From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Tuesday, March 04, 2003 8:32 AM
To: [purged]
Cc: Mail, Ocr (OS)
Subject: RE: HIPAA & foreign locations (Canada)

Dear Dr. [purged],

The best organization to contact at this time for information and guidance regarding HIPAA is the Department of Health and Human Services' Office of Civil Rights. You can contact them by sending an email message to ocrmail@hhs.gov or call their Washington D.C. office at 202-260-3314.

I've taken the liberty of forwarding your email message to the OCR email account.

Sincerely,

Pat Beers Block
Special Assistant to the Director
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner/ FDA

-----Original Message-----
From: [purged]
Sent: Monday, March 03, 2003 7:52 AM
To: OC GCP Questions
Subject: Re: HIPAA & foreign locations (Canada)

Dear Ms. Block
I had reviewed all the websites and guidance documents before I
contacted you but could find nothing refering to foreign data. We are
currently in negotiations with pharmaceutical sponsors regarding
clinical trials and cannot wait for general FAQ responses. Please refer
my questions to a more senior administrator who can provide a response.

most sincerely

[purged]
> **********

OC GCP Questions wrote:
>
> "Dear Ms. [purged],
>
> Thank you for your inquiry regarding HIPAA and its implementation. 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/). We 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.
>
> You may want to note that most covered entities have until April 14, 2003,
> to comply with the patient privacy rule; under the law, certain small health
> plans have until April 14, 2004 to comply.
>
> Additional guidances, including one that is expected to address frequently
> asked questions related to the implementation of HIPAA for FDA regulated
> products, are being developed. Once these documents are finalized, they too
> will be electronically available from the OCR web site.
>
> I hope this information helps.
>
> Sincerely,
>
> Pat Beers Block
>
> -----Original Message-----
> From: [purged]
> Sent: Thursday, February 13, 2003 10:47 AM
> To: gcpquestions@oc.fda.gov
> Subject: HIPAA & foreign locations (Canada)

>
> Good Morning
>
> What is the HIPAA authorization requirement for data collected in Canada
> for FDA regulated clinical trials? As a Canadian Research Ethics Board
> (IRB) we are now being asked by sponsors to include a HIPAA
> Authorization form (that meets US requirements) in addition to the
> normal Letter of Information given to patients at time of recruitment.
> When questioned as to the need for this form the response is "...
> because the data is ultimately being sent to the US this form is an FDA
> requirement."
>
> To date it has been our position that HIPAA regulations do not apply in
> Canada, (In fact, many of our provinces have their own Personal Health
> Information privacy requirements) irrespective of where the data ends up
> and we have rejected the use of such form and the inclusion of the
> wording in our consent documentation.
>
> As HIPAA moves closer to implementation I know that this issue will
> arise more frequently and I would appreciate receiving a definitive
> statement from your office regarding this HIPAA matter.
>
> Most sincerely
>
> [purged]
>