From: OC GCP Questions
To: [redacted]
Subject: Request for medical device clinical trial guidance document
Date: Friday, November 13, 2015 7:00:35 AM

Good morning –

The 1572 form is used for IND studies. An investigator agreement is needed for FDA-regulated device research. If you have specific questions regarding medical devices, you can contact the Center for Devices (CDRH) directly at DICE@fda.hhs.gov

Kind regards,

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

From: [redacted]
Sent: Thursday, November 12, 2015 8:08 PM
To: OC GCP Questions
Subject: RE: Request for medical device clinical trial guidance document

Good Evening.

I could not find the information on form 1572; whether it is required for the medical device clinical research or not. I greatly appreciate your help!

Thank you

[redacted]