

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Crowd Funding for Research under IND
Date: Wednesday, July 16, 2014 9:04:38 AM

Good morning –

Sorry for the delay in responding. We sent your question to the Center for Drugs (CDER). Please see their response below.

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: Dada, Kavita
Sent: Wednesday, July 16, 2014 8:20 AM
To: OC GCP Questions
Cc: Defronzo, Kimberly; CDER OSI PM TRACK
Subject: FW: Crowd Funding for Research under IND

Hi Doreen,

Per OSI reg counsel, there is no requirement to disclose funding source. Generally, funding or finances are outside the scope of FDA unless it creates a conflict, which then needs to be dealt with in disclosures.

Thanks,
Kavita

From: [Redacted]
Sent: Tuesday, July 08, 2014 7:53 AM
To: OC GCP Questions
Subject: Crowd Funding for Research under IND

Good Morning,

Is it ok for Clinical research conducted under IND to be funded by donations utilizing crowd funding websites (Gofundme.com)? The websites solicit donations to cover the cost of the clinical trial.