

HUMAN RESEARCH AFFAIRS

QUESTIONS, CONCERNS, OR COMPLAINTS FROM SUBJECTS OR FAMILY MEMBERS

Massachusetts General Brigham is committed to protecting the rights, safety and welfare of subjects participating in research conducted by Mass General Brigham. Consistent with this commitment, the Mass General Brigham Research Consent Form template includes a section that addresses whom to contact if subjects or family members have questions, concerns, or complaints about the research. This section includes the name of the investigator responsible for the research and their contact information as well as the name and contact information for others on the study team who are available to answer the subject's questions or address any concerns or complaints they might have about the research or their participation in the research. The Mass General Brigham Research Consent Form template also includes the telephone number for the Mass General Brigham IRB should subjects wish to discuss their rights as a research subject, their concerns about the research, or a complaint about the research with someone not directly involved in the research. When the Mass General Brigham IRB waives the requirement for the investigator to obtain a signed consent form, contact information for the investigator is included in a study information sheet or other written statement about the research, or in other written materials used during the recruitment and consent process.

Mass General Brigham IRB contact information is available to subjects, family members, and the public on the Mass General Brigham IRB website.

Subjects are encouraged to ask questions or voice any concerns or complaints they may have about the research or their participation in the research during the consent process and throughout the study period. The investigator is responsible for answering all questions, addressing all concerns, and responding to all complaints raised by subjects to the best of their ability.

Subjects are also encouraged to contact the Mass General Brigham IRB office if they have any concerns that they do not want to discuss with the research staff, e.g., feeling pressured to take part in the research or, after enrollment, to continue to take part.

Handling Questions, Concerns, or Complaints

Prospective subjects and subjects enrolled in the research may ask questions or voice concerns or complaints directly to the investigator responsible for the research, a member of the study staff, or to a representative of the Mass General Brigham IRB, verbally or in writing before, during or after taking part in the research.

Complaints Received by Investigators/Study Staff

Investigators are responsible for ensuring that subject complaints are handled in a respectful manner and that subjects are not penalized or lose any benefits they are receiving or have a right to receive. Complaints should be resolved and documented thoroughly and in a timely manner.

When, despite their best efforts, the investigator is unable to resolve a complaint thoroughly or in a timely manner, the complaint should be referred to the Director of the IRB Office. The Director will work

with the investigator and Senior Chair of the Mass General Brigham IRB (or delegate) and other hospital representatives, such as the Privacy Officer or Accounting and Finance, as appropriate, to resolve the complaint. The IRB Office Director and Mass General Brigham IRB will address the complaint in a timely manner and communicate its resolution to the complainant, generally within 30 days.

Complaint by/on behalf of a research subject that indicates that the rights, welfare, or safety of the subject have been adversely affected or any complaints that cannot be resolved by the investigator must be reported to Mass General Brigham IRB in an expedited manner per the Reporting Unanticipated Problems policy. In addition, investigators must document all complaints received from subjects or family members and their resolution and report them to the Mass General Brigham IRB at continuing review.

Complaints Received by the Mass General Brigham IRB Office

Complaints received by the Mass General Brigham IRB office will be addressed by the Director of the IRB Office (or designee). When the complaint is received by telephone, the IRB staff receiving the complaint will record the information provided by the complainant. The Director or their designee may inform the investigator of the complaint and request a response to the issues raised in the complaint. The Mass General Brigham IRB will maintain privacy of the complainant.

Investigators and study staff are expected to cooperate with internal efforts to investigate and resolve complaints. The Mass General Brigham IRB and/or the investigator will address the complaint in a timely manner and communicate its resolution to the complainant, generally within 30 days of receipt of the complaint. The IRB Office will maintain records of subjects' complaints and their resolution.

Remedial Action, Suspension or Termination of Research, and Noncompliance

The Director and Senior IRB Chair will be responsible for determining whether remedial action is necessary. Should the complaint result in an allegation of noncompliance or be cause for suspension or termination of the research, the Mass General Brigham IRB will follow the procedures outlined in the policies related to *Noncompliance in Human Subject Research*, *Suspension or Termination of Human Subjects Research*, and *Reporting to Institutional Officials, Regulatory Agencies and Accrediting Organizations*.

For questions, contact the MGB IRB Office at partnersirb@partners.org.