From: OC GCP Questions
Sent: Friday, January 09, 2015 1:21 PM
To: [redacted]
Subject: Question about financial disclosure form Investigators

Good afternoon --
FDA's guidance on the 1572 form http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf states --

7. When must a 1572 be updated or a new 1572 completed and signed by an investigator to reflect new or changed information?
There are two instances when it is necessary for an investigator to complete and sign a new 1572: when an investigator is participating in a new protocol that has been added to the IND and when a new investigator is added to the study (21 CFR 312.53(c)).
If there are other changes to information contained on a signed and dated 1572 (e.g., an IRB address change, the addition of new subinvestigators, the addition of a clinical research lab), the investigator should document the changes in the clinical study records and inform the sponsor of these changes, so that the sponsor can appropriately update the IND. The 1572 itself does not need to be revised and a new 1572 need not be completed and signed by the investigator. The sponsor can accumulate certain changes and submit this information to the IND in, for example, an information amendment or a protocol amendment.

However if you are still unsure if a new FDA form 1572 needs to be collected/submitted please contact the FDA review division that is overseeing your IND.

For studies that are conducted under an IND, the regulations require the clinical investigator (CI) at the study site to complete and sign a Form FDA 1572 even if it is a foreign site. It spells out the obligations of the CI under 21 CFR 312 and, once signed, becomes a contract to abide by the protocol and applicable regulations.

You may wish to review FDA's guidance document on determining whether human research can be conducted without an IND. Please see the link below.

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.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, January 09, 2015 12:12 PM
To: OC GCP Questions
Subject: Re: Question about financial disclosure form Investigators

Dear Doreen,
I really appreciated the response that you provided last year regarding completion of the 3454 and 3455. I have 2 additional questions for you.

1. We are in the process of collecting updated 1572s for a study which was submitted to the FDA as an amendment but involves a significant protocol title change. In this situation, is it still not required to collect updated 1572 from sites?
2. We have a study ongoing in Europe and have collected 1572s for most countries. I just wanted to check with you if there is an exception for Germany to not submit 1572s. They claim a local law permits them to not submit 1572s.

Thank you for all your help!

Warm regards,
[redacted]