From: OC GCP Questions
To: [redacted]
Subject: RE: Essential documents
Date: Monday, July 20, 2015 4:23 00 PM

Dear [redacted] -

Thank you for your question. I do not have any insight for you about why the ICH GCP E6 requirement at 8.4.7 does not include sponsor notification of the site's closeout with the IRB, where such a report is required.

As a sponsor, you are free to have Standard Operating Procedures (SOPs) that require your investigators to notify you, the sponsor, of their notification of study closeout to their respective IRB and any subsequent IRB confirmation/notification. If you choose to do that, you will need to ensure that all of your investigators are aware of your sponsor SOPs and are given information on how to comply.

As I'm sure you are aware, the IND and IDE regulations have requirements for final reports from investigators to sponsors – see the following regulations:

1. 21 CFR 312.64(c) (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.64)

> Subpart D--Responsibilities of Sponsors and Investigators
>
> Sec. 312.64 Investigator reports.
>
> (c) *Final report* An investigator shall provide the sponsor with an adequate report shortly after completion of the investigator's participation in the investigation.

2. 21 CFR 812.150(a)(6) (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.150)

> Subpart G--Records and Reports
>
> Sec. 812.150 Reports.
>
> (a) *Investigator reports* An investigator shall prepare and submit the following complete, accurate, and timely reports:
>
> (6) *Final report* An investigator shall, within 3 months after termination or completion of the investigation or the investigator's part of the investigation, submit a final report to the sponsor and the reviewing IRB.

FDA provides a suggested content for investigator final reports for medical devices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046717.htm#invann

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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From: [redacted]
Sent: Friday, July 17, 2015 11:09 AM
To: OC GCP Questions
Subject: Essential documents

Dear GCP questions,

Can you possible shed some light on why there is no requirement for site to provide IRB closeout confirmation/notification to sponsor? ICH/GCP 8.4.7. only documents final report by investigator/site to IRB of completion of trial. There is no subsequent required notification (e.g. 8.4.7a) that site is actually closed… IRB's do generate this though.

Thank you,

[redacted]