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BC/IMcK

Directors Dr. R. J. Perry

24th April 1985.

POS,

Ela

Prof. R. Weiss Institute for Cancer Research Royal Cancer Hospital Chester Beattie Laboratories Fulham Road LONDON SW3 6JB

Dear Robin

INACTIVATION EXPERIMENTS WITH HTLVIII

The HSE have finally sent us a report of their recent visit to our containment facility and have agreed that we can perform the freeze-drying experiments provided that we convert our Class I safety cabinet to a Class III - this is in hand.

It would appear, therefore, that our planned experiment can go shead. I would suggest the following outline protocol.

- 1. You ship us the virus.
- 2. We spike our product at a ratio of lml virus to 19mls FVIII.
- 3. We freeze-dry the vials.
- We heat the FVIII (at 68°C) for various times, probably 2, 12, 24, 48 hours.
- 5. We return the following samples to you for assay of residual infectivity.
 - FVIII control.
 - 2. Spiked, Frozen FVIII control.
 - 3. Spiked, Freeze-Dried FVIII control.
 - Spiked, heat-treated FVIII (four temperatures).

Thus, I would envisage 7 samples for assay and a requirement for 6mls of virus solution. Does this seem reasonable?

The/

Prof. R. Weiss Royal Cancer Hospital London

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24th April 1985.

The HSE gave also passed their verdict on our ultracentrifuge and consider it suitable providing that we fit a filter to the exhaust line. We can do this if required. Can you advise me whether you think that your cultures will require ultracentrifugation?

We do not yet have any data on infectivity from the model retrovirus experiments which were set up but we do know that reverse transcriptase activity in freeze-dried FVIII spiked with murine leukaemic virus can withstand heating at 68°C for 48 hours with little activity loss. This kind of data makes us keener than ever to validate our conditions using the real thing.

I look forward to hearing your comments on my proposals.

With many thanks for agreeing this collaboration.

Yours sincerely

GRO-C

Bruce Cuthbertson, PhD Microbiologist