

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Query on FDA Form 1572
Date: Wednesday, May 11, 2016 1:09:18 PM

Good afternoon –

Please see FDA's guidance on the 1572 form.

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf>

A sponsor is required to obtain a completed and signed Statement of Investigator, Form FDA 1572, from its clinical investigator(s) before conducting a clinical study under an investigational new drug application (IND). So, if a sponsor is conducting a clinical bioequivalence study, assuming that is what is meant by "Therapeutic Equivalence Study," under an IND, then sponsor must obtain a completed and signed Form FDA 1572 from the clinical investigator.

The determination on whether the specific clinical study, including a clinical bioequivalence study, is a phase 1 or phase 2 or 3 depends on the characteristics of the study, which is described at 21 CFR 312.21.

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: Wednesday, May 11, 2016 6:30 AM
To: OC GCP Questions; CDER DRUG INFO
Subject: Query on FDA Form 1572

Dear Sir/Madam,

This email is with reference to FDA 1572 form (Statement of Investigator), kindly request you to provide clarification on following points:

- (1) Is this compulsory for Investigator to sign FDA 1572 form for Therapeutic Equivalence Study (as per OGD Guideline) for USFDA submission?
- (2) If Yes for above mentioned Question, then which points to be selected for Therapeutic equivalence Study (either Phase I or Phase II/III) on page# 2?

Thank you very much.

With Best Regards,

[REDACTED]