

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: FDA 1572
Date: Wednesday, July 03, 2019 1:03:19 PM
Attachments: [REDACTED]

Good afternoon –

No, this office does not keep copies of the 1572 form. You might need to contact the Center for Drugs (CDER) at druginfo@fda.hhs.gov. They most likely will need to contact the review division of the IND. Some 1572 forms are submitted by the sponsor to FDA under the IND but this is not required. If you are not the sponsor, you might also ask the sponsor of the study for the 1572 form.

Kind regards,

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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, July 03, 2019 12:58 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: FDA 1572

Hello,

I am a coordinator for study [REDACTED]. I have taken the study over from a previous coordinator and I am unable to locate the original FDA 1572 form in our files. Do you keep copies of these documents? Or can you advise me on how best to access them?

Thank you very much,

[REDACTED]

