From: Toth-Allen, Jean
Sent: Thursday, September 14, 2006 2:05 PM
To: **[Redacted]**
Subject: Updating the sponsor about personnel changes

Dear **[Redacted]**:

Your inquiry was referred to us for response.

The main purpose of the Form FDA 1572 is to provide a consistent means for supplying essential information to the study sponsor about a study site while providing an agreement, once signed by the designated clinical investigator, affirming commitment to proper conduct of the study at the site in question. If changes are made with regard to individuals participating at the site during the course of the study, the sponsor needs to be informed of these changes so that information can be included in the next study progress report to FDA. It would appear that use of a revised delegation of responsibility form to update the sponsor with regard to such changes should serve such a purpose, particularly if this form adequately specifies each individual's role in the conduct of the study. There is no need to actually update the Form FDA 1572 itself.

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.

-----Original Message-----

From: **[Redacted]**
Sent: Tuesday, September 12, 2006 4:10 PM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: **[Redacted]**

E-Mail: **[Redacted]**

Comments: My question pertains to section 6 of the form 1572. At our CRO our practice is to list one sub-investigator in the initial form 1572 who will work with the Principal Investigator and who will be involved in the study. If additional sub-investigators later become involved in the study, we have the following procedure:
We issue a Delegation of the Responsibility form signed by Principal Investigator, indicating that he has authorized the other sub-investigators to be involved in the study and on the form we list those sub-investigators. We are sending the Sponsor, (together with form
1572) the Delegation of the Responsibility, informing the Sponsor of new
sub-investigators prior to his/her involvement in the study

Please comment if this Delegation of the Responsibility form is sufficient (note that this is an internal form) or do we still need to update form 1572 at the end of the study with inclusion (a revised list)
of sub-investigators who participated in the study and keep original 1572, and use our internal form to serve as interim document or bridge between original and updated form 1572.

Thanks