From: Toth-Allen, Jean
Sent: Wednesday, June 21, 2006 12:25 PM
To: [Redacted]
Subject: RE: GCP Query- Urgent
Dear [Redacted],

Thank you for your inquiry. Hopefully this response is timely enough for your needs, as I noticed you sent it 2 days in a row, adding an urgent yesterday. Sorry I was not able to get to it sooner.

There is nothing in FDA regulation that would prevent a study monitor from directly contacting a study subject. The informed consent document should inform subjects that regulatory and study sponsor personnel could/will have access to their records. Monitors are considered agents of the sponsor. Since subject rights and welfare are of paramount concern to regulatory agencies, we would not expect a monitor to contact subjects routinely but only for serious reasons and then that their privacy and confidentiality will be maintained. It is assumed that if a monitor feels it is necessary to contact a study subject or subjects there is concern about the safety of the subjects, the completeness of the informed consent process, the integrity of the data, or some other significant issue related to one or more of these. Given your urgency in needing a response, I am assuming there is a serious concern that you or one of your colleagues or employees is trying to pursue. Regulatory authorities would also want clarification of major concerns through contact with the most relevant source which, in the case of a clinical study, is often the study subjects.

Hope this information is useful.

If you need further information and/or have further questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov. Please do not respond to my personal e-mail account directly.

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: Tuesday, June 20, 2006 12:30 AM
To: OC GCP Questions
Subject: GCP Query- Urgent

Dear Sir / Madam,

Kindly let me know, if a trial monitor can ever contact a trial subject personally or telephonically, if yes, under what circumstances and if no, why?

Thanks in advance
[Redacted]