From: OC GCP Questions
To: [redacted]
Subject: Review of Financial Disclosures and 1572
Date: Wednesday, April 01, 2015 12:09:10 PM

Good afternoon –

The Form FDA 1572 (the 1572), while an official FDA form, is meant to provide full information about a study site to the study sponsor and to serve as a commitment to compliance with the investigational plan and pertinent regulations by the clinical investigator signing it. There is no requirement that the form be submitted to FDA, though most study sponsors do so, as it is a quick way to provide much of the information required for an IND. As an official agreement between the clinical investigator and the sponsor, as with most such agreements, the sponsor should keep the original form since once signed it represents a contract between the clinical investigator and the sponsor to adhere to the investigational plan and pertinent regulations.

You might find FDA's 1572 form guidance helpful. Please see the link below.
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

The sponsor should obtain the original signed document for the 1572. Per the instructions on the 1572 form, the clinical investigator is instructed to:

5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

The IRB is not required to collect the 1572 form.

Likewise the IRB is not required to collect financial disclosure information (Form FDA 3455). Please see the guidance document below.

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 if you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, March 31, 2015 11:19 AM

To: OC GCP Questions
Subject: Review of Financial Disclosures and 1572

Good Day,

I have a question regarding if there is a requirement that the IRB must collect the 1572 and Financial Disclosure of the Investigator/Sub-Investigators. Although we collect information on our submission form related to study sites where the study will be performed, we do not require the 1572. Also we have a conflict of interest policy and we require the investigator to disclose financial interests as part of the policy, however we do not require the Financial Disclosures.

Please confirm whether or not our practice of not requiring these documents as part of the IRB application is acceptable.

[redacted]