From: OC GCP Questions
To: [redacted]
Subject: Filing of SIV Report at Investigator Site
Date: Friday, November 07, 2014 11:25:53 AM

Good morning –

FDA regulations pertaining to recordkeeping practices for clinical trial records are fairly general. The regulations do not specifically address the situation in your email. I am unclear why you would want to send a letter to the sponsor rather than just provided the SIV report. It seems this would duplicate work. That said, when the regulations are silent, sites and institutions can develop their own standard operating procedures for addressing a specific situation or issue.

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

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Friday, November 07, 2014 9:37 AM
To: OC GCP Questions
Subject: Filing of SIV Report at Investigator Site

Dear GCP questions,

ICH GCP E6 requires that the SIV be filed at the investigator site. In your opinion would a follow-up letter that provides the required information satisfy this requirement or does the report that is filed with the Sponsor have to exactly match the report that is filed with the Investigator.

Kind regards,

[redacted]