From: Toth-Allen, Jean
Sent: Tuesday, May 02, 2006 10:46 AM
To: [Redacted]
Subject: RE: Clinical Monitor

Dear [Redacted]:

Thank you for your inquiry and please excuse the delay in responding to you.

The FDA regulation regarding the conduct of device clinical trials (21 CFR part 812 - Investigational Device Exemptions) defines a monitor as an individual designated by a sponsor or contract research organization to oversee the progress of an investigation (812.3(j)). It does not however distinguish among types of monitors. The regulation governing pharmaceutical clinical trails (21 CFR part 312 - Investigational New Drug Application) does not define a monitor nor does the ICH GCP guidance which FDA has formally adopted (found at http://www.fda.gov/cder/guidance/959fnl.pdf). Both of the latter two documents, however, include the term monitor in the body of the document, the ICH GCP guidance when describing study monitoring (section 5.18) and the regulation when discussing the responsibility of study sponsors to choose appropriate individuals for this task (312.53(d)). None of the above refer to individuals who may be clinical liaisons to an investigational site.

If you and/or the organization with which you work plans to use one or both of these terms to designate individuals associated with the conduct of clinical trials, it is best to define the duties and qualifications of such individuals in your standard operating procedures (SOPs) for the conduct of clinical trials or similar documents. If FDA or other regulatory agencies were to inspect your study, the position description defined in your company's documents would be used as the basis to judge the qualifications and conduct of these individuals in any given study.

As to who is responsible for ensuring that such individuals are appropriately chosen and functioning, that would also be a decision made by company policy. The pharmaceutical regulation at 312.52 specifically speaks to the possibility of transfer of sponsor regulatory responsibilities to other parties. While the device regulation does not have a comparable section, it is understood that such contracts are often undertaken, however, the sponsor retains regulatory responsible for any duties so contracted.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [Redacted]
Sent: Wednesday, April 12, 2006 4:38 PM
To: OC GCP Questions
Subject: Clinical Monitor

To Whom It May Concern:

I am trying to distinguish the difference between a clinical Monitor and a clinical liaison for an investigative device study. What are the roles and guidelines for roles for each if possible, also who should bear the responsibility for having a clinical monitor or liaison, would it be the group in the study who is interested in the data and results or the group who is not interested in the results.

Sincerely,
[Redacted]