From: OC GCP Questions
To: [redacted]
Subject: RE: Investigator site file-blank copies of case report forms
Date: Tuesday, October 10, 2017 3:32:54 PM
Attachments: [redacted]

Dear [redacted] -

Thank you for your question. The regulations at 21 CFR 312 subpart D address the responsibilities of sponsors and investigators for drug and biologic studies being conducted under an Investigational New Drug (IND) Application. The regulations at 312.62 specifically address investigator recordkeeping and record retention – see https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.62. 312.62(b) addresses the requirement for investigators to keep adequate and accurate case histories, which includes case report forms and supporting data.

The ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance – see http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf) addresses the essential documents for the conduct of a clinical trial in section 8, and includes mention of signed, dated and completed case report forms. There are other FDA guidance documents that mention case report forms, however, I am not aware of any regulation or guidance that specifically requires an investigator site to maintain a blank copy of the case report forms for each protocol. However, this may be a requirement of the site or the sponsor, so you should discuss with the appropriate representatives at your site, and any sponsor(s) you are working with. When the regulations and guidance are silent, investigators, sites, sponsors, CROs, institutions, and IRBs are free to develop their own procedures and practices as long as applicable regulatory requirements are met.

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
Policy Analyst

Office of the Commissioner
Office of Good Clinical Practice
U.S. Food and Drug Administration

From: [redacted]
Sent: Thursday, October 05, 2017 2:51 PM
To: OC GCP Questions
Subject: Investigator site file-blank copies of case report forms

Hello,
Is there a guidance or regulation specifying that investigator sites should maintain a blank copy of the case report forms for each protocol?
Thanks,
[redacted]