

From: OC GCP Questions
To: [REDACTED]
Subject: Form FDA 1572 per Principal Investigator or per Study?
Date: Friday, August 04, 2017 11:35:00 AM
Attachments: [REDACTED]

Good morning –

Please see FDA's 1572 guidance
<https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf> It states --

1. What is the Statement of Investigator, Form FDA 1572?

The Statement of Investigator, Form FDA 1572 (1572), is an agreement signed by the investigator to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic.

The clinical investigator must sign a separate 1572 form for each study that he/she is overseeing.

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.

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From: [REDACTED]
Sent: Friday, August 04, 2017 10:06 AM
To: OC GCP Questions
Cc: [REDACTED]
Subject: Form FDA 1572 per Principal Investigator or per Study?

Good morning,

Can you please tell me if 1572 FDA form needs to be completed for **each study**, or does the Principal Investigator fill out one FDA 1572 form to **cover all studies** that he/she is serving as Principal Investigator?

Thank you,

[REDACTED]