From: OC GCP Questions
To: [redacted]
Subject: Source document worksheets created by sponsor
Date: Monday, May 14, 2018 8:04:00 AM
Attachments: [redacted]

Good morning –

FDA's regulations do not address how initial study data, that is, source data, are collected. Sponsors are not prohibited from providing a specialized form (worksheets) for use in the study on which information is directly entered.

There may be some pros and cons to the use of sponsor provided worksheets. Most sites have their own documents they routinely use to capture medical information regarding patients treated there. The site personnel are familiar with these forms and are more likely to capture pertinent data in an effective, efficient manner using their own forms. However, in studies where specialized testing or questionnaires are employed, there may be a benefit to using specific forms to capture this information. When sponsor worksheets are used, training of site personnel in the use of the worksheets may be necessary. SOPs may also be needed to ensure that the subject's case histories and medical records are accurate and complete (for example, by ensuring a copy of the worksheet in included in the subject's medical records).

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

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, 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: [redacted]
Sent: Thursday, May 10, 2018 1:38 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Source document worksheets created by sponsor

Hi,

Would you please let me know whether source document worksheets created by the sponsor that mirror the eCRF are permissible? These source document worksheets are paper documents provided to sites to capture study information. Is this an acceptable way to document study activity in place of record keeping in a Medical record, shadow file or other traditional methods which require sign off by the PI or medical staff. In the past, it was common to see these worksheets

however now this practice is frowned upon. Is that correct?

Thank you in advance for your help.

Kind regards,

[redacted]

[redacted]