

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: 1572 question
Date: Wednesday, August 07, 2019 12:04:32 PM
Attachments: [REDACTED]

Good afternoon –

The 1572 is a sponsor form. The updated form should be sent to the sponsor. Please also see FDA's guidance on the 1572 form. <https://www.fda.gov/media/78830/download>

If you are the sponsor, please question 7, page 6 of the guidance.

Kind regards,

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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 06, 2019 4:53 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: 1572 question

Hello, I am a regulatory coordinator here at [REDACTED] and I have an updated 1572 that I need to submit. Where should this be sent? Thank you!

[REDACTED]

[REDACTED]

[REDACTED]