From: OC GCP Questions
To: [redacted]
Subject: participants in Investigational Drug Studies
Date: Tuesday, June 09, 2015 2:51:53 PM

Good afternoon –

The CFR 56.102(e) states “Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or the control. A subject may be either a healthy individual or a patient.”

CFR 312.3(b) states “Subject means a human who participates in an investigation, either as a recipient of the investigational new drug or as a control. A subject may be a healthy human or a patient with a disease.”

CFR 812.3(p) states “Subject means a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease.”

Generally FDA regulations refer to participants of a clinical trial as subjects.

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

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, June 09, 2015 11:59 AM
To: OC GCP Questions
Subject: Participants in Investigational Drug Studies

I was wondering if the FDA considers participants in investigational drug participants to be “patients” of the doctors overseeing the study. Any insight or pointers would be most appreciated.
Sincerely,
[redacted]