

Human Tissue Authority

Code of Practice – Consent

Code 1 July 2006

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Introduction

- 1 **The Human Tissue Act 2004** (The Act) which extends to England, Wales and Northern Ireland only, sets out a new legal framework for the storage and use of tissue from the living and for the removal, storage and use of tissue and organs from the dead. This includes 'residual' tissue following clinical and diagnostic procedures.
- 2 The Act repeals and replaces the Human Tissue Act 1961, the Anatomy Act 1984 and the Human Organ Transplants Act 1989 as they relate to England and Wales. It also repeals and replaces the Human Tissue Act (Northern Ireland) 1962, the Human Organ Transplants (Northern Ireland) Order 1989 and the Anatomy (Northern Ireland) Order 1992. There is separate legislation for Scotland – the Human Tissue (Scotland) Act 2006 – and the HTA will perform certain tasks on behalf of the Scottish Executive. For the purpose of these codes, the term 'NHS Trusts' includes Health and Social Services (HSS) Trusts in Northern Ireland.
- 3 The Act also establishes the **Human Tissue Authority** (HTA) as the regulatory body for all matters concerning the removal, storage, use and disposal of human tissue (excluding gametes and embryos) for scheduled purposes. This includes responsibility for living donor transplantation. This is one of the functions which the HTA will carry out on behalf of the Scottish Executive.
- 4 The HTA is also responsible for giving advice and guidance on the Act and for licensing establishments that carry out particular activities under the Act.
- 5 One of the HTA's statutory functions is to issue codes of practice. This is one of the first six codes, which should be regarded as complementary:
 - 1 Consent
 - 2 Donation of organs, tissue and cells for transplantation
 - 3 Post mortem examination
 - 4 Anatomical examination
 - 5 Removal, storage and disposal of human organs and tissue
 - 6 Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation.
- 6 These codes give practical guidance to those carrying out activities which lie within the HTA's remit and lay down the standards expected. These are not a definitive guide to the law and licence holders should refer to the Act and keep themselves informed about future legal developments.
- 7 The guidance given applies to anyone undertaking relevant activities. Failure to follow this guidance is not in itself a criminal offence under the Act, but the HTA may take any such breach into account when carrying out its responsibilities in respect of licensing.

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- 8 The codes have been approved by the Secretary of State and laid before Parliament in accordance with Section 29 of the Act.
 - 9 Any references to the terms 'tissue', 'organ', 'part organ', 'material,' 'body parts' or 'cells' in this code refers to 'relevant material'. For definitions of terms used, please refer to the glossary at the back of this code.

The scope of the Human Tissue Act

- 10 The Act, and the HTA's codes of practice, encompass consent provisions on:
- the storage and use of dead bodies
 - the removal, storage and use of 'relevant material'¹ from a dead body and
 - the storage and use of relevant material from the living.
- 11 The Act does not deal directly with the removal of tissue from the living. Although the process of seeking consent for the storage and use of tissue from patients will often be undertaken at the same time as consent to investigation or treatment, the consent for removal itself in these circumstances remains a matter of common law.
- 12 Consent under the Act relates to the purposes for which material might be stored or used. These purposes are set out in Schedule 1 of the Act and are hereafter referred to as 'scheduled purposes'.
- 13 Anyone removing, storing or using material in circumstances for which the Act requires consent, must be satisfied that the consent is in place. They do not need to have taken or recorded the consent personally, but must ensure that procedures are in place giving the necessary assurance. These procedures should be robust and reviewed regularly. It is a defence that the person acts with a reasonable belief that consent is in place or is not necessary.
- 14 The use of photographic or electronic images of human tissue is outside the remit of the Act. However, as part of this code of practice, the HTA endorses the guidance on this issue provided by the General Medical Council: *Making and using visual and audio recordings of patients*.²

¹ See glossary

² www.gmc-uk.org/guidance/library/making_audiovisual.asp

The question of consent

- 15 At the heart of the Act lies the need to obtain consent for the removal, storage and use of human tissue or organs and the storage and use of whole bodies for certain scheduled purposes. This code gives guidance on the need for consent, and also addresses the closely related issues of communication and consultation with patients and their families which should support the consent process.
- 16 The Act requires consent for the removal, storage and use of human tissue, but it does not (other than in the cases of donations for anatomical examination and public display after death) define what constitutes appropriate consent.
- 17 The giving of consent is a positive act. The absence of refusal is not evidence of consent.
- 18 The Act specifies whose consent is needed in all the relevant circumstances but it does not generally give details of how consent should be sought or recorded, or of what information should be given. This code advises on these issues.
- 19 Before deciding whether to proceed with the removal, storage or use of tissue for scheduled purposes, the following should be considered:
 - Does the activity require consent? For post mortem cases consent is required for all scheduled purposes. Consent is not required under the Act for tissue from living patients in some circumstances (paragraphs 21–29).
 - Who has authority to give consent? (paragraphs 30–66)
 - Has sufficient written or verbal information been provided for the person giving consent to understand the issues? (paragraphs 77–84)
 - How will the consent be given and recorded? (paragraphs 85–96)
 - When is written consent required? (paragraphs 97–100)
 - Is consent needed for more than one purpose? (paragraphs 101–104)
 - If a child is involved, is s/he competent to consent and/or has s/he expressed particular wishes or views? (paragraphs 41–44, 60–65)
 - If an adult who lacks capacity is involved, is s/he competent to make this decision? Is the proposed action in his/her best interests? (paragraphs 35–40)
 - Is DNA analysis likely to be involved? (paragraphs 116–123)
 - Is the consent for research appropriately specific/general? (paragraphs 111–115)
- 20 A person's agreement or refusal to consent to the donation, storage or use of tissue for purposes under the Act must not affect the investigation or treatment that s/he receives.

Statutory requirements for consent

21 All those involved in the removal, storage and use of human tissue in any form should be aware of the following statutory requirements for consent:

The living

22 Consent for treatment and examination including removal is a common law matter dealt with in the Department of Health's *Reference guide to consent for examination and treatment*.³ Under the Act, tissue may be taken in a variety of circumstances. For example:

- in the course of diagnostic procedures, e.g., taking a blood or urine sample, tissue biopsy, cervical screening, etc.
- in the course of a treatment procedure, e.g., removing tissue (organs, tumours, etc.) during surgery
- when removed specifically for the purpose of research.

23 Once tissue has been taken from patients, for whatever purpose, it can be stored and used without consent for a number of purposes.

24 Consent from the living is needed for storage and use of tissue for:

- obtaining scientific or medical information which may be relevant to any other person, now or in the future (i.e. where the purpose is storage or use

in relation to another person, rather than where it might, incidentally, be of future relevance to another person)

- research in connection with disorders, or the functioning, of the human body (but see paragraph 28 below)
- public display, and
- transplantation.

25 Consent from the living is not needed for storage and use of tissue for:

- clinical audit
- education or training relating to human health (including training for research into disorders, or the functioning, of the human body)
- performance assessment
- public health monitoring
- quality assurance.

The deceased

26 Consent is needed:

- where, after a coroner's *post mortem*, the continued storage or use of material no longer required to be kept for the coroner's purposes
- for the removal, storage and use for the following scheduled purposes:
 - anatomical examination
 - determining the cause of death
 - establishing, after a person's death, the efficacy of any drug or other treatment administered to them

³ www.dh.gov.uk/policyandguidance/healthandsocialcaretopics/consent/consentgeneralinformation/
The DHSSPS (Northern Ireland) has published its own reference guide to consent for examination and treatment:
<http://www.dhsspsni.gov.uk/consent-referenceguide.pdf>

- obtaining scientific or medical information, which may be relevant to any other person now or in the future ('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 and
- quality assurance.

This applies to all tissue removed at post mortem, including small samples such as blocks and slides, and samples that might be kept as part of the record. For detailed guidance, see the HTA's *Code of practice on post mortem examination*, the Coroner's (Amendment) Rules 2005⁴ and the Coroner's Practice and Procedure Rules (Northern Ireland) 1963.

27 Consent is not needed for:

- carrying out an investigation into the cause of death under the authority of a coroner
- keeping material after a post mortem under the authority of a coroner, for as long as the coroner requires it
- keeping material in connection with a criminal investigation or following a criminal conviction.

Exceptions for research in specific circumstances

28 Tissue from the living may be stored for use and/or used without consent, provided that:

- the research is ethically approved⁵
- the tissue is anonymised such that the researcher is not in possession of information identifying the person from whose body the material has come and is not likely to come into possession of it.

This does not mean that samples must be permanently and irrevocably unlinked – linking can be made through a third party where necessary – nor that the persons holding the samples cannot themselves carry out the research.

If members of the clinical team take part in the research, links may be retained to the relevant clinical or patient records, but they must not contain information giving direct patient identification.

29 In general, obtaining consent is preferable to developing complex systems for keeping samples unlinked. It represents best practice and has the added benefit of facilitating the process of obtaining ethical approval.

⁴ www.opsi.gov.uk/si/si2005/20050420.htm

⁵ Defined under Regulations 2006 (The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) to mean approval given by a research ethics authority.

Who can give consent?

30 The general legal principles applying to consent for treatment and examination apply equally to consent for the storage and use of tissue for other purposes. Guidance is available from the Department of Health's *Reference guide to consent for examination and treatment*.

31 For consent to be valid it must be given voluntarily by an appropriately informed person who has the capacity to agree to the activity in question.

32 The seeking and taking of consent from patients before death or from those close to them after their death, demands great sensitivity. This is especially true for donations for transplantation, post mortems and the retention of tissue and organs for research, etc. (Comprehensive guidance is set out in the *Codes of practice on post mortem examination and Donation of organs, tissue and cells for transplantation* and the following information should be read in conjunction with those codes).

Tissue from the living – competent adults

33 If an adult is competent, only they are permitted to give consent.

34 The Act allows residual tissue samples left over following a diagnostic or therapeutic intervention or research to be disposed of lawfully. However, residual tissue is often an important source of material for research, and surgical consent forms may

include an agreement to the use of such tissue for purposes such as research, education and training.

Tissue from the living – adults who lack capacity

35 Adults are competent to consent if they can:

- understand the nature and purpose of the proposed procedure
- understand and retain information relevant to the decision
- weigh the necessary information to arrive at a choice.

36 The Act does not specify the criteria for considering whether an adult has capacity. This should be approached on the same basis as considerations of competency to consent to medical procedures. (While the basis for considering whether an adult has capacity will be the same, the conclusion could differ, as some people might have the capacity to make some decisions, but not others). Guidance is available from the Department of Health's *Reference guide to consent for examination and treatment*. In addition, regard must be had to the provisions of the Mental Capacity Act 2005⁶ (MCA 2005). The MCA 2005, which comes into force in 2007, governs decision-making on behalf of adults who lack capacity including adults who lose mental capacity during their lifetime and those with an incapacitating condition from birth. MCA 2005 defines persons

⁶ <http://www.opsi.gov.uk/acts/acts2005/20050009.htm>. Note this Act does not extend to Northern Ireland.

who lack capacity and contains a set of key principles and a checklist to be used in ascertaining best interests.

- 37 It should be assumed that a person is competent to make a decision unless there is reason to believe otherwise. Individuals affected by trauma, illness, shock, etc., are sometimes temporarily unable to make a decision. Some adults may be competent to make decisions about some matters, but not others. Care should be taken to ensure that patients are given every opportunity, and support where needed, to understand what is proposed.
- 38 The ability of adults with learning difficulties, or with limited capacity, to understand should not be underestimated. Where appropriate, someone who knows the individual well, such as a family member or carer, should be consulted as s/he may be able to advise or assist with communication.
- 39 Storage or use of tissue from adults who lack capacity, other than in accordance with the Regulations under the Act, is unlawful and is an offence under the Act.
- 40 The Act enables the Secretary of State to make Regulations setting out the circumstances in which it is lawful to store, or use for a Schedule 1 Part 1 purpose, relevant material from an adult who lacks capacity to consent.

The Regulations⁷ provide for the circumstances in which consent can be deemed to be in place. These are:

- storage and use of relevant material for certain scheduled purposes by a person who is acting in what s/he reasonably believes to be in the best interests of the person lacking capacity from whose body the material came. The scheduled purposes provided for under the Regulations are obtaining scientific or medical information about a living or deceased person which may be relevant to another (including a future person) and transplantation.
- storage and use of relevant material from a person who lacks capacity for the purposes of a clinical trial authorised and conducted in accordance with the clinical trials Regulations.⁸
- where it is consistent with sections 30–34 of MCA 2005, allowing for the storage and use of relevant material from persons lacking capacity for research in circumstances provided for in that Act. However, as MCA 2005 is not expected to take effect until 2007, these Regulations will, in the meantime, (in the case of England and Wales)⁹ allow for the storage and use of relevant material for certain research where it is ethically approved by a Research Ethics Authority and in accordance with the Regulations.

⁷ Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006.

⁸ Clinical Trials Regulations are the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031 (or any amending or replacing Regulations) and any other Regulations designated as such by the Secretary of State.

⁹ The MCA 2005 does not extend to Northern Ireland and accordingly the research must always be approved by a Research Ethics Authority.

Tissue from the living – children

- 41 Under the Act, a child is defined as being under 18 years old.
- 42 Children may consent to a proposed medical procedure or the storage and use of their tissue if they are competent to do so. In the *Gillick*¹⁰ case, the court held that a child is considered to be competent to give valid consent to a proposed intervention if they have sufficient intelligence and understanding to enable them fully to understand what is involved. Seeking consent from children is dealt with in the Department of Health's guide *Seeking Consent: working with children*.¹¹
- 43 A person who has parental responsibility for the child can consent on his/her behalf only if the child has not made a decision and:
- is not competent to do so; or
 - chooses not to make that decision, although s/he is competent to do so.

A person who has parental responsibility will usually, but not always, be the child's parent.¹²

- 44 However, it is good practice to consult the person who has parental responsibility for the child and to involve them in the process of the child making a decision. It is also important to make sure that a child

has consented voluntarily and has not been unduly influenced by anyone else. Courts have identified certain important decisions which require court approval where one person with parental responsibility consents against the wishes of another. If there is any dispute between persons with parental responsibility or any doubt as to the child's best interests, the matter should be referred to court for approval.

Tissue from the deceased – adults

- 45 Where an adult has, whilst alive and competent, given consent for one or more of the scheduled purposes to take place following their death, then that consent is sufficient for the activity to be lawful. This applies in respect of all the scheduled purposes.
- 46 However, in the case of donation of the deceased person's body or relevant material for anatomical examination (other than excepted material) or for public display, consent needs to be written down (the deceased person's signature, or oral consent recorded) and witnessed (see paragraphs 67 onwards below). There is an exemption for excepted material which is defined as material which has come from the body of a living person or from a deceased person's body obtained other than in the course of an

¹⁰ *Gillick v West Norfolk and Wisbech Area Health Authority* [1985] 3 All ER 402 (HL).

¹¹ http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4007005&chk=xFifXP

¹² The category of persons with parental responsibility is as set out in the Children Act 1989 as amended. Further guidance is available in the Department of Health's *Reference guide to consent for examination and treatment*.

anatomical examination. Neither the next of kin nor any other person can agree to the use of an individual's body after their death for these purposes.

- 47 If the family or those close to the deceased person object to the donation, for whatever purpose, when the deceased person (or his/her nominated representative – see below) has explicitly consented, clinicians should seek to discuss the matter sensitively with them. They should be encouraged to accept the deceased person's wishes and it should be made clear that they do not have the legal right to veto or overrule those wishes.

Tissue from the deceased – nominated representatives

- 48 If a deceased adult has neither consented to nor specifically refused any particular donation or the removal, storage or use of their body or tissue or scheduled purposes, those close to them should be asked whether a nominated representative was appointed to take those decisions.
- 49 A nominated representative is empowered to consent to the carrying out of a post mortem and to the removal, storage and use of the body or tissue for any of the scheduled purposes, other than anatomical examination and public display.

- 50 The appointment of a nominated representative and its terms and conditions may be made orally or in writing. If in writing, it must be signed by the person making it, or signed at their direction in the presence of a witness who attests the signature, or be contained in a valid will. If made orally, it must be made before two witnesses present at the same time. If someone comes forward as a nominated representative, their authority to act on the deceased person's behalf must be verified, including what decisions they have the authority to make. The Act sets out the requirements for a valid appointment. The appointment of a nominated representative may be revoked at any time.

- 51 If the deceased person appointed more than one nominated representative, only one of them needs to give consent, unless the terms of the appointment specify that they must act jointly.
- 52 The nominated representative's consent cannot be overridden by other individuals, including family members. It is advisable, nevertheless, to ensure that appropriate consultation and discussion takes place between all those involved. The nomination may be disregarded if no-one is able to give consent under it, which includes where it is not reasonably practicable to communicate with the nominated representative within the time available if the consent is to be acted upon.

Tissue from the deceased – qualifying relationships

53 If the deceased person has not indicated their consent (or refusal) to post mortem removal, storage or use of their body or tissue for scheduled purposes, nor appointed a nominated representative (or the nomination has been disregarded in accordance with paragraph 52), then the appropriate consent can be given by someone in a 'qualifying relationship' to the deceased immediately before their death. Those in a qualifying relationship to the deceased person are (highest first):

- a) spouse or partner (including civil or same sex partner)¹³
- b) parent or child (in this context a 'child' can be any age)
- c) brother or sister
- d) grandparent or grandchild
- e) niece or nephew
- f) stepfather or stepmother
- g) half-brother or half-sister
- h) friend of long standing.

54 Consent should be obtained from the person ranked highest.

55 Relationships listed together, for example 'brother or sister', are accorded equal ranking, in which case it is sufficient to obtain consent from just one of them, provided they are ranked equal highest.

56 If the relationship of each of two or more persons to the deceased is accorded equal

highest ranking, it is sufficient to obtain the consent of any of them. For example, if the deceased person has no spouse or partner, but has several children, the consent of only one child is required.

57 In applying the principles set out above, a person's relationship shall be left out of account if:

- they do not wish to deal with the issue of consent
- they are not able to deal with that issue, or
- having regard to the activity in relation to which consent is sought, it is not reasonably practicable to communicate with that person within the time available if consent in relation to the activity is to be acted on.

This means a person can be omitted from the hierarchy if they cannot be located in reasonable time for the activity in question to be addressed, declines to deal with the matter or is unable to do so, for example, because they are a child or lack capacity. In such cases, the next person in the hierarchy would become the appropriate person to give consent.

58 While the Act is clear about the hierarchy of consent, the person giving consent should be encouraged to discuss the decision with other family members.

59 Seeking and obtaining consent can be a difficult task and healthcare professionals

¹³ Section 54(9) states for these purposes a person is another person's partner if the two of them (whether of different sexes or the same sex) live as partners in an enduring family relationship

need the sympathetic support and guidance of their seniors/managers to develop the necessary skills. NHS Trusts and other establishments should ensure that appropriate training is given where necessary. (More detail on obtaining consent from those in qualifying relationships and handling disagreements between relatives, is given in the *Code of practice on post mortem examination*).

Tissue from the deceased – children

- 60 The position of a child who, before they died, was competent to reach a decision and gave consent for one or more of the scheduled purposes to take place after their death, is no different from that of an adult. Their consent is sufficient to make lawful the removal, storage or use of tissue for that purpose.
- 61 In the case of anatomical examination (other than excepted material – see paragraph 46 above) or public display, written, witnessed consent is needed. As with adults, neither the next of kin nor any other person can agree to the use of a child's body after death for these purposes.
- 62 Clearly, in any case where a child has consented to the use of their body or any tissue, it is essential to discuss this with the child's family and to take their views and wishes into account before deciding how to proceed. In some cases it may also be advisable to discuss with the person who had parental responsibility for the deceased child whether the child was indeed competent to make the decision.
- 63 If a child did not make a decision, or was not competent to make a decision, the Act makes clear that the appropriate consent will be that of a person with parental responsibility for the child. The consent of only one person with parental responsibility is necessary.
- 64 The issue should be discussed fully with relatives and careful thought should be given as to whether to proceed if a disagreement arises between parents or other family members. Any previously stated wishes of the deceased child should be considered, taking into account their age and understanding. (Further guidance on these points is included in the *Codes of practice on post mortem examination and Donation of organs, tissue and cells for transplantation*.)
- 65 If there is no person with parental responsibility (e.g., if the parents have also died, perhaps at the same time as the child), then consent should be sought from someone in a qualifying relationship, as set out in paragraph 53 above.

Fetal Tissue

66 The law does not distinguish between fetal tissue and other tissue from the living – fetal tissue is regarded as the mother’s tissue. However, because of the sensitivity attached to this subject, consent should be obtained for the examination of fetal tissue and for its use for all scheduled purposes, regardless of gestational age. It is considered good practice, that wherever practicable, consent should also be obtained for the use in research of non-fetal products of conception. Research Ethics Committee approval is always required for the use of fetal tissue and products of conception in research.

(For guidance on the disposal of fetal tissue see the *Code of practice on removal, storage and disposal of human tissue*).

The process of consent

When to seek consent

- 67 Consent is usually sought in a clinical setting for treatment, research, or following the death of a patient. But this is not always the case. Samples may be sought from volunteers in research settings outside a medical or clinical context. The following paragraphs refer generally to clinical settings, but apply equally to other circumstances.
- 68 It is important to establish clearly when consent has been given, to ensure the removal, storage or use of any tissue is lawful. However, giving consent should not be seen as a single act – the signing of a consent form. Rather, it should be seen as part of a continuing process in which individuals, and their relatives or close friends, can discuss the issue fully, ask questions and make an informed choice.
- 69 For major interventions, it is good practice where possible to seek the person's or donor's consent to the proposed procedure well in advance. There is then time to respond to their questions and provide adequate information. Clinicians should check before starting the procedure that the person still consents.
- 70 Equally, discussions with relatives can often take place in hospital prior to a person's death. Relatives may know the person's wishes in respect of, for example, donating organs for transplantation.

Who should seek consent?

- 71 It is the treating clinician's responsibility to seek consent from a person, person with parental responsibility or relative. The clinician may delegate this task to someone else, usually another healthcare professional, as long as that person is suitably trained and qualified. In particular, they must know enough about the proposed treatment, the intended use of the tissue and the risks involved to adequately brief the person. Responsibility may be given to a dedicated transplant coordinator or to an appropriately qualified member of a bereavement services team.
- 72 Anyone seeking consent for a hospital post mortem examination should be sufficiently senior and well informed, with a thorough knowledge of the procedure. They should have been trained in the management of bereavement and in the purpose and procedures of post mortem examinations and they should have witnessed a post mortem examination.
- 73 It is usually the responsibility of the deceased person's clinician to seek consent, knowing the medical problems and the unresolved aspects that merit investigation. There may be different options for choosing who actually discusses the post mortem and obtains consent, but most will involve a team approach. Every establishment carrying out these activities must have an effective

procedure in place. Responsibility for obtaining consent should not be delegated to untrained or inexperienced staff.

Religion, culture and language

- 74 Attitudes towards the use of tissue, and especially towards post mortems, can vary widely among cultures and religions. All healthcare professionals must be sensitive to this. However, each case and decision is an individual and personal one, and must be treated as such. NHS Trusts and other establishments should ensure their employees are given the necessary training and support to help them identify and meet the widest possible range of needs and wishes.
- 75 Valid consent can only be given if proper communication has taken place. Particular consideration should be given to the needs of individuals and families whose first language is not English. Where consent forms are used, these should be available in English and the main local community languages. Staff should take care to establish whether or not those concerned can read them.
- 76 If necessary, information should be made available in other formats, such as video or audiotape. Wherever possible, professional translators trained in interpreting for the bereaved and in maintaining confidentiality should be used.

What information should be given?

Tissue storage and use from the living

77 To give consent, patients (or the person with parental responsibility) must understand the nature and purpose of what is proposed and be able to make a balanced judgement. They should be told of any 'material' or 'significant' risks inherent in the way the sample will be obtained, how the tissue will be used and any possible implications of its use, e.g., genetic tests.

(If the person concerned is not a patient, and is volunteering samples purely for research, the general principles of providing adequate information should still apply.)

- 78 Clinicians should try to find out about patients' individual needs and priorities when telling them about their options. Some patients may not be interested in knowing about the proposed use of the tissue and it is good practice to record this fact in the notes. Patients should nevertheless have all their options explained to them and be provided with an appropriate level of information.
- 79 If identifiable tissue is to be used for research, patients should be told about any implications this may have. For example, they may be contacted by researchers, given feedback, or be asked for access to their medical records. Patients should be told whether the consent is generic (i.e. for use in any future research project

which has ethical approval) or specific. If it is the latter, detailed information about the research project should be provided, in line with good practice.

- 80 Patients should be told if their samples will or could be used for research involving the commercial sector. They should be given appropriate information on the range of activities and researchers which may be involved and whether these include commercial pharmaceutical companies.

Tissue storage and use from the deceased

- 81 Whether seeking consent from a nominated representative or from a person in a qualifying relationship, full and clear information should be provided to allow him/her to make a properly considered decision. This information should include the nature of the intended activities and the reasons for them. It should be borne in mind that some people will want more detail than others about, for example, post mortem procedures (see *Code of practice on post mortem examination*).
- 82 Care should be taken regarding the possible disclosure of information, such as genetic information or HIV status, which the deceased person may not have wished to be disclosed, or which may have significant implications for other family members.

83 While consent is needed from only one person in the hierarchy of qualifying relationships (paragraph 53 above), it is always important to consider the particular circumstances of the family. Information should be given to those who may need it, and discussions about the options available should involve the wider family wherever appropriate. (More detailed guidance on discussion with relatives is included in the *Code of practice on post mortem examination*.)

- 84 The way in which the options are discussed with the deceased person's relatives is extremely important. They should be approached with sensitivity and given:
- honest, clear, objective information
 - the opportunity to talk to someone they can trust, and of whom they feel able to ask questions
 - reasonable time to reach decisions (about a hospital post mortem and about any donation of organs or tissue)
 - privacy for discussion between family members, if applicable and
 - support if they need and want it, including the possibility of further advice or psychological support.

Use of documentation

- 85 Standard information leaflets are useful and recommended for:
- post mortem (short and long versions) and
 - anatomical examination.
- 86 It is helpful to give information about research projects – usually this is required when giving ethical approval.
- 87 Many establishments, including NHS Trusts, have policies on consent that include the use of standard documentation. Such documentation should be reviewed to ensure that it is consistent with the Act and with this code, as well as the requirements of the Clinical Negligence Scheme for Trusts and the relevant Department of Health consent guidance.
- 88 Consideration should be given as to whether, in the case of residual tissue from patients, the documentation includes details of the purposes for which tissue may be stored and used and for which consent is not required – for example, clinical audit, quality control, public health monitoring, education and training and research (subject to the anonymisation of samples and ethical approval).
- 89 Where appropriate, leaflets and forms should be available in a number of local languages and in a variety of formats, e.g., Braille, audio-visual, etc.

Form of consent

- 90 The guidance in the code is based on these key principles:
- as a first step, a willingness to discuss the question of consent should be established
 - full information about the consent process should be provided where possible and in a variety of formats
 - consent must be based on an understanding of what the procedure involves
 - consent need not always be given in writing to be appropriate and informed
 - consent should be generic, i.e. consent could be obtained for all scheduled purposes, where appropriate.
- 91 The validity of the consent does not depend on the form in which it is given except for anatomical examination and public display. The information required and the manner in which consent is taken and recorded can vary depending on the particular circumstances.
- 92 Seeking consent is a process which involves listening, discussing, and questioning so as to arrive at a shared understanding – a signed form is not necessarily an indication that such an understanding has been reached. For consent to be valid it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. If these elements have not been satisfied, a signature on a form will not make the consent valid.
- 93 The Act requires that consent must be in writing for anatomical examination and public display, but not for other scheduled purposes. Nevertheless, it is good practice to obtain written consent for significant procedures such as post mortem or organ donation.
- 94 Consent may be expressed verbally or non-verbally. An example of non-verbal consent would be where a person, after receiving appropriate information, holds out an arm for blood to be taken.
- 95 When consent is obtained for future storage or use of samples, but the consent itself is not in writing, an appropriate note should be kept of the fact that consent has been given, and for what purpose(s). This could be entered in the patient record, the laboratory records, or both.
- 96 The process of seeking, gaining and recording consent should be appropriate and proportionate to the type of procedure for which it is being obtained, the sample required and its proposed use. Those involved in seeking consent should receive training and support in the implications and essential requirements of taking consent.

Written consent

- 97 Written consent is always needed for anatomical examination and the use of dead bodies, or body parts, for public display. (See the *Codes of practice on anatomical examination and public display for detailed guidance*).
- 98 Written consent should be obtained wherever possible for all other post mortem activities, such as the post mortem itself, and the removal of organs or tissue for transplantation (see paragraph 92 above).
- 99 As noted earlier, written consent is good practice for significant procedures such as post mortem or organ donation. If verbal consent is obtained, this should be clearly noted in the patient's records.
- 100 Model consent forms will be available on the HTA's website¹⁴.

Multiple consents (e.g. post mortem examination/research)

- 101 When someone has died, it may be appropriate to seek consent for more than one of the scheduled purposes. For example, if a post mortem examination is to be carried out, some tissue samples could also usefully be taken for research purposes. In this case, it would be appropriate to seek the relevant consent to both activities.
- 102 Equally, if consent has been given to the use of tissue or organs post mortem for transplantation, it may be helpful to seek consent for storage and use for research purposes. In such cases, the necessary consents should ideally be sought in a single consent process and, where possible, on a single consent form.
- 103 In the case of post mortem tissue, all storage and use requires consent, including storage and use of retained samples for all scheduled purposes.

Nature and duration of consent

- 104 When a person gives valid consent to an intervention, that consent usually remains valid unless the person withdraws it.
- 105 Consent can be:
- general, i.e. if someone consents to the use of tissue for research, it need not be limited to a particular project
 - specific, i.e. a person limits their consent – a sample can only be used for research into a particular condition
 - both general and specific, i.e. a general consent subject to specific exceptions.
- 106 When seeking consent, clinicians should ensure that it is appropriate to the intended purposes, and that the person understands this.

¹⁴ In Northern Ireland, HSS Trusts and other relevant organisations should use the standardised consent forms agreed with the DHSSPS.

Withdrawal of consent

- 107 A competent person is entitled to withdraw consent at any time. However, if samples have already been used for a purpose such as research, the withdrawal of consent to any further use does not mean all existing information has to be withdrawn from the research project. Nevertheless, as set out in paragraph 29, it is generally good practice to meet the wishes of patients regarding the use to which their samples are put.
- 108 If someone withdraws consent to the storage or use of tissue for scheduled purposes such as research, this does not necessarily mean that the sample or samples have to be removed or destroyed. If samples from a living person are being stored for the purpose of maintaining a diagnostic record, or for other purposes such as audit or quality control, consent is not required.
- 109 But, if consent to the storage or use of post mortem samples by whoever originally consented to their storage or use is withdrawn, this must be respected for any samples that are still held. Clinicians should discuss with the person concerned how the samples should be returned to them or disposed of, and tell him/her about any samples that may have already been used or disposed of.

Donated material

110 In addition under section 8 of the Act, where the body of a deceased person or relevant material from a human body is the subject of appropriate consent (i.e. donated material), it may not be used or stored for use for purposes other than:

- Scheduled 1 purpose
- Medical Diagnosis or treatment
- Disposal

A person who uses or stores such material for any other purpose will commit an offence and will be liable to a fine and / or term of imprisonment of up to three years. It is a defence that the person reasonably believes that the body or material is not donated material.

Existing Holdings

- 111 It is lawful to store and use for scheduled purposes, without consent, human tissue that is already held in storage for a scheduled purpose on 1 September 2006. However, where the views of the deceased person or of their relatives or friends are known, those views must be respected.
- 112 Collections of organs and tissue can make an important contribution to training, education, audit and public health monitoring. Computerised images and photographs are not always an adequate substitute. Some of these collections are irreplaceable and of national or international importance. The fact that there is no evidence of consent to their storage and use should not be a reason for destroying existing collections. Samples may be retained and used for these purposes without consent.
- 113 If the family of a deceased person asks for the return or disposal of tissue or organs, their request should be complied with – unless the samples are retained under the authority of a coroner, or in connection with criminal justice purposes.

Research

114 There are no statutory requirements as to the need for consent to the storage or use of tissue (whether from living patients or post mortem) from existing holdings for research. This does not mean that all such human tissue can be used freely and without regard to issues of consent or other ethical considerations. In the case of organs or tissue used for research, the HTA endorses the principle that research should be ethically approved by a research ethics authority and that the potential benefits must outweigh any potential harm to donors of the samples.

115 Where the use for research of existing stored tissue (which may include post mortem samples retained following hospital or coroner's post mortems) is proposed for the first time, a decision should be taken as to whether consent (or further consent) needs to be sought. The following questions require consideration:

- (i) *has valid consent previously been given?*
- (ii) *can it still be considered as valid today?*
- (iii) *where valid consent has not already been obtained, can it be obtained from the donor, or if the person concerned is no longer alive, from someone who is or was close to him/her?*
- (iv) *where the identity of the donor is unknown or s/he cannot reasonably be traced, such tissue should not be*

used without careful consideration; although it would be wrong to conclude that the use of unidentifiable tissue is necessarily unethical.

- (v) *additionally, in the case of unidentifiable organs and tissue removed surgically,*
 - *whether there is suitable tissue for which valid consent has already been given or could be obtained? and*
 - *whether the researcher has satisfied him/herself that there is no evidence that the samples have been obtained unethically or that there are no other ethical concerns regarding usage?*
- (vi) *whether the samples constitute unidentifiable organs and tissue removed at post mortem?*
- (vii) *whether the research anticipated or proposed constitutes genetic research? Further guidance is provided in ACGT's Advice to Research Ethics Committees (1998)¹⁵, the MRC's Guidance on Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines (2001)¹⁶ and the MRC's Research using Human Nervous System Material (2003): Interim Guidance¹⁷.*

¹⁵ <http://www.dh.gov.uk/assetRoot/04/10/41/56/04104156.pdf>

¹⁶ http://www.mrc.ac.uk/pdf-tissue_guide_fin.pdf

¹⁷ http://www.mrc.ac.uk/pdf-nervous_tissue_guidance.pdf

Consent and the use of DNA

116 The consent requirements of the Act do not make separate provision for DNA or other genetic analysis. Where consent has been given for the removal, storage or use of tissue and organs for Scheduled Purposes, it is lawful to carry out that activity by means of DNA analysis. This does not mean that it would always be good practice to do so without seeking specific agreement to the genetic analysis. The relevant professional guidance should be sought in circumstances in which agreement to the use of genetic analysis is or is not required when carrying out activities for which general consent has otherwise been given.

117 While consent makes it lawful to store and use tissue for Scheduled Purposes, it is an offence under section 45 of the Act to have any bodily material (i.e. material which has come from a human body and which consists of or includes human cells) with intent to analyse the DNA in it without qualifying consent, subject to certain exceptions. Unlike the other parts of the Act, which do not apply to Scotland, this offence applies to the whole of the UK.

118 The offence does not apply if the results of the analysis are to be used for 'excepted' purposes. The following are 'excepted' purposes:

- medical diagnosis or treatment of that person
- coroner/procurator's fiscal purposes
- prevention/detection of crime or prosecution
- national security
- court/tribunal order or direction
- where the bodily material is from the body of a living person – use for clinical audit, education or training relating to human health, performance assessment, public health monitoring and quality assurance
- where the bodily material is an existing holding – use for clinical audit, determining the cause of death, education or training relating to human health, establishing after death the efficacy of any drug or treatment administered, obtaining scientific or medical information about a living or deceased person which may be relevant to another person (including a future person), performance assessment, public health monitoring, quality assurance, research in connection with disorders or functioning of the human body and transplantation
- where the DNA has come from an adult lacking capacity under the law of England, Wales and Northern Ireland or is an adult with incapacity under the law of Scotland and neither a decision of that person to or not to consent is in force, use for any purposes specified in Regulations made by the Secretary of State (see below),
- obtaining scientific or medical information about the person from whose body the DNA has come where the bodily material is the subject of either a direction by the HTA or a court order under paragraph 9 Schedule 4 of the Act and the information may be relevant to the person for whose benefit the direction or order is made, and

- research in connection with disorders or functioning of the human body, provided the bodily material comes from a living person, the person carrying out the analysis is not in, and not likely to come into, possession of identifying information and the research is ethically approved by a research ethics authority. The Secretary of State may also specify the circumstances in which the High Court, or in the case of Scotland, the Court of Session may order that use of the results of DNA analysis for research purposes is an 'excepted' purpose.

119 For the purposes of the offence of non-consensual analysis of DNA, an existing holding is defined as bodily material held immediately prior to commencement of section 45 of the Act.

120 If consent to use material has been obtained under the Act for a Scheduled Purpose, other than anatomical examination or public display, it is not necessary to obtain separate consent where that use involves DNA analysis.

121 Under Regulations¹⁸ made by the Secretary of State, the following are 'excepted' purposes for which DNA analysis from adults who lack capacity, or in the case of Scotland, adults with incapacity, can be carried out in the circumstances set out in paragraph 117 above:

England, Wales and Northern Ireland:

- Any purpose which the person analysing the bodily material reasonably believes to be in the person's best interests;
- Purposes of a clinical trial authorised and carried out in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004; and
- Research which is ethically approved where
 - the research is in connection with disorders or the functioning of the human body;
 - there are reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the research is confined to, or relates only to, persons who have capacity to consent to taking part in it, and
 - there are reasonable grounds for believing that research of comparable effectiveness cannot be carried out in circumstances such that the person carrying out the research is not in possession of information identifying the person from whose body the material has come and is not likely to come into possession of it. In this bullet point, reference to material means bodily material in relation to which an analysis of DNA is to be carried out.

¹⁸ See Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006.

Additionally, in the case of England and Wales only:

- Purposes of intrusive research under the Mental Capacity Act, 2005 in accordance with sections 30–33 or 34 of that Act which is carried out on or after commencement of section 30 of that Act.

Scotland

- Any purpose for which the person carrying out the analysis has obtained the consent of a person with authority under specified provisions of the Adults with Incapacity (Scotland) Act 2000;
- Purposes of a clinical trial authorised and carried out in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004; or
- Surgical, medical, nursing, dental or psychological research permitted under section 51 of the Adults with Incapacity (Scotland) Act 2000.

122 Qualifying consent may be given to analysis of DNA for any purpose by the person from whose body the material came. In the case of a living child¹⁹, a person with parental responsibility (or in Scotland a person with parental responsibilities in relation to the child) may give qualifying consent on their behalf where no decision of the child to or not to consent is in force and either s/he is not competent to consent or though competent, chooses not to make that decision. After death, consent may be

given by anyone who stood in a qualifying relationship (see paragraph 53 above) with the deceased adult immediately before their death. In the case of a child, after death, consent may be given by a person with parental responsibility or where none, a person in a qualifying relationship immediately before they died. The ranking referred to in paragraph 53 does not apply in the case of qualifying consent for DNA analysis – it is sufficient that any person in a qualifying relationship gives consent. As the issue of paternity testing is a sensitive one, further guidance has been published by the Department of Health in this area.

123 The offence does not apply to ‘excepted’ material which is:

- material from the body of a deceased person who died at least 100 years before commencement of section 45 of the Act;
- an existing holding and the person holding it is not in, and is not likely to come into, possession of information from which the individual can be identified; or
- an embryo outside the human body.

There is also a defence that the person holding the material reasonably believes it to be ‘excepted’ material.

¹⁹ In its application to Scotland, a child for the purposes of this section is a person who has not attained the age of 16 years.

Powers of the court / the Human Tissue Authority to dispense with the need for consent

- 124 The HTA has the power to deem consent to be in place for relevant material from someone who is untraceable, or who has not responded to requests for consent to use of his/her material, if that material could be used to provide information relevant to another person. This may be important where information could be obtained about the treatment and diagnosis of the applicant. The HTA will prepare procedures and issue guidance on the implementation of these provisions.
- 125 Similarly, the Secretary of State can make Regulations empowering a court to deem consent to be in place where relevant material or a body could be used for health-related research. It is envisaged that this power would be exercised only in rare and unusual cases where the research is in the public interest, for example, if a person had died of an unknown and potentially infectious virus. No such Regulations have yet been made.

Glossary

These terms have been defined with reference to the Human Tissue Act and the HTA's Codes of Practice and should be read in that context.

Allogeneic use: Cells, tissue or organs²⁰ removed from one person and applied/transplanted into another.

Altruistic non-directed donation A form of non-directed living donation, where an organ or part organ is donated by a healthy person who does not have a relationship with the recipient and who is not informed of whom the recipient will be.

Anatomical examination: Macroscopic examination of the body of a deceased person, or separate parts of such a body, by dissection for anatomical purposes (teaching or studying, or researching into, the gross structure of the human body).

Anatomical specimen: The body of a deceased person, including separated parts of such a body, to be used or in the course of being used for the purpose of anatomical examination. A former anatomical specimen is a deceased body, organ or body part donated for anatomical examination which is held once the examination of the rest of the body has been completed.

Anatomist: An expert in anatomy.

Anatomy: The science of the structure and organisation of the body and its parts.

Anonymisation: is a procedure to ensure that if relevant material is removed from a human body, all necessary steps are taken to prevent identifying the person from whose body the material has come.

Appropriate consent: is defined in the Act by reference to the person who may give consent.

Autologous use: Cells, tissue or organs removed from and applied/transplanted into the same person.

Autopsy: A post-mortem examination.

Biopsy: A procedure where tissue is removed from a living body for examination under a microscope.

Cells: Individual human cells or a collection of human cells when not bound by any form of connective tissue.

Clinical audit: A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria. Stored tissue previously needed for diagnosis, for example, may need to be reviewed as part of this process.

Clinical diagnosis: A process where a disease is identified from medical history-taking, diagnostic tests and physical examination.

²⁰ Wherever the term 'organ' is referenced, this also includes 'part organs'.

Designated Individual: means the individual designated in the licence as the person under whose supervision the licensed activity is authorised to be carried on. This person is responsible for securing that other persons to whom the licence applies are suitable persons, that suitable practices are carried out in the course of carrying-on the licensed activity and for compliance with the conditions of the licence. The HTA must be satisfied as to the suitability of this person.

Diagnosis: A process where a disease is identified by signs and symptoms, a history and laboratory tests.

Directed donation: A form of donation where a healthy person donates an organ (usually a kidney) or part of an organ (for example liver or lung lobe) to a specific recipient. The recipient could be known to the donor (in the case of genetically or emotionally related donation) or unknown to the donor (in the case of paired / pooled donation).

DNA (deoxyribonucleic acid): the genetic material of humans which is located in the cell nucleus and controls heredity.

Domino donation: When an organ is removed as part of a person's treatment, it may be suitable for transplant into another person (e.g. a heart originally removed from the recipient of a heart and lung transplant).

Donation: The act of donating human tissue, cells or organs for a scheduled purpose.

Donor: Every human source, whether living or deceased, of human tissue, cells or organs.

Embryo: means a live human embryo where fertilisation is complete and includes an egg in the process of fertilisation.

Ethical Approval: Defined under Regulations²¹ made under Section 1(9) of the Act to mean approval given by a research ethics authority.

Existing holdings: Body of a deceased person or relevant material which has come from a human body held immediately prior to the commencement of section 1 of the Human Tissue Act 2004 for use for a scheduled purpose.

'Gillick'²² competent (now also referred to as Fraser competent): A test of competence and method of determining the ability of a young person under the age of 16 to make decisions regarding their own healthcare.

Haemopoietic: Relating to the production of blood cells.

Heart-beating donors: This refers to the circumstances where organs and tissue for transplantation are removed from donors fulfilling the nationally agreed and legally defined criteria of brainstem death.

²¹ The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

²² Gillick v West Norfolk and Wisbech Area Health Authority [1985] 3 All ER 402 (HL).

Human application: The use of tissue or cells on or in a human recipient.

Independent Assessor: A person who acts as a trained and accredited representative of the HTA, to conduct an interview and prepare a report in circumstances envisaged under the Regulations²³, for some living organ donations for transplantation.

JACIE: Joint Accreditation Committee – International Society for Cellular Therapy and European Group for Blood and Marrow Transplantation.

Licensing: A number of activities can only be carried out where the establishment is licensed under the Act by the HTA for that purpose. The activities are:

- the carrying out of an anatomical examination;
- the making of a post-mortem examination;
- the removal from the body of a deceased person (otherwise than in the course of the activities mentioned above) of relevant material of which the body consists or which it contains, for use for a Scheduled Purpose other than transplant;
- the storage of an anatomical specimen;
- the storage (other than of an anatomical specimen) of the body of a deceased person or relevant material which has come from a human body for use for a Scheduled Purpose;
- the use, for the purpose of public display, of the body of a deceased person, or relevant material which has come from the body of a deceased person.

Licence Holder: The person who applies for and is granted a licence who can be, but is not necessarily the Designated Individual. The Licence Holder is responsible for the payment of any fees charged by the HTA including fees charged in respect of superintending compliance with licences and any other fees as specified by the HTA from time to time. The Licence Holder can be a corporate body. Where the applicant is not the proposed Designated Individual, the HTA must be satisfied that the applicant is a suitable person to be the holder of the licence.

Licensed premises: Where the licensed activity (e.g. storage, or public display) takes place. If the licensed activity will take place at more than one place, a separate licence will need to be issued. Premises in different streets or with different postal codes will be considered as being in different places. In contrast, different buildings on a hospital site could be regarded as the same place.

Living donors: The person donating tissue, cells or organs for transplantation. The most common forms are live kidney donation (where one kidney is removed), or live bone marrow donation.

NHS Organ Donor Register: A confidential, computerised database managed by UK Transplant, which holds details of people who have signed up to become organ donors in the event of their death. The register is used after a person has died to help establish whether they wanted to donate and if so, which organs.

Non-directed donation: A form of donation where a person donates tissue, cells or organs an unknown recipient. Most commonly, this is deceased donation where the organ is allocated to the most suitable person on the transplant waiting list.

Non-heartbeating donation: A form of donation in circumstances where the deceased donor was not ventilated at the time of death. Donation therefore occurs once death is certified following cardiorespiratory arrest (i.e. the donor's heart has stopped beating).

Organ: A differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy.

Paired donation: Where a close relation, friend or partner is fit and able to donate an organ but is incompatible with the potential recipient, that couple can be matched to another couple in a similar situation, so that both people in need of a transplant receive a compatible organ.

Peripheral blood stem cells: Cells found in the bloodstream which are able to differentiate into all the cell types found in the blood.

Pooled donation: Where a close relation, friend or partner is fit and able to donate an organ but is incompatible with the potential recipient, that couple can be matched to other couples in a similar situation, so that

all people in need of a transplant receive a compatible organ.

Post mortem: Dissection and examination of a body after death, principally in order to determine the cause of death or the presence of disease processes. A hospital post mortem examination is carried out with appropriate consent to gain a fuller understanding of the deceased person's illness or the cause of death, and to enhance future medical care. Coroners' post mortem examinations are carried out under the authority of the Coroner and without consent to assist Coroners in carrying out their functions.²⁴

Preservation: The use of chemical agents, alterations in environmental conditions or other means during processing to prevent or retard biological or physical deterioration of cells or tissues.

Processing: All operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human applications.

Procurement: A process by which tissues or cells are made available.

Public display: includes organised displays and exhibitions held in museums, galleries, exhibition venues and educational establishments, but not for the purpose of education or training. This definition is subject to change pending further consideration by the HTA.

²⁴ Coroners' post mortems are carried out in accordance with the provisions of the Coroner's Act 1988 and the Coroner's Rules 1984 (amended 2005) and the Coroners Act (Northern Ireland) 1959 and the Coroners (Practice and Procedure) Rules (Northern Ireland) 1963.

Public health monitoring: Using population-based or epidemiological techniques to ascertain the prevalence, spread and pattern of an established disease or condition in the community and relating its occurrence to public health programmes and activities.

Quality assurance: A programme for the systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that standards of quality are being met.

Relevant material: is defined by the Act as material other than gametes, which consists of or includes human cells. In the Act, references to relevant material from a human body do not include:

- (a) embryos outside the human body, or
- (b) hair and nail from the body of a living person.

Research: is concerned with creating new knowledge by addressing clearly defined questions with systematic and rigorous methods. It is about testing innovations or discovering the right thing to do e.g. finding out whether new treatments work and whether certain treatments or models of service delivery work better than others. Research forms the basis of nationally agreed clinical guidelines and standards and is designed to establish best practice.

Research ethics authority: an ethics committee established or person appointed to advise on, or on matters which include, the ethics of research investigations on relevant material which has come from a human body.

Residual tissue: is material left over from a diagnostic or therapeutic intervention.

Scheduled purposes: Scheduled Purposes are the activities relating to the removal, storage and use of human organs and other tissue, listed in Schedule 1 of the Act that require consent. The Purposes are divided into 2 parts:

Part 1: Purposes Requiring Consent: General

- 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

Part 2: Purposes Requiring Consent:

Deceased persons

- Clinical audit
- Education or training relating to human health
- Performance assessment
- Public health monitoring
- Quality assurance

Serious adverse event: Any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissue and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients,

or which might result in, or prolong, hospitalisation or morbidity.

Serious adverse reaction: An unintended response, including a communicable disease, in the donor or in the recipient, associated with the procurement or human application of tissue and cells that is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity.

Stem cell: A precursor cell that can develop into more than one kind of cell. For example, early bone marrow cells can develop into red blood cells, white blood cells or platelets.

Storage: Maintaining the tissue under appropriate controlled conditions.

Surplus tissue: Relevant material which has come from a person's body in the course of his receiving medical treatment, undergoing diagnostic testing, or participating in research.

Tissue: Any and all constituent part(s) of the human body formed by cells.

Tissue establishment: A tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissue and cells are undertaken. It may also be responsible for procurement or testing of tissue and cells.

Transplant: An implant of an organ, tissue or cells either from and into the same body or from one person to another.

Transplant coordinator: A person who helps a potential transplant recipient to understand the transplant process and also coordinates the transplant evaluation between the dialysis unit, transplant surgeon, and tissue typing laboratory. After a transplant, the nurse provides a communication link between the recipient and the transplant doctors for post-transplant care.

Transplantable material: Defined under Regulations²⁵ made under Section 34 of the Act to mean the whole or part of any of the following organs if it is their function to be used for the same purpose as the entire organ in the human body: kidney, heart, lung or a lung lobe, pancreas, liver, bowel, larynx, face, or limb. Defined in the same Regulations under Section 33 of the Act to mean organs or part of an organ if it is to be used for the same purpose as the entire organ in the human body, bone marrow and peripheral blood stem cells.

Background reading

Learning from Bristol: the report of the public inquiry into children's heart surgery at Bristol Royal Infirmary 1984-1995, Bristol Royal Infirmary, July 2001

Report of the Royal Liverpool Children's Inquiry, January 2001

Department of Health (May 2003) *The investigation of events that followed the death of Cyril Mark Isaacs*; Department of Health Isaacs Report Response, July 2003