From: OC GCP Questions
To: [redacted]
Subject: Urgent question
Date: Tuesday, November 10, 2015 11:37:43 AM

Good morning--

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 registry study will support a research or marketing application or submission, it could be required to register on ClinicalTrials.gov. Please note, it is more likely that a medical device study conducted as a registry study could support an application or submission than a drug or biologics registry study. This is due to the fact that investigational new drugs and biologics require controlled clinical trials to support marketing and what is generally understood as a registry study would not meet that requirement.

What FDA requires is contained in our regulations, that is in Title 21, Code of Federal Regulations (21 CFR). ICH E6 is official FDA guidance but it is just guidance for FDA-regulated studies. What is required for the conduct of the study is found in the regulations for the particular product type. If a study is FDA-regulated, IRB review and approval and subject informed consent, as described in 21 CFR parts 56 and 50 respectively, are required.

One of FDA's basic required elements of informed consent under 21 CFR 50.25(a) is as follows:

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. [21 CFR 50.25(a)(4)]

FDA's Guide to Informed Consent (http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm) states the following on this requirement:

To enable a rational choice about participating in the research study, subjects should be aware of the full range of options available to them. Consent documents should briefly explain any pertinent alternatives to entering the study including, when appropriate, the alternative of supportive care with no additional disease-directed therapy. While this should be more than just a list of alternatives, a full risk/benefit explanation of alternatives may not be appropriate to include in the written document. The person(s) obtaining the subjects' consent, however, should be able to discuss available alternatives and answer questions that the subject may raise about them. As with other required elements, the consent document should contain sufficient information to ensure an informed decision.

If you are still unsure if your registry study requires IC and IRB oversight, you can always consult your reviewing IRB and/or institutional research officials

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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Office of the Commissioner, FDA

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: Monday, November 09, 2015 2:41 PM
To: OC GCP Questions
Subject: Urgent question

Can you clarify if ICF and IRB regulations apply to non-interventional trials, that are not conducted under an IND.
Examples would be registry trials etc.)

Thank you

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