MASS GENERAL BRIGHAM HUMAN RESEARCH OFFICE

INFORMATION SHEET

INVESTIGATORS AND STUDY STAFF

The study staff is made up of the individuals to whom the Principal Investigator has assigned study-specific roles and responsibilities and includes, among others, co-investigators, research nurses, research coordinators, and research assistants. All employees or agents of Mass General Brigham who intervene or interact with subjects OR who access identifiable private information about the subjects of the research for the purposes of the research must be listed as Study Staff in the Mass General Brigham IRB Application.

Members of the hospital workforce, such as laboratory technologists/technicians, radiological technologists/technicians, phlebotomists, patient care services staff, interviewers or administrative staff who provide standard clinical services, perform routine clinical tests, or make appointments as part of their institutionally designated non-research responsibilities are not considered Study Staff and should not be listed in the Mass General Brigham IRB Application.

Individuals who are involved in the research BUT do not intervene or interact with subjects or do not access identifiable private information about the subjects should not be listed as Study Staff in the Mass General Brigham IRB Application. This includes individuals whose role in the research is limited to providing consultation on the development of questionnaires or analyzing de-identified data.

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 involving an intervention or interaction with subjects 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.

Principal Investigator

The Principal Investigator (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 and have a clinical or non-clinical staff appointment above the level of resident, fellow or student. When the research involves administration of a drug or use of a device for research purposes, the PI must be a licensed physician. Exceptions to this requirement will be made by the Mass General Brigham IRB Office on a case-by-case basis; exceptions require a licensed physician co-investigator and approval of thedepartment chair/chief or designee.

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, when applicable, any required hospital credentialing and privileges. See Mass General Brigham IRB Office guidance Principal Investigators and Delegation of Study-related Tasks to Co-Investigators and Study Staff.

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 a single IRB-approved protocol (one protocol #), there must be a Site Responsible Investigator for each Mass General Brigham institution. The Site Responsible Investigator is responsible for the conduct of the study at his/her 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 subjects or others). The responsibilities and requirements for hospital credentialing and privileges for Site Responsible Investigators are the same as the requirements for the PI.

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, statistician, nutritionist, laboratory technician/technologist, intern/student. 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.