From: OC GCP Questions
To: [redacted]
Subject: OFICIAL IDENTIFICATION FOR CLINICAL SUBJECTS
Date: Monday, February 23, 2015 2:00:31 PM

Good afternoon –

There should be adequate provisions in place to protect the privacy of subjects and to maintain the confidentiality of data. Note that neither the regulations or even guidance do not specifically address the methods used to maintain the confidentiality of records identifying the subject nor do they prohibit sponsors/CROs from receiving subject information, even with identifiers. Typically, study sponsors, CROs, and sites usually follow their own Standard Operating Procedures (SOPs) that direct document handling and maintaining confidentiality.

You might be interested in FDA's guidance document on Protecting the Rights, Safety, and Welfare of Study Subjects. Link below.
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.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

From: [redacted]
Sent: Friday, February 20, 2015 5:28 PM
To: OC GCP Questions
Subject: OFICIAL IDENTIFICATION FOR CLINICAL SUBJECTS

Dear GCP experts:

One of the study sites for which I work for; commented to me that they were requested by the sponsor to obtain a copy of the official identification for all the subjects that are included into the study. The site is not comfortable because it will make easy for the CRAs to identify the study subjects while they are waiting at the living room.

Do you in USA request something similar? Do you think this request is against subject's rights?

Thanks in advance

[redacted]