From: OC GCP Questions
To: [redacted]
Subject: Guidance for Sponsor- Investigators of INDs
Date: Thursday, September 17, 2015 7:39:39 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

Please also see the links below to the regulations.
CFR - Code of Federal Regulations Title 21
CFR - Code of Federal Regulations Title 21
CFR - Code of Federal Regulations Title 21

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

Kind regards,

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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.

From: [redacted]
Sent: Wednesday, September 16, 2015 2:18 PM
To: OC GCP Questions
Subject: Guidance for Sponsor- Investigators of INDs

Hello Sir/ Madam: Can you provide guidance on the responsibilities of a Sponsor- Investigator of an IND? We would like to develop a policy and procedure for our research community. Thank you for your guidance.

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