From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, October 20, 2004 11:03 AM
To: [Redacted]
Subject: RE: company name change

Dear [Redacted],

FDA regulations really don't explicitly address the questions you ask. Based on the principle of respect for persons, however, it would seem reasonable to expect that you ought to try to keep all parties informed of your name change in case the individual (now or in the future) has some need to get in touch with you. I believe that you could provide notification forms to your investigators and ask them to convey, as appropriate, the information to subjects currently enrolled in their trials. I do not think that these forms would need to be signed--that may be up to the reviewing IRB. A change in name does not seem to me to be a significant change that would require document of receipt. As to subjects who have discontinued the study, again one could leave it up to the investigator/IRB. In some cases, it may be appropriate for the investigator to send a letter notifying them of the name change--in other cases (depending on the nature of the study), it could cause privacy risks to the subjects if their participation in the study was not otherwise known to individuals who may access their mail. In all likelihood, if these individuals had a need to contact your company, I think they would likely contact the investigator first, who could advise them of the name change. Finally, there are all sorts of automated devices (via phone, internet, etc.) that can be maintained for a period of time advising those who attempt communication of the name change. I hope this is helpful to you.

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

-----Original Message-----
From: [Redacted]
Sent: Monday, October 11, 2004 2:23 PM
To: gcpquestions@oc.fda.gov
Subject: company name change

Hello

Our company is currently conducting clinical trials in the US and overseas. Our company name has changed and we are in the process of notifying our investigators, IRBs, Ethics Committees, and regulatory authorities in other countries.

Could you please tell me what our responsibilities are towards reporting the change in company name to subjects who are currently enrolled and subjects who have discontinued the study. We are updating our informed consent form with the new company name for subjects yet to be enrolled, but would like to know what the requirements are for currently enrolled and discontinued patients. Is a notification form that the patient signs sufficient? Also, our company would not have contact information for patients who have discontinued the study, only

our investigators would have these patients' contact information. Is a letter to be sent to past participants required? I have spent many hours looking for information in various websites but have been unable to find specific information with regard to company name change. Any information that you may be able to provide to me would be greatly appreciated.

Thank you very much and best regards,
[Redacted]