

From: OC GCP Questions
To: [REDACTED]
Subject: Form 1572 and Device Trials?
Date: Tuesday, August 22, 2017 2:34:00 PM
Attachments: [REDACTED]

Good afternoon –

The 1572 form is used for drug and biologic trials only. Device trials require investigator agreements. For more information on FDA device clinical trials, you may contact the Center for Devices (CDRH) directly at DICE@fda.hhs.gov

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.

From: [REDACTED]
Sent: Tuesday, August 22, 2017 2:24 PM
To: OC GCP Questions
Subject: Form 1572 and Device Trials?

Does FDA have a problem with the use of Form 1572 for device trials?

