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With the Compliments of

Dr Patricia Hewitt
Acting Medical Director

hw 23.10.95

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Dr. M. CONTRERAS
Chief Executive – Medical Director

Professor Jean-Pierre Allain
Department of Haematology
MRC Centre Building
Hills Road
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PEH/mm/allain2

19 October 1995

Dear Jean-Pierre

Anti-HBc/Anti-HBs study at Cambridge and STBTS

You will be aware that I have had conversations with Lorna, and have written to ask for clarification on a number of issues arising from this study. I have only become involved latterly, in order to supervise the look-back part of the study at STBTS. I have now had an opportunity to read the original proposal and the minutes of the subsequent meetings held in relation to this study. There are a number of questions which remain unanswered.

1. Management of donors with isolated anti-HBc.

I recognise that this is not part of the look-back study. Nevertheless, I have raised the question since I am overseeing the donor counselling at STBTS. The original proposal states that "donors with isolated anti-HBc will be notified of the test results. Appropriate information will be given in a personal interview ...". I have already queried this with Lorna, since we do not have the resources at STBTS for personal counselling of donors found to be anti-HBc positive. When I raised this matter with Lorna, I indicated that our normal practice at NLBTC was to give the information in a letter to the donor. She has replied to me confirming that this would be the case for this study. However, the original proposal appears to include a personal interview. I am now confused! I cannot see that a personal interview with the donor is required to answer any of the objectives of the study. If it is thought necessary to obtain detailed epidemiological information, then this is a separate study (which has already been performed at NLBTC). If it is felt that this is necessary for the management of the donor, then we should discuss further since it is not part of our usual procedures. I have also asked that notification of donors will only take place after two separate samples have been tested and found positive for anti-HBc. This is our usual procedure at NLBTC and I would be unhappy to consider notification after testing of one sample. I note that the protocol for clinical investigation of the significance of isolated anti-HBc includes the question of testing of archive samples. It is not clear when this would be done. If archive samples are tested and found anti-HCV positive, then this would fulfil the requirement for results on two samples before notification of the donor. I would, however, welcome clarification of when the testing of archive samples will be done, since this is not specified.

2. Inclusion of children

I note that the minutes of 16th August 1995 state that "it was confirmed that there was no reason to exclude children from the look-back study". I remain concerned about the inclusion of children. Some ethical committees are very clear on the policy of excluding children from clinical trials and I would have welcomed the opportunity to discuss this point in more detail before commencing the submissions to ethical committees.

I hope that these points can be addressed at the next meeting of the Study Group.

With kind regards.

Yours sincerely

GRO-C

Patricia E Hewitt
Acting Medical Director

Copy: Dr S Knowles
Dr L Williamson