From: OC GCP Questions
To: [redacted]
Subject: RE: Question regarding modification of 1572 layout
Date: Tuesday, August 26, 2014 1:33:00 PM

Dear [Redacted]-

Thank you for your questions. I apologize for the delay in my response, but I needed to find out for you who within FDA might be best suited to answer your specific questions. I reached out to my CDER colleagues and they informed me that you should send your questions to the following FDA mailbox for a response:

ESUB@fda.hhs.gov

This particular group works on esubmissions and is best suited to help you with your questions. I suggest you just forward the same question you sent to the OGCP mailbox directly to the ESUB mailbox. Feel free to let them know that you initially sent your questions to the OGCP mailbox and, based on feedback from CDER, OGCP referred you to them. I thought about just forwarding your question to the ESUB mailbox, but I think it is best if you send your question directly to the ESUB mailbox so that they can respond directly to you.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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From: [Redacted]
Sent: Tuesday, August 19, 2014 12:07 PM
To: OC GCP Questions
Subject: Question regarding modification of 1572 layout

Good morning,

I would greatly appreciate your input regarding form 1572.

Several months ago we implemented an electronic regulatory document management system (RDMS). As part of this system we develop eForms and obtain eSignatures on regulatory documents.

The system does not allow the importation of forms, hence we have been creating a form that includes all of the information from your website but is not an exact copy of the 1572. We check the website frequently for updates, so believe that while the form is not your on-line pdf version, it does comply with the requirement to provide full information about a study site to the sponsor and also serves as a means for the investigator to assert his or her commitment to compliance with the investigational plan and pertinent regulations. (Please see Sample 1572 [Redacted]_redacted).

While the majority of sponsors have readily accepted the new system, including the 1572, one sponsor will not accept the electronic version of the 1572 (see sample), because the document has been modified. (Again, the content remains identical to that currently on your website).

If you feel we should not use the form in this manner, one suggestion has been to create a similar form, stating at the top "Being used to collect the same information as the 1572". Do you feel that this would be an acceptable solution? (I have attached two examples for your review).

We obviously wish to be compliant, yet as only one sponsor has expressed concern with the current process, I am concerned that deviating from it may upset the majority of our sponsors who have had no issues with it. Additionally, we are [Redacted] I am aware that the content of the [Redacted] of the 1572 has actually been modified. (Sample attached).

Your advice and assistance in resolving this matter is greatly appreciated,

Thank you,

[Redacted]