From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Monday, November 01, 2004 11:36 AM
To: [Redacted]
Subject: RE: Regulatory information on keeping data on screen failures
Dear [Redacted],

I suppose that you're at the PRIM&R meeting learning new things, sharing your knowledge, and most importantly seeing friends. While I miss the first two, Its for the latter that I'm most envious. I hope you had a great time there.

In terms of your question (below), I am not aware of any FDA regulation that would deal with retention of identifiable information of potential subjects, screened but not ultimately enrolled in FDA-regulated studies. The demographic information collected that would be subject to FDA regulation would be that information for research subjects in FDA-regulated studies (or, conceivably, for potential subjects if the specific protocol required the collection of that data). I think that your proposed solution to retain information but de-link the data from unique identifiers is a good one.

Please let me know if you need any other information.

My best,

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

-----Original Message-----
From: [Redacted]
Sent: Friday, October 15, 2004 5:33 PM
To: gcpquestions@oc.fda.gov
Subject: Regulatory information on keeping data on screen failures
Dear GCP Team!

I am requesting information on FDA regulations regarding retention of identifiable information on research subjects who are screened, but are not ultimately enrolled in FDA-regulated studies. Our IRBs are convinced of the importance of retaining demographic and clinical information about these people in order to provide useful data on study bias, etc. However, we have concerns about retaining identifiers such as names, Social Security numbers, hospital ID numbers, etc. that would limit the confidentiality of this information. Our proposed solution would be to retain the necessary demographic and clinical information on individual subjects, but de-link the data from any unique identifiers.

I have had conversations with our local FDA representatives who agree with our perspective, but we agreed that we should seek your advice. Please let me know if you need additional information.

Many thanks.

[Redacted]