Royal Society response to the Department of Health consultation on draft Regulations for the Human Tissue Act 2004

The Royal Society welcomes the opportunity to contribute to the Department of Health's consultation on the Human Tissue Act 2004: Draft Regulations. In preparing this response we have consulted with Fellows and other experts that have worked with us on relevant committees, working groups and science policy advisory groups.

The Human Tissue Act 2004 provides a consistent legal framework, based on consent, for issues relating to the taking, retention and use of human tissue and organs from adults or children. It also establishes the Human Tissue Authority to oversee the field, issuing licences and publishing Codes of Practice. The Act also includes provisions for Regulations to be made by the Secretary of State, subject to a process of Parliamentary approval, on a number of detailed points. Our response summarises the Royal Society's views on the draft Regulations.

The Royal Society would firstly like to reiterate its support for the aim of the Human Tissue Act to increase public confidence in the legislative process surrounding the storage and use of human tissues. The Society has taken an active role in voicing the views of the scientific community over the initial drafting of the Human Tissue Act and in particular the concerns that the Act may endanger the continuation of vital medical research.

In our letter to the Secretary of State for Health in February 2004 we outlined our key reservations about the draft Act. These included: concern that existing collections of stored tissues may become subject to additional legislation; that the Code of Practice may add additional legislation to the Act but not be subject to Parliamentary scrutiny; and the breadth of the legislation has the potential to place serious restrictions on legitimate work by scientific researchers. We were pleased that many of the issues raised by the Society and other stakeholders during the parliamentary process of the Bill were addressed. However we still have serious misgivings about a number of fundamental issues raised in the draft Regulations which relate to the conduct of scientific and clinical research.

Firstly, we are concerned that the draft Regulations will require researchers to obtain a licence for the storage of tissue for an unspecified research use which were taken from patients for purposes outlined in the Regulations that do not require a licence. In our opinion, this will apply to a large number of samples and therefore has the potential to place a huge burden on the researchers who will be required to obtain a storage licence for these samples. Clarification is needed on the circumstances for which a storage licence is required.

Secondly, the regulations are unclear as to whether research ethics committee approval needs to be sought for every new category of investigations on a set of appropriately anonymised samples where there is no need to contact the research subject, or whether a broader permission could be obtained. We suggest that ethics committee approval should be given for broad research into a particular disease/condition on a specific set of samples, in a named unit/laboratory at a named institution, for a specified period of time (which is either fixed by the committee or related to the research project funding). Furthermore, by appropriately anonymising the tissue such that the patient need not be re-contacted by those carrying out the research (either in the laboratory or in the analysis of data) there is no reason why a licence should be required for each new category of investigation.

For example currently researchers may maintain a bank of human tissue samples collected from patients as part of an ethically approved research project. Under existing regulations the researchers are able to respond rapidly to advances in their field, by re-analysing the samples to examine new hypotheses about diseases and their treatment. The results of such experiments may have implications for the life and health of thousands of patients. The requirement for ethical review of each new category of investigation on these tissue samples would delay, and in some cases prevent, this vital new research, even though the ethical treatment of the patient remains unchanged.

Finally, the approval of category-based research would reduce the burden on local research ethics committees (LREC) and multicentre research ethics committees (MREC) who would not be required to licence each individual research project. This would also reduce the administrative burden on individual researchers and the inevitable delays that would arise from waiting for LREC or MREC approval for each individual project.

We hope the Department of Health, in conjunction with the Human Tissue Authority, will consider a communication exercise to raise awareness within the clinical and research communities of the Regulations, particularly in light of the powers of entry and search outlined in the draft Regulations. The new proposals outlined in the Regulations, coupled with the severe penalties already in place in the Act, must be clearly conveyed to clinicians and the research community.

The Society continues to believe that these latest Regulations still come from a position of mistrust of the scientific community. We believe that flexibility within the Act, as outlined above, is required to allow legitimate work by scientific researchers to continue. The Act must protect the future of this valuable work and not discourage researchers working with human biological material.

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