From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, December 21, 2005 12:36 PM
To: [purged]
Cc: Kutkat, Lora (NIH)
Subject: RE: Need guidance/advice on developing a web-based consent
docume nt

Dear [purged],

From the information you have provided below, it does not appear that the research you contemplate is FDA-regulated. Further, your questions relate to the HIPAA regulation. As a result, I have forwarded your inquiry to Lora Kutkat, who is extremely knowledgeable in that area for a reply. (Lora, I hope you don't mind.) Happy Holidays to both of you.

Sincerely,

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: [purged]
Sent: Thursday, December 08, 2005 5:18 PM
To: 'gcpquestions@oc.fda.gov'
Subject: FW: Need guidance/advice on developing a web-based consent
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> I am developing a research registry database to collect demographic and
> medical history
> information (diagnosis and information regarding physical illnesses) from
> individuals diagnosed
> with a mental illness. I want to add a web-based component that will allow
> individuals to enter
> their name, address, age, medical diagnosis and history of physical
> illness (health related info
> will be optional) into an internet-based form.
>
> As such I need some guidance regarding informed consent and authorization
> to use identifiable health information for research.
> 1) Is it acceptable to use an on-line consent document for the web-based
> component of the registry?
> 2) Since I plan to collect health-related information directly from the
> subject and the research does not involve treatment, is the 'health
> related information considered to be PHI and subject to the HIPAA Privacy
> Rule?
> Thank you for your assistance.
>
> [purged]
>
>
>