

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Protocol Clinical trial name too long for the section 7 of the FDA1572
Date: Friday, July 26, 2019 9:51:51 AM
Attachments: [REDACTED]

Good morning –

Please see the 1572 Form guidance - <https://www.fda.gov/media/78830/download> It states -

18. How should the 1572 be completed?

The 1572 on FDA's website may be completed by typing the information directly into the fillable form and printing the completed form. Alternatively, it is acceptable to print the blank form from FDA's website and hand-write or type the information onto the form. Typed forms are preferable because they are usually more legible. The completed form must be signed and dated by the investigator (either by hand or using an acceptable electronic method).

You could hand write the name of the Protocol to fit into the space.

You can also consult the Center for Drugs (CDER) at druginfo@fda.hhs.gov for additional advice.

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, July 24, 2019 5:55 PM
To: CDER DRUG INFO <DRUGINFO@fda.hhs.gov>; OC GCP Questions <gcpquestions@fda.hhs.gov>
Cc: [REDACTED]
[REDACTED]
[REDACTED]
Subject: Protocol Clinical trial name too long for the section 7 of the FDA1572

Dear All,

I am completing the FDA1572 for 1 clinical study.

In the section 7, I am unable to enter the whole protocol title. The title is too long, and even when

changing the font there is not chance to get the full title in this section.
Unfortunately there is no "Continuation page" for the section 7 and I don't know how to proceed.

May you please provide me advice on how to proceed.

Thanks in advance,

Kind regards,

