From: OC GCP Questions
Sent: Thursday, April 17, 2014 10:07 AM
To: [redacted]
Subject: RE: question: definition of an investigator in a clinical trial

Dear [Redacted],

Please see below for information that should be helpful to you.

Investigator:
In FDA regulations, an "*investigator* means an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team" (21 CFR 50.3(d)). (See, also, the definition of "investigator" in 21 CFR 56.102(h)).

For additional information about investigator responsibilities under FDA regulations, please see the Guidance for Industry "Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects", (October 2009), at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf. Also, see the Guidance for Industry "E6 Good Clinical Practice: Consolidated Guidance" (ICH E6) that includes a section on the investigator (see section 4. Investigator, page 13, at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf).

The term "principal investigator" is used in the Form FDA 1572 when referring to the investigator. See Statement of Investigator, section 1, at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074728.pdf. For guidance about the Form FDA 1572, see "Frequently Asked Questions – Statement of Investigator (Form FDA 1572)", May 2010, at http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm214282.pdf.

Co-Investigator:
The term co-investigator commonly means an investigator performing the same tasks in a clinical study as the individual who is designated the clinical investigator. The coordinating investigator defined in the ICH E6 guidance is a different person and is not referenced as a co-investigator for this reason.

FDA regulations do not include the term co-investigator. The person who signs the Form FDA 1572 for drug (including biologics) studies, or the investigator agreement for device studies, is considered the clinical investigator. FDA prefers that an individual who would be a co-investigator sign a Form FDA 1572 or investigator agreement and be designated as a clinical investigator for the study.

Subinvestigator:
A subinvestigator is defined in the investigational new drug (IND) regulations (21 CFR Part 312) at the end of the definition of an investigator (21 CFR 312.3(b)) to mean "any other individual member of that team". While a subinvestigator is not defined in the investigational device exemption (IDE) regulations (21 CFR Part 812), FDA considers any study site team member who plays a significant role in the conduct of a clinical study regulated by FDA to fit that definition. This is reflected in the financial disclosure

regulations for clinical investigators found in 21 CFR Part 54, which applies to all FDA-regulated clinical studies with human subjects. (For additional information about 21 CFR Part 54, see the February 2013 guidance document, "Financial Disclosure by Clinical Investigators", at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf).

Your description of the physician in your email does not fit into the definition of "investigator" in FDA's regulations. Rather, the physician appears to be a contributing scientist or contributing physician.

I hope this information is helpful to you. If further assistance is needed, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov.

Best regards,
Kathleen Pfaender, RN, JD
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of Medical Products and Tobacco
Federal Food and Drug Administration
WO32/5129
301-796-8346

From: [Redacted]
Sent: Tuesday, April 15, 2014 3:43 PM
To: OC GCP Questions
Subject: question: definition of an investigator in a clinical trial

Hello, I have a query that I would really appreciate FDAs guidance on. Is it possible for a physician who, as an expert in the field, will contribute to the scientific interpretation of study results, assist in the writing of a clinical study report, write publications related to a study, however this physician will not be part of a study site nor enroll any subjects in the study.

Is it possible to call a person working in this capacity an "Investigator" (principal, lead, co- or otherwise) on the study?

Thank you in advance!
[Redacted]