

20 December 2011

Organ Directive Consultation
c/o Transplant Team
621 Wellington House
133-155 Waterloo Road
London SE1 8UL

Dear Sir / Madam

Public consultation on regulations to transpose Organ Directive 2010/53/EU into UK legislation

I am writing on behalf of the Nuffield Council on Bioethics, an independent body that examines and reports on ethical issues in biology and medicine.

In October 2011, the Council published a report, *Human bodies: donation for medicine and research*, which considers the ethical and social issues that arise when people are asked to donate bodily material (such as organs, blood, eggs and sperm) for medicine and research. The report was the result of a two-year independent inquiry led by Professor Dame Marilyn Strathern (Cambridge University) which sought to answer the question: how far should society go in encouraging people to donate their bodily material?

In coming to its conclusions, the Working Party consulted a wide range of people, including members of the public, patient and user organisations, academics and researchers, people involved in regulating donation and research, and professionals involved in transplantation and fertility services. More information about the inquiry and resulting report can be found at: www.nuffieldbioethics.org/donation

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Human tissue for research

Whilst the Council has no specific comment to make in relation to particular questions, there is one general point that we would like to highlight, relating to the use of human tissue for research purposes, which we feel that the implementation of the Directive might give a suitable opportunity to address.

The Council's report concludes that research, and the future health benefits that research seeks to bring, are of vital public interest, and it makes a number of recommendations that aim to improve access to human tissue for research purposes. **We urge the Government to take this opportunity to consider how the new regulations will impact on the use of human tissue in research.**

The new licensing regime aims to "ensure that the appropriate organisations are licensed while avoiding having to licence all hospitals where the retrieval takes place". However, we are aware that licensing issues under the Human Tissue Act (HTA) may lead to specific difficulties in accessing tissue for research. Researchers have expressed concerns about the practical impact of the HTA licensing regime, whereby it is sometimes impossible to remove small amounts of blood or tissue in order to carry out research into the effectiveness of organ transplantation techniques because the hospital premises where the donor organs are being removed are not licensed for research.

The HTA's Code of Practice states that tissue cannot be removed from a deceased person for the purposes of research without a licence being held by the institution where it will take place. Similarly, if bodily material removed for the purpose of transplantation is subsequently used for research, rather than transplantation, the material must be stored on licensed premises, unless it is for a specific research project that has been approved by a research ethics committee. However, many hospitals where bodily material is removed – either for the purpose of transplantation or other medical treatment – do not hold an HTA licence, as removing organs for transplantation is explicitly excluded from the licensing requirements. Such hospitals are unable to use any bodily material they remove for research purposes, regardless of the wishes of the deceased person or their relatives. **The Council emphasises the need for ongoing dialogue between the Human Tissue Authority and the transplant communities to find a proportionate way forward** (paragraph 7.60). The review of licensing arrangements in connection with the Organ Directive appears to offer a valuable opportunity to resolve the difficulties currently experienced in respect of material donated for research purposes.

Please do not hesitate to contact me if you would like further information or assistance.

Yours sincerely

A handwritten signature in black ink, reading "Hugh Whittall". The signature is written in a cursive style with a large, sweeping initial 'H'.

Hugh Whittall
Director