

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,

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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, 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]