during normal business hours.

XIII. CONFIDENTIALITY

IRB review proceedings and records of review activities are considered confidential and protected from access except as provided in this Policy and Governance document. IRB members or others with access to these proceedings or records will not use them for any purpose other than to carry out their review responsibilities and will not disclose them to others who are not authorized under

these procedures to have access. Such protection is essential to encourage open discussion by the IRB in review of proposed research, maintain the integrity of the deliberative process, safeguard the privacy and confidentiality of participants in research and avoid disclosure of information that is proprietary to the research sponsor or other third party and which the institutions may be contractually obligated to keep confidential.

Without limiting any of the above, HRA specifically prohibits distribution of documents and records containing confidential and proprietary information of Mass General Brigham or of a third party beyond the research team and others within Mass General Brigham with a need to know without prior written approval of Mass General Brigham or the third party involved, as applicable.

XIV. INCIDENT REPORTING

Consistent with the federal regulations, the VP HRA reports any unanticipated problems involving risks to subjects or others; any serious or continuing noncompliance with DHHS or FDA regulations or the requirements or determinations of the IRB; and any suspension or termination of IRB approval in accordance with the IRB policy *Reporting to Institutional Officials, Regulatory Agencies, and Accrediting Organizations*.

XV. HUMAN RESEARCH OFFICE (HRO)

HRO provides administrative infrastructure to support the mission of the IRB. The primary responsibility of HRO is to support the IRB members and chairs as they fulfill their review and other regulatory responsibilities. HRO retains physical space, equipment and the resources required for the functioning of the IRB. The Director, HRO oversees the day to day operations of HRO and delegates responsibilities to HRO staff as appropriate in order to ensure completion of tasks.

XVI. POLICIES AND PROCEDURES

The IRB operates under Policies and Procedures and associated guidance as may be necessary for the review of human subject research in compliance with federal, state, and local laws and regulations and accreditation requirements. Policies implementing the authorities of the IRB or concerning IRB operations are developed by the HRO and IRB Executive Committee and approved by the VP HRA. Polices intersecting with or affecting other institutional offices or processes may be developed in consultation and coordination with those offices or institutional research leadership and are generally approved by the Mass General Brigham Chief Academic Officer. All IRB policies and procedures comply with Mass General Brigham HealthCare Policy Management Process. The IRB policies and procedures, including IRB guidance documents and significant policy-related communications to the research community, are made available on the Navigator website and are maintained by the HRO for at least seven (7) years from the date of their adoption/distribution and are made available upon request to authorized representatives of the sponsor and, when applicable, authorized representatives of DHHS, FDA and other federal agencies for inspection within a reasonable time frame and copying onsite during normal business hours.

Appendix I: Entities owned by Mass General Brigham Incorporated

The Brigham and Women's Hospital, Inc. (BWH)
Brigham and Women's Faulkner Hospital, Inc. (BWH/F)
The General Hospital Corporation doing business as Massachusetts General Hospital (MGH)
The MGH Institute of Health Professions, Inc. (MGH IHP)
The McLean Hospital Corporation (McLean)
North Shore Medical Center, Inc. (NSMC)
The Spaulding Rehabilitation Hospital Corporation (SRH)
Spaulding Hospital - Cambridge, Inc. doing business as Spaulding Hospital for Continuing Medical Care Cambridge (Spaulding Cambridge)
Spaulding Hospital of the Cape and Islands Corporation (Spaulding Cape Cod)
Partners Private Care, LLC (PPC)
Partners Home Care, Inc. (PHC)
Newton-Wellesley Hospital (NWH)
Massachusetts Eye and Ear Infirmary (MEE)
The Schepens Eye Research Institute, Inc. (SERI)