

From: [OC GCP Questions](#)
To: [redacted]
Subject: FDA website info
Date: Monday, October 20, 2014 2:13:14 PM

Good afternoon –

All guidance and information sheets can be found on our website including the past query answers. Please see the links to the left of the page. (Guidance documents – Including information sheets and notices and Replies to inquiries to FDA on good clinical practice).

[Clinical Trials and Human Subject Protection](#)

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

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: Saturday, October 18, 2014 9:42 AM
To: OC GCP Questions
Subject: FDA website info

To Whom It May Concern:

I'm in the process of writing an article that references the FDA GCP question department. With that, can you confirm and/or provide a link on the FDA website that houses past GCP questions posed via your GCP question email?

Also, can you advise if hard copies of the FDA Information Sheet Guidances (updated as of April 1, 2009) are still available to industry members and, if so, how they can request a copy. I'm referring to the FDA Information Sheet Guidances version that was originally published in 1984 as the FDA Information Sheets and included topics such as Frequently Asked Questions, Guide to Informed Consent, Recruiting Study Subjects, Pre-Study Screening Tests, Drug Study Designs, etc.

Thanks for any assistance you can provide.

Regards,

[redacted]