From: OC GCP Questions
To: [redacted]
Subject: Question regarding Registry study
Date: Thursday, April 13, 2017 12:22:00 PM
Attachments: [redacted]
Sensitivity: Confidential

Good morning –

The patient can stay with the patient's regular physician for patient care (practice of medicine). For study related activities the subject would need to receive this care from the CI. Generally communication between the two physicians takes place. This scenario and others would be outlined in the ICD and the protocol.

Please see FDA's guidance document about IRBs. Search for FDA Guidance Documents > Institutional Review Boards Frequently Asked Questions - Information Sheet It states --

51. Must informed consent documents be translated into the written language native to study subjects who do not understand English?

The signed informed consent document is the written record of the consent interview. Study subjects are given a copy of the consent to be used as a reference document to reinforce their understanding of the study and, if desired, to consult with their physician or family members about the study.

The relationship between patient-physician is different than between subject-investigator.

Kind regards,

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

FDA U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Wednesday, April 12, 2017 7:21 PM
To: OC GCP Questions; CDER DRUG INFO
Cc: [redacted]
Subject: RE: Question regarding Registry study
Sensitivity: Confidential

Thank you for your response. For further clarification this is a post marketing safety study to assess long term safety and tolerability of a drug which was mandated by FDA. It is being conducted both in the US and ex US. Investigators are required to complete a 1572 and patients

are required to consent. The question is whether or not the patient would need to transfer under the care of the PI listed on the 1572 or if it is okay for them to remain under the care of the other physician (who is not listed as PI or Sub I on the 1572).

[redacted]

From: OC GCP Questions [mailto:gcp.questions@fda.hhs.gov]
Sent: Wednesday, March 29, 2017 11:57 AM
To: [redacted]
Subject: Question regarding Registry study
Sensitivity: Confidential

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
Senior Health Policy Analyst
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!