From: OC GCP Questions
To: [redacted]
Subject: FDA Site Audit- Documentation of subject compensation
Date: Wednesday, September 12, 2018 1:26:00 PM
Attachments: [redacted]

Good afternoon –

I reached out to a few of my colleagues in OGCP as well as the Office of Regulatory Affairs (ORA). ORA performs FDA inspections. Please see their answer below.

My question to ORA - During an inspection, is financial documentation for subject compensation ever reviewed or looked at? Is documentation even required?

ORA answer to my question - As part of our review of the process used by the firm to recruit subjects, we verify that the informed consent process and form is free of the possibility of coercion or undue influence. Since subject compensation could influence the subjects' decision to consent we may ask questions and/or review compensation documentation if needed and if available. However, there is no regulatory requirement for maintaining financial documentation of subject compensation.

Additionally, there is not enough information to fully answer your question. For example, what if the sponsor provides the compensation but the compensation is given to the subject by way of the clinical investigator research staff, who provides the documentation, sponsor or CI site? I wouldn't think that the sponsor would not always be present at the CI site when the financial compensation transaction takes place. You will have to have a conversation between the site and the sponsor to determine who documents the financial transaction. As stated above, there is no regulatory requirement for maintaining financial documentation of subject compensation.

Kind regards,

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

U.S. FOOD & DRUG ADMINISTRATION

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: Monday, September 10, 2018 11:57 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: RE: FDA Site Audit- Documentation of subject compensation

This is not helpful. We need to know whose responsible for maintaining the financial documentation for subject compensation where the sponsor/CRO is providing the funds for compensation.

In th situation of an investigator initiated study it seems logical that the investigator would be responsible because they would control the accounts that provide the compensation but in Sponsor/CRO initiated studies it would seem logical that the party controlling the accounts from which compensation is drawn would be the responsible party for maintaining the documentation. Can you please elaborate on how the FDA views these situations?

From: OC GCP Questions <gcpquestions@fda.hhs.gov>
Sent: Monday, September 10, 2018 9:43 AM
To: [redacted]
Subject: FDA Site Audit- Documentation of subject compensation

Good morning –

FDA recently updated (1/25/18) their Information Sheets on Payment and Reimbursement to Research Subjects. See the link below. It has valuable information.

Search for FDA Guidance Documents > Payment and Reimbursement to Research Subjects - Information Sheet

It does not outline how payments should be documented. This would be up the sponsor/site/IRB. IF a FDA inspection should occur at your site, you would want to make sure the documentation is detailed enough to demonstrate accurate payments to each subject.

As it states in the guidance, the IRB should review the payment to research subjects and the payment schedule should be set for in the informed consent document. This document should outline who is responsible for the payments. (sponsor or investigator).

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

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From: [redacted]
Sent: Thursday, September 06, 2018 2:54 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: FDA Site Audit- Documentation of subject compensation

Good Day,

I was wondering in the event of an FDA audit of a site/investigator does the FDA require the site maintain documentation of subject compensation in the form of logs or check stubs when it is the Sponsor/CRO who is providing the checks for subject compensation?

Does the FDA view that financial relationship as between the subject and the investigator or between the sponsor/CRO and the subject since the investigator has no access to the accounts from which the compensation is drawn? And what documentation, if any, is expected to be maintained at the site relative to subject compensation?

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]