

The Lothian University Hospitals NHS Trust



DEPARTMENT OF CARDIOLOGY

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Professor R G Will
Consultant Neurologist
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Dear Professor ~~Will~~ ^{Bell}

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

As you know, your letter dated 22 November, addressed to Dr Palmer, was passed to me, as I am currently Chairman of the Medicine/Clinical Oncology Research Ethics Sub-Committees. I found our subsequent conversation helpful in clarifying my understanding of this issue.

As you know, our Committee (under a previous Chairman) gave approval to the above study being performed. It was intended that the CJD Surveillance Register and Blood Transfusion Service records should be used to see:

- 1) whether patients with CJD may have given blood donations and, if so, whether any patient receiving that blood is also known to have CJD, and
- 2) whether any patient with CJD has ever received a blood transfusion and, if so, whether any of the donors are now known to have CJD.

Crucially, you felt at that time that it would be inappropriate to contact either blood donors or recipients, as it was felt unjustifiable to give these individuals information which might suggest that they are at risk of developing CJD. This decision was based on the fact that there is neither a test nor effective treatment for the disease.

As you have indicated, this course of action appears to conflict with the stance adopted by the NBA, as described in Dr Hewitt's letter dated 12 October 1999. As you know, this followed a recommendation from MSBT that blood donations from individuals who had received blood from donors who later developed nvCJD should not enter the blood supply. It seems to have been agreed that such a donation would be discarded and that the donor would be contacted and informed, at a face to face interview, that the blood could not be used and the reasons for the decision. Professor Doyal's letter to Dr Hewitt (dated 20 December 1999) states that it would be "immoral and illegal" to act otherwise. He also clearly argues that the lack of an effective intervention is not a justification for non-notification, stating that "many

terminally ill people both need and want to know information about their diagnosis and prognosis, despite the absence of effective treatment". I would agree that it is usually reasonable to tell someone that they are definitely terminally ill so that they may, as the saying has it, "put their affairs in order". I know that we both feel that this is a far cry from being told that there is a possibility (which can be neither confirmed nor refuted) that one may have been "donated" a virus, which may or may not be responsible for causing a lethal illness at some undetermined time in the future!

Nevertheless, a National Policy, with which the Department of Health is in agreement, must be adhered to. As a consequence I have no alternative to refuse your request for renewal of Ethical Approval for the above study. If you wish to discuss this further I should be happy to do so.

With best wishes

Yours sincerely

GRO-C

Dr Ian R Starkey

Chairman, Lothian Medicine/Clinical Oncology Research Ethics Sub-Committees.