From: OC GCP Questions
To: [redacted]
Subject: clinical trial regulations
Date: Wednesday, April 04, 2018 12:13:00 PM

Good afternoon –

Yes for IND and IC and IRB approval. Please see the weblinks below for the Center for Food Safety and Nutrition.

Infant Formula Guidance Documents & Regulatory Information

Foods Please see "Contact FDA" at the bottom right of the page.

Kind regards,

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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.

-----Original Message-----
From: [redacted]
Sent: Wednesday, April 04, 2018 11:59 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: clinical trial regulations

Can you advise on what regulations are applicable for an infant formula/ nutrition clinical trial.

Is an IND required? (21 CFR 312)

Is it just consent and IRB approval? (parts 50 and 56?)

Where does the regulation or guidance address how to manage infant formula / nutrition trials.

Please advise?

Regards,

[redacted]