Mass General Brigham

HUMAN RESEARCH AFFAIRS

STUDY STAFF IN HUMAN SUBJECT RESEARCH: ENGAGEMENT AND RESPONSIBILITIES

Study Staff Engaged in Research

Federal research regulations require oversight of all individuals engaged in human subject research. Mass General Brigham is considered engaged in human subject research when its employees or agents receive an award directly from a federal agency or when employees or agents obtain:

- data about the subjects of the research through intervention or interaction with them;
- identifiable private information or identifiable specimens about the subjects of the research; or
- the informed consent of human subjects.

Employees or agents refers to individuals who: (1) act on behalf of Mass General Brigham; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. Employees and agents can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

Mass General Brigham employees engaged in the above research activities must be listed as study staff in the IRB Application in Insight. Please see Person of Interest section below for information about non-employees.

Study Staff Responsibilities

The study staff is made up of the Principal Investigator (PI) and individuals to whom the PI has assigned study-specific roles and responsibilities and includes, among others, co-investigators, research nurses, research coordinators, and research assistants.

The Department Chair/Chief

The Department Chair/Chief is responsible for ensuring that the principal investigator, site-responsible investigators, and other members of the professional staff conducting human-subjects research with participants are qualified by training and experience and have the necessary hospital credentials and privileges to conduct the research. The Department Chair/Chief may delegate signatory authority to another faculty member with delegated responsibility for oversight of research conducted by members of the department.

The Department Chair/Chief signs off on the proposed general concept of the research, confirming the department's support for the study and that it can be conducted as described.

Principal Investigator

The PI must be qualified by training and experience and must have the necessary hospital credentials and privileges to conduct the research. The PI must be a member of the professional staff at Mass General Brigham and have a clinical or non-clinical staff appointment above the level of resident, fellow

or student. Exceptions to this requirement will be made by the Mass General Brigham IRB Office, the PI's Department Chair/Chief, and the Institutional Official on a case-by-case basis and may require a licensed physician co-investigator. Exceptions may be made when trainees are required to serve as PIs as a condition of training grants. An approval letter from the Department Chair/Chief should be submitted, along with the name of the mentor PI.

The PI is responsible for personally conducting or supervising the research and is allowed to delegate certain study-related tasks to appropriately qualified co-investigators and study staff. The PI is responsible for ensuring that co-investigators and other study staff are appropriately qualified by training and experience to conduct the study-related tasks delegated to them including. The PI must have a plan for supervision and oversight of the research. The type of the supervision should take into consideration the study personnel conducting the research, the nature of the research, and the subject population. For more information refer to Mass General Brigham IRB guidance *Principal Investigators and Delegation of Study-related Tasks* .

The PI or other identified qualified individual(s) must be available to provide study participants with reasonable medical care for any medical problems that arise during participation in the research that are, or could be, related to the research. Additionally, when participation in the research might impact the participant's health and/or medical care, the PI should inform the participant's physician about the participant's participation in the research if the participant agrees to the physician being informed.

When protecting the rights, safety, and welfare of research participants, the PI must ensure that:

- They or another specific qualified individual are available to study participants to answer questions or provide care during the conduct of the research; and
- They and all research staff conducting the study adhere closely to the research plan, such as inclusion/exclusion criteria, safety assessments, safety monitoring and reporting of unanticipated problems, and procedures to protect privacy of participants and confidentiality of identifiable data, in order to minimize risks to participants.

The PI should not commence the research without adequate resources to protect participants enrolled in the research and should stop the research if the resources necessary to protect participants become unavailable. These resources might include research personnel, space, equipment, time, and availability of medical or psychological care for problems that arise during participation in the research.

The PI is also responsible for maintaining adequate and accurate source documents and study records that include all pertinent observations and information for each participant in the study. The PI must ensure the accuracy, completeness, legibility, and timeliness of the study data. The PI must maintain the essential study documents in accordance with relevant research regulations and institutional policies. The PI is responsible for documenting and explaining any deviations from the approved protocol. If the study involves investigational drugs or devices (including non-significant risk devices), the PI is responsible for ensuring product accountability is documented and maintained and that the product is stored in accordance with the protocol and product information. (ICG GCP E6(R2) Sections 4 and 8)

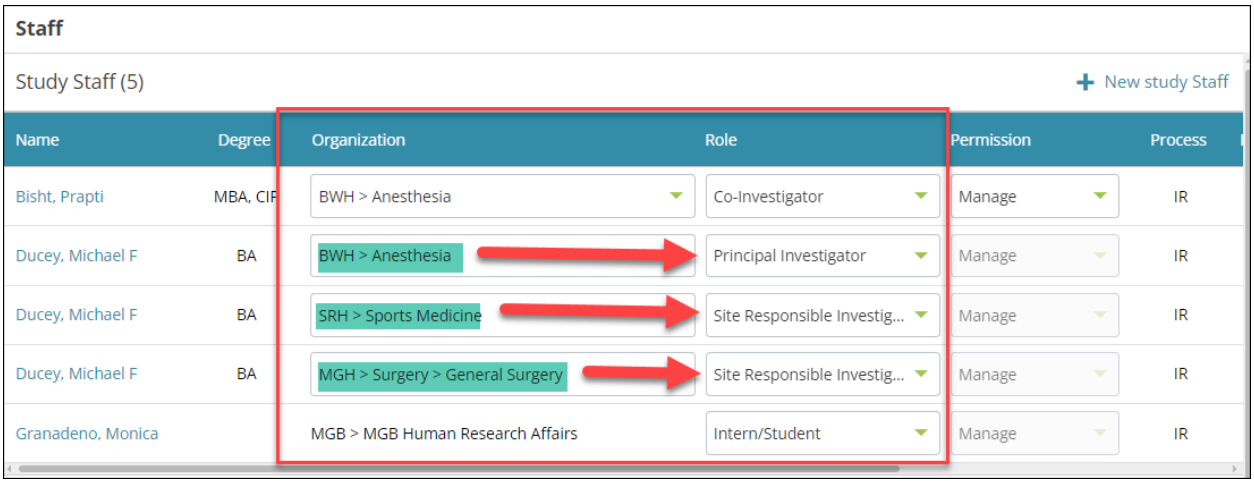
For FDA regulated research, the PI is the responsible leader of the team as defined by the term

investigator in FDA regulations 21 CFR 312.3(b) and 21 CFR 812.3(i).

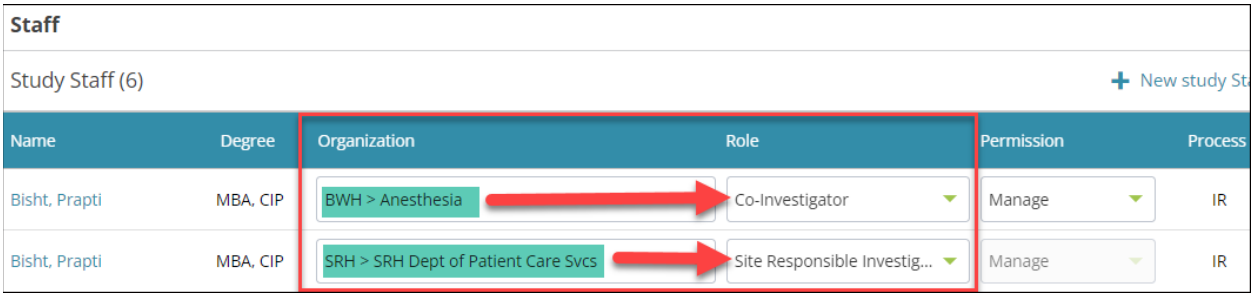
Site Responsible Investigator

When a study will be conducted at multiple Mass General Brigham sites under one IRB-approved study (one study #), there must be a Site Responsible Investigator for each Mass General Brigham institution. When working at more than one Mass General Brigham institution, an investigator can be both PI and Site Responsible Investigator. The same investigator may also serve as the Site Responsible Investigator at more than one Mass General Brigham site. The responsibilities and requirements for hospital credentialing and privileges for Site Responsible Investigators are the same as the requirements for the PI.

When an investigator is the PI and/or will serve as the Site Responsible Investigator at one or more MGB sites, they will need to be added to the Staff page multiple times. There needs to be one entry for each site the investigator will act as the Site Responsible Investigator and each entry needs to reflect the appropriate affiliation(s). The investigator/PI's Insight profile needs to be up to date reflecting all affiliated institutions to be able to act as the PI and or Site Responsible Investigator at multiple sites; for example, PI at BWH, affiliated and serving as the Site Responsible Investigator at Spaulding and MGH will need to be added with each affiliation and with the Site Responsible Investigator Role. See the example below.



Other staff members properly credentialed can also have multiple roles with different institutions; for example, co-investigator at BWH serving as the Site Responsible Investigator at SRH. See the example below.



A Site Responsible Investigator is required when a study involves interventions, interactions with participants and/or uses clinical resources (e.g., access to clinical unit or personnel). Examples include, but are not limited to, when a study involves blood draws (clinically indicated or research-specific), the pharmacy preparing the study drug, and/or interviews/surveys with participants. For surveys/interviews/focus groups, a Site Responsible Investigator is required only if there is an in-person interaction to complete these activities at an MGB site. If procedures are limited to online surveys or virtual visits, a Site Responsible Investigator is not required. A Site Responsible Investigator is also not required if in-person interactions are limited to a non-MGB off site location (e.g., a foodbank, a community center, etc.) and no in-person interactions take place at an MGB site. A Site Responsible Investigator is not necessary when a study does not involve interventions or interactions with participants (e.g., a medical records study involving records from multiple sites). Site Responsible Investigators are responsible for the conduct of the study at their institution and for providing site-specific information to the PI for continuing review and for fulfilling Mass General Brigham IRB Office reporting requirements (e.g., unanticipated problems involving risks to participants or others).

Co-Investigators

Co-investigators are typically individuals with doctoral or other professional degrees who contribute to the scientific development or execution of a study in a substantive, measurable way. Co-investigators must be qualified by training and experience and, when applicable, have the necessary hospital credentials and privileges to conduct the study-related tasks delegated to them by the PI.

Other Study Staff

Members of the study staff may include research nurse/manager, research coordinator/manager, research assistant, regulatory coordinator/manager, data coordinator/manager, laboratory technician/technologist, intern/student, among others. Study staff must be qualified by training and experience and, when applicable, have the necessary hospital credentials and privileges to conduct the study-related tasks delegated to them by the PI.

Persons of Interest (POIs)

Non-employees are onboarded as "Persons of Interest," or POIs, through hospital-required processes. Investigators should consult their Department's Administrative Director or equivalent to obtain details of POI onboarding.

If POIs or non-employees are from another institution (e.g., Harvard Medical School, Boston Children's Hospital), their activities may also engage the home institution in research. Aside from the exceptions noted below, individuals who are affiliated with another institution cannot be listed as study staff in Insight.

- The POIs should consult with the IRB office at their home institution regarding their role in the research and request oversight from them.
- Engagement in federally funded non-exempt research would require oversight by a Single IRB. POIs must obtain an IRB reliance agreement, as determined by the IRB, in order to ensure appropriate regulatory oversight of their respective research activities.
- The Mass General Brigham IRB will not serve as a Single IRB or rely on another IRB for exempt studies. Therefore, for exempt research, the POI will need to secure a determination from their home institution. Information about Single IRB and Reliance Agreements is available on

Research Navigator: Pages - sIRB Overview (sharepoint.com).

If POIs are not affiliated with another institution, an Individual Investigator Agreement (IIA) will be required for the Mass General Brigham IRB to provide oversight of the POI. The need for an IIA will be determined by the IRB Office. A reliance agreement is not needed for Mass General Brigham visiting or post-doc fellows, research trainees, or Fulbright scholars.

For U.S. students with a POI designation added to the study staff list as "Student/Intern," the PI and the student must sign the Individual Student Investigator Agreement (ISIA). A copy of the ISIA can be accessed on Research Navigator here: Pages - IRB Forms and Templates (sharepoint.com).

- During the review of the study staff amendment, the IRB reviewer will request a copy of the ISIA.
- All student researchers must reach out to their home institution's IRB to determine whether there are local submission requirements. This is a term of the ISIA.
- The ISIA is not applicable for students located outside the U.S as they will need to obtain a determination from their home institution.
    - These individuals do not need to be added to study-staff since the Mass General Brigham IRB will not have oversight of their research activities.
    - Any exceptions are considered on a case-by-case basis as part of the review process.

POIs cannot serve as a Principal Investigator on a research study overseen by the Mass General Brigham IRB.

Other Personnel

Members of the hospital workforce, who provide standard clinical services or perform routine clinical procedures or tests as part of their institutionally designated non- research responsibilities are not considered study staff and should not be listed in the IRB Application. These could include:

- laboratory technologists/technicians, radiological technologists/technicians, phlebotomists, patient care services staff, who provide standard clinical services or perform routine clinical procedures or tests in the course of carrying out their usual non-research related responsibilities.
- nurses, pharmacists, or anesthesiologists who perform services or duties as part of their usual care without otherwise contributing to the research endeavor.
- individuals whose role in the research is limited to providing consultation on the development of questionnaires or analyzing de-identified data.
- individuals whose sole responsibility is to perform administrative tasks such as entering data from source documents into a database when they are not engaged in research, or individuals who maintain research databases or provide technical support.

The IRB may need to assess certain roles on a case-by-case basis. If there are questions about engagement, contact the IRB office.