From: OC GCP Questions
Sent: Thursday, July 10, 2014 10:04 AM
To: [redacted]
Subject: RE: co-PI FDA 1572

Dear [redacted],

FDA's regulations do not define a co-investigator, only an investigator (clinical investigator – CI) and subinvestigator. If the interventional radiologist is not taking a primary role in the study (where he/she conducts all essential aspects of the study for at least some study subjects) but instead only a supportive role, he/she should be designated a subinvestigator and listed in section 6 of the Form FDA 1572 (1572). If the interventional radiologist will be conducting all essential aspects of the study for at least some study subjects, then he/she should be designated a CI for the study and would then need to complete and sign a separate 1572. For the latter scenario, it would still be possible for both CIs to work together to support each other with the conduct of the study, for example doing follow-up visits for subjects that are designated as the subjects of the other CI. If they are both CIs and do choose to support each other in the conduct of the study, they should each name the other as a subinvestigator for their study on their respective 1572s so the study sponsor is aware of their mutually supportive roles. We would also expect them to list as their specific study subjects those subjects for whom they conducted most of the essential study aspects.

Hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Sincerely yours,

Jean Toth-Allen, Ph.D.
Office of Good Clinical Practice
Office of the Commissioner, US FDA

From: [redacted]
Sent: Thursday, July 10, 2014 8:44 AM
To: OC GCP Questions
Subject: co-PI FDA 1572

Hi I am Coordinating a study with an IND (ώNŜŘI·ŎűŜŘ). The Principal investigator of the study has an FDA1572 on file and a
NCI number . We have listed an interventional radiologist as a co-pi on our roster to perform
Chemoembolizations (with ώNŜŘI·ŎűŜŘ) . Does the interventional radiologist need
To complete the FDA1572 form, too? Thanks, ώNŜŘI·ŎűŜŘ6