DON 8

Lindsey Davies

From: Rowena Jecock

Date: 26 July 2004

Copy: Ailsa Wight Richard Gutowski Carole Fry John Stephenson Terry Stacey

RE: Blood Services and Advice on Ethics

Lindsey,

You have received a letter dated 22 June from Angela Robinson at NBS, to say that the NBS does not have access to a central ethical committee, and is particularly keen to obtain ethical advice in relation to possible vCJD risk mitigation measures.

Dr Robinson says that the NBS has consistently failed to get agreement from DH to establish a central ethical committee to advise all the UK blood services. Neither the CJD nor the blood policy teams were aware of this, but it appears that NBS has approached the DH R&D Division, requesting that DH set up a central ethics committee to advise the blood services. This is not an appropriate function for the Department, and I understand that this has been made clear to the NBS.

Dr Robinson requests your view on extending the terms of reference of the CJD Incidents Panel to provide ethical advice to the blood services. This too, is completely inappropriate. The CJDIP advises healthcare organisations on the management of incidents that have occurred where patients may have been exposed to CJD. This advice is provided on a case-by-case basis. Although it has ethicists amongst its membership, the Panel is not constituted to provide ethical advice on generic options for prospective risk management measures.

If NBS or the UK blood services as a whole require ethical advice on potential risk mitigation measures, there appears to be no reason why they should not set up their own panel of ethicists to advise them. Should NBS decide to do this, such a panel would not be able to provide "approval" if a research project is involved. The attached draft makes this clear.

Terry Stacey has kindly offered COREC's assistance to NBS by providing names of "working" ethicists, should NBS wish to draw on COREC's knowledge of people with practical rather than just theoretical experience. His note to me is attached for information.

Rowena

DRAFT

Dr Angela Robinson Etc

Thank you for your letter of 22 June requesting advice on whether the CJD Incidents Panel could assist the NBS by providing ethical advice on prospective vCJD risk mitigation

measures.

As you may know, the Panel's function is to provide advice on a case by case basis to health care organisations on the management of patients who may have been exposed to CJD transmission risk. I am advised that, although the Panel has ethical expertise amongst its membership, it is not equipped to provide ethical advice on generic options for prospective risk management measures.

Neither I, nor colleagues in the Department of Health, see any reason why the UK blood services should not establish an ethical panel to specifically advise them on issues such as those mentioned in your letter. Professor Terry Stacey has kindly offered to provide you with the assistance of the Central Office for Research Ethics Committees in providing the names of a number of ethicists with practical experience, whom you may wish to consider. I must make clear however, that any mechanism that you may choose to establish internally to provide ethical advice, cannot provide ethical approval for research projects. Any research in the NHS, which comes under the remit of NHS Research Ethics Committees (REC), needs the explicit approval of an appropriate NHS REC, irrespective of any advice that may have been given by an in-house ethics advisory panel.

Yours sincerely,

Etc.