From: OC GCP Questions
To: [redacted]
Subject: 1572 Form Completion
Date: Wednesday, July 20, 2016 2:26:00 PM

Good afternoon –

There is no FDA requirement that the addresses of testing facilities be included in the informed consent document. However the procedures being performed during the research need to be explained in the IC. Please see the link below for basic elements of informed consent.

CFR - Code of Federal Regulations Title 21

That said there are no specific FDA regulatory requirements regarding documentation that needs to be maintained for an imaging center that will be used to perform protocol procedures. If an imaging facility is being used for the study, the name and address for the facility should be documented in the study files. This can best be accomplished by identifying the name and address of the facility in the Form FDA-1572 in blocks 3 or 4.

Also please see the FDA 1572 guidance link below.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.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: Wednesday, July 20, 2016 8:34 AM
To: OC GCP Questions
Subject: 1572 Form Completion

Hello,

I was hoping you can clarify requirements regarding the 1572. Do all addresses listed under section 3 where patients will physically be including imaging centers need to be listed on the IRB approval documents and on the final approved ICF? I am working with sites that are unsure about this requirement, in a lot of cases the addresses they have provided under section 3 are imaging centers that they have contracted out. In that scenario, they don't want to include those addresses on their

approval documents. Can you please confirm/clarify what the requirements are for section 3 (patients seen addresses)?

Regards,

[redacted]

[redacted]

[redacted]