From: Woollen, Stan - OC
Sent: Thursday, March 06, 2003 9:47 AM
To: [purged]
Cc: Lepay, David
Subject: RE: Question Re: release of personal patient info to ECOG

Dear [purged]
Thank you for your inquiry regarding the practice of releasing patient identifiers to Cooperative Oncology Groups such as ECOG. As always your questions are most challenging. In discussing this with Dr. Lepay, he and I agreed that our first inclination here would be to ask what your IRB thinks about this practice and seek their advice on protecting subject confidentialty.
As you know 50.25 requires that the consent form disclose the extent, if any, to which confidentiality of records will be maintained. Since this appears to be an established practice in the past, I assume the IRB may be aware of it. If not however, I would start with them for their advice regarding the adequacy of the consent form vis a vis this practice.
I am really not in a position to comment on the possible HIPAA implications of this practice. However, there are a number of guidance documents about HIPAA that are available from the Department of Health and Human Service's (DHHS) Office of Civil Rights (OCR) web site (http://www.dhhs.gov/ocr/hipaa/). OCR has ultimate responsibility for interpreting the provisions of HIPAA. I would suggest you visit this web site and review these guidances. Should you continue to have questions about the implementation of HIPAA after you have reviewed information posted to the OCR web site, there are instructions on that web site for submitting your questions to OCR.
FDA is developing a separate guidance document the will address frequently asked questions related to the implementation of HIPAA for FDA regulated products. Once this document is finalized, it too will be electronically available from the OCR web site.
I hope this information is helpful, as usual you seem to have your hands full.
Sincerely,
Stan W. Woollen
Associate Director for Bioresearch Monitoring
Good Clinical Practice Programs
OSHC, Office of the Commissioner

-----Original Message-----
From: [purged]
Sent: Friday, February 28, 2003 4:54 PM

To: Lepay
Cc: Stan Woollen
Subject: FW: Question Re: release of personal patient info to ECOG

Now I'm having the opposite problem and the message I intended for you went to my secretary. So much for auto address!

[purged]
-----Original Message-----
From: [purged]
Sent: Friday, February 28, 2003 4:51 PM
To: Stan Woollen; David Tester
Subject: Question Re: release of personal patient info to ECOG

With HIPAA looming a question recently came to us about how to deal with ECOG and other cooperative groups that want personal information regarding Patient name, employer, home address and phone number, work address and phone number, social security number, insurance provider and numbers etc. (yes...etc.). I found this both surprising and unique since, as a sponsor, the private personal information of the research subject should be held confidential and protected from outright distribution to the sponsor.

We, as an institution, are pretty uncomfortable about this but we want to be discreet because our clinical teams are concerned that their questioning the appropriateness of this request and disclosure might jeopardize their relationship with these cooperative groups. This is (and has always been) a standard practice for these groups and when the practice was apparently questioned in the past (of the cooperative group) it was not well received. I would ask you to be discreet with my question for the moment as we are concurrently trying to get a sense of where some of our other academic peers are on this issue. Early sense is that they are uncomfortable as well but there is reluctance for anyone of them to feel like they want to push the point alone. I think the HIPAA issue makes very legitimate a "new opportunity" to ask the question. Do you have any thoughts on this??? [and no the IC forms do not have any additional information under confidentiality than would typically be in place for a sponsored trial]

As always, thanks

[purged]