

Title:	Policy for Mass General Brigham Investigators Leaving the Institution
Department:	Human Research Office
Policy Type:	Mass General Brigham System-wide
Applies to:	Employees, Professional Staff or Other Agents of Mass General Brigham
Approved by:	Chief Academic Officer
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Next Review Date:	January 15, 2020
Contact Person:	Director, Human Research Office

KEYWORDS:

IRB

PURPOSE:

The purpose of this policy is to describe the Mass General Brigham IRB's policies and processes related to Mass General Brigham investigators leaving the institution.

POLICY STATEMENT:

Research investigators who were part of the workforce at Mass General Brigham who leave their positions may still need to complete certain tasks (e.g. data analysis, preparation for publication) associated with specific research projects that they initiated and conducted at Mass General Brigham. Completion of these tasks may require investigators to take copies of research data or research records with them or otherwise to use such data/records after they leave the institution. This data may include research subjects' individually identifiable information ("Protected Health Information" or "PHI").

This policy addresses access by departing investigators to research data/records needed to complete specific projects. It does not by itself address or permit continued access to Mass General Brigham electronic systems (such as e-mail, H drives, clinical applications, or electronic databases). Departing investigators who seek continued access to such systems, whether for general purposes or as a means to access specific research data/records, must contact the appropriate person at their site. This means that in some cases (e.g. an investigator who wishes to access research data/records for a specific study where the means of access is through Mass General Brigham electronic systems), the investigator will need to contact the appropriate person at the site AND follow the process outlined in this policy below.

PROCEDURES:

1. In order to allow specific research projects to be completed while still reasonably addressing the goals of the HIPAA Privacy Rule, Mass General Brigham may, on a case by case basis and in its discretion, continue to consider a departing investigator to be part of the Mass General Brigham workforce for the limited purpose of HIPAA compliance in connection with the investigator's completion of the research project.
2. Only investigators who meet the following criteria may be eligible for this designation:
 - Were part of the Mass General Brigham workforce;
 - Still have an open study under the oversight of the Mass General Brigham IRB;
 - Will have no further role in study enrollment or procedures; and
 - Will be completing the research in their individual capacity (and not in connection with their new institution).
3. Continued access to Protected Health Information by investigators who are so designated will be use of PHI for purposes of the Privacy Rule.
4. The investigator's designation as part of the Mass General Brigham workforce will conclude when the study at issue is closed by the Mass General Brigham IRB.
5. The following requirements must be met in order for the designation to apply:
 - The investigator must notify his/her department head of his/her wish to take copies of or access research data after leaving Mass General Brigham to complete the research project. As noted above, the investigator must be completing the project in his/her individual capacity and not in collaboration with his/her new institution, and the investigator may not share any of the research data with the new institution.
 - The investigator must de-identify the research data or reduce them to a Limited Data Set (within the meaning of the Privacy Rule) to the extent possible before taking them.
 - As a workforce member, the investigator will have undergone HIPAA training at Mass General Brigham and signed a Mass General Brigham confidentiality agreement with respect to patient/research subject information. Before leaving Mass General Brigham, the investigator will have to sign a new confidentiality agreement with his/her department head covering the research data and forward a copy to the Mass General Brigham IRB. In any study initiated or conducted at Mass General Brigham in which informed consent and authorization are required, and the investigator knows that he/she will leave his/her Mass General Brigham position before analysis of the research data is completed and may need to continue to access PHI, the consent/authorization should so state.

OTHER APPLICABLE MASS GENERAL BRIGHAM POLICIES:

None.

REFERENCES:

None.

DEVELOPMENT AND CONSULTATION:

Human Research Office