From: OC GCP Questions
To: [redacted]
Subject: Investigator Initiated Study
Date: Tuesday, April 28, 2015 11:03:22 AM

Good morning –

Although you say our study is exempt from IND regulations, FDA refers to individuals who initiate clinical trials as sponsor-investigators (Investigator-initiated study}. 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, April 27, 2015 1:26 PM
To: OC GCP Questions
Subject: Investigator Initiated Study

Good Afternoon:

My office is considering conducting an Investigator Initiated study. The study meets all of the requirements for exemption from the IND regulations and, therefore, an IND is not required to conduct the investigation as granted by the FDA in July 2013.

Are there any guidelines, responsibilities, and/or regulations that specifically pertain to Investigator Initiated trials. Given our lack of experience in this area I would like to gather as much information as possible so that we may make an informed decision.

Regards,
[redacted]