From: OC GCP Questions
To: [redacted]
Cc: CDRH Small Manu. Assistance
Subject: Chart Review Question
Date: Thursday, October 18, 2018 9:16:02 AM
Attachments: [redacted]

Good morning –

Somehow your email was forward to the Good Clinical Practice Office.

Generally speaking, there are no FDA regulations that specifically speak to studies that involve chart reviews. If the results of such a study are for submission to FDA to support a change to conditions of approval for an approved medical product (medical device), e.g., to support a labeling change, it could be considered an FDA-regulated study regardless of whether the study design is prospective or retrospective. If the study will not support an application to FDA, as you describe, it is not likely to be an FDA-regulated study.

Your description of the study raises some questions about the proposed study, particularly the fact that the investigators may be prospectively studying the safety and effectiveness of an approved product. Consideration may need to be given as to whether the study is looking at the product's approved indication and how the investigators intend to use the data.

This CDRH web page might be helpful to you. Search for FDA Guidance Documents > Devices Guidances

Since you sent your first email to the Center for Devices (CDRH) at DICE@fda.hhs.gov it is probably best to wait for a response from them as your email mentions medical devices and the 812 regulations.

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

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: noreply@salesforce.com <noreply@salesforce.com> **On Behalf Of** DICE
Sent: Wednesday, October 17, 2018 3:18 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: FW: Chart Review Question

---------- Original Message ----------
From: [redacted]
Sent: 10/17/2018 3:08 PM
To: dice@fda.hhs.gov
Subject: Chart Review Question

To whom it may concern:

I'm writing for guidance on the applicability of FDA regulations to retrospective chart reviews of FDA regulated devices.

I know that investigation is defined by 21 CFR 812.3(h) as "a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device" and subject is defined as "a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is sued or as a control…..".

45 CFR 46 defines human subject as "a living individual about whom an investigator (whether professional or study) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

It's unclear to me if reviewing the chart of an individual that received an investigational device meets the 21 CFR 812 definition of subject.

Often the proposals for chart reviews will state as an objective that the investigator intends to evaluate the effectiveness of (at times) an investigational device. The procedures describe chart review procedures (i.e. reviewing records for specific data points) and the procedures relating to the use of the device itself are briefly described as clinical procedures.

Do FDA regulations apply to these types of chart review studies?

Thank you,
[redacted]

[redacted]

[redacted]

[redacted]