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PEH/mm/williams

18 October 1995

Dear Lorna

Anti-HBc look-back study

Thank you for your letter of 15th October 1995 confirming our telephone conversation.

We have now appointed the Research Nurse at Tooting and she will be commencing duties on the 14th November. I am confident that she will be able to start, after some initial familiarisation, with submission of South Thames Ethical Committee applications.

On the subject of inclusion of children, I must state my views very firmly. I have not, as you know, been involved in the design of this study to date. As I told you, the Kings Healthcare Ethics Committee application guidelines state clearly "research proposals should involve children only when absolutely essential and when the information cannot be obtained from adult subjects." In these circumstances, I feel it would be foolish to indicate that we wish to include children. We cannot argue that the information is available only from children, and ignoring the specific guidelines of the Ethics Committee could jeopardise the whole application. As I told you, we have had vast experience of submitting to Ethical Committees in North Thames (18 submissions to different Hospital Ethics Committees). In one case, an individual in the hospital took exception to our proposal and effectively made it impossible for us to continue our research. I do not think it is wise to submit an application which includes proposals contrary to the Ethics Committee guidelines. As Kings is one of the largest users for STBTS, it is crucial that we have Ethical Committee support.

I cannot agree that we should emphasise that the findings of the look-back study may be of benefit to individual children. This is not the purpose of the study. In that case, we should be performing a look-back on all recipients of anti-HBc positive donations. That approach is second guessing the results of the look-back study. If the look-back study on adults shows that there is significant risk of transmission from anti-HBc only donors, then a full look-back of all recipients should follow. In that case, infected children would be identified. The purpose of this study is to examine the risk of infection. We cannot argue that the findings may be of benefit to individual children until the study has been performed on adults. I note that this was not a subject raised by the Addenbrooke's Ethics

Committee but I understand that similar guidance about non inclusion of children was not given by Addenbrookes.

I will submit the Kings Healthcare Ethics Committee application, with children excluded. Once the Research Nurse is in post, we shall work our way through the list of other hospitals supplied by STBTS.

With best wishes.

Yours sincerely

Patricia E Hewitt
Acting Medical Director

Copy: Professor J-P Allain
Dr S Knowles