

**From:** OC GCP Questions  
**To:** [REDACTED]  
**Cc:** [CDER DRUG INFO](#)  
**Subject:** FDA . Form 1572/ Question for Section 4  
**Date:** Monday, May 01, 2017 9:35:00 AM  
**Attachments:** [REDACTED]

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Good morning –

It is not necessary to include the second emergency hospital on the 1572 form as it is being used to treat the subject in the practice of medicine for an adverse event.

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.

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**From:** [REDACTED]  
**Sent:** Thursday, April 27, 2017 1:47 PM  
**To:** OC GCP Questions  
**Cc:** [REDACTED] [druginfo@fda.hh.gov](mailto:druginfo@fda.hh.gov)  
**Subject:** FDA . Form 1572/ Question for Section 4

Hello:

We want to confirm the following question for Section 4.

The address Site where the protocol will be done is identified as ([REDACTED] see below in Yellow)

But this site, has a contract with a [REDACTED] this Hospital, would only be used in case of an emergency, to treat the patient for a Serious Adverse Event.

This Hospital [REDACTED], is not part of the procedures that will be done to the patient.  
But this Hospital, CAN be used to treat the patient in case of an Emergency.

Can you confirm if it's OK to include the [REDACTED] in any section of the FDA?

Thanks for the clarification.

**HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL  
INVESTIGATION(S) WILL BE CONDUCTED**

***25. What address(es) should be entered in Section #3?***

The address(es) of the location(s) where the **investigation will be conducted and to where the test articles will be shipped**, if different from the investigator's address of record, should be entered in Section #3.

