

<b>Title:</b>	Suspension or Termination of Human Subject Research
<b>Department:</b>	Human Research Affairs
<b>Policy Type:</b>	Mass General Brigham System-wide
<b>Applies to:</b>	Employees, Professional Staff or Other Agents of Mass General Brigham
<b>Approved by:</b>	Chief Academic Officer
<b>Original Approval Date:</b>	June 4, 2007
<b>Original Effective Date:</b>	June 4, 2007
<b>Revision Approval Date(s):</b>	December 6, 2007; February 5, 2009; September 8, 2010; March 7, 2014; May 1, 2017
<b>Current Revision Effective Date:</b>	December 1, 2020
<b>Next Review Date:</b>	January 15, 2022
<b>Contact Person:</b>	Director, Human Research Office

**KEYWORDS:**

IRB, Institutional Review Board

**PURPOSE:**

The purpose of this policy is to define the procedures the Mass General Brigham IRB follows when suspending or terminating Mass General Brigham IRB-approved human subject research and clinical investigations.

This policy is established to comply with the regulatory requirement in 45 CFR 46.108(a)(4)(ii), 45 CFR 46.113 and 21 CFR 56.108(b)(3) requiring IRBs to have written procedures ensuring prompt reporting to the IRB, appropriate institutional officials, Office for Human Research Protections, and, when applicable, the Food and Drug Administration (FDA), of any suspension or termination of IRB approval.

**POLICY STATEMENT:**

Consistent with federal regulations, the Mass General Brigham IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with regulations, the requirements or determinations of the Mass General Brigham IRB or that has been associated with unexpected serious harm to subjects. Additionally, the Institutional Official may suspend or terminate research approved by the Mass General Brigham IRB for human subject protection, administrative, financial or other reasons. The Vice President, Human Research Affairs (VP HRA) and the Senior IRB Chair has the authority to suspend research.

When the Institutional Official suspends or terminates Mass General Brigham IRB-approved research, s/he is responsible for promptly notifying the Principal Investigator, Department Chair/Chief of Service, and the Mass General Brigham IRB in writing of the suspension or termination and the reasons for

doing so. Suspension or termination directives made by the Institutional Official will be reported to the convened IRB for review.

When the Mass General Brigham IRB suspends or terminates approved research, the IRB sends written notification to the PI through the Insight system.

**PROCEDURES:**

When research approved by the Mass General Brigham IRB is suspended or terminated, the VP HRA, Senior IRB Chair, or Mass General Brigham IRB considers actions to protect the rights and welfare of currently enrolled subjects and determines whether:

- subjects currently on active treatment must be withdrawn from the study;
- subjects will be placed at risk of harm by withdrawing them from the study; and
- subjects must continue to be followed for safety reasons.

When the suspension or termination involves withdrawal of subjects from an interventional study, the VP HRA, Senior IRB Chair, or Mass General Brigham IRB considers and determines what, if any, withdrawal procedures are required for the safety and welfare of those subjects. Withdrawal procedures may include, but are not limited to the following:

- Requiring notification to the subjects including the content and manner of notice. The notification may be to
  - all subjects who have been or are enrolled;
  - subjects currently on protocol; or
  - subjects who participated in a certain aspect of the protocol.
- Tapering of the drug
- Making a final study visit at which a physical exam and/or laboratory or other tests will be performed; or
- Making arrangements for subjects to receive medical care by their primary care physician or specialist or through referrals to other healthcare providers.

When research is suspended, the investigator is subject to the requirement for continuing review (if required for the study) and all reporting requirements for the duration of the suspension.

The Mass General Brigham IRB reports suspensions or terminations in accordance with the policy *Reporting to Institutional Officials and Regulatory Agencies*.

**OTHER APPLICABLE MASS GENERAL BRIGHAM POLICIES:**

Reporting to Institutional Officials and Regulatory Agencies

**REFERENCE:**

45 CFR 46  
21 CFR 56

**DEVELOPMENT AND CONSULTATION:**

Human Research Office  
Office of the General Counsel