From: OC GCP Questions
To: [redacted]
Subject: Potential Clinical trial question
Date: Friday, December 07, 2018 12:45:59 PM

Good afternoon –

A "claim extension study" is not defined in FDA regulations. It is best to reach out to the Center for Devices (CDRH). See the information below.

For specific questions about a device study, you should contact the CDRH per the information provided in the guidance (link below), Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff, which can be found at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm311176.pdf

You may also contact CDRH at DICE@fda.hhs.gov
Phone: 1-800-638-2041
Phone: 301-796-7100
Fax: 301-847-8149

Kind regards,

The OGCP Group

-----Original Message-----
From: [redacted]
Sent: Thursday, December 06, 2018 10:34 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Potential Clinical trial question

I work for a sponsor that wants to perform a claim extension study on one of our devices. We have found a site that uses our device/test routinely and proposed that we would simply obtain a copy of the routine test results for our study (following informed consent of course) rather than requiring an additional blood draw specifically for our study and performing the additional test. The area that we are concerned about is that the site is actually performing the test off label (hence the purpose of the claim extension study). We are trying to be proactive to ensure that we perform our study with the highest of standards and are concerned that if we obtained a copy of the test results and determined a potential issue with the sample when we analyzed the data, we would then have an obligation to inform the PI of the concern. We are also concerned that if we conducted a study knowing a test result was being used off-label this may also potentially present a problem. What are your thoughts on this situation? Any feedback you could provide would be much appreciated.

Kind regards,

[redacted]