EXPLANATORY MEMORANDUM FOR

THE HUMAN TISSUE ACT 2004 (PERSONS WHO LACK CAPACITY TO CONSENT AND TRANSPLANTS) REGULATIONS 2006

2006 No. 1659

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Description

2.1 The Human Tissue Act 2004 ("the Act") Act sets up a framework to regulate the storage and use of human organs and tissues from the living and the removal, storage and use of tissues and organs from the deceased, for specified health related purposes and public display. The Act establishes a regulatory authority, the Human Tissue Authority ("the HTA"), to regulate these activities and transplantation.

2.2 The Act contains a number of powers to allow the detailed requirements to be set out in Regulations. This instrument:

- specifies the circumstances in which an incapacitated adult can be deemed to have consented to the storage and use of their bodily material for the specified health-related purposes in Part 1 of Schedule 1 to the Human Tissue Act 2004 (the Act)[1] and to the analysis of his or her DNA
- defines transplantable material, and
- specifies the circumstances in which it is permissible to carry out donor transplants from living persons, the procedures that the HTA must follow in deciding whether or not to grant permission to carry out live donor transplantation and appeals.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This instrument makes the first use of powers under sections 6 (see regulations 3 and 4) and 33 (see regulations 9 to 14) of, and paragraph 12(2) of Schedule 4 (see regulations 5 to 7) to, the Act. These regulations are subject to the affirmative resolution procedure, as provided for in section 52(4) of the Act.

4. Legislative Background

4.1 One of the primary objectives of the Act was to rationalise and update a wide range of existing legislation into one Act of Parliament. The existing law on retention and use of organs and tissue was reviewed following public concern into events at Bristol Royal Infirmary and the Royal Liverpool Children's Hospital**.** The Kennedy

[1] Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person); research in connection with disorders, or the functioning, of the human body and transplants.

and Redfern inquiries at these hospitals, together with the Isaacs Report, which focussed on retention of adult brains following coroners' post-mortems, showed that storage and use of organs and tissue without proper consent after people had died were commonplace. The legal review showed that the law on tissue retention, both from the living and the deceased, was inadequate and that the law on anatomical examination and transplants needed to be updated.

4.2 Part 1 of the Act sets out the requirement for consent to carry out activities for particular purposes[2] regulated by the Act. This instrument sets out the circumstances where there is to be deemed consent to activities regulated by the Act in relation to adults who lack capacity to consent for themselves. Section 6 of Act states that where a living adult lacks capacity to give consent to the storage and use of their bodily material, the Secretary of State can specify in Regulations circumstances where consent can be deemed to have been given. Paragraph 12(2) of Schedule 4 provides a corresponding power for the Secretary of State to make Regulations to allow the use of tissue for DNA analysis in cases that would otherwise be unlawful under Section 45 of the Act (non-consensual DNA analysis).

4.3 The circumstances in which it was envisaged that section 6 would be used was signalled by Ministers in Parliament during the passage of the Act (Common's Debate 28th June 2004 : Columns 34-36) and these circumstances were:

a. where it would be in the best interests of an incapacitated person from whose body the material came;

b. for research, where the research is authorised under the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031); and

c. for research in circumstances that would be consistent with sections 30-33 of the Mental Capacity Act 2005. As the Mental Capacity Act is not expected to be brought fully into force until 2007, these Regulations have a transitional provision that will allow the storage and use of tissue for research where the research project has ethical approval.

4.4 Section 33 of the Act repeals, replaces and extends the provisions in the Human Organs Transplants Act 1989. This section sets out the offence and penalties related to the removal and transplantation of organs and other material from living donors. This instrument provides the circumstances in which transplants will be permitted. The Authority will regulate transplants from living donors and this instrument sets out the procedure for decision making and appeals. As stated by the Government during the passage of the Human Tissue Act (Lords' Debate 11 October 2004: Column GC10) the Human Tissue Authority will regulate transplants from living donors and the approval process would be the subject of further consultation in preparation for Regulations.

[2] The purposes that are regulated are listed in Schedule 1 to the Act (and are referred to as scheduled purposes) and are: anatomical examination; determining the cause of death; establishing after a person's death the efficacy of any drug or other treatment administered to him; obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person); public display; research in connection with disorders, or the functioning, of the human body; transplantation.

4.5 There is a further instrument that forms part of the implementation package for the Act - the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006. That instrument is subject to the negative resolution procedure and it is intended that it will be laid at the same time as this instrument. That instrument provides the definition of research ethics authority for the purposes of regulation 8 (which defines ethical approval for the purposes of deemed consent for adults lacking capacity) of this instrument. This instrument defines, in regulation 9, transplantable material for the purposes of the information requirements for transplants that is provided for in the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations.

4.6 This instrument makes the first use of powers under sections 6 and 33 of, and paragraph 12(2) of Schedule 4 to, the Act.

5. Extent

5.1 This Instrument applies in relation to England and Wales and Northern Ireland subject to the exceptions in this paragraph. Regulations 1 and 2 apply to Scotland as well as England and Wales and Northern Ireland. Regulations 3 and 5 apply in relation to England and Wales only. Regulations 4 and 6 apply in relation to Northern Ireland only. Regulation 7 applies to Scotland only.

6. European Convention on Human Rights

Rosie Winterton has made the following statement regarding Human Rights:

In my view the provisions of the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 are compatible with the Convention rights.

7. Policy background

7.1 The Act is a framework for regulating the storage and use of human organs and tissue from the living, and the removal, storage and use of tissue from the deceased, for specified health related purposes and public display. These Regulations set out some of the detailed requirements of the Act following the agreement of the broader principles in primary legislation.

7.2 The Mental Capacity Act 2005 provides a framework in relation to consent and persons who lack capacity. The Government has taken a regulation making power in the Human Tissue Act 2004 to specify circumstances in which consent may be deemed from a person who lacks capacity (in the absence of a prior decision) to the keeping or use of tissue (once lawfully removed) for regulated activities, including DNA analysis. This was intended to ensure that, given that the Human Tissue Act 2004 will be brought into force before the Mental Capacity Act 2005, legitimate activities will not fall foul of one Act pending implementation of the other.

7.3 The Department of Health has worked closely with stakeholders, including representatives in Scotland, Wales and Northern Ireland, patient representative groups, healthcare professionals and interested individuals whilst drafting these Regulations.

7.4 These Regulations were the subject of a formal consultation exercise for a period of twelve weeks between 11th July and 4th October 2005.

7.5 Of the 45 responses received, around 20 respondents commented on the proposals put forward in this instrument. There was broad support for the proposals that were put forward in the draft Regulations, although 5 respondents noted some inconsistencies between the draft Regulations and the Mental Capacity Act 2005. As the Mental Capacity Act is unlikely to be implemented until 2007, these Regulations establish an interim, or transitional, position regarding the storage or use of tissue for research pending implementation of the Mental Capacity Act, with full alignment between the two statutes upon implementation of the Mental Capacity Act. The amended Regulations now deal explicitly with this as a transitional measure.

7.6 Whilst almost all respondents welcomed the intentions of the Regulations in permitting transplantations to be carried out from non-related living donors, opinions were almost equally divided upon the level of scrutiny that should be applied by the Human Tissue Authority in terms of the approval process that should be adopted. Of particular interest to some respondents, was the approval mechanism to be adopted for transplantation procedures involving only regenerative tissue, particularly given that such procedures are not currently regulated. The draft Regulations proposed an approval procedure for all cases of bone marrow donation. Respondents felt in equal measure that the Regulations should, and should not, extend to these procedures.

7.7 The Department has ultimately decided upon a position that Human Tissue Authority approval is needed in situations involving (i) child donors, (ii) adults who are not capable of giving consent, and (iii) competent adults donating organs or part organs. Autologous donations and domino donations will not require Authority approval[3]. In all cases requiring approval, the HTA must be satisfied that no reward has been given for the donation, that proper consent has been obtained and that the procedure is otherwise lawful. In cases of greater complexity[4], the decision to approve the donation must be made by a panel of at least three members of the HTA.

7.8 It is intended that the Act will be brought fully into force on 1st September 2006. The Act will be in force to the extent necessary to enable the Authority to license the storage of human tissue for the purposes specified in Schedule 1 to the Act from 7th April 2006. This is in order to comply with the obligations under the European Union Tissue and Cells Directive (Directive 2004/23/EC). The Act provides that the Authority may prepare and issue codes of practice giving guidance and setting standards in relation to activities within its remit. The HTA has prepared five Codes of Practice on the following issues: Consent, Donation of Organs, Tissue and Cells for Transplantation, Post Mortem Examination, Anatomical Examination, The Removal, Collection, Storage and Disposal of Human Organs and Tissue. These Codes will support the implementation of the Act and Regulations.

[3] A domino donation means the removal of transplantable material from a donor in order to allow the transplant to him of other transplantable material. An autologous donation is where transplantable material is removed from a person's body for their own treatment and is not used for transplant into someone else.

[4] These cases are specified in regulation 12 of the Regulations as children and incapacitated adults donating organ or part organs and competent adults in paired donations, pooled donations or non-directed altruistic donations.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

9. Contact

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PARTIAL REGULATORY IMPACT ASSESSMENT

1. HUMAN TISSUE BILL

This partial Regulatory Impact Assessment provides the Government's assessment of the likely impact of the Human Tissue Bill on business, charities and voluntary organisations.

2. Purpose and intended effects of measure

Issue

The Bill arises primarily out of the *Kennedy* and *Redfern* inquiries into events at the Bristol Royal Infirmary and the Royal Liverpool Children's Hospital ('Alder Hey') in 2001. These inquiries, along with the Chief Medical Officer's subsequent census of organs and tissue holdings by pathology services, and the *Isaacs Report* in April 2003, showed that organ retention, with or without consent, had taken place on a large scale. In particular, it was clear that the current law on human organs and tissue was neither comprehensive nor always as clear and consistent as it might be. The following concerns were highlighted:

- the requirement under the Human Tissue Act (1961) to establish 'lack of objection' from relatives leaves it unclear that consent should be sought for the taking, storing and use of human organs and tissue after death;

- the current law on human organs and tissue is inconsistent and has gaps. Donation of bodies for anatomical dissection, for example, is strictly regulated, while the legislation providing for hospital post mortems and the donation of bodies and body parts for research and other forms of education has no regulatory structure, penalties or enforcement. Import and export of human bodies and body parts and their use in public display are not covered by the current law at all;

- current legislation is now out of date in terms of society's changing attitudes towards the role of consent and the relationship between the patient, those close to the patient and the healthcare professional.

Objectives

Objectives of the Bill are to:

- avoid the distress of future scandals like Alder Hey;

- improve public confidence and willingness to assist research and other valuable uses of human tissue;

- modernise current legislation by establishing the principle of consent as the basis for the taking, storing and use of human tissue, from both adults and children, from living patients and from those who have died.

The Bill will extend England, Wales and Northern Ireland, with the exception of an offence of testing DNA without consent, which will also extend to Scotland.

Risk Assessment

The current legal situation risks further scandals arising. These have three costs: compensation payments (and possible litigation costs), the interruption of normal activity, particularly research, while guidelines are reviewed, and changes to practice once guidelines are changed. They also undermine public confidence and willingness to assist in research and agree to other valuable uses of tissue.

3. Options

Option 1: Do nothing

Risks: This option does not achieve the objectives. Availability of tissue for research, particularly related to disorders of babies and children, will remain a difficulty.

Option 2: Implement the policy of requiring consent to be obtained by means of DH guidance and existing regulatory bodies, such as Commission for Health Improvement (CHI) and the National Care Standards Commission (NCSC). Continue with voluntary scheme whereby the Medicines and Healthcare products Regulatory Agency (MHRA) accredits tissue banks which store tissue for human use.

Risks: Guidance cannot resolve the gaps, ambiguities and inconsistencies in the current law. DH guidance would carry little weight in the private and non-health sectors (coroners, public display). Inspections by existing bodies may increase the chances of compliance on consent in health settings, but without underpinning legislation this cannot be assured. Experience with the current voluntary code of practice on safety and quality for tissue banks, for example, has shown that they are slow to respond to a voluntary scheme. Public confidence will not be improved. Potential costs of litigation and compensation may still apply.

Option 3: Establish a comprehensive and consistent regulatory structure to oversee the uses of human tissue set out in the Bill, set standards and introduce penalties in areas where they do not currently exist to ensure that practices are based on consent. Make obligatory the existing voluntary scheme of accreditation of tissue banks which store material for human use.

Risks: In the areas where statutory Regulation is new, (conduct of post mortems, storage of tissue, tissue banking and public display) an over-burdensome regulatory scheme might get in the way of the practice of pathology and hinder research.

4. Benefits

Option 1

Benefits: This avoids imposing a new regulatory system on pathology services, tissue banks and those undertaking public display of human remains. Public outcry over the events at Alder Hey and elsewhere has meant that many pathologists and pathology services do now seek consent and are keen to be seen to do so.

Option 2

Benefits This would also avoid setting up a new regulatory system for areas not currently regulated and could achieve some of the objectives in the public sector where DH has influence. Using the inspection structures of CHI, NCSC and MHRA could help to ensure compliance in the NHS and independent health care sector without adding an additional inspection regime.

Option 3

Benefits: This achieves all the objectives comprehensively across the public, voluntary, charitable and private sectors. It ensures consistency of approach, compliance and penalties. It avoids the anomaly of having different pieces of legislation and regulatory schemes for anatomy, for transplantation and for other uses of human tissue, and the potential for gaps and overlaps between these. It streamlines current regulatory approaches. To avoid a burdensome regulatory system, existing bodies can be commissioned to carry out inspections where appropriate, as in option 2, but underpinned by statutory authority.

Business sectors affected

We do not expect the legislation on consent and the new regulatory regime for pathology services, tissue banks and public display of human remains to have a significant impact on charities, voluntary organisations or business. (The main impact of the proposed legislation will be on the public sector.)

Pathology services in the independent healthcare sector should not be affected. Our information is that hospital pathology services in the private sector, around 30 in number, neither carry out post mortems, nor retain tissue for purposes other than those related to treatment of patients, which will not be regulated.

Tissue banks storing human material for research will be licensed and inspected for the first time. There are about 5 tissue banks for research in England and Wales, with 3 more planned. Most are funded by the NHS or a mix of NHS/academic institutions/MRC and Wellcome. We are aware of only one private tissue bank.

Tissue banks storing tissue for human use will be licensed and inspected for the first time on a statutory basis. However, they have been subject to a voluntary accreditation scheme and code of practice issued by DH since 2000. The Department currently commissions the MHRA to operate the scheme for the UK

and underwrites the cost. MHRA estimates there to be about 350 tissue banks storing tissue for human use in England and Wales, of which 5 are in the private sector.

The pharmaceutical industry and other researchers will not be directly affected by the proposals as they obtain material from tissue banks. This makes them end-users of tissue for which consent will already have been obtained, and they will therefore not fall under the licensing regime. They may be affected indirectly where tissue banks pass on to them the costs of licensing and inspection, though they have recognised that they will benefit from the assurance of properly regulated procurement and handling of tissue.

Private Museums which display human remains for commercial gain will be affected by the licensing and inspection regime. They are likely to pass on the costs to the paying public.

Issues of equity and fairness

The regulatory impact of the proposals does not in principle discriminate between the private and public sectors, except in regard to public display, where publicly-funded museums are excluded from the regulatory scheme for the time being. In practice the burden will fall mainly on the public sector, where the activities to be regulated mostly take place. Researchers in both sectors should benefit from the security of access to a supply of tissue, the use of which is properly authorised by a statutory regime.

5. Costs

Compliance costs

Option 1: Maintaining the legal status quo has no direct compliance costs. It does not prevent costs to the NHS from possible future litigation due to legal uncertainty in this area. For example, some compensation claims arising out of events at Alder Hey have reached a settlement of £5 million, and a national settlement for other groups is still to be agreed.

Option 2: Costs of a voluntary regime of central guidance on obtaining consent to post mortems etc have already been somewhat discounted in the NHS by DH baseline expenditure of £300,000 for 3 years from 2003-4 for training

initiatives and consent forms in England. The NHS in England has also been given £2.7m for three years to develop bereavement services.

There would also be a small increase in fees already charged to the independent sector by the NCSC and MHRA, to allow for inspection work in addition to that which they already carry out for other purposes. (The NCSC currently charges £1,320 to register and then an annual flat rate fee of £3,000 for acute hospitals. MHRA expects to charge around £7,537 in the first year to accredit tissue banks for safety and quality, and £5,132 every two years thereafter.)

Option 3: The Human Tissue Authority to be set up under the Bill is not expected to require additional funding at the outset. It is expected to incorporate several existing organisations and their budgets. Currently these are:

Organisation	Budget	Notes
Retained Organs Commission (ROC)	£1m per annum, included in the DH baseline.	ROC was set up to oversee the return of organs to bereaved families. It is due to close on 31 March 2004.
HM Inspector of Anatomy (HMIA)	Total running costs for 2002-3 were £88,000.	HMIA also licenses and inspects persons and premises for the carrying out of anatomical dissections.
ULTRA	£40,000 per annum. includes secretarial support from DH.	Advisory NDPB set up under Regulations under the HOT Act 1989.
Total	£1,128,000	

The HTA will also cover its costs by charging fees for licensing and inspection. Where possible, it is expected to commission organisations already inspecting regulated premises, such as the MHRA, and the new Commission for Healthcare Audit and Inspection (CHAI). The checking of consent procedures required by the Bill could be undertaken at the same inspections as those undertaken for other purposes, to avoid duplication and burden on those licensed. Many of these organisations already charge fees for inspections as explained in option 2 so that any extra cost should not be significant.

For these reasons the costs to the private and voluntary sector of licensing and inspection under option 3 should be similar to the costs of option 2. However the costs of licensing tissue banks which store material for human use, of which only 5 are in the private sector, would be transferred from DH to the banks themselves. Theses costs would be as for option 2. Some additional private organisations would be regulated:

tissue banks which store material for research would be inspected and licensed for the first time. The cost of this would be less than that for banks keeping material for human use (perhaps £2,000 initially and £2,000 for biennial inspections thereafter). Banks would pass these costs on to researchers but the amounts should be insignificant given the numbers of organisations supplied by each banks (Peterborough tissue bank supplies 80 biotechnology labs). The Association of the

British Pharmaceutical Industry has indicated that companies are prepared to absorb this additional administrative cost in return for assurance that properly authorised supplies of tissue for research will be maintained;

private organisations exhibiting human bodies and body parts on a commercial basis will need to be licensed to ensure that the proper consents have been obtained. They will likely pass on this cost to the public so that it should have insignificant impact on profits. Very few such exhibitions have taken place or are anticipated.

An additional advantage to setting up the Human Tissue Authority on a statutory basis is that it will be able to take on regulatory functions that may arise from an EU Directive on Human Tissues and Cells which is currently being negotiated in the European Parliament. This Directive, if implemented, will require member states to regulate safety and quality of human tissue for human application.

6. Consultation with small business: the Small Firms' impact test

A Small Firms impact test has not been undertaken as the Bill will have no significant impact on small business. This view is supported by the Small Business Service.

7. Competition assessment

We do not expect there to be any significant change in the services offered as a direct result of the creation of the Human Tissue Authority and its regulatory powers.

8. Enforcement and Sanctions

The Bill introduces penalties for acting without appropriate consent and for carrying out licensable activities without a licence. The Bill will also incorporate the offences prohibiting commercial dealing and on provision of information which are currently in the Human Organ Transplants Act 1989, but extend these to cover all tissue within the remit of the Bill, and not just organs.

The Bill provides for an appeal mechanism regarding licence decisions through the HTA and the expectation is that the regulatory framework will ensure that penalties are rarely resorted to. Comparison with similar legislation suggests that the introduction of penalties and appeals is likely to have a low practical impact. There have been no prosecutions under the Human Organ Transplants Act or the Anatomy Act 1984. Experience under the Human Fertilisation and Embryology Act 1990 (which established a similar regulatory structure based on consent) is that there is about one appeal every 2 years, from 120 licensed centres. There have been no prosecutions under the Human Fertilisation & Embryology Act.

9. Monitoring and Review

It will be for the Secretary of State for Health, the National Assembly for Wales, the appropriate department in Northern Ireland and the Scottish Executive to ensure that the

changes proposed are put into effect. The HTA will be required to report once a year to the Secretary of State and the National Assembly for Wales, and the report will be laid before Parliament and the assembly. Monitoring and review of the HTA will be carried out as part of the normal accountability process for arm's length bodies.

10. Consultation

The Department of Health and Welsh Assembly Government consulted on the document *Human Bodies, Human Choices*[5] between July and October 2002. The document reviewed the current law in England and Wales on the removal, retention and use of human organs and tissue from living people and those who have died, both adults and children (including stillborn children and fetuses), and sought views on changes for the future. 5,000 copies of the document were distributed. 200 people attended workshops and a national conference. 231 written responses were received and a report on the results of the consultation was published in April 2003.

A leaflet on legislative proposals arising from the consultation was issued in September 2003 and a series of eight workshops was held in September and October with stakeholders from inside and outside Government, to discuss the proposals and work through their implications in more detail.

11. Summary and recommendation

Option 1 – do nothing – has no direct implementation costs but does not achieve the desired policy objectives of ensuring consent and consistency, and avoiding future risk. Option 2 – the voluntary guidance option – has implementation costs for the Department of Health, no mechanism for achieving compliance with the desired policy of requiring consent, and maintains legal inconsistencies. The public would not be reassured and research would be impeded. Option 3 – the statutory option with a regulatory system and penalties for non-compliance - is recommended. It should ensure, at no significant cost to the private and voluntary sector, that the provision of human tissue for valuable transplantation, research and education purposes is maintained, to the benefit of society as a whole.

12. Ministerial Declaration

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed: Rosie Winterton

Date: 25th April 2006

Minister of State, Department of Health.

[5] *Human Bodies, Human Choices. The Law on Human Organs and Tissue in England and Wales. A Consultation Report,* (July 2002).

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