Mass General Brigham

HUMAN RESEARCH AFFAIRS

PRINCIPAL INVESTIGATORS AND DELEGATION OF STUDY-RELATED TASKS

The Principal Investigator (PI) is responsible for personally conducting or supervising the conduct of the study. However, PIs are allowed to delegate certain study-related tasks to co- investigators and study staff. When tasks are delegated, the PI is responsible for providing adequate supervision of those to whom tasks are delegated and is accountable for regulatory violations (e.g., noncompliance) resulting from failure to adequately supervise the conduct of the study.

When delegating study-related tasks to co-investigators and study staff, the PI must ensure that:

1. Designated individuals are qualified to perform such tasks

The PI must ensure that any individual to whom a task is delegated is qualified byeducation, training, and experience to perform the delegated task.

When delegating tasks that are clinical or medical in nature, such as evaluating study subjects to assess clinical response to an investigational therapy (e.g., global assessment scales, vital signs) or providing study-related medical care to subjects, thePI must ensure that the individual has the relevant formal medical training and, whenappropriate, licensing and/or certification.

Examples of inappropriate delegation include:

- Screening evaluations, including obtaining medical histories and assessmentof inclusion/exclusion criteria, conducted by individuals with inadequate medical training;
- Physical examinations performed by unqualified personnel;
- Evaluation of adverse events by individuals lacking appropriate medicaltraining, knowledge of the clinical protocol, and knowledge of the investigational product;
- Assessments of primary study endpoints (e.g., tumor response, global assessment scales) by individuals lacking appropriate medical training andknowledge of the protocol; or
- Informed consent obtained by individuals who lack the medical training, knowledge of the clinical protocol, or familiarity with the investigational product needed to be able to discuss the risks and benefits of a clinical trialwith prospective subjects.
    - Note: Please reference “Individuals Who Can Obtain Informed Consent in Human Subject Research” for general guidelines of study staff roles/qualifications which are required for obtaining informed consent for different types of studies. Study staff roles that will be permitted to obtain informed consent must be approved prospectively by the IRB for each protocol.
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Investigators are required to maintain a list of the appropriately qualified persons to whom study-related tasks have been delegated, which tasks have been delegated to them, and the dates of their involvement in the study.

- Note: The Mass General Brigham Compliance & Education Office has developed a Study Site Signature/Delegation of Responsibility Log template which may be used for this purpose.

2. Co-investigators and study staff receive adequate training on how to conduct the delegated tasks and are provided with an adequate understanding of the study

The PI must ensure that there is adequate training for all staff participating in the conduct of the study. The investigator should specifically anticipate the possibility of staff turnover during the conduct of the study (particularly if the study is of long duration) and plan to ensure that there is adequate training of any replacement staff.

The PI must ensure that co-investigators and study staff:

- Have a specific understanding of the details of the protocol relevant to the tasks they will be performing and, when applicable, the investigational product;
- Are aware of regulatory requirements and acceptable standards for the conduct of human subjects research, both with respect to conduct of the study and human subject protection;
- Are competent to perform the delegated tasks; and
- Are informed of any pertinent changes to the protocol during the conduct of the study and are educated or given additional training as appropriate.

If the sponsor provides training materials for investigators in the conduct of the study, the PI must ensure that staff receives and reviews these materials and/or participates as necessary in any training sessions pertinent to their role in the study.

Documentation of training – whether provided by the PI, sponsor, or another entity – must be maintained in the study files.

3. There is adequate supervision and involvement in the ongoing conduct of the study

The PI must have a detailed plan for the supervision and oversight of a study. Supervision and oversight should be provided even for individuals who are highly qualified and experienced. An oversight plan might include the following elements, to the extent they apply to a particular study:

- Routine meetings with co-investigators and study staff to review progress ofthe study and update them on any changes to the study or other procedures;
- Routine meetings with the sponsor's monitors;
- A procedure for correcting problems identified by co-investigators or study staff, outside monitors or auditors, or other parties involved in the conduct ofa study;
- A procedure for documenting the performance of delegated tasks in a satisfactory manner and, where appropriate, verifying findings (e.g., observation of the performance of selected assessments or independentverification by

repeating selected assessments);

- A procedure for ensuring that the consent process is being conducted in accordance with federal regulations 45 CFR 46 and 21 CFR 50 and the Mass General Brigham IRB Informed Consent of Research Subjects Policy;
- A procedure for ensuring that information in source documents is accuratelycaptured on the Data Collection Forms, Case Report Forms, or elsewhere asappropriate to the study;
- A procedure for dealing with data queries and discrepancies identified by thestudy monitor or other individuals responsible for oversight of the study; and/or
- Procedures for ensuring co-investigators and study staff comply with the IRB-approved protocol and reporting requirements of the IRB and sponsor.

There should be documentation in the study records for all oversight activities such as Meeting Minutes or an internal QA monitoring log.