



"Bonnie Kaplan" <Bonnie.Kaplan@CRHA-Health.Ab.Ca> on 2001/05/07 05:43:14 PM

To: ian.mitchell@CRHA-Health.Ab.Ca, Philip Waddington@HWC  
cc:

Subject: re: CHREB guidelines

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Dr. Ian Mitchell  
Office of Medical Bioethics

Dear Dr. Mitchell,

I have been asked by Dr. Phil Waddington, Director General of the National Health Products Directorate of HPB, for a simple, explicit statement of the guidelines followed by the Conjoint Health Research Ethics Board of the University of Calgary. I was able to say "Tricouncil Policy," but could go no further.

Is there anything you can add to that? When you answer, would you please hit "Reply All" so that Dr. Waddington receives your reply?

Thanks for your help,  
Bonnie

--  
Bonnie J. Kaplan, PhD  
Professor, Dept of Pediatrics  
Univ of Calgary, Alberta Children's Hospital  
Phone: 403-229-7365 FAX: 403-543-9100

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"Bonnie Kaplan" <Bonnie.Kaplan@CRHA-Health.Ab.Ca> on 2001/05/08 02:08:58 PM

To: Ian Mitchell <Ian.Mitchell@CRHA-Health.Ab.Ca>  
cc: Philip Waddington@HWC

Subject: Re: CHREB guidelines

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Hello again,  
I'm sorry, Ian, if I did not give you sufficient background material. The request truly is quite a simple one, but here's the background. Naturally, it involves our research protocols on the nutritional supplement.

In August 1999 we were told by the HPB Transition Team working toward developing the now-established Natural Health Products Directorate that there was no need for us to apply for an IND or anything given the transition situation --- but that approval by our university ethics committee would be sufficient. There are now some people at HPB who feel that we should have \*some type\* of review/clearance, and I'm happy to comply, but they have to figure out what such a review process would be, because it cannot be the traditional TPD/IND evaluation. So.....Dr. Waddington would like to be able to cite documents that the CHREB uses as guidelines for ethics approval, I think sort of as background to indicate what our protocols are, actually, already complying with. I spoke to Margaret in your office, and she of course mentioned the TriCouncil document, but believed there might be more.

The situation we are in presently is that the NHP Directorate now exists, but they still don't have their guidelines in place to evaluate clinical trials. I've been keeping in close touch with them and with the Therapeutic Products Directorate, and I'm sure they are going to figure out some way to put together a review for us.....but it hasn't happened yet. As I have said to Dr. Waddington a couple of times, I try to follow "the rules" in my research, but in this case the rule book hasn't been written. Both he and Dr. Mithani (from TPD) are being very helpful, and I'm sure this will all be resolved at some point.

Does that information help? Thanks.  
Bonnie

--  
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discussed, I do not have a copy of these specific messages being forwarded and I apologize if information was missed because of that.

Phil

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Forwarded by Philip Waddington/HC-SC/GC/CA on 10/10/2001 09:32 AM



"Bonnie Kaplan" <Bonnie.Kaplan@CRHA-Health.Ab.Ca> on 05/07/2001  
05:43:14 PM

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Forwarded by Philip Waddington/HC-SC/GC/CA on 10/10/2001 09:32 AM



ian.mitchell@CRHA-Health.Ab.Ca (Ian Mitchell) on 05/08/2001 11:45:21 AM

To: "Bonnie Kaplan" <Bonnie.Kaplan@CRHA-Health.Ab.Ca>, ian.mitchell@CRHA-Health.Ab.Ca, Philip Waddington@HWC

cc:

Subject: re: CHREB guidelines

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