From: Toth-Allen, Jean
Sent: Wednesday, March 08, 2006 2:55 PM
To: **[Redacted]**
Subject: RE: 1572 updated address

No, they do not need to rewrite and sign a new 1572 but they do need to get the pertinent information to anyone who will need it - anyone who will have a need, related to the study, to send them anything.

-----Original Message-----
From: **[Redacted]**
Sent: Wednesday, March 08, 2006 2:24 PM
To: Toth-Allen, Jean
Subject: RE: 1572 updated address

So then they don't need to make updates to the 1572 if their address is changing?

[Redacted]

-----Original Message-----
From: Toth-Allen, Jean
Sent: Wednesday, March 08, 2006 2:11 PM
To: **[Redacted]**
Subject: RE: 1572 updated address

[Redacted],

We have a guidance document - FAQs on the 1572 - ready to issue. (It is somewhere in final clearance and has been for some time and will eventually issue as level 1 guidance.) I also answered a similar question recently, in that they wanted to know if they needed to officially update the 1572 if a sub-investigator left the study. I answered that in the following way:

The main purpose of the 1572 is to provide information to the study sponsor. Therefore, if a sub-investigator who was originally listed on the 1572 has left the study, this information should be documented in the study records and provided to the sponsor so that the IND is properly updated. However, the 1572 itself does not need to be revised and signed by the investigator.

The address information may be important for shipping purposes but does not affect the essential information on the 1572. (We can still find them should we need to go out and inspect if the actual address is the same!)

Hope this is helpful.

Jean

-----Original Message-----
From: **[Redacted]**
Sent: Wednesday, March 08, 2006 10:15 AM
To: OC GCP Questions
Subject: FW: 1572 updated address

I can't seem to find the answer to this anywhere. Can you please answer?

Thanks

[Redacted]

-----Original Message-----
From: **[Redacted]**
Sent: Monday, March 06, 2006 12:42 PM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: **[Redacted]**

E-Mail: **[Redacted]**

Comments: We need to add a suite number to our address per the United States Postal Service, but in no way is our location changing. Thus we have the question of, do we need to complete updated 1572's with this change for each study we are involved in?