

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: PI wants to resign from a SMO because of noncompliance
Date: Monday, May 04, 2015 10:44:04 AM

Good morning –

A clinical investigator (PI) can resign at any time. The sponsor or SMO would need to find another clinical investigator to take over the study and follow-up with the study subjects. If the study is under IND, the new clinical investigator will need to sign a 1572 form.

I hope this information is helpful.

Kind regards,

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From: [REDACTED]
Sent: Thursday, April 30, 2015 10:09 AM
To: OC GCP Questions
Subject: PI wants to resign from a SMO because of noncompliance

Dear FDA:

I am coaching to a junior PI.

He has an issue: He was invited to collaborate in a SMO as PI for an specific clinical protocol phase III, and he was expected to attend the study for a couple of hours during the week. The PI signed contract with the SMO but not with the Sponsor (because the economical arrangement is between the SMO-Sponsor). The study is already starting but the PI has faced several issues of no compliance:

- The SMO staff uses to perform activities no delegated at the Delegation Log.
- The staff do not follow up PI's directions even he performs meetings.
- The SMO is not aware about PI's authority at IRB and MoH the consider him one more employee that have to follow up SMOs directions.
- The SMO schedule subjects visits when is impossible for the PI to attend to this SMO
- The staff is not aware about the Protocol nor the GCPs even they received training.
- The PI has the feeling that this SMO could perform misconducts at his back and at the end of the day he is the responsible of this protocol at IRB and Mexico's MoH.

This PI resigned but the Sponsor is not accepting the resignation and wants the PI working 4 months more until they find another PI and the MoH approves the next.

I recommended to PI to perform a final meeting with the SMO and resign, but I would like to know if is allowed by GCP/ICH.

Is it acceptable for a PI to abruptly resign from a SMO?

Regards

[REDACTED]