From: Toth-Allen, Jean
Sent: Thursday, June 22, 2006 10:47 AM
To: [Redacted]
Subject: RE: medical monitor?

Dear [Redacted],

Thank you for your inquiry regarding medical monitors.

While both the pharmaceutical and device industries often refer to a variety of specialized types of monitors, FDA regulations and guidance only use the term "monitor" in the broadest sense, meaning someone who has the responsibility for oversight of the conduct of a study. The only FDA document in which the term "medical monitor" is found is the compliance program for the inspection of sponsor/monitors/contract research organizations. (This compliance program is available at http://www.fda.gov/ora/compliance_ref/bimo/7348_810/48-810.pdf and the term is found in section B, item 3(b).) This compliance program is the directive to the FDA investigators as to how to inspect the entities listed in its title. The particular reference to medical monitor is within an example for the investigator of the different types of monitors that may be involved in monitoring a study. The medical monitor is defined in this reference as the monitor responsible for medical aspects of the study and the document notes that this individual may be a physician.

While FDA regulations pertinent to clinical trials (21 CFR Part 312 for pharmaceuticals and Part 812 for devices) require that a sponsor adequately monitor all trials, there is no description of these individuals other than that they be qualified by training and experience.

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: Thursday, June 15, 2006 3:56 PM
To: OC GCP Questions
Subject: medical monitor?

Sometimes IRBs want to know who is the "medical monitor" for the study. Does FDA have an official defintion for medical monitor, and does such a person have to be a physician? Is a medical monitor required for all clinical investigations?

Thank you.

[Redacted]