From: OC GCP Questions
Sent: Friday, December 19, 2014 1:59 PM
To: [redacted]
Subject: RE: 3rd Party Vendor Question

Dear [redacted],

Your questions relating to the scenario, as written below, cannot be answered directly as written as there are many variables involved. My advisement would be for you to go directly to the IRB/EC(s) involved which has oversight of the site(s) utilizing the 3rd party vendor for specific advisement in this area.

I hope that this information is helpful.

Sincerely,

Bridget A. Foltz, MS, MT(ASCP)
Policy Analyst, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration

From: [redacted]
Sent: Monday, December 15, 2014 10:22 AM
To: OC GCP Questions
Subject: 3rd Party Vendor Question

Hi,

I have questions about a 3rd party vendor being used to help recruit study subjects.

For a few studies, we are using a 3rd party vendor who contracts with physicians (non PIs) to help refer subjects to participating study sites. These referring physicians would be compensated for their effort directly by the 3rd party vendor. The process, as I understand it, is that the physician would review their patients against publically available study information to see if that patient may qualify for the study. Then they would talk to their patient about the study and ask if they are interested and if so, the physician would call a local study site, discuss the patient and refer the patient for official screening into the study.

My questions are, would this 3rd party vendor need to be submitted to IRBs based on this process they perform? Do they need to be listed on the 1572?

Thanks!
[redacted]