From: OC GCP Questions
To: [redacted]
Subject: pragmatic trials
Date: Monday, August 29, 2016 8:05:00 AM

Good morning –

Yes informed consent is required for pragmatic trials. The only time IC can we waived under FDA regulations is for 50.23 and 50.24 clinical trials.

Kind regards,

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

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: Friday, August 26, 2016 12:45 PM
To: OC GCP Questions
Subject: RE: pragmatic trials

Thanks. They referred me to you for a high level answer to the question of whether pragmatic trials can be done without individual consent,

Thanks,
[redacted]

[redacted]