EXPLANATORY MEMORANDUM TO

THE HUMAN TISSUE ACT 2004 (ETHICAL APPROVAL, EXCEPTIONS FROM LICENSING AND SUPPLY OF INFORMATION ABOUT TRANSPLANTS) REGULATIONS 2006

2006 No. 1260

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 This Instrument provides the detail for the framework provisions of the Human Tissue Act 2004 ("The Act") concerning ethical approval, exceptions from licensing, and supply of information about transplants.

2.2 This instrument defines ethical approval for the purposes of research projects using relevant material and for those projects involving relevant material from incapacitated adults (a transitional measure in place until the commencement of the Mental Capacity Act 2005). It provides specified exceptions to the statutory requirement for a licence to store relevant material. This instrument also requires persons who remove and/or receive certain organs or part organs for the purpose of transplantation to supply specified information to NHS Blood and Transplant.

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

3.1 These Regulations are subject to the negative resolution procedure, as provided for in section 52(3) of the Act. This memorandum is submitted by the Department of Health because this is the first use of powers under section 1(9) of, and paragraph 10(b) of Schedule 4 to, the Act (see Regulation 2), section 16(3) (see Regulation 3) and section 34(1) of the Act (see Regulations 4 and 5).

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 Act sets up a framework for regulating 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. It sets up an authority, the Human Tissue Authority (HTA), to regulate activities through licensing.

4.2 The Act contains a number of powers to allow the detailed requirements to be set out in Regulations. These Regulations make the first use of the powers in sections 1(9), 16(3), 34(1) and 52(1) of, and paragraph 10(b) of Schedule 5 to, the Act.

4.3 Section 1(7) of the Act allows the storage for use for research of human tissue taken from a living person without consent provided the research project has ethical approval in accordance with these Regulations and the tissue is anonymised.

4.4 The policy intention of Regulation 2 was signalled during the passage of the Act through Parliament [Common's Debate 28 June 2004: Column 97]. Ethical approval would be required from the existing system of recognised research ethics committees to avoid setting up a new set of ethical bodies, which would have been unnecessary. These recognised committees are approved at a national level by the United Kingdom Ethics Committee Authority (UKECA) under Regulation 6 of the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031). UKECA itself is established under Regulation 5 of the clinical trials Regulations and consists of the Secretary of State, the Welsh Assembly, Scottish Ministers and Department for Health, Social Services and Public Safety for Northern Ireland to advise on clinical trials, or are otherwise established by or on behalf of the Secretary of State, National Assembly for Wales and Department of Health, Social Services and Public Safety in Northern Ireland to advise on the ethics of other research investigations.

4.5 Section 16 of the Act prohibits the carrying on of specified activities without a licence. Section 16(2)(e)(ii) requires a person to hold a licence to store relevant material for use for a scheduled purpose**1**. Section 16(3) of the Act allows the Secretary of State, through Regulations, to specify circumstances in which storage by a person intending to use tissue for a scheduled purpose is exempt from the licence requirement. Ministers indicated in Parliament (Lord's Debate 22 July 2004 : Column 371) that this would allow a distinction to be made between large tissue banks, for example, and individuals using tissue in research projects, who might not be required to be licensed**.** This would mean that "end user" researchers could hold tissue for their individual ethically approved research projects without needing a licence. However, tissue banks that hold tissues for generic research purposes would still be required to hold a licence. This fulfils the policy intention to exempt, where possible, collections of tissue that were being held by researchers for specific ethically approved research projects.

4.6 The Regulations specify the following storage of tissues does not require a licence under the Act:

1) The purposes that are regulated are listed in Schedule 1 to the Act (and are referred to as scheduled purposes) 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; clinical audit; education or training relating to human health; performance assessment; public health monitoring; quality assurance.

- Where tissues are from a living person, unless storage is for transplantation that falls outside of the transplantation exemption (detailed below) or for ethically approved research. This ensures that the majority of transplantable material and any research samples held for generic research purposes are stored on licensed premises.

- Where the relevant material has come from a human body (this covers material taken from the body of a living person or a deceased person) and storage is for the purpose of transplantation of an organ/part organ or the material for transplantation is to be held for less than 48 hours. This permits organs or other tissues being used for transplantation to be stored for a limited time period on unlicensed premises, which provides for some flexibility.

- Where the relevant material has come from a human body (see above could be living or dead) and is stored for ethically approved research as defined in the Regulations or where an application for ethically approval is pending. This exempts all material held by researchers for specific ethically approved research projects.

- Where tissues are from a deceased person and storage is for the sole purpose of analysis for a scheduled purpose other than research. This permits post mortem samples to be released from a licensed premise to an unlicensed facility to allow specialised analysis to be carried out. The exemption only extends to the time that the material needs to be held for the analysis to be carried out. Once the analysis is completed the material must be returned to licensed premises for continued storage.

4.7 Regulation 4 requires persons who remove certain organs or part organs for the purpose of transplantation to supply information specified in Schedule 1 of the Regulations. Regulation 5 requires that persons who receive such organs or part organs must provide the information set out in Schedule 2. The Regulations specify that the information should be provided to NHS Blood and Transplant; the successor body of UK Transplant and the National Blood Authority. Transplantable material for which this information must be submitted is defined in Regulation 9 of the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006.

5. Extent

5.1 This Instrument applies to England, Wales and Northern Ireland.

6. European Convention on Human Rights

6.1 As this instrument is subject to the negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 The Human Tissue Act 2004 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.

7.2 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**.** These inquiries, together with the Isaacs Report, which focussed on retention of adult brains following coroner's 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.

7.3 The purpose of storage licensing is to help restore public confidence in the proper use of human organs and tissue by ensuring compliance with the consent provisions of the Human Tissue Act 2004, so that tissue donation is encouraged for the public good. However, the Government does not wish to impose unnecessary regulatory burdens and therefore Regulation 3 of these Regulations specifies the circumstances where licensing is not necessary.

7.4 Since the introduction of the Human Organs Transplant Act in1989, it has been the Government's policy and a legal requirement that information, which allows the use of organs to be tracked, should be required to be collected nationally as a deterrent to trafficking and misuse of organs for transplantation. These Regulations largely replicate the requirements of the Regulations made under section 3 of the Human Organ Transplants Act 1989 which is being repealed by the Act.

7.5 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.

7.6 These Regulations were the subject of a formal consultation exercise for a period of twelve weeks (11th July– 4th October 2005).

7.7 During the consultation period, 45 written responses were received from a diverse range of individuals, groups and professional bodies. In addition, several meetings were held with stakeholders within specific fields of expertise to discuss the Regulations in more detail. Overall, there was broad support for the proposed system of ethical review, which involved

adopting much of the existing good practice in this field. A small number of respondents suggested that the Regulations should ensure that any ethical approval system adopted is flexible enough to allow non NHS organisations, such as the Museum sector, to benefit from the exemption. In addition, almost all respondents gave their support to the proposed exemptions from licensing within the Regulations, stating that any system of licensing needed to ensure that there are no unnecessary regulatory burdens. However, approximately half of all respondents felt that an exemption of just 24 hours for organs intended for transplantation was too short. Various reasons for this were given, principally around recent advances in medical technology along with practicality.

In addition, many respondents, particularly those from medical institutions, provided further examples of situations where additional exemptions were needed, for example the need to classify material, in relation to determining the necessity for a storage licence by means of its 'primary purpose' where that material could be used in multiple situations. The Department has included several of the suggested amendments put forward during the consultation period, and these are reflected within the Regulations.

8. Impact

8.1 The impact of the new framework for regulating the removal, storage and use of human organs and tissue will not have a significant impact on the business, charitable and voluntary sectors.

9. Contact

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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*[2] 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.

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

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