From: OC GCP Questions
To: [redacted]
Subject: Investigator Initiated study
Date: Tuesday, July 22, 2014 10:09:25 AM

Good morning –

FDA refers to individuals who initiate clinical trials as sponsor-investigators. As that term implies, they are considered the sponsor and the investigator for the study and thus are responsible for complying with regulations pertinent to both entities. As a sponsor, they would be responsible for obtaining the IND/IDE when necessary, obtaining Form FDA 1572s or investigator agreements for any other investigators who choose to participate in the study, ensuring IRB approval prior to initiate of the study across all sites, submitting progress reports and other required reports to FDA, etc. A 1572 form will need to be signed.

Please see the link below to the 1572 guidance document.
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

I hope this information was helpful. Please contact us at gcp.questions@fda.hhs.gov if you have further questions.

Kind regards,

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

From: [redacted]
Sent: Monday, July 21, 2014 5:41 PM
To: OC GCP Questions
Subject: Investigator Initiated study

Dear Sirs,
My office is considering conducting an Investigator Initiated study. The compound will be registered with an IND. I have never heard of an Investigator Initiated study needing a 1572. Does this change because we will be getting/holding an IND?

Thank you for your assistance.
Sincerely,

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