

From: OC GCP Questions
To: [REDACTED]
Subject: FDA Form 1572
Date: Friday, June 10, 2016 11:56:00 AM
Attachments: [REDACTED]

Good morning -

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.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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Office of Good Clinical Practice
Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----

From: [REDACTED]
Sent: Thursday, June 09, 2016 7:08 PM
To: OC GCP Questions
Subject: FDA Form 1572

*What is the purpose of the Financial Disclosure FDA 1572 Form ?