

Human Tissue Authority

Code of Practice – Donation of allogeneic bone marrow
and peripheral blood stem cells for transplantation

Code 6 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 this code

- 10 This code sets out guidance for the donation of allogeneic bone marrow, peripheral blood stem cells (PBSC) and lymphocytes for transplantation and sets the standards which practitioners are expected to meet. It includes the principles relating to consent and communication for donation. The approval procedures referred to in paragraphs 38-52 do not apply to lymphocytes as they fall outside the scope of the Regulations.
- 11 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.
- 12 The removal of organs, tissues and cells from a living person, including the removal of bone marrow, PBSC and lymphocytes, 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 bone marrow, PBSC and lymphocytes 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 (hereafter "DH Reference Guide to Consent") which contains detailed guidance on the position at common law.¹

Consent

Consent – general

- 13 Consent under the Act relates to the purposes for which material might be used or stored. These purposes are set out in Schedule 1 of the Act and include the use of human tissue for transplantation. The HTA's *code of practice on consent* provides an interpretation of the law and guiding principles on how it should be applied. This code should be consulted and read in conjunction with this code of practice.
- 14 If material is removed, stored or used in circumstances for which the Act requires consent, it is mandatory to check that the appropriate consent has been obtained and that the necessary procedures are in place to provide the necessary assurance. These procedures should be robust and reviewed regularly. It is an offence to carry out an activity – in this case donation for transplantation of bone marrow, PBSC or lymphocytes – without appropriate consent. It is a defence that the person has acted with the reasonable belief that consent is in place or is not necessary.
- 15 Consent for first and each repeat donation must be obtained before harvesting bone marrow, PBSC or lymphocytes from a donor for transplantation. A consultant or other senior member of the clinical Bone Marrow Team (BMT) or donor registry team will normally undertake the assessment and counselling of the donor. They must at least ensure that the principles and processes described in this code are implemented.
- 16 The person obtaining consent must complete:
- a donor consent form that includes a statement by the donor that s/he has received and understood sufficient information to give informed consent; and
 - a declaration by the clinician that they have read and applied this code and the HTA's *codes of practice on consent and donation of organs, tissue and cells for transplantation*.
- 17 This consent form and declaration can be on the same form and must be attached to the donor's notes and made available when requested by the HTA or a person or organisation acting on behalf of the HTA
- Special procedures will be needed in cases involving donors unable to give consent themselves – i.e. children who are not Gillick²-competent and incapacitated adults. (See paragraphs 40–44 and 48–52).

² Gillick v West Norfolk and Wisbech Area Health Authority [1985] 3 All ER 402 (HL).

Consent – adults

- 18 Consent from an adult is appropriate if the person consenting is
 - a. competent to do so; and
 - b. does so voluntarily; and
 - c. is given full information about the procedure and risks.
- 19 Competence refers to the individual having the mental capacity at law to consent. Practitioners are referred to the *DH Reference Guide to Consent* which provides guidance on the issue of competence (see paragraph 12 above). Consent may be given verbally or in writing.
- 20 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 *DH Reference Guide to Consent* (see paragraph 12 above). In addition, the provisions of the Mental Capacity Act 2005³ (MCA 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 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.
- 21 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 (see paragraph 26 of code of practice on donation of organs, tissue and cells for transplantation).

Consent – children

- 22 Under the Act, a child is defined as being under 18 years old. Before proceeding, the consultant, senior person from the BMT team, or another senior paediatrician must ensure that it is not possible to identify an appropriate adult donor. Preference should be given to a donor over 18 unless there are specific clinical indicators that suggest otherwise.
- 23 Young children are unlikely to have a frame of reference for understanding the procedure for donating bone marrow, PBSC or lymphocytes, or to be aware of the risks involved. In consequence, they may find the act of speaking to a doctor about the process of donation quite daunting. It is therefore strongly recommended that for children capable of giving consent a play therapist, psychologist or specialist nurse is involved in the communication process so that the child may better understand what is proposed and be able to give his or her fully informed consent.

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

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- 24 A child may only consent to the donation if they are competent to do so. In the Gillick 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.
- 25 Any decision to proceed with removal of bone marrow, PBSC or lymphocytes 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 her. A person who has parental responsibility will usually, but not always, be the child's parent.⁴ 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. Practitioners are referred to the DH *Reference Guide to Consent*, referred to in paragraph 12 above for detailed guidance on this issue.
- 26 A person who has parental responsibility for the child can consent to the storage and use for transplantation of bone marrow, PBSC or lymphocytes on his or her behalf only if no previous decision by the child to consent or not to consent is in force and the child:
- is not competent to do so; or
 - chooses not to make that decision, although s/he is competent to do so.
- 27 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.
- 28 Even if the child is competent, it is good practice to consult the person who has parental responsibility and to involve him and/or her in the child's decision-making process regarding storage and use of bone marrow, PBSC or lymphocytes for transplantation by the child. However, it must be emphasised that, if the child is competent, the decision to consent must be the child's.
- 29 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.
- 30 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 26 apply.

⁴ 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*.

Communication

- 31 If a translator is used, he or she should have no personal involvement with either party to the transplant. S/he should, by preference, 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 the manner of communication required.
- 32 Communication should occur well in advance of the donation to leave sufficient time to respond to the donor's questions and provide as much information as necessary.

Information for donors – general

- 33 The decision about whether a person is medically fit and suitable to donate bone marrow, PBSC or lymphocytes 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.
- 34 The decision to donate bone marrow, PBSC or lymphocytes rests with the potential donor, who can change his or her mind at any time before the procedure. Potential donors must be given as much time as they need to make a decision and the practitioner obtaining informed consent should ensure that all their concerns are answered.

- 35 Potential donors must be provided with sufficient information for them to reach an informed decision and give their consent.

Adults

- 36 Potential adult donors should be advised about:
- the donation procedure, the long and short term risks, and that a further collection of stem cells or lymphocytes might be needed;
 - 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 screening for transmissible infections including Hepatitis B and C, Human T-cell Lymphotropic Virus (HTLV), Human Immunodeficiency Virus (HIV) and other such diseases and the implications of any positive tests;
 - the requirement for anonymity where unrelated donors are involved;
 - 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 Accredited Assessor (see paragraphs 41 and 42);

- the fact that it is an offence to seek or receive payment or any other benefit for providing relevant material removed for transplantation⁵ and will attract a penalty (see Paragraph 68 of the *code of practice on donation of organs, tissue and cells for transplantation*);
- reimbursement of expenses where appropriate (see the section on payment below).
- the consequences of the withdrawal of consent, especially if it is withdrawn late in the process;
- that they should feel free to discuss any worries with others members of the bone marrow transplant team (including nurses, play therapists, psychologists) and other family members, teachers or friends.

Children

37 For children who are able to understand the donation procedure and give consent, the following should be explained in terms that they find easy to understand – with help from other appropriately qualified staff, as required:

- the donation procedure and the long and short term risks; and that a further collection of stem cells or lymphocytes might be needed;
- 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;
- that blood or marrow is always tested for viruses or infections and the implications of positive results;
- the fact that donation is an entirely voluntary act and that they have a right to be free of any kind of coercion or pressure (for example, by family);
- that the child has the right to withdraw consent at any time;

Approving the donation – competent adults

38 Approving donations of bone marrow and PBSC by competent adults fall outside the scope of the Regulations and are dealt with locally. When the consultant or senior member of the BMT or donor registry team is satisfied that the requirements of this code have been met, s/he must complete:

- a consent form that includes a statement by the donor that s/he has received and understood sufficient information to give informed consent;
- a declaration by the clinician that they have read and applied this code and the HTA's *code of practice on consent*.

39 This consent and declaration can be on the same form and must be attached to the donor's notes before the bone marrow or PBSC harvest proceeds and made available when requested by the HTA or a person or organisation acting on behalf of the HTA.

⁵ In the Act this is called 'controlled material'

Approving the donation – adults who lack capacity

- 40 Any decision to proceed with removal of bone marrow or PBSC from an adult who lacks capacity, should be governed by a test of best interests. The removal of bone marrow or PBSC continues to be governed by the Common Law and prior to any procedure being undertaken, the decision must be referred to court for approval. This test should not be limited to medical interests and should therefore take account of emotional, psychological and social benefits and other welfare considerations. The senior clinician involved must assess the person's best interests, by discussing the matter with the potential donor and ascertaining his or her views, if any. This would be supported in the assessment of best interests, together with the views of family, relatives and carers.
- 41 When an adult lacks the capacity to consent and no decision was made while they were competent, and after court approval to the removal has been obtained, first or repeat donation may proceed only if the HTA and an Accredited Assessor are satisfied that:
- the best interests of the donor have been properly considered; and;
 - the HTA's codes of practice, in particular the *code on the donation of organs, tissue and cells for transplantation* have been properly implemented.
- 42 The Accredited Assessor is a person who is accredited by the HTA to represent the Authority in determining that the BMT team have complied with the provisions of the codes of practice, the Act and Regulations made by the Secretary of State. It is good practice should be that the Accredited Assessor is not a person who is directly involved with the procedure⁶. The Assessor's responsibility is to interview the donor and his or her family, as well as the senior physician and to prepare a report that states s/he is satisfied that:
- the senior clinician has taken all reasonable steps to ensure that a suitable alternative donor is not available;
 - the best interests of the donor have been properly considered (an explanation of why is required);
 - the senior clinician has explained to the donor's family the nature of the medical procedure in question, including the risks and the possible after-effects.
- 43 This report must be submitted, electronically if possible, to the HTA to approve the donation. A copy should go on the patient's notes.
- 44 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 ensure circumstances have not changed. If the Accredited Assessor is not satisfied with the new findings or needs further advice, they should consult with the HTA for assistance or a final decision.

⁶ The Accredited Assessor could be a clinical nurse specialist, BMT coordinator, social worker, psychologist or senior play therapist.

Approving the donation – Gillick-competent children

- 45 Approving donations of bone marrow and PBSC by Gillick-competent children fall outside the scope of the Regulations and are dealt with locally. Gillick-competent children can consent to the donation of bone marrow or PBSC. When the consultant or senior member of the BMT team is satisfied that the requirements of this code have been met, s/he must complete
- a consent form that includes a statement by the donor that s/he has received and understood sufficient information to give informed consent;
 - a declaration by the clinician that they have read and applied this code and the HTA's *code of practice on consent*.
- 46 This consent and declaration can be on the same form and must be attached to the patient's notes before the bone marrow or PBSC harvest proceeds, and made available when requested by the HTA or a person or organisation acting on behalf of the HTA.
- 47 If there is any doubt about the competence of the child, the matter should be referred to court for approval.

Approving the donation – children who are not Gillick-competent

- 48 Any decision to proceed with removal of bone marrow or PBSC from a child who is not Gillick competent should be governed by a test of best interests. 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. This test should not be limited to medical interests, and should therefore take account of emotional, psychological and social benefits, as well as the risks. The senior clinician involved must assess the child's best interests, by discussing the matter with the child and ascertaining his or her views, if any.
- 49 Allogeneic first or repeat donation of bone marrow or PBSC from a non Gillick-competent child may proceed only if the HTA and the Accredited Assessor are satisfied that:
- the best interests of the child have been properly considered; and;
 - the HTA's codes of practice have been properly implemented.

50 The Assessor's responsibility is to interview the child and the person who has parental responsibility for him or her and to prepare a report that states s/he is satisfied that:

- the senior clinician has taken all reasonable steps to ensure that a suitable adult donor is not available;
 - the best interests of the donor have been properly considered (an explanation of why is required);
 - where appropriate, the child has received all the necessary information in a way they are most able to understand;
 - the senior clinician has explained to the person who has parental responsibility for the child the nature of the medical procedure in question, the risks involved and any other wider implications. 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 person with parental responsibility understands the nature of the medical procedure in question, including the risks and the possible after-effects has the capacity to consent, and consents to the removal of the bone marrow or PBSC;
 - the consent has been obtained from the person who has parental responsibility for the child;
 - the 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 person with parental responsibility understands that they are entitled to withdraw consent at any time and understands the consequences of withdrawal for the recipient;
 - there were no difficulties in communicating with the person with parental responsibility. If there were, an explanation of how those difficulties were overcome. Any translator used should have no personal connection to either the person with parental responsibility, the donor or the recipient, should have some understanding of medical matters and speak the language of the person with parental responsibility fluently. In the case of someone with a speech or hearing disability, a translator should be used with experience in signing.

51 This report must be submitted, electronically if possible, to the HTA to approve the donation. A copy should go on the patient's notes.

52 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 ensure circumstances have not changed. If the Accredited Assessor is not satisfied with the new findings or needs further advice, they should consult with the HTA for assistance or a final decision.

Documentation

- 53 A model consent form and model declaration referred to in paragraph 38 will be available on the HTA's website (www.hta.gov.uk).

Payment

- 54 The Act makes it lawful for the donor to receive reimbursement of expenses, such as travel costs and loss of earnings that are reasonably attributable to and directly result from a bone marrow or PBSC donation.

- 55 If reimbursement of expenses is appropriate, it must be made by a proper authority, e.g. an NHS Trust or an established stem cell transplant registry; or, in the case of a private patient, the hospital. Information about the levels of reimbursement are available on the Department of Health website⁷.

- 56 Donors must not be reimbursed directly by the recipient or by their family or friends. The Authority 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.

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 organs⁸ 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.

⁸ 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 Regulations⁹ 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'¹⁰ 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.

⁹ The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

¹⁰ 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 Regulations¹¹, 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.

¹¹ <http://www.opsi.gov.uk/acts/acts2005/20050009.htm>. Note this Act does not extend to Northern Ireland.

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.¹²

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.

¹² 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 Regulations¹³ 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.

¹³ 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.

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