

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Question about FDA Form 1572
Date: Thursday, February 15, 2018 1:30:00 PM
Attachments: [REDACTED]

Good afternoon –

If you have pre-populated with the old form and the investigator has not signed it yet, it is probably best to start using the new form. Please see FDA's 1572 guidance <https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf> specifically questions 7 and 16. Question 16 refers to the form that has already been signed by the clinical investigator.

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: Tuesday, February 13, 2018 5:44 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Question about FDA Form 1572

To whom it may concern:

I work for a CRO and we provide pre-populated FDA Form 1572 to our clinical sites on a study (e.g. central lab, central IRB, Protocol number and title, etc.). Before each study we check the FDA website to be sure we are using the most current version of the form. The expiration date of February 28, 2019 and the version date (2/16) have not changed, but it was brought to our attention that box #1 of the form itself has been changed. The Name of Principal Investigator has been changed to Name of Clinical Investigator. Will this change be a problem or concern going forward?

Thank you for your reply.

Kind regards,

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