PRINCIPAL INVESTIGATORS AND DELEGATION OF STUDY-RELATED TASKS TO CO-INVESTIGATORS AND STUDY STAFF

The Principal Investigator (PI) is responsible for personally conducting or supervising 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 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 by education, 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, the PI must ensure that the individual has the relevant formal medical training and, when appropriate, licensing and/or certification.

   Examples of inappropriate delegation include:

- Screening evaluations, including obtaining medical histories and assessment of inclusion/exclusion criteria, conducted by individuals with inadequate medical training;
- Physical examinations performed by unqualified personnel;
- Evaluation of adverse events by individuals lacking appropriate medical training, 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 and knowledge 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 trial with prospective subjects. Note: For most studies involving more than minimal risk and all studies involving investigational drugs/devices, the PHRC requires that a licensed physician investigator listed on the protocol obtain informed consent.

Investigators are advised to maintain a list of the appropriately qualified persons to whom significant study-related tasks have been delegated. This list should also describe the delegated tasks, identify the training that individuals have received that qualifies them to perform delegated tasks, and identify the dates of involvement in the study. Note: UH Office of Research Compliance and Education has developed a Delegation of Authority Log/Staff Signature Log 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 should 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 and credentialed 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 in person training sessions pertinent to their role in the study.

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. A 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 of the study and update them on any changes to the study or other procedures;
- Routine meetings with the sponsor's monitors;
- Training on SOPs
- A procedure for correcting problems identified by co-investigators or study staff, outside monitors or auditors, or other parties involved in the conduct of a 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 independent verification 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 UH IRB requirements and that study subjects understand the nature of their participation, risks, etc.;
- A procedure for ensuring that information in source documents is accurately captured on the Data Collection Forms, Case Report Forms, or elsewhere as appropriate to the study;
- A procedure for dealing with data queries and discrepancies identified by the study 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.

Guidance based on United States. U.S. Dept. of Health and Human Services, Food and Drug Administration, et al. Guidance for Industry: Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects. Draft Guidance May 2007; Final October 2009

Additional Resources

Information Sheet Guidance for Sponsors, Clinical Investigator, and IRBs – Frequently Asked Questions – Statement of Investigator (Form FDA 1572). Final May 2010

FDA – Guidance documents

UHCMC IRB Policy – Investigator Responsibilities

UH Research Standard Operating Procedures (SOPs)

UH Office of Research Compliance & Education – Clinical Research Tools

21 CFR 812 Investigational Device Exemptions