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LW/CET

10 July 1992

Dr R Lane
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13 JUL 1992

Dear Richard

Here is the final version of the Clinical Protocol for the SD FFP Study. This has not gone to Octapharma or elsewhere yet, pending your comments on the following (see also attached letter from Michel Golde).

1. Octapharma wish to be co-sponsors. What do you think? I have no strong views on the matter.

2. Has the question of indemnity been clarified (see Chris Prowse's letter of 22 June 1992)? I have faxed Michel Golde on this, and made a presumptive statement regarding ABPI Guidelines in the Protocol.

3. In your specification for source plasma, you indicate that plasma frozen within 8-24 hours would be acceptable. Surely this cannot apply to 'FFP', as per National Guidelines ('red book'). In fact, I am sure that all plasma collected for the Study would have been frozen within six hours.

4. The specification for Octaplas, dated 24 June 1992 gives a Factor VIII level (one stage assay) of $\geq$0.5 iu/ml. The data sheet which I drafted based on previous data from Octapharma stated >0.6 iu/ml. Can Andrew West-Watson rectify this?

5. The Octaplas storage life dates from date of manufacturing, not collection. Is a maximum storage time prior to SD-treatment stated elsewhere?

I will next be in the office on Tuesday, 14 July 1992.

Yours sincerely

GRO-C

Dr Lorna Williamson
Consultant/University Lecturer in Transfusion Medicine

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