

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: GCP
Date: Thursday, October 09, 2014 2:02:18 PM

Good afternoon --

Adherence to the principles of good clinical practices (GCPs), including adequate human subject protection (HSP) is universally recognized as a **critical requirement to the conduct of research involving human subjects**. Many countries have adopted GCP principles as laws and/or regulations. The Food and Drug Administration's (FDA's) regulations for the conduct of clinical trials, which have been in effect since the 1970s, address both GCP and HSP.

Please see links to GCP guidances and FDA regulations.

[Clinical Trials and Human Subject Protection > Regulations](#)

[Guidance Documents \(Including Information Sheets\) and Notices > Selected FDA GCP/Clinical Trial Guidance Documents](#)

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf>

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

Kind regards,

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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: GYXUWHXQ
Sent: Wednesday, October 08, 2014 3:05 PM
To: OC GCP Questions
Subject: GCP

Hello,

I have a question regarding the Good Clinical Practice. Is it a requirement towards FDA? Thank you in advance.

GYXUWHXQ