From: OC GCP Questions
To: [redacted]
Subject: Sponsor can utilize other company/CRO sop to conduct clinical trial
Date: Thursday, June 21, 2018 7:30:00 AM
Attachments: [redacted]

Good morning –

FDA regulations do not specifically address your question. If you are using information (documents/forms) from another company, I assume you have permission to do so from that organization and the forms are pertinent to your particular study. This is not a question that FDA can specifically answer. I suggest you consult your legal experts at your institution.

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, June 21, 2018 1:43 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Sponsor can utilize other company/CRO sop to conduct clinical trial

Hi,

Good morning..!

Please provide clarification of below questions for FDA submission clinical trial.

1. Can sponsor utilize the another company/CRO SOPs, forms and logs to fulfill sponsor responsibility (i.e., selection of investigator, monitoring). If yes, then is there any written documents required for same? or mutual agreement between both parties and training person who performing activities ofhat SOPs, forms and log is acceptable.

Thank you.

Regards
[redacted]