



DEPARTMENT OF CARDIOLOGY

Western General Hospital, Crewe Road South, EDINBURGH EH4 2XU

Dr Ian R Starkey

Tel: 0131 537 1845

Fax: 0131 537 1844

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Professor R G Will

Professor of Clinical Neurology

National Creutzfeldt-Jakob Disease Surveillance Unit

WGH

Dear Bob

Lookback Study in Creutzfeldt-Jakob Disease (Ethical Approval 1702/96/4/169)

Thank you for your letter dated 23rd May and its enclosures, notably the copy of Dr McGovern's letter dated 12th January 2000.

As you know, I wrote to you on 30th January, withdrawing ethical approval for the above study, after we had discussed the matter in some detail. This decision was made predominantly because the National Blood Authority had decided that recipients of blood from patients who later developed variant CJD should themselves be deferred as blood donors and that these individuals might need to be informed of the reasons for this deferral.

As we have since discussed, the position has changed once more. I agree that Dr McGovern's letter, describing the formation of the "Expert Group on the Management of CJD Incidents", specifically mentions that "the appropriate Health Authority" will be charged with the responsibility of considering whether or not to tell "deferred blood donors" why their blood cannot be accepted. I am not at all clear how such incidents will be "discussed and managed on a case by case basis", but I agree that this proposal does clearly separate research and clinical practice, suggesting that further research may be entirely ethical.

Dr McGovern's statement that "the policy will be kept under review in the light of developing science" is clearly appropriate. I know that you see the Lookback Study as a very important part of that "developing science" and that, under these circumstances one could argue (as you have!) that it may be unethical not to perform this study, as it may be the only way that certain important information can be obtained.

Under the circumstances, I am happy to respond positively to your request to reinstate ethical approval for the above study. I know that you will keep me informed of any further developments that might affect this decision.

With best wishes
Yours sincerely

GRO-C

Ian R Starkey
Chairman, Medicine / Clinical Oncology Research Ethics Subcommittees.

Cc Val Stewart, Administrator, Lothian Research Ethics Committee