

## Good Clinical Practice Q&A: Focus on Investigator Delegation

**In Section 4.1.5, the ICH GCP guideline states that the investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties. What are considered significant duties to be included on this list and what are considered non-significant duties that should not be delineated on this list?**

In a January 2005 informal response to this question, the FDA stated that, "the ICH guidance doesn't elaborate on what is meant by significant trial related duties, leaving this open to opinion. However, it seems reasonable that in the context of this section of the guidance one can assume that the investigator would be delegating trial related duties for which the investigator would normally be responsible. For example, screening and enrolling subjects, performing protocol required tests and exams, and evaluating subjects' responses to the test article (e.g. assessing AEs, etc.). In general, any duty that would impact significantly on subject safety, protocol compliance, and quality and integrity of important study data could be considered significant."<sup>1</sup>

### **To what category of staff may a principal investigator delegate study tasks?**

The principal investigator may delegate many study tasks to site staff – provided that they are qualified to perform the task and it is within the scope of that person's professional licensure if the task requires a license. Such determinations are based not on FDA requirements alone, but on local laws and regulations as well.

The principal investigator, for example, may delegate physical exams to a nurse practitioner, advanced practice nurse, or PA. Most state Nurse Practice Acts do not permit an RN without an advanced practice certification to perform physical exams (not to be confused with physical assessments, which RNs routinely perform). In the same manner, a principal investigator may delegate administration of an intravenous study drug to an RN, but not to a medical assistant. Informed consents should be obtained by staff who are qualified by education and background to adequately explain the details of the study.

In recent industry talks, FDA compliance officials have noted that clinical investigators should not "over-delegate to non-physicians." For example, noted Robert Shibuya, M.D., a medical officer in the Good Clinical Practice Branch II within CDER's Division of Scientific Investigations in a May 2004 speech, investigators should not delegate responsibility for making a "diagnosis that qualifies/determines eligibility for entry into a clinical study."

Clearly, there are other tasks that a principal investigator cannot delegate. The principal investigator, or another study staff physician, is responsible for determining if a subject must go off study because of an adverse event, for example. In all cases, the principal investigator holds sole responsibility for the general conduct of the study at his or her site, including, but not limited to, ensuring that all study-related processes and procedures are conducted in a safe manner and as specified in the protocol.<sup>2</sup>

### **Is it considered acceptable for a study coordinator to sign documentation for an investigator?**

While it is acceptable for study coordinators to sign certain documentation for an investigator, there are important caveats. Certain documents, such as the Form FDA 1572-

Statement of Investigator, financial disclosure forms, and protocols, cannot be signed by the study coordinator on the investigator's behalf. When the study coordinator signs for the principal investigator, the coordinator must initial the signature.

If the investigator gives the study coordinator authority to sign for him or her, the parameters (type of document and special circumstances) must be clearly delineated in a document, which should be maintained in the study binder. The sponsor should be made aware of this practice, and should receive a copy of this documentation. Some IRB correspondence and simple queries and routine, straightforward correspondence with the sponsor or CRO are examples of documents that may be signed by the study coordinator.

All individuals who may make changes to the case report forms or source documents must be identified in study documentation. A signature/delegation log, which is an "essential document" according to the ICR GCP guideline (E6), is used for this purpose.<sup>3</sup>

### **References**

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2005, pg. 33
2. *ibid*, pg. 33-34
3. *ibid*, pg. 42-43

### **Source**

"Good Clinical Practice: A Question & Answer Reference Guide 2005," is available for \$39.95 at <http://www.barnettinternational.com/>