From: OC GCP Questions
To: [redacted]
Subject: FDA Forms 1572, 3454 and 3455
Date: Thursday, January 19, 2017 8:27:00 AM
Attachments: [redacted]

Good morning –

FDA expects laboratories that are used to do clinical testing associated with clinical trials to be qualified to perform the testing involved. In the US that usually means CLIA certification. It is also possible that an individual (possibly at a research institute or academia) is the only qualified laboratory for a highly-specialized study. In the latter case, this would be spelled out in the IND/IDE and so conditions of validation will be worked out ahead of time. For drug and biologics studies, it is required to list laboratories and other diagnostic centers on the 1572 so the study sponsor knows which was used should discrepancies across study sites appear in the data. This allows the sponsor to follow-up on the discrepant laboratories. It would be at that time that the credentials of the facility and/or essential personnel would be requested if it appears that a laboratory's results could be inaccurate. There is no requirement - or suggestion in guidance - that I am aware of that requires collection of this information under ordinary circumstances, however. Nevertheless, it is the purview of a study sponsor to request such information upfront if they so choose. If a specific test is highly specialized, the sponsor may want to be assured beforehand that the laboratories used across the study are indeed qualified.

Please see FDA's financial disclosure guidance.
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf specifically page 2 section III. It appears that these forms would need to be completed. The applicant (who is often--but not always--the same as the sponsor of a covered study) submits to FDA a Form FDA 3455 to disclose financial interests and arrangements, or a Form FDA 3454 to certify to the absence of any financial interests and arrangements.
The Form FDA 3454 is used to certify that there are no reportable financial interests or arrangements.

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For a sponsor-investigator, he would have to collect the information about his own financial interests or certify that there are not any financial interests to report.

He should report any equity interests in the manufacturer of the drug product used in the study, regardless of whether the manufacturer provides the supplies of the drug or the investigator obtains the study drug from a retail source. The reason for this is that the manufacturer or the sponsor-investigator himself may later decide to submit the study in support of an application. Whoever is the "applicant" needs to include the financial disclosure information when the application is submitted

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

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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.

From: [redacted]
Sent: Wednesday, January 18, 2017 11:34 AM
To: OC GCP Questions
Subject: FDA Forms 1572, 3454 and 3455

Hello,
I have the search published FDA guidance documents and could not find answers for the following questions:

FDA Form 1572: If a lab is performing standard of care clinical care labs that are being used for safety and efficacy assessments in a research protocol, does that laboratory need to be listed on the FDA Form 1572, and the CLIA, CAP, lab normal and lab Director CV be obtained for the regulatory binder?

FDA Forms 3454 and 3455: For a sponsor-investigator study under an IND, where the sponsor-investigator manufactures the investigational product and the sponsor is NCI/NIH, do Forms 3454 and 3455 need to be completed? As a caveat, if the compound shows success, there may be plans to partner with a biotech firm in the future.

Thank you for your guidance.
[redacted]

[redacted]

[redacted]