

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Question about the definition of CI vs. PI  
**Date:** Wednesday, July 30, 2014 12:33:12 PM

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Good afternoon –

FDA does not use the term principal investigator (PI). FDA regulations 21 CFR 312.3 defines an investigator ...

*Investigator means an individual who actually conducts a clinical investigation (i.e. , under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. "Subinvestigator" includes any other individual member of that team.*

Generally FDA will use the term clinical investigator or investigator interchangeably. Outside of FDA, the term PI is used often.

I hope this information is helpful. Please contact us again at [gcp.questions@fda.hhs.gov](mailto: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:** [redacted]  
**Sent:** Tuesday, July 29, 2014 9:29 PM  
**To:** OC GCP Questions  
**Subject:** Question about the definition of CI vs. PI

Hello. I'm working on some internal documents for our clinical department and am trying to locate the definition of "CI" vs. "PI" so I can be both accurate and consistent throughout them.

It seems to me that FDA is using the terminology CI these days (vs. PI), although the IDE definitions only contain a definition for the term "investigator". Recent draft and final FDA guidances as well as the BIMO manuals reference clinical investigator, even when discussing oversight responsibilities (delegating tasks to other qualified staff). (NIH may have its definitions for PI, although we are in the FDA regulated device arena.) (The only document in which I can locate an actual relatively recent definition of PI is ISO 14155:2011.)

So, for consistency's sake, can you tell me if FDA has a preferred term for the individual responsible for overseeing study activities at a site and what the definitional differences are

(if any) between CI and PI?

Thank you!

[redacted]