

A Guiding Principles and the Fundamental Principle of Consent

Code of Practice



Code A: Guiding principles and the fundamental principle of consent

Contents

Introduction to the Human Tissue Authority Codes of Practice	7
Introduction to this Code	9
Section One - Guiding principles	9
Section Two - The fundamental guiding principle of consent	11
The legal concept of consent	11
The activities for which consent is required	12
Appropriate consent	13
Valid consent	15
Conditions on consent	16
Duration of consent	17
Withdrawal of consent	17
Section Three - Consent requirements	17
Part 1: General provisions	17
Part 2: Tissue from the deceased	21
Who may give consent?	22
Providing information about the process	24
Disclosing information about the deceased	25
Written consent	26
Seeking consent for multiple activities	26
Part 3: Tissue from the living	27
Who may give consent?	28
Assessing capacity to consent in Northern Ireland	31
HTA powers to deem consent	32
Fetal tissue	32
HTA licensing Standards	33
Consent (C)	34
Governance and quality systems (GQ)	34
Traceability (T)	34
Premises, facilities and equipment (PFE)	35

Annex A – Legislative background and context.....	36
Legislative background and context	36
Scotland.....	37
Status and use of the Codes of Practice	37
Other advice and guidance	38
Charging	38
Annex B – Consent requirements for scheduled purposes	39
Annex C – Consent requirements and good practice	40
Glossary.....	42

Introduction to the Human Tissue Authority Codes of Practice

1. The Human Tissue Authority's (HTA) regulatory remit is defined in the Human Tissue Act 2004 (HT Act). The HTA regulates the following activities through licensing:
 - a) post-mortem examination;
 - b) anatomical examination;
 - c) public display of tissue from the deceased; and
 - d) the removal and storage of human tissue for a range of purposes, including research, medical treatment, education and training.
2. The HTA also assesses applications for organ, bone marrow and peripheral blood stem cell (PBSC) donations from living people.
3. Further information about the legislative background and context of the HTA (including geographic coverage) and its Codes of Practice is set out at Annex A.
4. This document is part of a suite of seven Codes of Practice produced by the Human Tissue Authority (HTA):
 - a) Code A: Guiding principles and the fundamental principle of consent;
 - b) Code B: Post-mortem examination;
 - c) Code C: Anatomical examination (including import/export);
 - d) Code D: Public display (including import/export);
 - e) Code E: Research (including import/export);
 - f) Code F: Donation of solid organs and tissue for transplantation¹;
 - g) Code G: Donation of allogeneic bone marrow and peripheral blood stem cells (PBSCs) for transplantation.
5. The Codes give practical guidance to professionals carrying out activities which lie within the HTA's remit under the HT Act and the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (the Regulations). Code A also applies to professionals carrying out activities under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (the Q&S (Organs) Regulations). They will also be of interest to members of the public.

¹ This has been revised for deceased donation to set out guidance following the Organ Donation (Deemed Consent) Act 2019.

6. The HTA Codes of Practice provide guidance on activities within the scope of the HTA's remit. Whilst the HTA may offer advice on matters outside its remit, it has no power to act in relation to these and will endeavour to provide signposts to other agencies where issues arise that are beyond its regulatory reach.
7. The Codes do not include information about the analysis of DNA. This is because the HTA has no regulatory or statutory powers in relation to the non-consensual analysis of DNA, for which the provisions are set out in Section 45 of part 3 and Schedule 4 of the HT Act. Separate guidance in the form of [frequently asked questions](#) is available on the HTA's website.
8. This Code contains information that is applicable to all establishments and professionals operating under the HT Act and the Regulations. It sets out four guiding principles on which the work of the HTA is founded and which should inform the actions of anyone undertaking activities falling within the remit of the HTA:
 - a) consent;
 - b) dignity;
 - c) quality; and
 - d) honesty and openness.
9. In combination, this Code and the sector-specific Codes aim to provide anyone undertaking activities relevant to each sector with a reference source which gives practical advice on the minimum steps necessary to comply with the relevant legislation and HTA policy.

Introduction to this Code

10. The Code is divided into three sections:

- a) Section One sets out the HTA's four guiding principles;
- b) Section Two explains, in detail, the importance of consent as the fundamental guiding principle explicit in the HT Act. All those involved in the removal, storage and use of human tissue, whether from the deceased or the living, should take into account the general provisions on consent set out in this section;
- c) Section Three provides guidance on the statutory requirements for consent. The requirements that apply when dealing with tissue from the deceased are different from those that apply to tissue from the living; these are set out in Parts Two and Three, which are further divided into consent requirements for adults and for children.

Section One - Guiding principles

11. The HTA's existence and approach are founded on four guiding principles. These principles are derived from the HT Act, explicitly or implicitly, and actively inform our overall approach to regulation, our Codes of Practice and our licensing Standards. The HTA believes that these principles should inform the actions of anyone involved in using materials originating from people, and therefore anyone undertaking activities falling within the remit of the HTA must give them due regard. Where the principles refer to tissue, they apply equally to entire organs.

12. **Consent** and the wishes of the donor, or where appropriate their nominated representatives or relatives², have primacy when removing, storing and using human tissue. This means:

- a) human tissue, or bodies of the deceased, should be used in accordance with the expressed wishes of donors or their relatives;
- b) donors and their relatives should be given the information they need to be able to make a decision that is right for them;

² Throughout the Codes, the term 'relatives' should be taken to include a spouse or partner and, in cases where there are no relatives, close friends of the deceased person. Decisions regarding consent should be made according to the hierarchy of qualifying relationships as set out in the HT Act.

- c) those seeking consent should do so with sensitivity and an appreciation of the particular circumstances in each case.

13. **Dignity** should be paramount in the treatment of human tissue and bodies. This means:

- a) the dignity of the donor should be respected at all times;
- b) there should be mechanisms in place to protect bodies and human organs and tissue from harm;
- c) the privacy of the individual should be maintained;
- d) the disposal of human tissue should be managed sensitively and the method of disposal should be appropriate to the nature of the material;
- e) disposal of human tissue from the deceased should, where possible, be in line with their wishes, if known, or the wishes of the deceased person's relatives;
- f) where human tissue is imported, importers should endeavour to ensure that it is sourced from a country that has an appropriate ethical and legal framework.

14. **Quality** should underpin the management of human tissue and bodies. This means:

- a) practitioners should be competent, have undertaken appropriate training and work with care in accordance with good practice and other relevant professional guidance;
- b) practitioners' work should be subject to a system of governance that ensures the appropriate and safe storage and use of human tissue and which safeguards the dignity of the living or deceased;
- c) premises, facilities and equipment should be clean, secure and subject to regular maintenance;
- d) proper and accurate records and information should be maintained to ensure full traceability of human tissue and bodies of the deceased and donor tissue;
- e) patient data should be held securely and confidentially.

15. **Honesty and openness** should be the foundation of communications in matters pertaining to the use of human tissue and bodies. This means:

- a) communication with a donor, or person from whom consent is being sought, should be open, honest, clear and objective;
- b) serious incidents involving human bodies and tissue should be subject to rigorous investigation to ensure that lessons are learned and the risk of reoccurrence is minimised;
- c) establishments should adopt a policy of candour and transparency when dealing with serious incidents, as well as meeting their other, statutory and professional, duties of candour where appropriate;

- d) discussions about medical investigation or treatment are kept entirely separate from discussions relating to consent for scheduled purposes;
- e) establishments should be open and transparent in relation to arrangements for charging and reimbursement.

16. Detailed practical guidance on the application of these principles is available in the HTA's sector-specific Codes and licensing Standards.

Section Two - The fundamental guiding principle of consent

17. The guidance outlined in this section highlights the importance of consent, which is a legal requirement under the HT Act. The following topics are central to the application of the consent provisions:

- a) the legal concept of consent;
- b) the activities for which consent is required;
- c) appropriate consent;
- d) valid consent;
- e) conditions on consent;
- f) duration of consent;
- g) withdrawal of consent.

The legal concept of consent

18. The HT Act establishes the concept of appropriate consent (defined in terms of who may give consent). The HT Act describes specific circumstances under which appropriate consent is required for removing, storing and using relevant human material for scheduled purposes.

19. The concept of valid consent is established in common law and mental capacity legislation.

20. If appropriate and valid consent has been provided, then this is sufficient for an activity covered by the HT Act to proceed (subject to licensing and other legislative requirements having been met). Throughout this Code, references to consent should be taken to mean appropriate and valid consent. The Human Transplantation (Wales) Act 2013 and [The Organ Donation \(Deemed Consent\) Act 2019](#) modify the appropriate consent provisions of the HT Act 2004 and allow consent to be deemed in certain circumstances for the purpose of organ and tissue donation after death in England and Wales. This is dealt with in depth in the Code of Practice on the Human Transplantation (Wales) Act 2013 for

practitioners in Wales, and the Code of Practice on Donation of solid organs and tissue for transplantation for practitioners in England.

21. The existence of consent permits an activity to proceed, but does not mandate that it must. However, once someone has given consent, no other person has a legal right to revoke it and the decision whether to proceed with an activity rests with the person who will be undertaking it. The HT Act and common law establish the principle that the decision to consent rests first and foremost with the person whose body, organ, tissues or cells are being used. Where that person has died, their nominated representatives or relatives should be sensitively supported to respect that person's consent to ensure the best chance of their wishes being fulfilled.
22. Where a person with capacity has made the decision not to consent to an activity covered by the HT Act, then the activity must not proceed as there is no consent in place.

The activities for which consent is required

23. Consent under the HT Act relates to the purposes for which relevant material might be removed, stored or used. These purposes are set out in Schedule 1 of the HT Act and are called scheduled purposes (see Annex A).
24. The HT Act does not require an activity for which consent has been given to proceed (see paragraph 21).
25. It is not a legal requirement for consent to be obtained for the disposal of material. However, it is good practice for disposal options to be given, and for the wishes of the donor or their relatives obtained during the process of seeking consent (see HTA's Codes of Practice on Post-mortem examination and Anatomical examination) to be respected, where possible.
26. In broad terms, the HT Act and the HTA's Codes of Practice require that consent must be in place to:
 - a) store and use bodies of the deceased;
 - b) remove, store and use tissue from the body of a deceased person;
 - c) store and use tissue from the living.
27. Annexes B and C set out in detail the purposes for which consent is required under the HT Act.

28. Anyone removing, storing or using material in circumstances for which the HT Act requires consent, must be satisfied that consent is in place. The HTA has set Standards on consent for those working in licensed establishments. The Standards and associated guidance include how the consent process should be governed, the information that should be provided to those from whom consent is sought and the training that staff should receive.
29. There are certain exceptions to the consent provisions set out in the HT Act in relation to the activities of coroners and the police. Further information can be found in the HTA's Code of Practice on Post-mortem examination. There are also other limited situations where consent may not be required (see Annex B).

Appropriate consent

30. The HT Act defines 'appropriate consent' by reference to the person who may give consent. This is broadly either the person concerned, their nominated representative (see paragraphs 79-85), or, in the absence of either of these, a person in a 'qualifying relationship' with them immediately before they died. In the case of anatomical examination and public display, consent can only be given, in writing, by the person concerned.
31. An adult may appoint one or more nominated representatives to carry out their wishes after death in relation to activities for which consent under the HT Act is required. An executor is not automatically classified as a nominated representative and would need to be specifically appointed to this role in line with the requirements of the HT Act.
32. Those in a qualifying relationship are found in the HT Act in the following order (highest first):
- a) spouse or partner (including civil or same sex partner). The HT Act 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;
 - b) parent³ or child (in this context a child may be of any age, but must be competent if under the age of 18, and means a biological or adopted child);
 - c) brother or sister;
 - d) grandparent or grandchild;
 - e) niece or nephew;
 - f) stepfather or stepmother;
 - g) half-brother or half-sister;

³ Refer to the glossary for the definition of a parent for the purposes of the HT Act.

h) friend of long standing.

33. Consent is needed from only one person in the hierarchy of qualifying relationships and should be obtained from the person ranked highest. If a person higher up the list refuses to give consent, it is not possible to act on consent from someone further down the list. For example, if a spouse refuses but other relatives wish to give consent, the wishes of the spouse must be respected. However, the guidance in paragraphs 34 and 36 should be observed in line with this principle. If there is no one available in a qualifying relationship to make a decision on consent (and consent had not been indicated by the deceased person or a nominated representative), it is not lawful to proceed with removal, storage or use of the deceased person's body, organs or tissue for scheduled purposes.
34. While the HT Act is clear about the hierarchy of consent, the person giving consent should be encouraged to discuss the decision with other relatives. This may include people not on the list, for example, an aunt or uncle.
35. Relationships listed together, for example 'brother or sister', are accorded equal ranking, in which case it is sufficient to obtain consent from just one of them, provided they are ranked equal highest. For example, if the deceased person has no spouse or partner, but has several children, the consent of only one child is required.
36. Where there is a conflict between those accorded equal ranking, this should be discussed sensitively with all parties, whilst explaining clearly that so far as the HT Act is concerned, the consent of one of those ranked equally in the hierarchy is sufficient for the procedure to go ahead. This does not mean that the consent of one person must be acted on, and a decision not to proceed may be made on the basis of the emotional impact that this would have on family and friends.
37. If those close to the deceased person object to the activity, for whatever purpose, when the deceased person (or their nominated representative) has explicitly consented, the healthcare professional 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 revoke valid consent (see also the Code of Practice on Donation of solid organs and tissue for transplantation).
38. The emphasis in these difficult situations should be placed on having an open and sensitive discussion with those close to the deceased where the process is explained fully to them.

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

Valid consent

40. For consent to be valid it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. The person should understand what the activity involves, any reasonable or variant treatment and, where appropriate, what the material risks are. The test of materiality is 'whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach a significance to it'.

41. Consent may be specific or it may be broader in its scope, sometimes referred to as 'generic consent'. Specific consent is given in relation to a defined project, treatment and/or use. Generic consent refers to a broader permission, where consent may, for example, be given to allow the storage and use of tissue for an as yet unknown research project. In practical terms, specific and generic consent may be sought at the same time, to derive the greatest benefit from valuable human tissue donated for research.

42. While obtaining broad or generic consent offers the widest benefit for future research, the seeking of such consent should be supported by safeguards and assurances for donors. For example, if a donor expresses objections to specific types of research, these must be respected, and donors should be provided with information about how future research will be approved within the scope of the consent they have given. A donation may not proceed if a donor places conditions on their consent which cannot be met or guaranteed. Further information about conditions on consent can be found in paragraphs 45-48 of this code. Further guidance on consent to research is included in the Code of Practice on Research.

43. To ensure that consent is properly informed, commercial organisations offering services related to the removal, storage and use of human tissue and cells must ensure that materials provided to customers to aid their decision-making, such as marketing and advertising materials, are accurate and abide by the Advertising Standards Agency's guidelines. Non-commercial organisations must also ensure that materials provided to individuals to aid their decision-making are accurate.

44. To ensure that the removal, storage or use of any tissue is lawful, it is important to establish clearly that consent has been given. Consent may be expressed in various ways, and does not necessarily need to be in writing, unless the HT Act requires it to be; however, it should be recorded wherever possible. Written consent serves as evidence of consent, but a signature on a form will not, in itself, make the consent valid. Valid consent presupposes that individuals, including their families, where appropriate, have had the opportunity to discuss the issue fully, ask questions and make an informed choice. When consent is obtained but it is not in writing, for example for future storage or use of samples, this should be clearly documented in the patient's clinical and/or laboratory records. The record should detail when consent was obtained and the purposes for which the consent was given.

Conditions on consent

45. Consent may be limited in a variety of ways. The HT Act does not prevent an individual from placing limits on their consent via the imposition of conditions, for example, to particular research studies or to donate specific organs.

46. The HT Act recognises that individuals have the autonomous right to give or refuse consent to the use of relevant material for scheduled purposes.

47. Whilst respecting this autonomous right, no material should be removed, stored or used for a scheduled purpose under a form of consent which seeks to impose restrictions on the class of the beneficiary of the scheduled purpose. For example, a medical practitioner should not remove an organ for transplantation if the donor imposes a condition that the recipient of a transplanted organ must be a man, or must not be an alcoholic. This includes any restriction based on a beneficiary's sex, sexual orientation, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status (including characteristics protected under the Equality Act 2010). This position reflects Article 14 of the European Convention on Human Rights, as set out in the Human Rights Act 1998, and arises from the equality duty placed on the HTA and other public authorities by the Equality Act 2010.

48. Where any conditions attached to consent cannot be acted upon, the person who has attached the condition should be made aware of this and asked whether they are willing to put these conditions aside in order to allow the activity to proceed. It would be an offence to proceed with an activity for a scheduled purpose in the knowledge that a persisting condition on consent could or would not be fulfilled, as valid consent would not be in place. Only the person who has attached the condition to the consent can put the condition aside.

Duration of consent

49. Consent may differ in its duration. It may be enduring or time-limited.
50. Enduring consent means that it remains in force unless consent is withdrawn. A person may, however, specify a time limit for how long they wish their consent to remain in force. In both cases the decision should be clearly documented in the patient's records, and/or the records of the establishment holding the material (see section on format of consent, paragraphs 57-60 for further detail).

Withdrawal of consent

51. Consent may be withdrawn at any time, whether it is generic or specific. Withdrawal should be discussed at the outset when consent is being sought. The practicalities of withdrawing consent and the implications of doing so should be made clear. Withdrawal of consent cannot be acted upon where tissue has already been used. In the case of organ donation from the deceased, consent cannot be withdrawn once the retrieval of the organ has commenced.
52. If someone gives consent for their tissue to be stored or used for more than one scheduled purpose and then withdraws consent for a particular scheduled purpose, such as research, this does not necessarily mean that the sample or samples have to be removed or destroyed. However, the samples may no longer be stored or used for the particular purpose for which consent has been withdrawn. In addition, if someone withdraws consent for samples to be used in any future projects, this does not mean that information and research data should be withdrawn from any existing projects.

Section Three - Consent requirements

53. This section is divided into three main parts:
- a) Part 1: General provisions;
 - b) Part 2: Tissue from the deceased;
 - c) Part 3: Tissue from the living.

Part 1: General provisions

54. Before deciding whether to proceed with the removal, storage or use of tissue for scheduled purposes, the following should be considered:

- a) does the activity require consent and what, if any, exceptions to the consent provisions of the HT Act apply in this case? For tissue from the deceased, consent is required for all scheduled purposes (paragraph 76). Consent is not required under the HT Act for storage and use of tissue from the living in some circumstances (see Annex B);
- b) has the appropriate person given consent? (paragraphs 78-94 and 113-134)
- c) has sufficient written (in paper or electronic format) or verbal information been provided for the person giving consent to make a properly considered decision? (paragraphs 95-99)
- d) how will the consent be given and recorded? (paragraphs 57-60);
- e) is written consent required? (paragraphs 102-104);
- f) is the consent needed for more than one purpose? (paragraphs 105-107);
- g) if a child is involved, are they competent to consent and have they expressed particular wishes or views? (paragraphs 87-94 and 128-134);
- h) if an adult lacks capacity to consent, how should the provisions of the Mental Capacity Act 2005 (MC Act) be applied? (paragraphs 114-127).

55. Consent does not have to be sought by the person directly responsible for carrying out the activity in question. They may assign the task to someone else so long as that person is appropriately trained. In particular, they should know enough about the proposed procedure, the intended use of the tissue and the risks involved, for the subject to make an informed decision.

56. The MC Act applies to adults who are unable to make particular decisions for themselves as a result of a temporary or permanent impairment or disturbance in the functioning of the mind or brain. Establishments should take into consideration the MC Act when seeking consent. Further guidance is available from the Office of the Public Guardian's website and in the MC Act Code of Practice. There is separate guidance for Wales and for Northern Ireland.

Format of consent

57. The HT Act does not specify the format in which consent should be given or recorded, except in relation to anatomical examination and public display, when consent must be in writing and witnessed (see sector-specific Codes). The information required and the manner in which consent is obtained and recorded may vary depending on the particular circumstances.

58. Written consent, either in paper or electronic format, serves as evidence of consent, but a signature on a form does not of itself make the consent valid (see section on valid consent, paragraphs 40-44). Protocols should be in place to ensure that the consent process has been completed, that there is valid consent

and that the decision has been properly recorded. Establishments seeking to update existing consent forms or develop new protocols should ensure that they comply with this Code and other relevant HTA guidance.

59. When consent is obtained but it is not in writing, this should be clearly documented, for example in the patient's records where applicable. The record should detail when consent was obtained and the purposes for which the consent was given.
60. The NHS Organ Donor Register (ODR) operates throughout the UK to allow people to record their wishes about organ donation. Further information on the ODR as a source of consent can be found in the HTA Code on Donation of solid organs and tissue for transplantation. In addition, the HTA has produced a Code of Practice on the Human Transplantation (Wales) Act 2013, which provides guidance on arrangements in Wales.

Religion, belief and culture

61. Attitudes towards the use of tissue, and especially towards post-mortem examinations, may vary widely among cultures and religions. All healthcare professionals should be mindful and sensitive to this. However, each case and decision is an individual and personal one, and should be treated as such. Trusts and other establishments should ensure that their employees are given the necessary training and support to help them identify and meet the widest possible range of needs and wishes.

Communication

62. Consent is valid only if proper communication takes place and the person has a reasonable understanding of what is being explained to them. Particular consideration should be given to the needs of individuals and families whose first language is not English. Any difficulties in communicating with the person interviewed, (for example, because of language, literacy or hearing difficulties) and an explanation of how these difficulties were overcome should be recorded.
63. Under the MC Act, efforts should be made to provide information that is appropriate in terms of culture and language when assessing capacity; see chapter 3 of the MC Act Code of Practice, MC Act: making decisions, for further information on adults who lack capacity to consent.

Use of documentation

64. Establishments should provide appropriate information on the activities for which they are seeking consent. The information might be in the form of leaflets or information sheets, or it might be contained within the consent form.
65. Patient information sheets should be provided about research projects; these are also usually required by ethics committees approving research projects. The Health Research Authority (HRA) has issued guidance on developing model consent forms and information sheets for research establishments to use when seeking consent.
66. Many establishments, including Trusts, have policies on consent that include the use of standard documentation. Such documentation should make reference to the HT Act and the role of the HTA and be reviewed to ensure that it is consistent with this Code.
67. Where appropriate, information should be available in a variety of languages and formats such as video, audio or Braille, and in line with other legislation, such as the Equality Act 2010. Wherever possible, professional translators trained in translating for the bereaved and in maintaining confidentiality should be used.

Existing holdings

68. The consent requirements of the HT Act are not retrospective. This means it is not necessary to obtain consent for material that was already held for use for a scheduled purpose when the HT Act came into force on 1 September 2006.
69. Although there are no statutory requirements to obtain consent for the storage or use of tissue that is an existing holding, this does not mean that all such human tissue can be used freely and without regard to issues of consent or other ethical considerations.
70. The views of the deceased person, or of their relatives, (if known) should be respected if the tissue is disposed of.
71. Under the HT Act, consent is not required for carrying out research on existing holdings of human tissue and organs. Ethical approval may be required for research involving existing holdings and, as the HTA's remit does not include the ethical approval of research, reference should be made to the guidance produced by the HRA.

72. Although existing holdings are exempt from the consent provisions in the HT Act, the HTA's licensing requirements may still apply where material is being stored or used for a scheduled purpose.

Use of images

73. The making and displaying of images (including photographs, films and electronic images) falls outside the scope of the HT Act. However, the HTA requires Designated Individuals (DIs) to put systems in place to ensure suitable practices are carried out.

74. The HTA endorses the guidance on images provided by the General Medical Council (GMC) in its publication Making and using visual and audio recordings of patients.

75. Ensuring suitable practices where licensable activities are concerned includes the DI ensuring that the dignity of deceased people is maintained at all times. Therefore, the HTA expects DIs to put systems in place to prevent the inappropriate use of images.

Part 2: Tissue from the deceased

76. Under the HT Act, consent is needed for the removal, storage and use of material from the deceased for all scheduled purposes, as listed below (see Annex B):

- a) anatomical examination;
- b) determining the cause of death;
- c) establishing after a person's death the efficacy of any drug or other treatment administered to them;
- d) obtaining scientific or medical information, which may be relevant to any person including a future person;
- e) public display;
- f) research in connection with disorders or the functioning of the human body;
- g) transplantation;
- h) clinical audit;
- i) education or training relating to human health;
- j) performance assessment;
- k) public health monitoring; and
- l) quality assurance.

77. Although consent is not required for a coroner's post-mortem examination, consent is required under the HT Act for the storage or use of tissue, for

scheduled purposes once the coroner's purposes are complete. See the Code of Practice on Post-mortem examination for further guidance.

Who may give consent?

Adults

78. Where an adult has given valid consent for any particular donation or the removal, storage or use of their body or tissue for scheduled purposes to take place following their death, then that consent is sufficient for the activity to be lawful, subject to any other legislative requirements (for example, written consent or death certification). Where an adult has refused to give consent this cannot be revoked after their death.

Nominated representatives

79. If an adult did not consent to, or specifically refused, any particular donation or use of their body or tissue for scheduled purposes prior to their death, their relatives should be asked whether a nominated representative (or an appointed representative in Wales) was appointed to take those decisions.

80. A nominated representative may be empowered to consent to the carrying out of a post-mortem examination and to the removal, storage or use of the tissue for any of the scheduled purposes. They cannot consent to use of the body for anatomical examination or public display. The appointment of a nominated representative may be general or limited to certain activities.

81. The appointment of a nominated representative and its terms and conditions may be made orally or in writing. The HT Act sets out the requirements for a valid appointment. The appointment of a nominated representative may be revoked at any time.

82. If a person appointed more than one nominated representative, only one of them needs to give consent unless the terms of the appointment specify that they must act jointly.

83. If the nominated representative(s) does not consent to an activity, this cannot be overridden by other individuals, including relatives. Where they do give consent, but relatives object, it is advisable to ensure that appropriate consultation and discussion takes place between all those involved; there may be circumstances where the activity for which consent is given does not proceed.

84. The nomination may be disregarded if no one is able to give consent under it. This includes situations where it is not practical to communicate with the nominated representative within the time available if the consent is to be acted upon. In the event that a nomination is disregarded, consent may be given by a person in a 'qualifying relationship' (see paragraph 32). For organ and tissue donation in England this situation is slightly different. For further information please see Code F.
85. Under the HT Act, children cannot appoint nominated representatives and therefore provisions related to seeking consent from nominated representatives do not apply.

Those in a qualifying relationship

86. If, prior to their death, the deceased person had not indicated their consent (or refusal) to post-mortem examination or removal, storage or use of their tissue for scheduled purposes and had not appointed a nominated representative, then consent may be given by someone who was in a 'qualifying relationship' with the deceased person immediately before their death (see paragraph 32).

Children

87. Under the HT Act, a child (except in the context of qualifying relationships) is defined as being under 18 years old. The position of a child who, before they died, was competent to reach a decision and gave consent for one or more scheduled purposes after their death, is no different from that of an adult. Their consent is sufficient for medical practitioners to make lawful under the HT Act the removal, storage or use of tissue for the specified scheduled purpose(s). Additional requirements may apply under other legislation. For example, clinical research may also be regulated by the Medicines and Healthcare products Regulatory Agency (MHRA) and clinical trials regulations.
88. The principle of 'Gillick competence' applies to the assessment of a child's competence to consent in these circumstances. In the Gillick case, the court held that a child was considered competent to give valid consent to a proposed intervention if they had sufficient intelligence and understanding to enable them to fully understand what was involved.
89. If a competent child consents to an activity, or activities, covered by the HT Act, that consent carries over into adulthood unless it is withdrawn. This is a principle of common law.

90. If a child did not make a decision, or was not competent to make a decision, before their death, 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.
91. In some cases it may be advisable to establish with the person who had parental responsibility for the deceased child whether the child was competent to make the decision. A person who has parental responsibility will usually, but not always, be the child's parent (see the Children Act 1989 for the legal position). In any case where a child has consented to the use of their body or tissue, it is essential to discuss this with the child's relatives.
92. The issue should be discussed fully with relatives, and careful thought should be given as to whether to proceed if a disagreement arises between parents or other relatives. Any previously stated wishes of the deceased child should be considered, taking into account the child's age and understanding at the time of stating the wish. Further guidance is included in the Code of Practice on Donation of solid organs and tissue for transplantation and the Code of Practice on Post-mortem examination.
93. If there is no person with parental responsibility (for example, if the parents died at the same time as the child), then consent should be sought from someone in a qualifying relationship, (see section on qualifying relationships, paragraph 32). Under the HT Act children cannot appoint nominated representatives and therefore provisions related to seeking consent from nominated representatives do not apply.
94. For the anatomical examination or public display of tissue from a deceased child to take place, written (either by the child or at their direction) and witnessed consent is required from the child before they die. Those with parental responsibility at the time of the child's death cannot agree to the use of the child's body after death for these purposes.

Providing information about the process

95. When seeking consent, whether from the person themselves, their nominated representative or from a person in a qualifying relationship, full and clear information should be provided about the purpose for which consent is being sought. This should allow them to make a properly considered decision. This information should include the nature of the intended activities and the reasons for them.

96. Healthcare professionals and other suitably experienced people involved in seeking consent need to tailor the information they provide to each specific situation, considering the above advice and the *Montgomery*⁴ case law. Some people may require in-depth detail, whereas others may prefer to give consent having only had the basics of the procedure explained to them. The establishment's policy should set out a minimum amount of information to be provided in relation to each activity. Further information may be found in the sections on the duration of consent (paragraphs 49-50) and use of documentation (paragraphs 64-67).

97. The way in which the options are discussed with the deceased person's relatives is extremely important. They should be approached with sensitivity and given:

- a) honest, clear, objective information;
- b) the opportunity to talk to someone of whom they feel able to ask questions;
- c) reasonable time to reach decisions;
- d) privacy for discussion between relatives, if applicable;
- e) access to support if they need and want it.

98. Discussions with relatives may take place in hospital before a person's death. The relatives may know the person's wishes in respect of, for example, donating organs and tissues for transplantation. Further information can be found in the Code of Practice on Donation of solid organs and tissue for transplantation.

99. Consent conversations about death require sensitivity. This is especially true for donations for transplantation, post-mortem examinations and the retention of tissue and organs for research. Further guidance is set out in the Code of Practice on Post-mortem examination and the Code of Practice on Donation of solid organs and tissue for transplantation.

Disclosing information about the deceased

100. Care should be taken regarding the possible disclosure of information, such as genetic information or the presence of an infectious disease, which the deceased person may not have wished to be shared, or which may have significant implications for other relatives. Healthcare professionals will have to make a decision, based on the individual circumstances of each case, about whether or not it is appropriate to disclose information about the deceased's medical history or sensitive information that the Trust may hold about the deceased. In making decisions, healthcare professionals must have regard to their duty of patient

⁴ *Montgomery v Lanarkshire Health Board* (Scotland) 2015

confidentiality.

101. In certain circumstances it may be necessary to share sensitive information with the relatives if the results of the activity have the potential to affect them or other relatives. For further guidance see GMC guidance on confidentiality and the Department of Health and Social Care guidance on confidentiality which deals with disclosing information after a patient has died. See also the Welsh Government's guidance on confidentiality.

Written consent

102. Written, witnessed consent is always needed for anatomical examination and for public display of bodies or body parts (see the Codes of Practice on Anatomical examination and Public display for detailed guidance).
103. Written consent should be obtained wherever possible for all other activities involving the deceased. If verbal consent is obtained, this should be clearly documented in the patient's records (see paragraph 57-60).
104. Model consent forms are available for post-mortem and anatomical examination on the HTA's website. The forms are not prescriptive due to local variations in practice and may be adapted, as necessary, providing they comply with the HT Act and the Codes of Practice. In Northern Ireland, Health and Social Care (HSC) Trusts and other relevant organisations should use the standardised consent forms agreed with the Department of Health. Consent forms are only one part of the consent process and should be completed after appropriate discussion and more detailed explanation, where necessary.

Seeking consent for multiple activities

105. When someone has died, healthcare professionals may wish to seek consent for more than one scheduled purpose. For example, if a post-mortem examination is to be carried out, some tissue samples could also usefully be obtained for research purposes. In this case, it would be necessary to seek consent for both activities. Anticipating and explaining the purpose for which tissue could be used will avoid the need for seeking consent on repeated occasions.
106. Where consent has been given for the use of tissue or organs after death for transplantation, separate consent is required for storage and use for research purposes. In such cases, the necessary consents should ideally be sought at the same time and recorded in the same place.

107. Unless authorised by a coroner, the storage and use of post-mortem tissue for scheduled purposes requires consent. If consent to the storage or use of post-mortem samples is withdrawn, this must be respected for any samples that are still held. Healthcare professionals should discuss with the person concerned how the samples should be returned to them or disposed of, and tell them about any samples that may have already been used or disposed of.

Part 3: Tissue from the living

108. Under the HT Act, consent is needed for storage and use of tissue from a living person for the following scheduled purposes⁵:

- a) obtaining scientific or medical information which may be relevant to any person including a future person;
- b) public display;
- c) research in connection with disorders, or the functioning, of the human body; and
- d) transplantation.

109. Tissue may be taken in a variety of circumstances, for example:

- a) in the course of diagnostic procedures, such as taking a blood or urine sample, tissue biopsy, cervical screening;
- b) in the course of treatment, such as removing tissue (organs, tumours) during surgery; and
- c) when removed specifically for the purpose of research.

110. Although consent for treatment and examination is dealt with under common law and consent for scheduled purposes is dealt with under the HT Act, the consent for each activity may be obtained at the same time. It is still important to explain clearly the activity for which consent is being obtained, including the risks and wider implications. Further guidance on this issue in respect of seeking consent for organ and tissue donation may be found in the Code of Practice on Donation of solid organs and tissue for transplantation.

111. To give consent, the individual should understand the nature and purpose of what is proposed and be able to make an informed decision. They should be told of any material or significant risks inherent in the way the sample will be obtained, how the tissue will be used and any possible risks or implications of its use, such as genetic tests. The test of materiality is set out in paragraph 40. If the person concerned is not a patient, and is volunteering samples purely for

⁵ See Annex B.

research, the general principles of providing appropriate information still apply (see paragraphs 40-44 on valid consent).

112. Healthcare professionals should try to find out about the individual's needs and priorities when telling them about their options. Some people may not be interested in knowing the full details about the proposed use of the tissue and this should be recorded in the notes. People should, nevertheless, have all their options explained to them and be provided with an appropriate level of information. See GMC guidance on Consent: patients and doctors making decisions together.

Who may give consent?

Adults who have capacity to consent

113. If an adult has the capacity to make the decision in question, then only they are permitted to give consent. This Code summarises the requirements of the MC Act and the MC Act Code of Practice. However, practitioners working with tissue or organs from an individual who may lack capacity must consider the MC Act and MC Act Code of Practice directly and should not rely solely on Code A.

Adults who lack capacity to consent

114. The HT Act does not specify the criteria for considering whether an adult has capacity to consent. The MC Act outlines the criteria to apply in England and Wales. The MC does not apply in Northern Ireland; the legal position for assessing capacity in adults there is outlined in paragraphs 135-138.
115. This Code summarises the requirements of the MC Act and the MC Act Code of Practice. However, practitioners working with tissue or organs from an individual who may lack capacity must consider the MC Act and MC Act Code of Practice directly and should not rely solely on Code A.
116. Under the MC Act a person aged 16 and over is unable to make a particular decision if they cannot do one or more of the following things:
- a) understand the information given to them that is relevant to the decision;
 - b) retain that information long enough to be able to make the decision;
 - c) use or weigh up the information as part of the decision-making process;
 - d) communicate their decision by any means.
117. Full guidance on how the MC Act defines capacity and how it should be assessed is given in chapter 4 of the MC Act Code of Practice.

118. The provisions of the MC Act should be considered together with general principles governing capacity to consent to medical procedures. Guidance is available from the Office of Public Guardian website and in the MC Act Code of Practice. The Welsh Government has published separate guidance, entitled 'Making decisions'.
119. The MC Act governs decision-making on behalf of adults (aged 16 and over) who lack capacity if unable to make a decision in relation to a matter at the relevant time because of an impairment of, or disturbance of, the mind or brain, whether permanent or temporary. For the purposes of the MC Act, unlike the HT Act, an adult is a person aged 16 or over. The MC Act only applies to people aged 16 or over, with very limited exceptions (see chapter 12 of the MC Act Code of Practice for further information).
120. There are detailed provisions contained in the MC Act concerning decisions made on behalf of adults lacking capacity. All decisions must be made in the person's best interests, as laid out in chapter 5 of the MC Act Code of Practice. Individuals providing care or treatment to a person have a legal duty to have regard to the MC Act Code of Practice when working with or caring for individuals who lack or may lack capacity to make decisions for themselves, as laid out in chapter 6.
121. The MC Act defines a person as lacking capacity in relation to a specific matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or disturbance in the functioning of, the mind or brain (chapter 4 of the MC Act Code of Practice). The MC Act contains a set of key principles and considerations when deciding what is in someone's best interests (further information is available in chapter 5 of the MC Act Code of Practice). The first core principle of the MC Act is that an adult must be assumed to have capacity to make a decision for themselves, unless it is established that they lack capacity to make the particular decision at the time the decision needs to be made. It should therefore always be assumed that an adult has the capacity to make a decision unless there is reason to believe otherwise.
122. Individuals may sometimes temporarily be unable to make a decision, for example, if they are affected by trauma, illness or shock. It may therefore not be appropriate to seek consent at that time and, in some cases, it may be necessary to delay the decision until the person regains the capacity to make it, as laid out in the MC Act (see chapter 4 of the MC Act Code of Practice for further guidance).

123. Some adults may have capacity to make decisions about some matters, but not others. The MC Act requires that care be taken to ensure that patients are given every opportunity, and support where needed to make their own decisions (see chapter 3 of the MC Act Code of Practice).
124. A person must not be treated as unable to make a decision unless all practicable steps to help them do so have been taken without success. Nor must they be treated as being unable to make a decision merely because they make an unwise decision.
125. The ability of adults with learning difficulties or with limited capacity to understand, should not be underestimated. Where appropriate, someone who knows the individual well, such as a relative or carer, should be consulted, as they may be able to advise on or assist with communication.
126. Under the MC Act, a person aged 18 or over may make a Lasting Power of Attorney (LPA). This allows for an attorney to make certain decisions in circumstances where the person no longer has capacity. One type is a personal welfare LPA, which provides for the appointment of a person to make welfare, including health and care decisions, on their behalf. Where a LPA exists, it is good practice to check the detail to see if the attorney has the authority to make the decision in question. Detailed guidance on the role of the attorney is set out in chapter 7 of the MC Act Code of Practice.
127. Storage or use of tissue from adults who lack capacity to consent is permitted in certain circumstances specified in the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006.

Children

128. The HT Act allows children to consent to activities for scheduled purposes if they are competent to do so (see paragraph 87 and Section 2 of the HT Act).
129. Where the child has died and the child had not made a decision to give or withhold consent, the HT Act allows a person with parental responsibility for him or her immediately before he or she died to consent. Where the child is alive and has not made a decision and is either:
- a) not competent to do so; or
 - b) competent to do so, but is unwilling to make that decision

a person who has parental responsibility for the child may consent on their behalf.

130. A person who has parental responsibility will usually, but not always, be the child's parent⁶. The Children Act 1989 is the relevant legislation for establishing who has parental responsibility.
131. The HT Act is silent on how to assess a child's competence. The responsibility for assessing competence rests with the person seeking consent. The *Gillick* test (see paragraph 88) is considered to be the appropriate benchmark for assessing a child's competence.
132. Where there is any dispute between people with parental responsibility or any doubt as to the child's best interests, the matter should be referred to court for approval. For further guidance on court approval in cases of potential donation, see the Code of Practice on Donation of solid organs and tissue for transplantation and Code of Practice on Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation.
133. Where a child has capacity to consent, and agrees to the sharing of their information, it is good practice to consult the person (or people) who have parental responsibility for the child and to involve them in the process of the child making the decision. However, it should be emphasised that, if the child has capacity to consent, the decision to consent and to share their information must be the child's. It is also essential to make sure that a child has consented voluntarily and has not been unduly influenced by anyone else.
134. If a child does have the maturity or understanding to make a decision about whether to disclose their information to those with parental responsibility for them, you may only disclose information where it is in the best interests of the child.

Assessing capacity to consent in Northern Ireland

135. The MC Act does not apply in Northern Ireland. The Mental Health Order 1986 covers the assessment, treatment and rights of children and adults with a mental health condition who may need to be admitted to hospital for assessment in treatment. Common law is used to assess the capacity of adults and children. A new Act, The Mental Capacity Act (Northern Ireland) 2016 was passed in May 2016 but at the time of publication has not yet been implemented.
136. The Department of Health published its own reference guide to consent for examination, treatment or care in 2003. This guidance is based on mental health and capacity case law. Each of the five Health and Social Care Trusts has published its own policy on the assessment of mental capacity, based on the

⁶ See the Children Act 1989.

2003 departmental guidance. These policies have taken some elements from the MC Act, with regards to its principles, the assessment of mental capacity and the best interests test. People are presumed to have capacity to make decisions unless it is established that they do not.

137. Advance decisions⁷ are made in Northern Ireland under common law and the 2003 departmental guidance, but these decisions are not legally binding under any statute. Enduring Powers of Attorney can be established under The Enduring Power of Attorney (Northern Ireland) Order 1987, but their decision-making powers are limited to financial matters and do not extend to welfare.

138. There is no Court of Protection in Northern Ireland, and therefore there are no Welfare Deputies; applications for decisions on welfare matters involving children, and adults who have been found to lack capacity, under common law and departmental guidance are made to the High Court.

HTA powers to deem consent

139. Section 7 of the HT Act allows the HTA to dispense with the need for consent in certain circumstances. Where relevant material from a living person could be used to obtain scientific or medical information which may be relevant to another person, the HTA has the power to deem consent to be in place where it is not reasonably possible to trace the person from whom the material came, or they have not responded to requests for consent to use of their material. This may be important where information could be obtained about the treatment and diagnosis of the other person.

140. This provision can only be used when there is no reason to believe that the person has died, they are not known to have refused to consent or they lack capacity to consent. The HTA has prepared guidance on the implementation of these provisions.

Fetal tissue

141. The law does not distinguish between fetal tissue and other tissue from the living; fetal tissue of less than 24 weeks gestation is considered to be the mother's tissue, as are non-fetal products of conception (i.e. placenta, membranes, umbilical cord, amniotic fluid). Consequently, fetal tissue and non-fetal products of conception are subject to the same consent requirements under

the HT Act as all other tissue from the living (see section on tissue from the living, paragraphs 108-112). However, because of the sensitivity surrounding pregnancy loss, consent should always be sought, even where it might not be lawfully required.

142. It should be noted that the reference to fetal tissue within this Code does not include stillbirths (babies born dead after 24 weeks gestation) or neonatal deaths (babies or fetuses of any gestational age which are born showing signs of life and die before the age of 28 days). Seeking consent for the removal, storage or use of the tissue of babies from stillbirths or neonatal deaths should be handled in accordance with provisions for seeking consent for use of the tissue of the deceased (see paragraphs 76-77). It is recommended that, whenever possible, the consent process for the examination of stillbirths and neonatal deaths involves the mother, and that, where appropriate, both parents are involved.
143. The HTA has published guidance on the disposal of pregnancy remains, which reflects the very sensitive nature of these.

HTA licensing Standards

144. In order to obtain a HTA licence, the applicant must demonstrate that they and the relevant premises are suitable. The HTA will assess suitability against a number of core Standards, which were developed in consultation with representatives from the regulated sectors. These relate to the consent provisions of the HT Act and the regulatory requirements for governance and quality systems, traceability and premises. They reinforce the HT Act's intention that:
- a) consent is paramount in relation to activities involving the removal, storage and use of human tissue;
 - b) bodies of the deceased and organs and tissue removed from bodies are treated with respect;
 - c) the dignity of the person, whether living or deceased, is maintained.
145. The HTA works with establishments through its inspection process to help them comply with these Standards.
146. Each licensed establishment is required to appoint a DI for their licence, who has a statutory responsibility under the HT Act to supervise activities taking place under a licence. The DI has a duty to ensure that suitable practices are carried out by those working under the licence that the conditions of the licence are complied with and that other people to whom the licence applies are suitable to

carry on the activity. By ensuring that the establishment is meeting the HTA's licensing Standards, the DI will be meeting their statutory responsibility.

147. When HTA staff undertake inspections of HTA-licensed establishments, they make judgements about the suitability of the Licence Holder (LH), the DI, the practices taking place and the premises on which they take place. They do this by assessing the establishment's compliance with the HTA's licensing Standards, which reflect the guiding principles set out in Code A and provide the operational detail of how establishments should meet the requirements of the HT Act and the Codes of Practice.
148. The HTA's licensing Standards are grouped under four headings: Consent (C); Governance and quality systems (GQ); Traceability (T); and Premises, facilities and equipment (PFE). Under each of these headings, there are overarching statements, from which the Standards flow.

Consent (C)

149. Establishments meeting the consent Standards will be able to demonstrate that their processes for seeking and gaining consent comply with the HT Act and the HTA's Codes of Practice. The Standards also cover the documentation and information used to support the establishment's consent procedures, and ensure that staff involved in seeking consent are suitably trained and equipped for the task.

Governance and quality systems (GQ)

150. Establishments meeting these Standards will be able to demonstrate that they have a suitable governance framework, underpinned by clear and controlled documentation, effective audit, staff training and organised record-keeping. In addition, they will have an effective system of risk management and suitable systems to deal with adverse events.

Traceability (T)

151. Establishments meeting these Standards will be able to demonstrate full traceability for the human material for which they are responsible, from receipt to final disposal/disposition. HTA inspectors will test this through traceability audits carried out on site and we expect establishments to take a pro-active approach to assuring themselves of effective traceability throughout the lifetime of their licence. In addition, as the final traceability step, they will have established

disposal arrangements which are in accordance with the HTA's Codes of Practice.

Premises, facilities and equipment (PFE)

152. Establishments meeting these Standards will be able to demonstrate that their premises and facilities are appropriate for their licensed activities and are safe, secure and clean. In addition, establishments will have systems for on-going monitoring to ensure all key quality specifications are maintained. These Standards also cover equipment, ensuring that it is appropriate, and suitably maintained, and that it does not present an impediment to the staff using it.
153. The HTA licensing Standards which will be applicable to each sector from April 2017 are included as an Annex in each of the relevant sector Codes and on the HTA website. The Standards are supported by comprehensive guidance notes.

Annex A – Legislative background and context

Legislative background and context

1. The Human Tissue Authority (HTA) is the regulator for human organs, tissues and cells. The HTA was established by the Human Tissue Act 2004 (HT Act) in 2005, following the discovery of establishments removing and retaining human organs and tissue without consent. The HT Act addressed this issue and brought together other existing laws that related to human tissue and organs.
2. The HT Act applies to the removal, storage and use of human organs and tissue for scheduled purposes⁸ in England, Wales and Northern Ireland, with the exception of the provisions relating to the use of DNA, which also apply to Scotland.
3. Under section 14(3) of the HT Act, the HT Act and the guidance given in the Codes of Practice do not apply to bodies or relevant material where:
 - a) the person died before the HT Act came into force on 1 September 2006; and
 - b) at least 100 years have elapsed since the date of the person's death.
4. The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (the Regulations) lay down the responsibilities of the HTA in relation to the donation of transplantable material from living donors, including those who lack capacity to consent.
5. The HTA is the Competent Authority in the UK for the implementation of the European Union Tissue and Cells Directive 2004/23/EC (EUTCD). The EUTCD sets standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.
6. The requirements of the EUTCD are transposed into UK law via the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations). With the exception of Code A: Guiding principles and the fundamental principle of consent, the Codes of Practice do not provide guidance on complying with the requirements of the EUTCD. Establishments licensed under the Q&S Regulations should refer to the HTA's Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment.
7. The HTA is the Competent Authority in the UK for the implementation of the European Union Organ Donation Directive 2010/53/EU (EUODD), which sets

⁸ Defined by the HT Act and explained in further detail in the glossary.

quality and safety standards for organ donation and transplantation. The requirements set out by the EUODD have been transposed into UK law through The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (the Q&S (Organs) Regulations) and The Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014. With the exception of Code A: Guiding principles and the fundamental principle of consent, the Codes of Practice do not provide guidance on complying with the requirements of the EUODD. Establishments licensed under the Q&S (Organs) Regulations should refer to the HTA's The Quality and Safety of Organs Intended for Transplantation: a documentary framework.

8. A deemed consent system for organ and tissue donation after death is operational in England and Wales. This does not have an impact on the HTA's regulation of living organ donation. These Codes of Practice do not apply to organ and tissue donation from the deceased in Wales; the HTA has published a Code of Practice on the Human Transplantation (Wales) Act 2013 for establishments in Wales.

Scotland

9. The HTA's remit does not extend to Scotland, and therefore the HTA's Codes of Practice do not apply to establishments in Scotland.
10. A separate piece of legislation, the Human Tissue (Scotland) Act 2006 (HT (Scotland) Act), applies to Scotland. The HTA's remit in Scotland is described in a letter titled Human Tissue (Scotland) Act 2006: A guide to its implications for NHs Scotland, which the Scottish Health Department letter issued on 20 July 2006⁹.
11. The HTA assesses applications for living organ donation and donation of bone marrow and PBSCs on behalf of Scottish Ministers who delegated this responsibility to the HTA. The law in Scotland is significantly different from that in the rest of the UK, so this Code does not apply in Scotland. Guidance for practitioners in Scotland is available here.

Status and use of the Codes of Practice

12. Throughout the Codes, the word '**must**' applies to all legal requirements derived from primary and secondary legislation (for example, the legal requirement to hold a licence to store human tissue for use for a scheduled purpose, the

⁹ Ref: NHS HDL (2006) 46.

conditions of any licence and the requirements set out in any directions issued by the HTA). It also applies to the duty to abide by the HTA's licensing Standards. We use the word '**should**' when providing advice on how to meet these requirements.

13. Establishments are expected to follow the guidance contained in the Codes. Observance of the guidance is one of the ways in which the HTA assesses that establishments are complying with legal requirements. Failure to follow a Code of Practice is not in itself a criminal offence under the HT Act, but the HTA will consider carefully any breach of a Code of Practice when considering whether there are grounds to take regulatory action.

Other advice and guidance

14. The Codes of Practice complement each other and should be read alongside other relevant advice and guidance, which is either referenced in the text or provided on the HTA's website. The Codes of Practice may also refer to guidance which has been produced by a number of other organisations. The HTA is not responsible for the content of others' guidance, but does recommend that practitioners follow this guidance when they fall within its remit. Guidance that has been produced in collaboration with the HTA will appear on our website.
15. The HTA's Codes of Practice and other HTA guidance should, however, be used as the definitive source of information for issues within our remit. If you are in any doubt, please contact the HTA or seek your own legal advice. Regulated sectors should also keep up to date with other relevant legislation.

Charging

16. Medical schools and research establishments may charge for providing human tissue to others for training and research, including those working for private companies so that the costs of providing the tissue are recovered. Where cost recovery, or any other charging mechanism, is in place it is important that establishments are able to satisfy themselves that the information provided to potential donors is sufficient to ensure they understand that their tissue may be shared, subject to a fee being charged. The HTA also recommends that establishments ensure transparency by providing easily accessible information about how and why they charge, and to whom they will supply tissue samples. This is important to ensure that the consent sought from donors is fully informed.

Annex B – Consent requirements for scheduled purposes

Table setting out consent requirements under the HT Act for scheduled purposes.

Scheduled purpose	Consent required for human tissue from the living			Consent required for human tissue from the deceased		
	Removal	Storage	Use	Removal	Storage	Use
Anatomical examination	N/A	N/A	N/A	✓	✓	✓
Determining the cause of death**	N/A	N/A	N/A	✓	✓	✓
Establishing after a person's death the efficacy of any drug or other treatment administered to them	N/A	N/A	N/A	✓	✓	✓
Obtaining scientific or medical information about a living or deceased person which may be relevant to any person (including a future person)	X*	✓	✓	✓	✓	✓
Public display	X*	✓	✓	✓	✓	✓
Research in connection with disorders, or the functioning of the human body	X*	✓	✓	✓	✓	✓
Transplantation	X*	✓	✓	✓	✓	✓
Clinical audit	X*	X	X	✓	✓	✓
Education or training	X*	X	X	✓	✓	✓
Performance assessment	X*	X	X	✓	✓	✓
Public health monitoring	X*	X	X	✓	✓	✓
Quality assurance	X*	X	X	✓	✓	✓

✓ Consent is required under the HT Act

X Consent is not required under the HT Act

* Consent is required under the common law on removal of tissue from the living

** Consent is not needed for investigating cause of death under coroner authority

Annex C – Consent requirements and good practice

The table below sets out when consent is required and when it is recommended as good practice.

Activity (Consent may be sought for more than one activity at the same time)	Consent required	Consent recommended as good practice	Guidance	
			Code reference	Further guidance
Storage and/or use of tissue from the <u>living</u> for the scheduled purposes of: <ul style="list-style-type: none"> obtaining scientific or medical information which may be relevant to any other person, now or in the future; public display; research; transplantation 	✓		Paragraph 108-109	
Storage and/or use of tissue from the <u>living</u> for research, where the research is ethically approved and the tissue is non-identifiable to the researcher	X	✓	Paragraph 108-109	
Storage and/or use of tissue from the <u>living</u> for the scheduled purposes of: <ul style="list-style-type: none"> clinical audit; education or training relating to human health; performance assessment; public health monitoring; quality assurance 	X		Paragraph 108-109	
Removal, storage and/or use of material from the <u>deceased</u> for any scheduled purpose	✓		Paragraph 76	

Activity (Consent may be sought for more than one activity at)	Consent required	Consent recommended as good practice	Guidance	
			Code reference	Further guidance
Diagnosis and treatment	X	Consent is required under the common law for removal of tissue from the living	Paragraph 109-110	Department of Health guidance Reference guide to consent for examination or treatment; DHSSPS Northern Ireland Reference guide to consent for examination, treatment or care; Welsh Assembly Government Guide to consent for examination or treatment
Coroner's post-mortem	X		Code of Practice on Post-mortem	The Cremation (England and Wales) Regulations 2008; HTA Code of Practice on Post-mortem examination
Criminal justice	X		Code of Practice on Post-mortem	Section 39 of the HT Act (Criminal justice purposes)
Making and displaying of images	X	✓	Paragraph 73-75	General Medical Council guidance on making and using visual and audio recordings of patients
Storage and/or use of existing holdings	X		Paragraph 68-72	

Glossary

Term	HTA definition
Advance Decision	An advance decision is a decision made by a living person, when they had capacity, to refuse a specific type of treatment at some time in the future. To be legally binding in England and Wales, an advance decision must comply with a number of criteria which are described in the Mental Capacity Act 2005. With regard to organ and tissue donation, an advance decision could be used to exclude the possibility of donation from a living adult who lacks capacity at the time of the proposed donation.
Anatomical examination	Macroscopic examination by dissection for the purposes of teaching or studying, or researching into, the gross structure of the human body.
Appropriate consent	Defined in the HT Act by reference to the person who may give consent. This is broadly either the consent of the person concerned, their nominated representative or (in the absence of either of these) that of a person in a qualifying relationship to them immediately before they died. Deemed consent modifies the appropriate consent provisions in England and Wales for organs and tissue donation for donation after death.
Best interests	A test of a person's best interests takes into account not only the medical aspects, but also the wider emotional, psychological and social aspects of the potential medical procedure, as well as the risks.
Biopsy	A medical procedure that involves taking a small sample of human tissue so it can be examined under a microscope.
Bone marrow	A spongy tissue found in the hollow centres of some bones. It contains specialist stem cells, which produce the body's blood cells.
Cells	Individual human cells or a collection of human cells that are not bound by any form of connective tissue.
Clinical trial	A type of clinical research that compares one treatment with another. It may involve people with specific medical conditions or healthy volunteers, or both.

Term	HTA definition
Clinical waste	<p>The Controlled Waste Regulations 1992 define clinical waste as any waste which consists wholly or partly of: human or animal tissue; blood or other body fluids; excretions; drugs or other pharmaceutical products; swabs or dressings; or syringes, needles or other sharp instruments which, unless rendered safe, may prove hazardous to any person coming into contact with it.</p> <p>Clinical waste also refers to any other waste arising from medical, nursing, dental, veterinary, pharmaceutical or similar practice, investigation, treatment, teaching or research, being waste which may cause infection to any person coming into contact with it.</p>
Coroner	<p>Coroners are independent judicial office holders, appointed by a local council. They investigate deaths that have been reported to them if it appears that the death was violent or unnatural, the cause of death is unknown or the person died in prison, police custody, or another type of state detention. In these cases coroners must investigate to find out, for the benefit of bereaved people and for official records, who has died and how, when, and where they died. As part of their duties, coroners authorise post-mortem examinations and conduct inquests.</p>
Court of Protection	<p>Makes decisions on financial or welfare matters for people in England and Wales who are unable to make decisions at the time they need to be made because they lack mental capacity to do so.</p>
Deemed Consent	<p>All adults over 18 in England and Wales are considered to have agreed to organ and tissue donation after their death, unless they make a decision that they do not want to be a donor, or are in an excluded group. The excluded groups are: people who lack mental capacity for a significant period before their death, children under 18 and people not ordinarily resident in England or Wales for at least 12 months immediately before their death.</p>
Designated Individual (DI)	<p>The person named on a licence issued by the HTA, under whose supervision licensed activities are carried out. The DI has a statutory responsibility to ensure that those carrying out licensed activities, and their practices, are suitable, and that the conditions of the licence are met.</p>
Diagnosis	<p>The identification of the nature of an illness or other problem.</p>

Term	HTA definition
DNA	<p>DNA stands for deoxyribonucleic acid. DNA is found in the nucleus of all cells, and contains the genetic information for the development and working of living organisms including human beings. The study of DNA is used in forensics, gene therapy, relationship (including paternity) testing and bioinformatics.</p> <p>Find out more information about the HTA's role with regards to DNA on the HTA's website.</p>
Donation	The act of giving human tissue, cells, organs or part organs for a scheduled purpose, either during life or after death.
Donor	Every human source, whether living or deceased, of tissue, cells, organs or part organs.
Existing holding	Material from the living or deceased that was already held for use for scheduled purposes when the HT Act came into force on 1 September 2006.
Export	The movement of human tissue from England, Wales or Northern Ireland to a place outside England, Wales and Northern Ireland.
Gillick competence	A term used to help assess whether a child has the maturity to make their own healthcare treatment decisions without the permission of their parents and to understand the implications of those decisions. A child will become legally competent to make their own decisions on medical treatment matters when the child has sufficient understanding and intelligence to fully understand what is proposed.
Health and Social Care (HSC) Trust	<p>Health and Social Care (HSC) Trusts provide integrated health and social care services across Northern Ireland.</p> <p>For further information see the Department of Health (Northern Ireland) website.</p>
Human application	In relation to tissue or cells, human application means use on or in a human recipient, including use in applications situated or occurring outside the body, but not including use when tissue and cells are removed from and applied in the same person within the same surgical procedure.
Import	The movement of human tissue into England, Wales or Northern Ireland from a place outside England, Wales and Northern Ireland.

Term	HTA definition
Incident	An event or circumstance that could have resulted, or did result, in unnecessary damage, loss or harm.
Lasting Power of Attorney (LPA)	A Lasting Power of Attorney (LPA) is a power of attorney under which the donor (a person aged 18 or over) confers authority to another person or people (a third party) to make certain decisions on their behalf, should they lose capacity in the future. An LPA is a legal document and decisions that the third party makes are as valid as any made by the donor. An attorney is bound by the principles set out in the Mental Capacity Act; for example, any decisions they make must be made in the best interests of the person lacking capacity. Further information about LPAs is set out at chapter 9 of Part One of the Mental Capacity Act. An LPA is only applicable in England and Wales.
Licensing	A number of activities can only be carried out when an establishment is licensed under the HT Act by the HTA. Organisations whose activities involve the removal, storage or use of relevant material may need to work under a HTA licence. All establishments working under a HTA licence must work to specified Standards set by the HTA.
Neonatal death	A foetus of any gestational age which is born alive and dies before the age of 28 days.
Nominated representative	A person appointed by a person to represent them after their death for the purposes of activities under the Human Tissue Act for which consent is required. A nominated representative may be entitled to consent to the removal, storage and use of the body or tissue for any of the scheduled purposes, other than anatomical examination or public display.
Organ	Defined by the Human Tissue Act (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, as amended, as a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with a significant level of autonomy. Part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirement of structure and vascularisation.

Term	HTA definition
Organ Donor Register (ODR)	A confidential, computerised national database managed by NHS Blood and Transplant (NHSBT), which holds details of people who have signed up to become organ and tissue donors in the event of their death. It also holds details of people who have stated they do not want to donate their organs or tissues after their death. The register is used to help establish whether they wanted to donate and if so, which organs and tissue.
Parental responsibility	A person who has parental responsibility will usually, but not always, be the child's parent. The category of persons with parental responsibility is as set out in the Children Act 1989.
Post-mortem examination	Dissection and examination of a body after death, principally in order to determine the cause of death or the presence of disease processes.
Practitioner	A person working with relevant material in an establishment licensed by the HTA.
Procurement	The processes by which tissues and cells are made available, including the physical act of removing tissue and the donor selection and evaluation.
Qualifying relationship	The relationship to the deceased of a person/s who can give consent for the removal, storage and use of tissue from the deceased person's body for scheduled purposes, if the deceased person did not indicate their wishes in life or appoint a nominated representative.
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.
Relatives	Throughout the Codes, the term 'relatives' should be taken to include a spouse or partner and, in cases where there are no relatives, close friends of the deceased person. Decisions regarding consent should be made according to the hierarchy of qualifying relationships as set out in the Human Tissue Act.
Relevant material	Defined by the HT Act as material other than gametes, which consists of, or includes, human cells. In the Human Tissue 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. See policy guidance on how to apply this definition on the HTA's website.

Term	HTA definition
Research	A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body. Research attempts to derive new knowledge and includes studies that aim to generate hypotheses, as well as studies that aim to test them or develop practical applications or new knowledge.
Scheduled purpose	<p>Under the Human Tissue Act, consent must be obtained to remove, store or use bodies or relevant material for scheduled purposes. The licensing requirements of the Human Tissue Act also refer to the scheduled purposes. Scheduled purposes are divided into those which apply generally, and those which apply to the deceased only.</p> <ul style="list-style-type: none"> • 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.
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.
Stillbirth / stillborn	A stillbirth is defined under section 41 of the Births and Deaths Registration Act 1953 as ‘where a child issues forth from its mother after the 24 week of pregnancy, and which did not at any time after being completely expelled from its mother, breathe or show any signs of life’.
Tissue	Any and all constituent part/s of the human body formed by cells.
Transplantation	An implant of an organ or part organ, tissue or cells either from and into the same body or from one person to another.

Term	HTA definition
Valid consent	Consent which has been given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. Valid consent is explained in detail in Code A: Guiding principles and the fundamental principle of consent.
Welfare deputy	A person who has been appointed and given the power to make certain decisions by the Court of Protection (see section 16(2)(b) of the Mental Capacity Act). Welfare Deputies are only appointed in England and Wales.