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Human Tissue Act 2004: The age of consent arrives in the UK

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Abstract

The organ collection scandals of Alder Hey and Bristol Royal Infirmary in the UK were the driving force for a comprehensive overhaul of the legislation and regulation of the handling and use of human tissues in the UK. The Human Tissue Act 2004 is due to come into force in April 2006 and will resolve a number of uncertainties for researchers. The adopted regulatory approach is not dissimilar to that adopted for the use of embryos in the UK. The legislation provides the framework but a body established under the Act – the Human Tissue Authority (HTA) – will be responsible for granting licences, determining what constitutes 'appropriate consent' and providing detailed guidance and regulations. The advantage of this approach is that it will allow the board of the HTA, whose members include experienced professionals in the medical and research communities, to adapt the system to keep up with scientific developments and possibly changes in public opinion more rapidly than would have been possible where guidance is set out within the legislation. Even before the HTA issues its first guidance, researchers can be clear that certain activities, such as those relating to cell lines, are not covered by the Act. Other processes, such as the anonymising and de-linking of patient data could be subject to additional regulation by the HTA although any guidelines must also conform with the provisions of the Data Protection Act 1998. This paper discusses the new regulatory framework and identifies the challenges for researchers in complying with an Act, which provides for criminal sanctions for breach.

Keywords: *data protection, human tissues, consent, healthcare, medical research, medical ethics*

THE NEED FOR REFORM

The Human Tissue Act 1961, as originally enacted, consisted of just four sections. Two of those sections concerned the removal and use of human organs and tissue and required that the tissues were only to be used for therapeutic, educational or research use. If a person had not made it clear that their body could be used for these purposes after they died, the person 'lawfully in possession' of the body could authorise such use if they had reason to believe that the deceased or their family had no objection. It was generally accepted that where a patient died in hospital, the hospital management was deemed to be 'lawfully in possession' of the patient's body. Consequently, in these circumstances, there was no specific requirement for consent to be obtained for the removal or use of a deceased's tissues or organs – only a 'reasonable enquiry' needed to be made of relatives where a patient had died without making their wishes known.

The limitations of this legislation were brought to public attention by the controversies surrounding collection of body parts in the Alder Hey and Bristol Royal Infirmary. This resulted in the Kennedy and Redfern inquiries and the Isaacs Report in 2003, which illustrated that storage and use of organs and tissue from both adults and children without proper consent had been widespread. The need for reform was identified in the results of the consultation 'Human Bodies, Human Choices' launched by the Department of Health in July 2002. After a troubled legislative journey, the Human Tissue Act 2004 (the 'Act') was granted Royal Assent on 15th November, 2004,

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and is expected to come into force in April 2006.

HUMAN TISSUE ACT 2004 – 'APPROPRIATE CONSENT'

'Appropriate consent' is the fundamental principle underpinning the storage and use of human tissues

The Act establishes a legal framework regulating issues relating to whole body donation and the taking, storage and use of human organs and tissue. 'Appropriate consent' has been established as the fundamental principle underpinning the lawful storage and use of human bodies, body parts, organs and tissue and the removal of material from the bodies of deceased persons.

The Act is structured in three parts: Part 1 outlines the requirement for the consent of the donor when removing, storing and using 'relevant material' from the human body; Part 2 details the establishment of the Human Tissue Authority (the HTA) and outlines its remit, and Part 3 of the Act contains miscellaneous provisions, in particular establishing an offence for nonconsensual analysis of DNA.

THE HUMAN TISSUE AUTHORITY

The HTA is responsible for drafting Codes of Practice and issuing appropriate licences

Responding to public concern about past practice of the removal, retention and disposal of human organs and tissues, the Act provides for the establishment of a new statutory body to oversee these activities. The HTA was formally launched on 1st April, 2005, and is chaired by the Rt Hon. Baroness Hayman. It will be responsible for drafting Codes of Practice and generating a coherent and comprehensive regulatory framework in order for the successful implementation of the Act by April 2006. The Act has given the HTA a broad remit – in order to store and carry out research on all 'relevant material' (see below), a licence must be obtained from the HTA. On its face, this suggests that all research institutions, hospitals, biotechnology and pharmaceutical companies that are participating in any medical research on relevant material will need to be licensed. However, the HTA has been instructed to ensure that the licensing process is proportionate and not unduly burdensome, especially to small research organisations. Indeed, the Act also gives the Secretary of State the power to waive the licensing requirement to allow distinction to be made between, for example, tissue banks (which would need to be licensed) and individuals using tissues in research projects (who would be exempt). Regulations are yet to be published and so it is vital for institutions engaged in such research to monitor developments in this area.

In time for April 2006, Regulations will also be issued to make the HTA the competent authority under the EU Tissues and Cells Directive (2004/23/EC). This Directive introduces new legal requirements for all units involved in the donation, procurement, testing, processing, storage and distribution of gametes and embryos and applies in respect of tissues that are intended for application in the human body, for example, stem cell treatment donors of reproductive cells. It is also expected that the HTA and Human Fertilisation and Embryology Authority will merge in 2008.

'RELEVANT' AND 'BODILY' MATERIAL COVERED UNDER THE ACT

'Relevant material' includes any material that consists of human cells other than hair or nails, and gametes or embryos (which are already regulated under the Human Fertilisation and Embryology Act 1990). With some important exceptions, which are discussed below, the Act requires that both living and deceased individuals must give their 'appropriate consent' if any of their 'relevant material' is to be stored or used for the 'scheduled purposes' documented in part 1 of schedule 1 of the Act (see Table 1). These purposes include conducting any research which establishes the efficacy of a drug, obtaining any scientific or medical information about a person that may be relevant to another person, or, indeed, medical research in

Table 1: The scheduled purposes

Part 1	Part 2
Anatomical examination	Clinical audit
Determining the cause of death	Education or training relating to human health
Establishing after a person's death the efficacy of any drug or other treatment administered to them	Performance assessment
Obtaining scientific or medical information about a living or deceased person which by be relevant to another person (including a future person)	Public health monitoring
Public display	Quality assurance
Research in connection with disorders, or functioning of the human body	
Transplantation	

The Act has a much broader remit than just regulating organ retention

general. Interestingly, if relevant or bodily material comes from a living person, appropriate consent is not deemed necessary for those purposes that are listed in part 2 of schedule 1 (for example education or training relating to human health, public health monitoring and clinical audit; see Table 1). This is presumably because these activities are thought to be either intrinsic to the proper treatment of a patient or necessary for public health purposes. Indeed, the removal of tissue from living persons is still covered by common law principles, which makes it an offence to interfere with a person's body without their consent.

Research on cell lines is not covered by the Act

The Act also establishes that it is an offence to store any 'bodily material' (*any* material that has come from a human body and that consists of or contains human cells) with the intent to analyse its DNA without 'qualifying consent' although, again, there are important exceptions to this rule detailed below.

Overall, therefore, the Act has a much broader remit than just regulating organ retention as it will regulate research on even minute samples of human tissue. On the other hand, it is important to note that any material created outside the human body, such as a cell line, is not considered to be relevant material and, therefore, is not covered by the Act.

'APPROPRIATE' AND 'QUALIFYING' CONSENT

Unfortunately, the Act does not provide a clear explanation of what 'appropriate consent' or 'qualifying consent' actually means. Although the Act does document the subtle differences in what amounts to 'appropriate consent' between adults, children or persons lacking the capacity to make the decision to consent on their own behalf, it does not define either the scope or the degree of detail needed to be given to an individual to make any type of consent lawful. It will be down to the HTA to determine exactly what 'appropriate consent' means and its decision will have enormous practical consequences for how medical research can proceed. It is hoped the final definitions will be consistent with the concept of 'consent' that has already become enshrined in the Data Protection Act 1998. Regardless, it is clear that the HTA needs to ensure explicit guidance is published that gives professionals in the field clear procedures to be followed for obtaining consent from individuals prior to their tissues being stored or used. This is particularly important as criminal sanctions could result for the professionals involved. The Codes of Practice to be issued by the HTA are, therefore, awaited with anticipation.

Definitions of 'appropriate' in a 'qualifying' consent will be determined by the HTA

EXCEPTIONS FOR THE NEED TO OBTAIN CONSENT

After extensive lobbying from the medical research community during the passage of the Human Tissue Bill through Parliament, the Act has granted a number of exceptions to the need to obtain

Research on existing samples is still currently lawful, even if appropriate consent was not originally obtained

consent to store and use both relevant and bodily material. For example, consent is not required in relation to relevant material that has been imported, or relevant material from living persons that is used for the purpose of education and training. In addition, until the requirement to obtain consent takes effect (expected to be in April 2006), medical research on existing samples will still be lawful even if appropriate consent was not obtained at the time of their extraction. However, such activities could be subject to a later Code of Practice from the HTA. Usefully, the Act has also provided that if consent has been given to use relevant material for a scheduled purpose, it is not then necessary to obtain separate consent to use the results of any DNA analysis from this material so long as these results are also for a scheduled purpose listed in the Act (see Table 1).

The HTA also has the power to grant 'deemed consent' for tissues to be analysed in order to obtain medical information that may be of benefit to another person. These provisions were debated at length in Parliament and were included with the aim of benefiting a particular individual (ie a family member who was at risk from a particular inherited disorder) rather than the public at large. 'Deemed consent' can be granted provided that the donor of the sample is presumed to be alive and has simply failed to respond to reasonable requests for consent, or indeed whether the donor simply cannot decide whether or not to consent to the use of the material for the purpose asked.

When the Act comes fully into force, research on anonymised tissue samples as part of an ethically approved research-project will be permissible, even without the consent of the donor

The Act also gives the Secretary of State the power to make regulations that would allow the High Court to make an Order that appropriate consent has been deemed to have been given when the use of relevant or bodily material is required for research purposes in connection with disorders or the functioning of the human body. However, it is envisaged that the circumstances in which the High Court will exercise these powers will only be in extreme cases, for example, when such research would be in the overwhelming public interest as public health is at risk. This provision is analogous to the provisions made in the Data Protection Act 1998 (Schedule 3, Condition 8) in respect of the waiving of the requirement for explicit consent to be given when processing of sensitive personal data is strictly necessary for medical purposes, and also with the provisions contained within the Health and Social Care Act 2001 (sections 60 and 61) which allows the Secretary of State for Health to authorise or require the disclosure or other processing of patient identifiable information for specified medical purposes where there will be a benefit to patient care or public health.

The Act also provides that research requiring the storage and use of both bodily and relevant material from living persons can be carried out without consent, provided that the research has been ethically approved, and that the researcher does not have information that can identify the donor (ie the samples and/or data are anonymised). The explanatory notes of the Human Tissue Bill suggested that existing Research Ethics Committees would grant ethical approval although this has yet to be confirmed by the HTA. A full anonymisation of data and/or samples could cause difficulties for researchers and companies engaged in pharmacogenetics research, for example, where it is essential for any genetic information derived from the stored material to be linked back to the patient record. Fortunately, the HTA does not seem to require that samples of human material have to be *permanently* unlinked from the patient record. On the other hand, the exact process by which samples can be unlinked and then lawfully linked back to the donor is not provided by the Act. This is another area that it is hoped will be clarified by the HTA.

Finally, the Act has provided a list of 'excepted purposes' that allow the analysis of DNA in a sample without obtaining the donor's qualifying consent. These 'excepted purposes' include the medical

treatment of the donor of the bodily material in question; the prevention and detection of crime; for purposes of national security; and for the conduct of a prosecution. Use of the results of an analysis of DNA for any of the scheduled purposes (but not transplantation or public display) is also deemed to be use for an excepted purpose if the bodily material concerned has already been collected (ie is an 'existing holding'). Qualifying consent is also not needed for DNA analysis if the bodily material from which the DNA was extracted was from a living person and the analysis is to be used for the purposes of clinical audit, education or training relating to human health; performance assessment; public health monitoring; or quality assurance.

FALLING FOUL OF THE ACT

If a person is found to have failed to have obtained 'appropriate consent' for the removal, storage or use of relevant material for any of the scheduled purposes (see Table 1); stores or uses human tissue donated for a specified purpose for a different purpose; participates in the trafficking of human tissue for transplantation; or carries out licensable activities without holding a licence from the HTA, he or she will have committed an offence under the Act and will be liable to a fine, up to three years' imprisonment on indictment, or both. In order to allow healthcare professionals and researchers time to study the standards required, the Act does state that offences relating to a failure to obtain consent will not take effect until three months after the HTA's publication of its Code of Practice on consent. Some comfort may also be gained from the fact that if a person 'reasonably believes' that appropriate consent has been obtained, an offence will not be deemed to have been committed under the Act.

Any person committing an offence under the Act is liable to a fine and/or imprisonment

The Act has also put penalties in place to prevent the unauthorised testing of DNA. A person will commit an offence if they has in their possession any bodily material with which they intend to carry out DNA analysis without the donors 'qualifying consent', and if they intends to use the results arising from that analysis for any purpose other than an 'excepted purpose'. A defence of 'reasonable belief' that qualifying consent was obtained is also available for the wrongful use of tissues for DNA analysis.

CONCLUSIONS

The Act provides a comprehensive legal framework for the handling and use of human organs and tissue. However, the full implications of the Act will remain uncertain until the codes of practice and regulations to be issued by the HTA and Secretary of State are published. In particular, the area of de-linking or anonymisation of data and/or samples will require careful consideration in medical and genetic research given the potentially different requirements under the Act and Data Protection Act 1998, as will the definition of both 'appropriate' and 'qualifying' consent. A clear and practical set of guidelines for organisations that collect or use human tissues is awaited with interest, and should be forthcoming over the next year.

Further reading

1. The Department of Health: The Human Tissue Act 2004 – New Legislation on Human Organs and Tissue (URL: http://www.dh.gov.uk/assetRoot/04/10/36/86/04103686.pdf).
2. The Cambridge Genetics Knowledge Park (URL: http://www.cgkp.org.uk/topics/human_tissue/).
3. The Human Tissue Act 2004 as enacted (URL: http://www.opsi.gov.uk/acts/acts2004/20040030.htm).
4. The explanatory notes to the Human Tissue Act 2004 (URL: http://www.opsi.gov.uk/acts/en2004/2004en30.htm).