From: OC GCP Questions
To: [redacted]
Subject: question
Date: Friday, October 24, 2014 11:48:35 AM

Good morning –

FDA does not post the completed 1572 forms. Many individuals do not realize that one of the main purposes of the 1572 is to provide the sponsor with advance information about the clinical site(s) where the research will take place, the investigator's qualifications, and information about other facilities that will be performing protocol required tests. Providing this information to the sponsor allows the sponsor to establish and document that the investigator and site are qualified to conduct the study. The other main purpose of completing the 1572 is to obtain the investigator's commitment to comply with FDA's regulations for conducting the clinical investigation. Although it is not required, many sponsors commonly submit a copy of the 1572 to FDA for IND studies as the information it contains is required for an IND application. The 1572 is meant to supply site-specific information to the sponsor. The IND application is considered confidential.

Please see link below for guidance on the 1572 form.

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 comments.

Kind regards,

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

From: [redacted]
Sent: Thursday, October 23, 2014 3:31 PM
To: OC GCP Questions
Subject: question

Hello. I was told there is a link on the fda website, or perhaps elsewhere, where we could find out which physician's have filed 1572's recently. If this is indeed true, can you share the link with me? Thank you!
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