From: OC GCP Questions

To:

Subject: Study Title on the 1572 and Financial Disclosures

Date: Tuesday, May 12, 2015 12:43:44 PM

Good afternoon -

Please see the 1572 form guidance document below. Both forms should be legibly completed. I believe it is best to use the full name of the study to make the forms more completed accurately.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

18. How should the 1572 be completed?

The 1572 on FDA's website may be completed by typing the information directly into the fillable form and printing the completed form. Alternatively, it is acceptable to print the blank form from FDA's website and hand-write or type the information onto the form. Typed forms are preferable because they are usually more legible. The completed form must be signed and dated by the investigator (either by hand or using an acceptable electronic method).

Please see the guidance document on financial disclosure.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, 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:

Sent: Monday, May 11, 2015 4:32 PM

To: OC GCP Questions

Subject: Study Title on the 1572 and Financial Disclosures

Should the 1572 and Financial Disclosures contain the complete study title or can

"Nicknames" for the study be used on these documents.	Where is this information located?
Thank you,	