From: OC GCP Questions
To: [redacted]
Subject: Question regarding Registry study
Date: Wednesday, March 29, 2017 11:56:00 AM
Attachments: [redacted]

Good morning –

It is unclear whether a post marketing observational study meets FDA's definition of a clinical investigation. If the study is under an IND, a 1572 would need to be signed by the clinical investigator. I am not sure that the subjects would need to be transferred to the clinical investigator.

The term "observational study" can be used for a broad range of studies. Some drug registry/observational studies may be considered clinical investigations and may be subject to FDA regulation under the investigational new drug application (IND) regulations (21 CFR part 312) if conducted in the U.S.

Additionally what someone means by a registry study can vary so it difficult to specifically answer your question. In addition, the purpose of the study will also determine if it is an FDA-regulated study. An example of an FDA-regulated registry study is one conducted to fulfill a condition for marketing approval. This is particularly true for certain medical devices. If a study is FDA-regulated, IRB review and approval and subject informed consent are required.

If the study is under IND you can always contact the regulatory project manager at FDA for guidance.

If I have not adequately answered your question, please contact the Center for Drugs (CDER) at druginfo@fda.hhs.gov

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Wednesday, March 29, 2017 8:34 AM
To: OC GCP Questions
Subject: Question regarding Registry study

Good Afternoon,

A site is participating in a post marketing observational study and they would like to enroll patients that are seen by other physicians in the

same clinic with the same database who are not listed on the 1572. My understanding is that if they are not under the care of the PI that is listed on the 1572 they would either need to be transferred under the care of the PI or their physician would need to agree to participate as a sub investigator. However since this is an observational study can you please confirm?

Thank you!