From: OC GCP Questions
To: [redacted]
Subject: FDA Guidance on using "Patient" versus "Subject" in clinical trials
Date: Thursday, April 05, 2018 11:09:00 AM
Attachments: [redacted]

Good morning –

FDA uses subjects rather than patients. Subject is defined in CFR 312.3(b).. "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." And for devices CFR 812.3(p)… "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."

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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Office of Good Clinical Practice
Office of the Commissioner, FDA

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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: Thursday, April 05, 2018 10:28 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: FDA Guidance on using "Patient" versus "Subject" in clinical trials

To Whom it May Concern,

The terms "patient" and "subject" are often used interchangeably when conducting or reporting on clinical research. Does FDA have a rule, guidance or preference on the usage of one term over the other? Your comment on this topic is appreciated. Thank you.

Regards,

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[redacted]