

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** FDA 1572 Continuation Page for item 3  
**Date:** Thursday, June 06, 2019 10:25:41 AM  
**Attachments:** [REDACTED]

---

Good morning again -

I just tried to access the continuation pages for the 1572 form and it worked for me. I accessed the form at the following web link:

[www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm074728.pdf](http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm074728.pdf) To get to the continuation page at the end of the document you must have all the information filled out on the selected form site.

First, I suggest that you ensure you have the most updated version of Adobe Reader. I also suggest you save the form as a PDF file to your desktop. You should fill in the particular section with information and then click on the Continuation Page link which should take you to the continuation page. When you click on the continuation page link, as stated previously, the continuation page appears at the END of the document.

If you continue to have issues with the form, you may need to try to open it in another browser. If that does not work, I suggest that you reach out to the appropriate contact for the Form FDA 1572 at CBER MATT at 240-402-8020 [industry.biologics@fda.gov](mailto:industry.biologics@fda.gov) or CDER Drug Info at 301-796-3400 [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov) .

See FDA forms list. [FDA Forms](#)

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, June 05, 2019 4:52 PM  
**To:** OC GCP Questions <[gcpquestions@fda.hhs.gov](mailto:gcpquestions@fda.hhs.gov)>  
**Subject:** RE: FDA 1572 Continuation Page for item 3

Hello Doreen,

It doesn't seem to appear for me:

Note page 2 of 2 at bottom.

4. Sign and date below.	
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.	
10. DATE (mm/dd/yyyy)  06/05/2019	11. SIGNATURE OF INVESTIGATOR <div style="text-align: center;">Sign</div>
(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)	
<p>The information below applies only to requirements of the Paperwork Reduction Act of 1995.</p> <p>The burden time for this collection of information is estimated to average 100 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right:</p> <p><i>"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."</i></p> <p>Department of Health and Human Services Food and Drug Administration Office of Operations Paperwork Reduction Act (PRA) Staff <a href="mailto:PRAStaff@fda.hhs.gov">PRAStaff@fda.hhs.gov</a></p> <p><b>DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.</b></p>	

FORM FDA 1572 (3/19)                      PREVIOUS EDITION IS OBSOLETE.                      Page 2 of 2

---

**From:** OC GCP Questions [<mailto:gcpquestions@fda.hhs.gov>]  
**Sent:** Wednesday, June 05, 2019 1:43 PM  
**To:** [REDACTED]  
**Subject:** FDA 1572 Continuation Page for item 3

Good afternoon –

The continuation pages appear at the END of the pdf. It is not intuitive, so I get this question often. Try to find it at the end. Otherwise I can send you another PDF.

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, June 05, 2019 4:19 PM  
**To:** OC GCP Questions <[gcpquestions@fda.hhs.gov](mailto:gcpquestions@fda.hhs.gov)>  
**Cc:** [REDACTED]

**Subject:** FDA 1572 Continuation Page for item 3

Hello,

I'm in need of adding a second site to section 3 of the 1572 form. After completing every section outside of section 11 (signature of investigator), I was unable to open the continuation page for item 3. Would you be able to instruct me on how to access the continuation page for item 3, or email me a clean version.



Clicking on this hyperlink did not bring me to the continuation page.

Thanks,

