

**MASS GENERAL BRIGHAM HUMAN RESEARCH
OFFICE**

**POLICY REGARDING NON-MASS GENERAL
BRIGHAM EMPLOYEES AS CO-INVESTIGATORS/STUDY
STAFF AND COLLABORATORS**

PURPOSE

This policy outlines how non-Mass General Brigham employees are credentialed to participate in the conduct of human research at Mass General Brigham as a co-investigator or other member of the study staff.

POLICY

Individuals who are not paid employees of Mass General Brigham, but who perform institutionally designated research activities or exercise institutionally delegated authority or responsibility for research, are acting as “agents” of Mass General Brigham. Therefore, these individuals are considered co-investigators/study staff and must be appropriately credentialed by Mass General Brigham to perform the research-related responsibilities delegated to them by the Principal Investigator. In some cases, these individuals are also acting as employees of their own institution, so in addition, must get their own IRB approval.

Note: For the purposes of this policy and for completing Mass General Brigham IRB forms, “collaborators” are defined as non- Mass General Brigham employees who are engaged in some aspect of the human research, but perform all of the research activities at their own institution. In such cases, collaborators engaged in human research must obtain IRB approval from their own institution.

GUIDANCE

Individuals, regardless of employment status, who assist the Mass General Brigham Principal Investigator and/or Site Responsible Investigator(s) with the conduct of human research, must be listed as Study Personnel (co-investigators or study staff) on the Mass General Brigham IRB Application. Study Personnel include individuals with research-specific roles, such as co-investigators, research nurses, research coordinators, and research assistants, among others, who do any of the following:

1. Obtain informed consent for research.
2. Perform invasive or noninvasive procedures or tests specifically for research purposes.
3. Conduct interviews, administer questionnaires, psychological instruments, or surveys specifically for research purposes.
2. Review health/medical information that is individually identifiable in original source documents (hospital or practice-based health/medical records) for research purposes.

Note: Individuals, such as laboratory technologists/technicians, radiological technologists/technicians, phlebotomists, patient care services staff, or interviewers, who provide standard clinical services or perform routine clinical tests in the course of carrying out their usual non-research related responsibilities are not considered study staff.

MGH policy regarding non-MGH employees who will work on MGH research studies:

For the MGH policy, refer to the MGH HR intranet site:

<https://hospitalpolicies.ellucid.com/documents/view/12073/19286>

BWH policy regarding non-BWH employees who will work on BWH research studies:

Licensed professional staff must be credentialed through the appropriate office and non-licensed

professionals must be registered with the Volunteer Office.

http://www.brighamandwomens.org/about_bwh/volunteer/SponsoredStaff.aspx

Study Staff who are not BWH Employees	Requirements for Study Staff who are not BWH Employees
Physicians (Residents/Fellows)	1. Registrar/Credentialing Office 2. CITI education certification
PhDs	1. Registrar/Credentialing Office 2. CITI education certification
Nurses	1. Nursing Department 2. CITI education certification
Medical/Dental Student	1. Volunteer Office 2. CITI education certification
Other (e.g., volunteers)	1. Volunteer Office 2. CITI education certification

Mass General Brigham IRB Policies and Procedures

Version Date: March 17, 2021