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*From the President Lord May of Oxford OM AC Kt PRS*  
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Policy no: 12/04

### **Human Tissue Bill**

I am writing to you to voice the Royal Society's concerns about the Human Tissue Bill, which is currently being debated in Parliament. Whilst we support the Bill's aims to increase public confidence in the legislative process surrounding the storage and use of human tissues and organs, the wide-ranging and unprecedented emphasis on consent within the Bill has resulted in serious concerns within the scientific community. These concerns are particularly focused on the Bill's potential to generate unintended consequences for the use of legitimately obtained human tissues and organs for research.

We are particularly concerned about the **Code of Practice** that is to provide guidance on the implementation of the legislation, which is to be devised by the Human Tissue Authority once the legislation has been passed. There is the possibility that the Authority may add extra detail to the legislation through this Code, and we are alarmed that this additional guidance will not be subject to Parliamentary scrutiny. There are no mechanisms within the Bill to ensure that the scientific community shapes this secondary legislation in accordance with scientific need. We believe that this is a failing of the draft legislation, and measures need to be urgently introduced to ensure that these guidelines are appropriately scrutinized. In particular we urge that researchers play a role in ensuring this legislation maintains access to these valuable tissues for research purposes. A similar situation occurred with the Export Control Bill and there were strong objections from myself and others during its passage through the Lords.

One particular area that could be restricted is research using **existing collections of stored tissues**, which are exempt under the new legislation but may be subject to additional legislation under the Code. Existing tissue collections date back many years, and provide a valuable historical resource about disease. These collections, even when anonymised to prevent individual identification, can be used to provide vital indications of disease incidence within the population as a whole. The legislation has the potential to make requirements for consent apply



retrospectively, which could have serious implications for the future use of existing collections of tissue samples.

We are concerned about the breadth of the legislation, both in terms of **the range of the work covered by the legislation and how this work is defined**. This has the potential to place serious restrictions on legitimate work by scientific researchers, and it is our opinion that this legislation needs considerable refinement in order to protect the future of this valuable work. In particular, there is a lack of clarity regarding the non-consensual analysis of DNA and a lack of distinction between various types of tissue sample that may be retained. These issues must be addressed so that the Human Tissue Bill enables the ongoing collection of tissues and organs to maintain and extend our understanding of disease, for the benefit to wider public health.

The Human Tissue Bill was drafted in response to the illegal removal of whole organs during post-mortem, but in its current form places severe restrictions on the use of **tissue samples routinely taken during clinical procedures**, which would often be discarded if not retained for research purposes. Whilst I appreciate the legitimate public concerns that prompted the creation of this Bill, the vast majority of the scientific community who carry out work using human material do so sensitively and with nothing but the greatest respect for the donated tissues and organs that their work relies upon. Disappointingly, the legislation contained within the Bill seems to start from a position of mistrust of the scientific community that is wholly unfounded. It is alarming that in addition to this atmosphere of suspicion, the legislation proposes severe penalties for any perceived breach of consent.

The attached document discusses a number of specific issues within the legislation that are of particular concern to the Royal Society. In conclusion, it is essential that any new legislation ensures an appropriate balance between the protection of individual rights and maintaining access to tissues and organs for the benefit of wider population. I welcome your assurances that the concerns I have outlined in this letter and attached document, which echo those voiced by other organisations, will be taken into account by the Department as the legislation progresses through Parliament. Consequently, I hope that it will not be necessary for me to raise these issues again when the legislation passes to the House of Lords.

We intend to publish this letter on our website, and would be happy to publish your response. I look forward to hearing from you.

Yours

Robert M May

cc. Sir Liam Donaldson, Lord Oxburgh, Lord Sainsbury of Turville, Lord Warner of Brockley, Rosie Winterton MP, Lord Winston



## **Human Tissue Bill – Comment from the Royal Society on specific issues of concern**

### **16 February 2004**

- *The lack of distinction between various types of tissue sample that may be retained*

One major failing of the legislation is not distinguishing between different types of human material. There needs to be a clear distinction between the retention of tissue samples, such as those from routine biopsies during surgical examination or post-mortem, and whole organs. As stated in the Royal Society response to the Retained Organ Commission consultation on Tissue Blocks and Slides (January 2003), “whole organs, which are removed during post-mortem examinations, may have significant personal value to family members. As tissue blocks usually originate from tissue samples taken during surgical biopsies or post-mortems for disease diagnosis, these may not be associated with the same levels of attachment as whole organs”. This response can be found on the Royal Society website at [www.royalsoc.ac.uk/policy](http://www.royalsoc.ac.uk/policy)

- *The scope and definition of the requirement for consent*

The Bill strongly emphasises the need for consent for all storage and use of human organs and tissues. This could severely impact on the use of tissue samples for diagnostic purposes, despite the fact that surplus tissue is routinely used for this research. The time and effort required to ensure that adequate consent has been obtained could substantially reduce the amount of research carried out on human tissue. We therefore recommend that the legislation should be modified to state that if these tissues samples are appropriately anonymised, then individual consent for research should not be necessary.

The definition of consent needs to be sufficiently broad to allow for the use of tissue for new or unforeseen modification of existing research, without the need for additional consent. Requiring researchers to specify how the stored tissue will be used is impractical and indeed impossible where research is conducted over a number of years, as the scope of research projects inevitably changes over time.

A specific clinical example is that in neuropathology diagnosis. Taking biopsies from live subjects is very rarely ethically justifiable, except under conditions of exceptional medical need. We feel that this legislation may restrict the current routine procedure of post-mortem biopsies, and consequently curtail research on key areas of neurodegenerative disorders, such as dementia, multiple sclerosis and Parkinson’s disease. It may also impact on research into conditions such as developmental disorders e.g. autism or Sudden Infant Death Syndrome.

- *Code of Practice*

The use of tissue collections of unclear or that lack consent is not adequately addressed in the Bill, as existing holdings are exempt under Section 7 of Part 1. However, there are concerns that additional conditions may be placed on existing holdings through the Code of Practice, which will be designed once the Bill becomes an Act. The Department of Health has reassured stakeholders on earlier occasions that no collection will have to be destroyed. However, there are worries that severe limits may be placed on these collections, so that they may become in



effect useless. As the Code of Practice will be drafted after the Bill has been passed, there does not appear to be an opportunity for researchers to comment on this secondary legislation even if it is too restrictive. If this is not done in consultation with the scientific community then the future of existing collections, which are of incalculable historical value, and provide an essential public health resource for ongoing disease monitoring and diagnosis, may be threatened. Additionally, as this legislation includes the potential to prosecute individuals who are considered not to have obtained appropriate consent, any secondary legislation should be subject to additional Parliamentary scrutiny. We therefore recommend that the future of existing holdings, defined as those in existence up to the day the Bill is passed, is determined through consultation with the scientific community, and with due care to ensure their future use.

- *The non-consensual analysis of DNA*

We believe that this issue of the non-consensual analysis of DNA is not appropriately addressed within this legislation. Concerns about the issue of the non-consensual removal and analysis of DNA are predominantly associated with issues such as paternity cases, and we believe that this issue has already been adequately addressed in the Government Genetics and Health White Paper. Any additional legislation for the analysis of DNA within scientific research should be very carefully assessed to ensure that it is in accordance with existing research needs, and that it does not restrict future developments in this important and constantly advancing field. We therefore recommend that more detailed consideration be given to how this issue is addressed within the Bill.

- *The severe penalties for any perceived breach of consent*

The penalties for being considered to have breached the requirement for appropriate consent are so severe that medical personnel may seek to avoid this risk by reducing the number of 'medical interest' post mortem examinations and therefore reduce the availability of tissue for research. This material is often anonymised and would be otherwise discarded, so placing restrictions on the use of material in this way would be of detriment to society as a whole. I was interested to note the Royal College of Pathologists' comment on this legislation, which pointed out that the penalties for an unreliable diagnosis, through obtaining inadequate information, are less punitive than the penalties for those who are considered to have breached the requirement for appropriate consent.