From: OC GCP Questions
To: [redacted]
Subject: GCP Audit Checklist
Date: Wednesday, February 28, 2018 8:38:00 AM
Attachments: [redacted]

Good morning –

This office does not have a GCP checklist. I have added a few links below to documents that might be helpful to you.

Clinical Trials and Human Subject Protection > Bioresearch Monitoring Program (BIMO)

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf

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: Tuesday, February 27, 2018 12:44 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: GCP Audit Checklist

Hi,

Can you send me the link or the document that we could use to audit our company against the GCP.

Thank you.

Sincerely,

[redacted]