From: OC GCP Questions
To: [redacted]
Subject: HIPAA violations
Date: Monday, June 27, 2016 6:26:00 AM
Attachments: [redacted]

Good morning –

Any payments and payment schedules should be reviewed by the Institutional Review Board that is responsible for the review and approval of the study at your site, to ensure that the amount(s) and the proposed method(s) of payment/timing of payments are neither coercive or present undue influence.

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

I have pasted the text of FDA's Information Sheet Guidance on this topic into this e-mail for your convenience.

Payment to Research Subjects

The Institutional Review Board (IRB) should determine that the risks to subjects are reasonable in relation to anticipated benefits [21 CFR 56.111(a)(2)] and that the consent document contains an adequate description of the study procedures [21 CFR 50.25(a)(1)] as well as the risks [21 CFR 50.25(a)(2)] and benefits [21 CFR 50.25(a)(3)]. It is not uncommon for subjects to be paid for their participation in research, especially in the early phases of investigational drug, biologic or device development. Payment to research subjects for participation in studies is not considered a benefit, it is a recruitment incentive. Financial incentives are often used when health benefits to subjects are remote or non-existent. The amount and schedule of all payments should be presented to the IRB at the time of initial review. The IRB should review both the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive or present undue influence [21 CFR 50.20].

Any credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study. Unless it creates undue inconvenience or a coercive practice, payment to subjects who withdraw from the study may be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn. For example, in a study lasting only a few days, an IRB may find it permissible to allow a single payment date at the end of the study, even to subjects who had withdrawn before that date.

While the entire payment should not be contingent upon completion of the entire study, payment of a small proportion as an incentive for completion of the study is acceptable to FDA, providing that such incentive is not coercive. The IRB should determine that the amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn. All information concerning payment, including the amount and schedule of payment(s), should be set forth in the informed consent document.

I repeat any payment to research subjects should be reviewed and approved by your IRB. You may also wish to seek guidance from your legal department at your institution on the situation you describe. From a FDA standpoint I cannot comment on the 1099 situation.

Unfortunately, I cannot advise you regarding matters concerning the Health Insurance Portability and Accountability Act (HIPAA) as HIPAA and its related statutes are under the jurisdiction of the Office for Civil Rights (OCR) and not FDA. For questions regarding issues pertaining to HIPAA, you may wish to contact OCR directly at OCRPrivacy@hhs.gov. I suggest you send your question to OCR to get their response. Here also is a link to OCR's general website for HIPAA www.hhs.gov/ocr/privacy/, and OCR also has HIPAA Frequently Asked Questions that can be accessed at www.hhs.gov/ocr/privacy/hipaa/faq/index.html

Again you may also wish to discuss your question with other in-house legal staff, including any Privacy Officer, within your sponsor organization.

You may report a complaint to FDA. Please see the link below. Also please know that the complaint is product specific.

Reporting Complaints Related to FDA-Regulated Clinical Trials

Kind regards,

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

From: [redacted]
Sent: Friday, June 24, 2016 1:01 PM
To: OC GCP Questions
Subject: HIPAA violations

I need some help with several issues of a new study.
The CRO and Sponsor have a strategic partnership. I realize that the goal with these companies are to streamline and keep cost down but I feel there is something wrong with this whole process.

They are using [redacted] (The CRO owns [redacted]) to pay the subject stipend and compensation from my site budget by reloadable cards or checks. We have to do this payment system or not get project. Subject can not do protocol unless they agree to payment terms.

[redacted] set up" Retention manager" online system that requests subject name, address, tel #, occupation and email for each subject that is enrolled!! They do not ask the SS#. I called them about payment system because I have never participated in this system. I am trying to get an answer about who gives my subjects the required 1099 that we need to do with this project. Plus why do they need this info? These subjects are not qualifying for a credit card- these are reloadable cards from my site budget. If I am doing the 1099 from my site then why is all info needed??

We have been doing research since 1995 and our most important concern is to protect the safety of subject medically and personally and that includes personal identifying information.
No where is this mentioned on the ICF nor is it IRB approved.
When I question them about who gives the 1099 to my subjects I was told it comes from [redacted] card company. [redacted] card company from [redacted] sends [redacted] card Global Master

Cards for reloadable cards to pay subjects. I was told by [redacted] that the card company gets the SS #. They will be the entity that give the 1099-- but when you look where they sign up for this card when site gives them a sealed envelope it is a site of [redacted].

Subjects are to get a reloadable MasterCard from [redacted]. Another person at [redacted] told me they get all their info. I need to be assured that this is all OK before we move forward. Do they qualify as a research entity so they get all past and present medical history? I don't feel comfortable putting a research subject in a vulnerable position. My job is to always protect the Subject.
This info is never collected by Sponsor.

All research subjects are vulnerable to a certain degree. We have to be very careful so has not to use monies as the main incentive.
It seems that the idea is to get them here then they have to agree to give personal identifying info to a marketing company and a card company in [redacted] to get paid.
They are not qualifying for a credit card so why do they have access to all info?? [redacted] is not a retention manager?? It is a recruiting site.
If they are not giving the 1099 why do they need personal information. They are not participating for research purposes.

ICF says "study information" (including all medical hx, procedures, test results can be shared with the Sponsor's consultants who are helping conduct this study (CRO and labs and affiliated companies.
We have always been upfront regarding any compensation per visit or any entity having access to their medical records. We have never not fully disclosed all in the ICF.

I think this is all BS just to get a bigger database ([redacted]) for recruiting subjects for PPD and their clients. I am worried about the implication of this whole set up.
The language acts as its up front but I am concerned that there is a privacy violation.

A HIPAA authorization, when executed, is the subject's permission for his/her identifiable health information to be used and/or "disclosed for a research purpose".

ICF should state all personal information is given to this recruitment company.

I have reached out to IRB, Sponsor and CRO and all have been dumb to the questions and said someone will get back to me. This has been going on for 2 weeks.

I need to speak with a person on this issue. Please advise if this is all ok.

I think this is a bigger problem out there in the research arena. Can you direct me to the right place.

[redacted]