From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Thursday, August 28, 2003 10:03 AM
To: [Redacted]
Subject: RE: questions

Hi [Redacted], Thanks for the clarification. If the IVRS represents the contracting of a sponsor regulatory responsibility to a contract research organization then the contract research organization would need to be listed. If not, I would agree with you that it would not be necessary to include this information on the 1572.

Bonnie

-----Original Message-----
From: [Redacted]
Sent: Wednesday, August 27, 2003 7:09 AM
To: OC GCP Questions
Subject: RE: questions

Hi Bonnie,

IVRS is Interactive Voice Response System which is used for randomizing patients. I doubt that it is a requirement for this to be included on the 1572 but I just need to be sure. Thanks for your response to my questions.

[Redacted]

OC GCP Questions <GCPQuestions@OC .FDA.GOV> Sent by: "Lee, Bonnie" <BLee@OC.FDA.GOV >	To: [Redacted] cc: Subject: RE: questions
08/26/03 11:24 AM	

Dear [Redacted], Could you please tell me with "IVRS" stands for? I could make a
few guesses, but I'd rather be sure! Also, there is no FDA mandate that states that one must use a separate informed consent form for drawing blood for genetic testing. However, I believe that it is not uncommon for an Institutional Review Board (IRB) to ask/require that this be separated from the consent form used for the actual study--either through use of a separate
document or a separate signature--in order to allow the subject to agree to one but not the other. I hope this is helpful to you. Please let me know

what/who IVRS is and I'll try to respond to that part of your question as well. Thanks.

Bonnie

Bonnie M. Lee
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Good Clinical Practice Program
OSHC, Office of the Commissioner
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-----Original Message-----
From: [Redacted]
Sent: Monday, August 25, 2003 12:07 PM
To: gcpquestions@oc.fda.gov
Subject: questions

To Whom It May Concern:

Is it mandatory to have a separate informed consent form if the study involves drawing blood for genetic testing?

Must the IVRS used in clinical trials be included on the 1572?

Thank you,
[Redacted]