

Human Tissue Authority

Code of Practice – Donation of organs,
tissue and cells for transplantation

Code 2 July 2006

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.

Scope of the code

- 10 This code sets out guidance for the donation of organs, tissue and cells for transplantation and sets the standards practitioners are expected to meet. It includes the principles relating to consent, communication and donation for organs, part organs, tissue and cells. This code does not include domino and autologous donations. In the case of domino donations, however, some guidance is provided (see paragraphs 103-104 below).
- 11 Guidance on donation of allogeneic bone marrow and peripheral blood stem cells for transplantation is provided in the HTA's *code of practice on donation of allogeneic bone marrow and peripheral blood stem cells for transplantation* and practitioners in the area are expected to familiarise themselves with the provisions of that code.
- 12 At the heart of the Act is the requirement that consent be obtained for the removal, storage and use of human tissue or organs and the storage and use of whole bodies for certain scheduled purposes. These purposes include transplantation.
- 13 The removal of organs, tissues and cells from a living person, whether for transplantation or otherwise, continues to be governed by the common law and is outside the scope of the Act. Detailed guidance on the common law position is beyond the scope of this code of practice. Practitioners and individuals responsible for obtaining consent for the removal of organs, tissue and cells from the living should ensure that they are familiar, and comply with, the general common law requirements with regard to consent to examination and treatment. Practitioners are referred to the Department of Health's *Reference Guide to Consent for Examination and Treatment 2001* which contains detailed guidance on the position at common law¹.
- 14 The removal of relevant material from a deceased person and the storage and use of relevant material taken from a living person for the purpose of transplantation is governed by the Act.

¹ www.dh.gov.uk/policyandguidance/healthandsocialcaretopics/consent/consentgeneralinformation/

Consent

- 15 Obtaining consent is the first mandatory step in removing, storing and using human tissue for transplantation.
- 16 The HTA's *code of practice on consent* sets out guiding principles on how the law should be applied to removal (from the body of a deceased person), storage and / or use. It should be consulted and read in conjunction with this code of practice.

Living donation

Appropriate consent – adults

- 17 Consent from an adult is appropriate if the person consenting is
 - competent to do so; and
 - does so voluntarily; and
 - is given full information about the procedure and risks.
- 18 Competence refers to the individual having the mental capacity at law to consent. Practitioners are referred to the Department of Health's *Reference Guide to Consent for Examination and Treatment* which provides guidance on the issue of competence². Consent may be given verbally or in writing, but written consent is recommended as best practice where a significant intervention such as donation is to take place.
- 19 The seeking and giving of consent should ideally be part of a continuing dialogue with the donor, rather than a single act. Wherever possible, the donor's consent to the proposed procedure should be sought well in advance, while there is still time to respond to their questions and provide as much information as necessary. Surgeons should always check before beginning surgery that the person still consents.
- 20 In the case of paired, pooled or non-directed altruistic donations from competent adults, the donation of transplantable material other than bone marrow must be approved by a panel of no fewer than three members of the HTA (see paragraphs 80-102 below). In other cases involving competent adults, the donation approval procedure will be in accordance with paragraph 93 below.
- 21 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. For further guidance see the HTA's *code of practice on consent* and the Department of Health's *Reference guide to consent for examination and treatment*. In addition, the provisions of the Mental Capacity Act 2005³ (2005) should be considered. 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

² www.dh.gov.uk/policyandguidance/healthandsocialcaretopics/consent/consentgeneralinformation/

³ <http://www.opsi.gov.uk/acts/acts2005/20050009.htm>. Note this Act does not extend to Northern Ireland.

from birth. The MCA 2005 defines persons who lack capacity and contains a set of key principles and a checklist to be used in ascertaining best interests.

- 22 The removal of an organ, part organ or tissue continues to be governed by the common law and, before any procedure is undertaken in respect of an adult lacking capacity to consent, the decision must be referred to a court for approval.
- 23 Where an adult lacks the capacity to consent to the removal of transplantable material, and no decision was made while they were competent, then donation may proceed in specified circumstances (see paragraph 24 below) once court approval for the removal has been obtained. Removal other than in accordance with the Act and Regulations made by the Secretary of State is an offence.
- 24 Under Regulations⁴ made by the Secretary of State the donation must be approved by a panel of no fewer than three members of the HTA where:
 - the donor is an adult who lacks capacity to consent to the removal of transplantable material;
 - a decision to consent or not to consent is not in force; and
 - the material is an organ or part of an organ (if used for the same purpose as an entire organ)

then the donation must be approved by a panel of no fewer than three members of the HTA.

In all other cases, the donation approval procedure will be in accordance with paragraph 93.

- 25 Storage and / or use of organs or tissue from adults who lack capacity, other than in accordance with Regulations made under the Act, is unlawful and is an offence under the Act.
- 26 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 Regulations provide for the circumstances in which consent can be deemed to be in place. These are:
 - Storage and/or 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/or 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 Regulations⁵.
- 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)⁶ 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.

Appropriate consent – children

- 27 Under the Act, a child is defined as being under 18 years old.
- 28 The removal of an organ, part organ or tissue continues to be governed by the common law and before the removal of a solid organ from a child, whether competent or not, it is good practice for court approval to be obtained. For further guidance see the Department of Health's *Reference Guide to Consent*, referred to in paragraph 18 above and the

Department of Health's *Guide to Seeking Consent: Working with Children*⁷ for detailed guidance on this issue.

- 29 Any decision to proceed with the removal of an organ, part organ or tissue from a child who lacks capacity is governed by a test of best interests. This test should not be limited to medical interests, and should take account of emotional, psychological and social benefits. It is good practice that the practitioners involved assess the child's best interests by discussing the matter with the child and the person who has parental responsibility for him or her⁸. In any case of doubt as to what is in the donor child's best interests, the practitioners should seek legal advice and if necessary, the matter should be referred to the court. (In the case of solid organs, the courts have indicated that prior court approval is required – see paragraph 28 above. Other non-therapeutic removal cases from a child may also require court approval).
- 30 Children can be considered as living organ donors only in extremely rare circumstances, and donation under the Act should go ahead only with the approval of a panel of no fewer than three members of the HTA (after court approval to the removal has been obtained, where necessary in accordance with paragraph 28 above). A child may

⁵ 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.

⁶ The MCA 2005 does not extend to Northern Ireland and accordingly the research must always be approved by a Research Ethics Authority.

⁷ http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4007005&chk=xFifXP

⁸ 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*.

only consent to the donation under the Act if s/he is competent to do so. In the Gillick⁹ 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.

31 Under the Act, a person who has parental responsibility for the child can consent, to the storage and use for transplantation of transplantable material, on his or 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.

32 A person with parental responsibility can consent on behalf of the child if the intervention is assessed as being in the child's best interests, taking into account medical, emotional, psychological and social aspects of the donation as well as the risks.

33 Even if the child is competent, it is good practice to consult the person with parental responsibility for the child and to involve him and/or her in the child's decision-making process regarding storage and use of transplantable material for transplantation. However, it must be

emphasised that, if the child is competent, the decision to consent (under the Act) must be the child's.

34 It is also crucial to make sure that a child has consented voluntarily and has not been unduly influenced by anyone else: where older children are the donors, matters should be discussed with them first, where possible without the person who has parental responsibility being present.

35 Written consent to donation which is signed by the child in the presence of a witness is recommended as best practice. The person who has parental responsibility for the child can sign the consent form if one or more of the situations described in paragraph in 31 apply.

36 Under Regulations (see paragraph 24 above) made by the Secretary of State the donation must be approved by a panel of no fewer than three members of the HTA where:

- the donor is a child, whether or not he/she is competent to consent to the removal of transplantable material; and
- the material is an organ or part of an organ (if used for the same purpose as an entire organ)

then the donation must be approved by a panel of no fewer than three members of the HTA.

In all other cases, the donation approval procedure will be in accordance with paragraph 93.

Removal other than in accordance with the Act and Regulations made under the Act is an offence.

Deceased donation

Adults

- 37 The Act makes clear that where an adult has, whilst alive and competent, consented to one or more of the scheduled purposes taking place after their death, then that consent is sufficient for the activity to be lawful.
- 38 In cases of potential donation, trained staff should determine whether the deceased person had given consent for organ, tissue or cell donation by checking with the NHS Organ Donor Register (ODR) or any other source, such as a will. If consent is established, the deceased person's relatives or those close to them should be told.
- 39 If no records are held, an approach should be made to the deceased person's relatives or close friends by a transplant coordinator or a member of the team who cared for the person, or both together, to establish any known wishes of the deceased person.

40 If the family or those close to the deceased person object to the donation, for whatever purpose, when the deceased person (or their 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. There may nevertheless be cases in which donation is inappropriate and each case should be considered individually.

41 If the deceased person's wishes are not known and the deceased has nominated a person to deal with the use of their body after death, then consent can be given by that nominated representative. If the deceased person has not indicated their consent (or refusal) to the removal, storage or use of their tissue for transplantation, nor appointed a nominated representative (or the nomination has been disregarded in accordance with paragraph 49 below), consent can be given by a person who was in a 'qualifying relationship' immediately before the death of the deceased person (see paragraph 50 below).

Children

42 The position for a child, who before they died were competent to reach a decision and consented to organ or tissue donation taking place after their death, is, legally, no different from that of an adult. The

child's consent is sufficient to make the removal, storage or use of tissue for a scheduled purpose lawful.

- 43 Clearly, in any case where a child has given consent to donation, especially if the child has self-registered on the ODR, it is essential to discuss this with someone who has parental responsibility for the child and 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.
- 44 In cases where the deceased child's wishes are not known, every effort should be made when the child dies to establish the wishes of the person with parental responsibility for the child. 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.
- 45 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 50 below.

Nominated representatives

- 46 This section applies to adults only.
- 47 Adults may nominate one or more people to represent them after death over the issue of consent. Trained healthcare professionals should make reasonable enquiries at the hospital, the prospective donor's GP or with the deceased person's relatives to establish if a representative has been nominated.
- 48 The appointment of a nominated representative and its terms and conditions may be made orally or in writing. If in writing, it must either 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.
- 49 Where more than one nomination is made, the nominees may act jointly or individually unless the conditions of the nomination state otherwise. Nominations can be revoked by the potential donor or renounced by the nominated person at any time.

Qualifying relationships

- 50 Where the deceased person has not indicated their consent (or refusal), and, in the case of an adult, a nominated representative has not been appointed (or the nomination has been disregarded in accordance with paragraph 49 above), someone close to them can give consent to the removal, storage and use of organs or tissue for transplantation. The Act ranks persons in a qualifying relationship for the purposes of obtaining consent in these circumstances in the following order (highest first):
- a) spouse or partner (including civil or same sex partner)¹⁰
 - b) parent or child
 - c) brother or sister
 - d) grandparent or grandchild
 - e) niece or nephew
 - f) stepfather or stepmother
 - g) half-brother or half-sister and
 - h) friend of long standing.
- 51 The ranking is intended to help those seeking consent to know who to approach and in what order. Consent should be obtained from the person ranked highest. (Relationships listed together, e.g., brother or sister, are accorded equal ranking. It is sufficient to obtain consent from just one of them, provided they are ranked equal highest.)
- 52 In circumstances where a person in a qualifying relationship does not wish to deal with the issue of consent, or is unable to do so (e.g. because they are a child or lack capacity), the principles applied to the ranking can be waived and the next person in the ranking approached, but it is advisable to record this in the case notes.
- 53 This is also the case if the activity for which consent is sought is such that it would not be practical to communicate with the highest ranking person within the time available.
- 54 Where a child is the prospective donor, special efforts should be made to obtain consent from a person with parental responsibility for the child, to use the child's organs for donation. If, there is no person with parental responsibility for the child (e.g., the parents died at the same time as the child), the consent of the person who was in the highest ranked qualifying relationship with the child at the time of death should be sought.
- 55 Where there are differences of opinion between people in qualifying relationships, decisions will need to be made on a case-by-case basis, taking into account:
- the views of the deceased person, which are paramount
 - the view of the highest-ranking person – if a spouse or partner refuses consent, then that must take precedence even if other family members would be willing to give consent and

¹⁰ Section 54 (9) states that 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.

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- the views of other qualifying persons. If, for example, a spouse consents to donation, but other family members object strongly, the benefits of carrying out the transplantation should be weighed against the distress and resentment that would be caused by proceeding in the face of strong opposition. This will be especially sensitive where people in equally ranked qualifying relationships disagree.

56 Obtaining appropriate consent only makes the activity lawful if it goes ahead – it does not mean that it is obligatory.

57 An agreed position should be reached by inclusive discussion, where possible. This will need careful explanation of the options and the potential benefits of donation. The ‘ranking’ provision in the Act should not be used to impose one family member’s wishes over others where there are strongly held objections that might outweigh any benefit. Great care should be taken to assess whether ignoring the family’s strongly held objections might outweigh the benefits of proceeding.

Communication

58 When deciding on the best method of sharing information with others, the procedures laid down in the HTA's *code of practice on consent* must always be taken into consideration.

Information for the prospective living organ donor

- 59 A transplant using an organ taken from a living donor is permitted only in certain circumstances. Notwithstanding any consent given, the HTA must be satisfied that all legal requirements have been met before the transplant can take place and in particular must be satisfied that no reward has been or is to be given and that all conditions set down in the Regulations have been complied with.
- 60 The decision about whether a person is medically fit and suitable as a living organ donor is a matter for the practitioners concerned who take legal responsibility for the donation procedure. Practitioners must explain to the donor what the procedures for donation involve, the chances of a successful transplant, the risks, and the possible after-effects to the donor.
- 61 The decision to donate an organ rests solely with the potential donor, who can change his or her mind at any time before the procedure. Potential donors should be given as much time as they need to make a decision and the practitioner obtaining informed consent should ensure that all their concerns should be answered.
- 62 Potential donors should be provided with sufficient information for them to reach an informed decision and give their consent. They should be advised about:
- the surgical procedures and medical treatments to which a donor may be subjected and the risks involved in both the short and long term;
 - the potential advantages for the recipient and the fact that a positive outcome for the recipient cannot be guaranteed; and that if there is an adverse outcome, it is not their fault;
 - the risks involved with the procedures, the chances of success and any possible side-effects;
 - the tests for transmissible microbiological diseases, such as HIV, hepatitis B and C, Human T-cell Lymphotropic Virus (HTLV) and other such diseases and the implications of any positive tests;
 - the requirement for anonymity in non-directed and paired/pooled donations;
 - the process of tissue typing for transplants that can sometimes reveal an unrecognised discrepancy between the biological and legal/recognised parents;
 - the counselling services that are available;
 - the right to withdraw consent at any time;
 - the consequences of the withdrawal of consent, especially if it is withdrawn late in the process;
 - their right to be free of any kind of coercion or threat against them or anyone else (for example, family or friends) and that consent deemed to be given under any such pressure will not be validated by the Independent Assessor;

- the fact that it is an offence to seek or receive payment or any other benefit for providing controlled material (see paragraphs 66 and 67 below) for transplantation and will attract a penalty (see below);
- reimbursement (see 'Payment' below) and
- the need to check with their insurance companies that their existing policies remain valid; or that they might wish to make arrangements for life insurance if they have not already done so.

Payment, advertising and commercial dealings

- 63 The Act allows the donor to receive reimbursement of expenses, such as travel costs and loss of earnings that are reasonably attributable to and directly result from donation of controlled material. Controlled material has the same meaning as paragraph 67 below.
- 64 All such payments must be made by a proper authority, e.g. an NHS Trust or foundation hospital, or, in the case of a private patient, the hospital. Details on the levels of reimbursement are available on the Department of Health website¹¹.
- 65 Donors must not be reimbursed directly by the recipient or by their family or friends. The HTA requires that checks are made to ensure that no other payment of any kind is made and that the donor does not make a profit from the donation.
- 66 The Act prohibits commercial dealings in human material for the purposes of transplantation. Unless designated by the HTA to carry out such activity, a person is committing an offence if they:
- give, offer or receive any type of reward for the supply or offer of supply of any controlled material;
 - look for a person willing to supply any controlled material for reward;
 - offer to supply any controlled material for reward;
 - initiate or negotiate any arrangement involving the giving of a reward for the supply of, or for an offer to supply, any controlled material;
 - take part in the management or control of any type of group whose activities consist of or include the initiation or negotiation of such arrangements; or
 - cause to be published or distributed, or knowingly publish or distribute, an advertisement inviting people to supply, or offering to supply, any controlled material or indicate that the advertiser is willing to initiate or negotiate any such arrangements. This covers all and any types of advertising.

67 Controlled material for the purposes of paragraph 66 above is material which

- consists of or includes human cells;
- is removed (or intended to be removed) from a human body (whether living or dead);
- is intended to be used for transplantation; and
- is not otherwise excepted material (gametes, embryos and material which by virtue of human skill has, at law, become the subject of property are all excepted material for this purpose).

In addition the body of a deceased person is regarded as controlled material where relevant material from such a body is to be used for transplantation and the material is not otherwise excepted (as above).

68 This offence carries the risk of a fine and up to three years imprisonment. No offence will be committed where:

- the HTA has designated a person who may lawfully engage in trade in controlled material;
- reimbursement is for expenses connected with transporting, removing, preparing, preserving, or storing controlled material including costs incurred by third parties and payment to licence holders in respect of these activities provided their licence does not expressly prohibit such payment; or
- reimbursement of reasonable expenses or loss of earnings incurred by the

donor of the controlled material provided they are reasonably and directly attributable to the donation.

Communication in cases of deceased donation

69 The Act makes it clear that where an adult, whilst alive and competent, consented to donation after their death, then that consent is sufficient for human tissue donation to be lawfully carried out.

70 In cases of potential deceased donation, the transplant coordinator or delegated person should be approached at an early stage and asked to determine whether the deceased person had indicated a wish to donate their organs and/or tissue after death, carried a signed organ donor card or had registered on the Organ Donor Register. This should be done before the relatives are approached.

71 Once it is known that the deceased person consented to donation, the matter should be discussed sensitively with the deceased's relatives. They should be encouraged to recognise the wishes of their relative and it should be made clear, if necessary, that they do not have the legal right to veto or overrule the deceased person's wishes.

72 If the deceased person's wishes are unknown and donation is a possibility, trained healthcare professionals should raise the subject of donation with the

family, the nominated representative or the person in the highest ranking qualifying relationship (see paragraph 50 above). This approach should be made as sensitively as possible and provide enough information to allow a decision to be reached. Once a decision has been made, it must be respected.

Deceased donor transplantation

Organ Donor Register

- 73 The Organ Donor Register (ODR) should always be checked at the earliest possible opportunity when trying to establish consent. The fact that the person has registered makes donation within the remit of that consent lawful.
- 74 In the case of an adult, no further consent should be necessary, but if the family object, the matter should be discussed with them sensitively (see paragraph 54 above). In the case of a child, i.e. under 18 years of age, the principles set out in paragraphs 42–45 apply. (See paragraph 46 onwards if the deceased person's wishes are not known).

Organ preservation in situ

- 75 The Act makes it lawful to retain a body and preserve part of a body for the purposes of transplantation, including in a situation where consent cannot be obtained. This is applicable in cases of non-heart beating donation, i.e. where the potential donor has died following cardio-respiratory arrest without being ventilated and action needs to be taken to preserve the organ's viability for donation before consent has been obtained.
- 76 In all cases, steps should be taken to ascertain the individual's wishes on donation, such as checking for a donor card or registration on the ODR. In cases

where consent for organ donation cannot be established, it is good practice to gain consent, where possible, before the preservation process begins.

- 77 However, it will not always be possible to gain consent from a nominated representative or the person in a qualifying relationship quickly enough to prevent the relevant organs deteriorating. In these circumstances, it is legal for the person in charge of the establishment (e.g. hospital, nursing home or other institution), or someone authorised to act on their behalf, to:
- take the minimum steps necessary to preserve the part for use in transplantation using the least invasive procedure and
 - retain the body of a deceased person for that purpose.
- 78 Guidance on the process for preservation is provided in the British Transplantation Society's *Guidelines relating to solid organ transplants from non-heart beating donors*.¹²
- 79 Permission to carry out preservation of this type ceases once it has been established that consent will not be given for the transplant to take place. All procedures to preserve the body must then be stopped.

Living donor transplantation

80 Living donor transplantation is an expanding area. Non-directed, altruistic and paired/pooled organ donations are relatively new areas of work in the UK that the HTA has a direct interest in both approving and monitoring for quality assurance.

81 It is an offence to remove or use any transplantable material from the body of a living person for transplantation unless the requirements of the Act and Regulations are met. It is a defence that the person has acted with the reasonable belief that the transplantable material has not come from the body of a living person. Under the Act and Regulations, the matter must be referred to the HTA which must be satisfied that:

- no reward has been or is to be given;
- there is consent to the removal for transplantation or the removal is otherwise lawful (e.g. where court approval for the removal has been obtained); and
- all other requirements laid down in the Regulations have been complied with.

Before a transplant involving a living donor takes place, interviews must be conducted on behalf of the HTA with the donor, the person giving consent (if this is not the donor) and the recipient, and a report prepared for the HTA in accordance with paragraph 88 below. The HTA will then make a decision as to whether the transplantation should proceed.

82 Donation of whole or part organs by adults who lack capacity or children is exceedingly rare. These cases and other novel forms of transplantation are treated differently to more routine forms of transplantation.

Under the Regulations¹³, the following cases must be approved by a panel of no fewer than three members of the HTA (hereafter 'the HTA panel'):

- where the donor is an adult who lacks capacity to consent to the removal of an organ or part of an organ (if used for the same purpose as the entire organ) and did not make a decision to consent (or refuse) whilst competent;
- where the donor is a child, whether or not he/she is competent to consent, to the removal of an organ or part of an organ (if used for the same purpose as the entire organ);

(In the above two cases, after prior court approval to the removal has been obtained, where necessary)

and

- In the case of paired / pooled or non-directed altruistic donations from competent adults, the donation of an organ or part of an organ (if used for the same purpose as the entire organ).

83 Guidance for the procedures to be followed by Independent Assessors in living donation cases is given in this

section. In all cases of living donation, the registered medical practitioner with clinical responsibility for the donor must make a written referral to the HTA.

Independent Assessors

- 84 Independent Assessors are trained professionals who are usually, but not exclusively, based in hospitals with transplant units. They will act both as a representative of the HTA and as an advocate for the donor.
- 85 They are trained to consider, and report on, all living organ donations for transplantation that fall into the following categories:
- directed:
 - genetically related
 - emotionally related
 - paired/pooled (the decisions in these cases should be referred to the HTA panel until practice is established as routine)
 - non-directed:
 - altruistic (the decisions in these cases should be referred to the HTA panel until practice is established as routine).

The Assessor's roles and responsibilities

- 86 The role of the Independent Assessor is to act on the HTA's behalf in an independent capacity to carry out

interviews and prepare a report for the HTA. Their report will assist the HTA in satisfying itself that the requirements of the Act and Regulations have been met, and in making its decision, on a case by case basis, as to whether or not to approve the donation.

- 87 The Assessor's responsibility is to interview the donor and recipient separately and to draw up a report on the proposed procedure. It may be appropriate and desirable in certain cases for the Assessor to also interview the donor and recipient together. There are two circumstances where the Assessor may not see the donor and recipient separately and together:
- When the recipient is a child, it is expected that the child and the person with parental responsibility for the child, would be seen together by the Assessor, even when the person with parental responsibility is the potential donor.
 - In non-directed altruistic donation, the Assessor would only see the donor (see paragraph 100).
- 88 The Independent Assessor's report should show that they are satisfied that:
- a registered medical practitioner has explained to the donor the nature of the medical procedure in question, the risks involved and any other wider implications – for example, the risks to both donor and recipient and the effect upon children and any other dependent relatives. This report should include the

information given as to the nature of the procedure and the risks involved, the full name of the registered medical practitioner and their qualification to give this information.

- the donor understands the nature of the medical procedure and the risks, as explained by the registered medical practitioner, has the capacity to consent, and consents to the removal of the organ or part-organ in question.
- the donor's consent was not obtained by duress or coercion or the offer of any other inducement.
- there is no evidence of an offer of reward.
- the donor understands that they are entitled to withdraw consent at any time and understands the consequences of withdrawal for the recipient.
- the donor–recipient relationship is as stated, where directed organ donation is involved. This will usually require appropriate supporting evidence.
- there were no difficulties in communicating with the donor and/or recipient, or other person interviewed. If there were, an explanation of how those difficulties were overcome. Any translator used should have no personal connection to either the donor or the recipient, should have some understanding of medical matters and speak the donor's and recipient's language fluently. In the case of someone with a speech or hearing disability, a translator should be used with experience in signing.

- 89 The report should provide the Independent Assessor's assessment based on the points in paragraph 88 and should be accompanied by a covering letter, stating whether it is recommended that the HTA approve the transplantation or not. In the case of routine transplantations, where the Independent Assessor's advice is that the transplant should proceed, the report should be submitted to the HTA Executive which will make the final decision on whether the proposed transplant can proceed. For all novel transplantations and cases involving children and incapacitated adults, these must be referred to the HTA panel to make the decision. In cases where the Independent Assessor is not in a position, and/or requires further guidance, to recommend approval, such cases may, at the discretion of the HTA, also be referred to the HTA panel.
- 90 This report is valid for six months. If the transplant does not happen within that time for whatever reason, a repeat report should be provided to the HTA to ensure circumstances have not changed and for a further decision. If the Independent Assessor needs further advice, s/he should consult with the HTA for assistance.
- 91 The Independent Assessor should be an NHS medical consultant or someone of equivalent senior professional status, who is not otherwise party to the transplantation process.

92 In order to become an Independent Assessor, a person must have completed the training required by the HTA and have been accredited by them to undertake the role. Independent Assessors can be accredited only if they attend an Authority-approved training course. (Further information can be obtained from the HTA).

Directed – genetically or emotionally related organ donation

93 Approval of genetically or emotionally related living organ donation requires the following:

- the clinician responsible for the donor makes a written referral to the HTA;
- the Independent Assessor meets the donor and recipient separately, and where appropriate, together (see paragraph 87 above) and ensures the seven points are met (see paragraph 88 above);
- the Independent Assessor produces a written report (in accordance with paragraph 88 above) for the HTA;
- if all requirements are met, the Independent Assessor confirms this in his report;
- if all requirements are not met, the Independent Assessor recommends in his report that the HTA do not approve the transplantation;
- following consideration of the Independent assessor's report and subject to being satisfied in accordance

with paragraph 81 above, the HTA will make its decision as to whether to approve the transplantation or not. If approval is given, the living donor transplant must go ahead within six months;

- once the transplant has taken place, the recipient's clinician completes all relevant documentation and informs the Independent Assessor. The clinician is responsible for reporting any delays in performing the procedure to the Independent Assessor;
- Medical practitioners who remove and receive transplantable material are responsible, under Regulations¹⁴, for supplying to NHS Blood and Transplant certain information about the transplant. Transplantable material for these purposes has a different meaning to that set out in paragraphs above and is defined under Regulations as meaning the whole or part of any of the following:
 - (a) kidney,
 - (b) heart,
 - (c) lung or a lung lobe,
 - (d) pancreas,
 - (e) liver,
 - (f) bowel,
 - (g) larynx,
 - (h) face, or
 - (i) limb.

The information which must be supplied by practitioners responsible for removal as well as those receiving the transplantable material is provided in Schedules 1 and 2 of the Regulations.¹⁵ Practitioners must comply with this obligation.

Directed – ‘paired/pooled’ organ donation

94 The term ‘paired donation’ relates to circumstances where a close relation, friend or partner is fit and able to donate an organ, but is biologically incompatible with the potential recipient. That potential donor and recipient can be matched to another donor and recipient in a similar situation, so that both those needing a transplant receive a compatible organ. The term ‘pooled donation’ relates to circumstances where there are more than two pairs involved in the swap.

95 As this is a new donation system, the HTA panel must give approval in each case. This allows the HTA to assess effectiveness and closely monitor the process, so that any problems can be identified and addressed at an early stage.

96 Approval of paired/pooled living donation requires the following that the potential donor/recipient is assessed, informed and deemed suitable by the transplant team. The possibility of paired/pooled donation is discussed with donor and recipient. If they are happy to proceed then the person is registered with UK Transplant and matched to another potentially suitable pair or pairs. A cross-match is then performed, anonymity is preserved and, if the results are negative, all parties are informed and this marks the end of the process. If the results of the cross match are positive, the process should continue as described below:

- the clinicians responsible for both donors must make written referrals to the HTA ;
- the two Independent Assessors see their respective donors and recipients separately, and where appropriate, together (see paragraph 87 above) and ensure the seven points outlined in paragraph 88 above are met;
- the Independent Assessors produce written reports (in accordance with paragraph 88 above) for the HTA;
- if all requirements are met, the Independent Assessors confirm this in their report and refer the matter to the HTA panel to approve the living donor transplant;
- if requirements are not met, the Independent Assessors recommend in their report to the HTA panel that the donation should not proceed;
- subject to the HTA panel being satisfied in accordance with paragraph 81 above, approval may be granted for the donation to proceed;
- if approval is given by the HTA panel, both living donor transplants should go ahead simultaneously within the next six months; and
- after the transplants, the recipients’ clinicians complete all the relevant Authority forms.

Non-directed – altruistic organ donation

- 97 Non-directed altruistic organ or part-organ donation occurs when a person offers to donate an organ to anyone who might benefit, i.e. a complete stranger.
- 98 As with paired/pooled organ donation, non-directed altruistic organ donation is a new form of donation. The HTA panel is therefore responsible for giving approval in each case and will control the procedure in order to monitor and evaluate effectiveness.
- 99 Before any such organ transplants are undertaken, it is essential that all medical, surgical and psychiatric assessments necessary to ensure fitness to donate have been completed. The accredited Independent Assessor must be satisfied that all these procedures have been fully complied with before any application for a non-directed altruistic donation is sent to the HTA panel for approval.
- 100 The Independent Assessor must interview the non-directed altruistic organ donor and provide a report to the HTA panel on the outcomes of the interview. The interviewer must:
- Make clear to the donor the meaning of non-directed organ donation, i.e. that under no circumstances will either the recipient or the donor know of each other's identity prior to donation and transplantation.
 - Be satisfied that a registered medical practitioner has given the donor an explanation of the nature of the medical procedure in question, the risks involved and any other wider implications – for example, the risks to both donor and recipient and the effect upon children and any other dependent relatives. This report should include the information given as to the nature of the procedure and the risks involved, the full name of the registered medical practitioner and their qualification to give this information.
 - Be satisfied that the donor understands the nature of the medical procedure and the risks, as explained by their clinician and has the capacity to consent, and consents to the removal of the organ or part-organ in question.
 - Be satisfied that the donor's consent to the removal of the organ or part organ in question was not obtained by duress, coercion or the offer of any other inducement.
 - Be satisfied there is no evidence of an offer of reward.
 - Be satisfied that the donor understands that they are entitled to withdraw consent at any time.
 - Be satisfied that the donor has no evidence of current or past mental illness that affects their ability to donate altruistically with full, informed consent.
 - Be satisfied that there were no difficulties in communicating with the donor and, if so, how they were overcome. Any translator used should have no personal involvement with

either party involved in the transplant, have some understanding of medical matters and speak the donor's language fluently or, in the case of someone with a speech or hearing disability, be experienced in signing.

101 The Independent Assessor should produce a report, which must be sent to the HTA panel along with the application.

102 The procedure set out below should be followed for the donation process:

- if a potential donor offers an organ, then:
- the donor is sent an information pack and invited to make further contact if wishing to take things further
- if the donor wishes to proceed, a detailed screening questionnaire must be completed
- medical, surgical and psychiatric assessments of the donor take place and further information is given
- an Independent Assessor sees the potential donor and a report is produced (including the information in paragraphs 88 and 100 above) for the HTA
- the HTA's panel considers the application and tells the donor's clinician and the Independent Assessor of its decision
- if the application is approved, a potential recipient is identified in accordance with UK Transplant National Organ Allocation rules. Anonymity should be preserved and this may require donor and recipient operations being done in different centres.

Non-directed – 'domino' organ donation

103 When an organ or part organ is removed for the primary purpose of that person's medical treatment, it may be suitable for transplant into another person (e.g., a heart originally removed from the recipient of a heart/lung transplant). Although it is a living donation, approval by the HTA will not be needed.

104 Approval of such a domino organ transplant requires as a matter of good practice the following:

- the prospective donor is identified, informed and gives agreement for the organ to be used;
- an application form is completed by the donor's clinician and signed by the donor;
- after the transplant, the recipient's clinician completes all the relevant documentation.

Tissue donation

Consent

- 105 Tissue donations from the living and from the deceased are only non-directed altruistic and are not paired/pooled or directed.
- 106 The principles relating to consent, as described in paragraphs 15–57 above also relate to tissue donation.
- 107 Donations of tissue from living donors are, in the majority of cases, made as part of a surgical procedure, for example femoral head donation from hip replacement operations or amnion donation from births. Occasionally heart valves may be donated from a living donor receiving a heart transplant. These types of donation do not carry additional risk over and above those of the operation. Establishments which store tissue (not organs or part organs) for transplantation purposes are required to apply to the HTA for, and hold a licence for, the storage of such tissue unless they store for less than 48 hours.
- 108 The principles for donation of tissue after death are the same as for donation of organs from the deceased (see paragraphs 37–57).
- 109 Access to the Organ Donor Register should be available to tissue bank coordinators to ensure that the deceased person's wishes about tissue donation after death are met.
- 110 Independent Assessors are not required for living donations made at the time of surgery or for tissue donation after death.

Reconstruction of the deceased tissue donor

- 111 The removal of tissue from a donor after death must be undertaken by staff who are trained in tissue retrieval and in reconstructing the body to appear as normal as possible, in a manner similar to that in surgical reconstruction taking place after theatre operations. This will help to minimise the distress to relatives wishing to view the body. It also maintains the dignity of the deceased donor.
- 112 Before providing consent, as part of the information process, donor families must be informed of the likely appearance of the donor following reconstruction.
- 113 The deceased tissue donor must be treated with respect during the retrieval of the tissue and during the reconstruction, including draping the body where appropriate.

Information for donor families

- 114 Whilst donor families need some core information to be able to give consent, their wishes about the amount and detail of the information they receive should be respected.

115 However, they should be informed about any test results from the deceased donor which may be relevant to their health.

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 organs¹⁶ 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.

¹⁶ 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 Regulations¹⁷ 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'¹⁸ 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.

¹⁷ The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

¹⁸ 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 Regulations¹⁹, 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.²⁰

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.

²⁰ 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 Regulations²¹ 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