

# B Post-mortem Examination

## Code of Practice and Standards



# Code B: Post-mortem examination

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## 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 and its Codes of Practice (including geographic coverage) is set out at Annex A.
4. This document is part of a suite of seven Codes of Practice produced by the HTA. 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). They will also be of interest to members of the public.
5. 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.
6. *HTA Code A: Guiding principles and the fundamental principle of consent* contains information that is applicable to all establishments and professionals operating under the HT Act and the Regulations. It sets out the following four guiding principles, 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.
7. For the Post Mortem sector, this means that bodies of the deceased, and tissue taken from the deceased, should be treated with respect in an environment that

is safe and secure, that the dignity of the deceased should be maintained at all times, that the needs of the bereaved should be met with care and sensitivity and that their wishes should be fulfilled where possible.

8. In combination, Code A and this Code aim to provide anyone undertaking activities relevant to this 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 the Post-mortem Examination Code

9. Post-mortem examination in all its forms is important for informing relatives<sup>1</sup>, healthcare professionals and other interested parties about the cause of death. It may also provide information about possible acquired or genetic diseases that may warrant treatment and care of the relatives of the deceased. More generally, post-mortem examination is considered by clinicians to be important in increasing understanding of disease, improving clinical care, maintaining clinical standards, identifying the spread of infectious diseases and supporting research and training.
10. The vast majority of post-mortem examinations are conducted under the authority of the coroner, when the death is unexpected or sudden, or of unknown cause. The consent of the family is not required in these cases. Occasionally, a post-mortem examination is requested by a clinician or clinical team, who wish to find out more about the illness of the person who has died. These are referred to as hospital or consented post-mortem examinations, because the consent of the family, or the person before they died, is required for the examination to take place.
11. The HTA's remit is to ensure that post-mortem examinations are undertaken with appropriate consent or under the authority of the coroner and on suitable premises licensed for that purpose, which is a statutory requirement under the HT Act. It is also to ensure that post-mortem examination and the removal and retention of any organs or tissue samples, including those processed into wax blocks and microscope slides, comply with the requirements of the HT Act.
12. This Code, and the associated licensing Standards, apply to those directly involved in performing post-mortem examinations – pathologists and anatomical pathology technologists (APT's). They may also inform the practice of others who are not subject to regulation by the HTA, such as coroners authorising post-mortem examinations; their officers, who are in direct contact with relatives; bereavement staff; and funeral service staff. Funeral service staff in particular may find sections of the Codes and Standards useful in informing their own practices.

### Scope of this Code

13. The HTA regulates, through its licensing and inspections process, establishments which carry out full, limited, and minimally invasive post-mortem

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<sup>1</sup> Throughout this Code, the term 'relatives' should be taken to mean those in a qualifying relationship to the deceased before they died, and includes partner and, in cases where there are no relatives, close friends of the deceased person.

examinations. This includes post-mortem examinations undertaken in emergency mortuaries. Further information on emergency mortuary licensing is available on the HTA's website, including the Standards that emergency mortuary facilities are expected to meet.

14. The licensing requirements do not apply to establishments where only post-mortem cross-sectional imaging is undertaken (i.e. post-mortem computed tomography [PMCT] or post-mortem magnetic resonance [PMMR]), whether in an NHS radiology department or on privately-owned premises (see paragraphs 62-63 for consent requirements in relation to post-mortem cross-sectional imaging). If, alongside this activity, samples are removed from the body of a deceased person in order to determine the cause of death, a removal licence will be required.
15. The licensing requirements also do not apply to premises where bodies are stored temporarily prior to post-mortem examination or to premises where they are stored prior to release for burial or cremation. However, much of the guidance contained in this Code may be taken to apply equally to these activities.
16. The guidance on consent in this Code applies to the removal, storage and use of relevant material from the body of a deceased person and the storage and use of a body after death for the scheduled purposes defined in the HT Act, including determining the cause of death. This includes full, limited and minimally invasive post-mortem examinations *and* post-mortem cross-sectional imaging. Establishments should have suitable procedures in place for ensuring proper compliance with the HT Act and observing the good practice set out in the HTA's Codes of Practice. This includes ensuring that the bodies of the deceased and tissue taken from them are treated with respect and the dignity of the deceased is maintained.
17. This Code contains guidance on how to communicate with the relatives of people whose death has required a post-mortem examination, whether or not ordered by the coroner. It also makes reference to the licensing Standards that professionals working within licensed establishments are expected to meet.
18. This Code seeks to ensure that:
  - a) those engaged in activities regulated under the HT Act are aware of statutory and regulatory requirements;
  - b) the guiding principles of consent, dignity, quality, and honesty and openness inform and underpin the conduct of these activities;

- c) relatives of the deceased person understand the reasons for the post-mortem examination, the processes involved and their rights in the decision-making process;
  - d) where possible, the wishes of the deceased person and their relatives are known, understood and taken into account;
  - e) tissue is only retained following post-mortem examination with consent, under the authority of the coroner or for criminal justice purposes; and
  - f) the essential nature of good communication between all parties involved is understood and acted upon.
19. This Code should be read in conjunction with Code A, Guiding principles and the fundamental principle of consent, which sets out the principles which govern the conduct of activities within the HTA's remit and informs the content of this and the other Codes. Those involved in carrying out post-mortem examinations should also familiarise themselves with the HTA's licensing Standards on post-mortem examination.

### **Offences under the HT Act**

20. The HT Act sets out a number of offences, for which the maximum penalty is three years imprisonment and/or a fine. In relation to the post mortem sector, the offences are as set out below.
21. Section 5 of the HT Act makes it an offence to remove relevant material from the deceased and to store and use bodies and relevant material for a purpose set out in Schedule 1 of the HT Act (a scheduled purpose), including determining the cause of death, without appropriate consent. Where there is consent to use material for one purpose, it may not be used for another purpose without appropriate consent for that purpose. Section 5 of the HT Act also makes it an offence to falsely represent that there is appropriate consent to undertake an activity, or that Section 1 of the HT Act does not apply. A person does not commit an offence if they reasonably believed that appropriate consent was in place, or that the activity carried out was not one that required consent.
22. Section 16(1) and (2) of the HT Act prohibit the following activities, except under the authority of a licence:
- a) the carrying out of a post-mortem examination;
  - b) the removal of relevant material from the body of a deceased person, other than in the course of a post-mortem examination, for use for scheduled purposes other than transplantation; and

- c) the storage of the body of a deceased person, or relevant material which has come from a human body, for use for scheduled purposes.
23. To undertake an activity listed in section 16(2) without the authority of a licence from the HTA is an offence under section 25(1). A person does not commit an offence if they reasonably believe the activity they are carrying out is not licensable, or that they are acting under the authority of a licence.

### **Structure and navigation**

24. As most adult post-mortem examinations are conducted under the authority of Her Majesty's Coroner, the first part of this Code gives information about these in the context of human tissue legislation.
25. There follows a section on hospital post-mortem examinations, which sets out the legal requirements in relation to consent, the information that should be provided to relatives of the deceased and how this should be conveyed.
26. The later sections of the Code cover a range of topics such as training and support for staff, the removal of post mortem tissue for use for scheduled purposes under the HT Act and storage. Finally, at the end of the Code there is a brief section explaining the HTA's licensing Standards.
27. A glossary with terms specific to this Code is available at the end of the document. You can view, download and print copies of all the Codes from the HTA's website.

### **The coroner's post-mortem examination**

28. Post-mortem examinations under coronial authority enable coroners to carry out their statutory functions to determine the identity of the deceased person and the cause of death. Coroners are empowered to authorise a post-mortem examination following an unexpected or sudden death of unknown cause.
29. A post-mortem examination and the removal and storage of tissue samples to determine the cause of death do not require consent from the relatives if these activities have been authorised by the coroner. This includes the removal of samples outside of the mortuary environment, for example in cases of sudden unexpected death in infancy, where samples may be taken from a deceased infant in the Accident and Emergency Department of an NHS hospital in line with [RCPATH's guidelines on sudden unexpected death in infancy and](#)

[childhood.](#)

30. Although the consent of relatives is not required, the reasons for the post-mortem examination, why the coroner is involved and the process that will be followed should be explained to them. As a coroner's post-mortem examination is primarily undertaken to identify the cause and circumstances of death, it should be explained to relatives that the results may be limited in scope.
31. As a minimum, the relatives should be given information about when and where the examination is to be performed. They should be given contact details for the coroner's officer, should they have questions about the process.
32. Relatives of the deceased have the right to be represented at the post-mortem examination by a medical practitioner. The post-mortem examination may be observed by healthcare professionals, police, paramedics and others as part of their training, with the agreement of the coroner.
33. It is the coroner's decision as to what type of examination is necessary, with the assistance of the pathologist, after there has been a thorough external examination of the body. In some cases, where it is the wish of the family, the coroner may consider use of post-mortem cross-sectional imaging, either instead of a post-mortem examination or as an adjunct to it (see paragraph 14). However, if this is the sole method of examination of the body, a cause of death may not be determined and a post-mortem examination may still be required. The family's expectations should be managed and they should be informed in advance that this may be the outcome.
34. For further information about coroners' post-mortem examinations, including the provision of the post-mortem report, see the Ministry of Justice (MoJ) Guide to coroner services.

### **Defence post-mortem examinations**

35. Defence post-mortem examinations are subject to the same regulatory requirements of the HT Act as any other post-mortem examinations, even though they are not conducted for the 'purposes or functions' of a coroner, but for criminal justice purposes.
36. Where samples taken at the first post-mortem examination are made available to the defence pathologist, they should be returned to the original pathologist after they have been examined by the defence, making sure that there is written evidence of continuity. If new 'sub-samples' are created from the original samples (for example, new slides from tissue blocks), it is important that the

pathologist acting for the defence should notify the pathologist instructed by the coroner of the existence of these sub-samples to ensure full traceability of all material.

37. Where additional samples are retained, either because new sub-samples have been made from existing material, or because new samples have been taken during the second post-mortem examination, they should be kept with the samples taken at the first post-mortem examination so that they can be retained or disposed of along with the original samples. Keeping them separately increases the risk of error and, potentially, means that families may need to be contacted twice in relation to two sets of tissue samples.

### **Retention of tissue with the authority of the Coroner**

38. Under the Coroners (Investigations) Regulations 2013, the pathologist must notify the coroner in writing of any material they have retained, setting out why they believe it relates to the cause of death or the identity of the deceased. The pathologist may suggest various retention periods. The coroner, in turn, must notify the pathologist of how long the material must be kept. This period must not exceed the time it will take to discharge the coroner's functions.
39. The coroner must then notify the relatives that material has been retained, how long it will be retained and the options for dealing with the material once it is no longer required for the coroner's purposes (see paragraphs 43-44) (these rules do not apply in Northern Ireland<sup>2</sup>).
40. A coroner's officer (in Northern Ireland, referred to as a coroner's liaison officer) will usually make contact with the family. However, the coroner's officer may not always be the best person to speak to relatives about the post-mortem examination and the issue of retention. Depending on the nature of the case and their concerns, relatives may need assistance from their GP or access to people with specialist knowledge, such as pathologists or Anatomical Pathology Technologists, to talk through any questions they may have. In any event, the person giving information to the family should have knowledge of the HT Act.
41. Toxicology samples may be taken at post-mortem examination, and also from deceased children under the sudden unexpected death in infancy protocols. Storage of toxicology samples for use for a scheduled purpose can only take place on HTA-licensed premises unless these are being held for criminal justice purposes, or have been sent to a specialist laboratory from HTA-licensed

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<sup>2</sup> In Northern Ireland, the coroner informs relatives or personal representatives about tissue retention and asks them what they wish to happen to the tissue at the end of the coroner's investigation.

premises and will be returned there following analysis or disposed of locally. Whilst taking toxicology samples from a deceased person for criminal justice purposes, or under the authority of HM Coroner, does not require consent, valid consent from a person in a qualifying relationship with the deceased is required to store these samples for use for a scheduled purpose when such authority ends.

### **Disposal or further retention following coroners' post-mortem examinations**

42. Once the coroner's authority has ended, it is not lawful to use or store tissue for a scheduled purpose set out in the HT Act without appropriate consent. Nor is it lawful to store tissue for a scheduled purpose without a licence, subject to certain exemptions.
43. The Coroners (Investigations) Regulations 2013 place an obligation on the coroner to inform the family of their disposal options, once the coroner's authority has ended. It is important that the family understands the options available to them to enable them to make a fully informed decision. The three options are:
  - a) disposal of the material by burial, cremation or other lawful means by the pathologist;
  - b) return of the material to relatives to make their own arrangements; or
  - c) further retention of the material with appropriate consent for use for medical research or other purposes in accordance with the HT Act.
44. Where a decision has been made, this should be documented and the coroner should inform the pathologist and/or establishment holding the material of the decision. Establishments should have a policy that governs the disposal of tissue when this is the decision of the relatives.
45. Establishments should work closely with the coroner authorising post-mortem examinations undertaken on their premises. A protocol should be established between the two parties identifying the roles and responsibilities of each, and be sufficiently flexible to meet relatives' needs sensitively.

**Example**

An establishment has worked with the local coroner to produce an information leaflet about the relatives' options for disposal or retention of tissue following a post-mortem examination. This document reflects the establishment's disposal policy and associated restrictions. For example, it notes that local crematoria will not accept blocks and slides, so cremation is not available for this type of material. The leaflet also provides information for relatives to help inform their decision about disposal. For example, explaining that the cremation of organs may not produce any ashes and that returning the material to the body may cause a delay to funeral arrangements. The document also contains useful contacts at the establishment storing the material, the local crematoria and the burial grounds.

46. When the coroner has communicated the family's decision to the pathologist or establishment holding the material, the pathologist should act on this information as soon as possible following the expiry of the coroner's authority.
47. Problems arise when relatives do not, or cannot, communicate their decision about what they wish to happen to the tissue. This creates uncertainty about the lawfulness of retention beyond the expiry of the coroner's authority. When advising families about the options for disposal, coroners should ask the family to make a decision by the time that the appropriate forms are issued releasing the body for burial or cremation. However, their failure to reach a decision by this time should not delay release of the body.

**Example**

A coroner's investigation has included a post-mortem examination. The coroner's officer has attempted to discuss the disposal of tissue removed during the post-mortem examination with the family, but they have said they are too upset to make a decision. Despite their bereavement, they still have to decide about their options for funeral arrangements. The coroner's officer respectfully and sensitively obtains a specific decision on the disposal / retention options when they discuss the procedure relating to various funeral options. The decision is then communicated immediately to the pathologist who takes the appropriate action as soon as possible following the expiry of the coroner's authority.

48. Laboratories that are not in a hospital environment and that carry out specialist analysis for the coroner, such as toxicology, should also be informed when the

coroner's authority has expired to avoid them storing samples unnecessarily and without consent. This includes organs sent for specialist examination.

49. Good communication between coroners and pathologists is essential to ensure that tissue is not stored indefinitely without consent. The HTA recommends that a nominated person is identified to handle the communications channels between the pathology department and the coroner's office and, where necessary, the family. The nominated person should ensure that decisions are passed to and within the pathology department and there is no uncertainty about tissue disposal or retention when the coroner's authority has expired. The HTA has published a model communication flowchart to support good communication between coroners and pathologists, which is contained in Annex B.
50. If the family does not, or cannot, communicate their decision about what they wish to happen to the tissue, the nominated person should advise the family that the pathology department will hold the tissue for three months after the coroner's authority ends, pending notification of a decision. In exceptional circumstances, the establishment may wish to extend this period. In any event, the nominated person should make it clear that if no decision is communicated within the time specified, the tissue will be disposed of. In such situations, the nominated person should inform the pathology department that the family has not made a decision, and at the end of the period the tissue should be disposed of (see section on disposal of post-mortem tissue, paragraphs 135-146).
51. There may be cases where three months is not a sufficient period for the family to make a decision about what they would like to happen to the tissue, for example, where there is the possibility of a legal claim. Establishments should have policies in place which are sensitive to the needs of the family and take into account circumstances that warrant the longer retention of tissue samples.
52. Sometimes, families express their wish for the samples to be returned to them but then do not arrange for collection. Where the family can be contacted, the establishment should inform them sensitively that they cannot hold the material indefinitely and that it will be disposed of within a certain period (see paragraph 47). Where the family cannot be contacted, the establishment should make a decision about the duration of continued retention, based on the nature of the material and the likelihood of the family making enquiries in the future. In any event, the material must not be used for a scheduled purpose and, if it is disposed of, this should be done in an appropriate manner and records kept.
53. It is important that the family is informed of the potential benefit to them of the tissue being kept, for example, if the post-mortem examination uncovers a

genetic condition which may affect future family members. It is also important that they understand what may be involved if they consent to the continued retention and use of the tissue for medical research or other purposes. Where the family decides that tissue may be kept, appropriate consent should be obtained in line with the provisions set out in Code A (see sections on nominated representatives and qualifying relationships).

54. Relatives should not be led to believe that if they consent to the use of tissue for medical research, it will definitely be used for this purpose. Knowing that it may not be, and that it may be disposed of instead, may affect the choice they make.

### **Criminal investigations**

55. If a person dies in circumstances which are considered suspicious or where homicide is suspected, the coroner may instruct a Home Office-registered forensic pathologist (or, in the case of Northern Ireland, a pathologist instructed by the State Pathologist Department) to perform a forensic post-mortem examination in order to ascertain the identity of the deceased and the cause and circumstances of death, and to allow the collection of evidence. During the post-mortem examination, tissue and/or organs may be removed from the body by the pathologist for the purpose of further investigation such as toxicology, histology and examination by other experts.
56. There are some exemptions in the HT Act in relation to criminal justice purposes. Consent is not required to retain material for the purposes of a criminal investigation, nor does material taken for this purpose need to be held on licensed premises. Such material is subject to the requirements of police legislation relating to the seizure and retention of evidence. Where material is held under the authority of the police, or joint authority of a coroner and the police, the section 39 exemptions of the HT Act apply.
57. Following a police investigation, the police will make a decision as to whether to continue retention of the tissue. If retention is no longer required, the tissue will be offered to the coroner as it may be relevant to the coronial inquiry. If the coroner does not require the tissue, the police will dispose of it. If the coroner does require the material, it must then be held on licensed premises.
58. Material held by the police or the coroner which is historic, and has not been appropriately disposed of, should be subject to review with the relevant party to determine whether its continued use is necessary. If it is not, it should be disposed of in line with the guidance contained in this Code.

## The hospital post-mortem examination

59. Following a death where a medical certificate of cause of death (MCCD) has been issued, the treating clinician may wish to request a post-mortem examination to further investigate the cause of death, to improve knowledge of the disease or the effectiveness of the treatment given. Where the cause of death has been determined, the issue of an MCCD should not be withheld in order to refer a death to the coroner nor to put pressure on the family to consent to a hospital PM examination
60. Consent must be sought for full, limited and minimally invasive post-mortem examinations and post-mortem cross-sectional imaging. The benefits and limitations of each of these should be explained to the family.
61. Where post-mortem cross-sectional imaging is used, there may also be an invasive procedure such as ventilation and angiography, or tissue samples may be removed for examination to determine the cause of death. Consent must be sought, and the removal of any samples must take place on premises licensed by the HTA.
62. Where consent has not been given by the person in life, consent for a hospital post-mortem examination, of whatever type, may be given by:
  - a. the deceased person's nominated representative (if there is one);
  - b. a person in a qualifying relationship (see paragraphs 32-33 of Code A); or
  - c. in the case of a child, those with parental responsibility.
63. 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.
64. 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) parent or child
  - c) brother or sister

- d) grandparent or grandchild
  - e) niece or nephew
  - f) stepfather or stepmother
  - g) half-brother or half-sister
  - h) friend of long standing.
65. Consent must be given before the post-mortem examination is undertaken to ensure proper compliance with the HT Act. Therefore, before the post-mortem examination begins, the pathologist must check that it has been properly consented to, either by the deceased person before they died, or their nominated representative, or their relatives.
66. Hospital staff should, when seeking consent for a hospital post-mortem examination, explain the significance of the qualifying relationship under the HT Act to the family and make enquires about who is the person in the highest ranking qualifying relationship to ensure that consent is being sought from the appropriate person. This information should be documented on the consent form.
67. To support staff taking consent for hospital PM examinations, the Designated Individual (DI) should ensure that the consent form used during the consent process includes a question to prompt the person seeking consent to ask the consent giver about their relationship to the deceased, where there is any doubt about whether they are the highest ranking person in a qualifying relationship.
68. There may be situations where it may not be possible to seek consent from the person in the highest ranking qualifying relationship. The HT Act allows for this person to be omitted from the hierarchy if they cannot be located, declines to deal with the matter or is unable to give valid consent; 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. This process should be documented on the consent form.
69. Where consent from a person in a qualifying relationship cannot be obtained, the post-mortem examination cannot proceed.
70. Consent is only valid if proper communication has taken place. Particular consideration should be given to the needs of individuals and families whose first language is not English. Any difficulties in communicating, for example, because of language, literacy or hearing difficulties, should be recorded along with an explanation of how these difficulties were overcome. Further information can be found in Code A.

71. Written consent is preferable and model consent forms for a hospital post-mortem examination of an adult are available on the HTA's website. The forms are not prescriptive due to local variations in practice, and may be adapted as necessary, provided they comply with the HT Act and the Codes of Practice. Consent forms are part of the consent process and should be supplemented with further discussion and more detailed explanation, where necessary.
72. In Northern Ireland, the Department of Health Northern Ireland has developed standardised consent forms for post-mortem examinations. In Wales, Public Health Wales has developed standardised consent forms for post-mortem examinations.
73. Accompanying information leaflets for each of these forms are also available.
74. During the post-mortem examination, tissue or whole organs, such as the heart, may be removed for further examination to determine the cause of death. In practical terms, this means that consent to the post-mortem examination, and consent to the removal, storage and use of organs and tissue to help determine the cause of death, are two separate decisions.
75. Tissue or organs may also be retained for future use for other scheduled purposes, such as research or education and training. Separate consent should be obtained for the removal and future storage and use of organs and tissue (including blocks and slides) for scheduled purposes.
76. A signed copy of the consent form should be included in the medical record of the deceased person. A copy of the consent form should also be given to the person giving consent.

## **Religion and culture**

77. Attitudes towards post-mortem examination, in particular the removal of organs and tissue and their use after death, differ greatly and the individual needs of each family must be considered. For example, for religious reasons, a family may prefer post-mortem cross-sectional imaging to a post-mortem examination, or they may wish for the funeral to take place as soon as possible. Without making assumptions about what a family may or may not wish to happen, there should be an awareness of different cultural and religious imperatives, and requests should be discussed sensitively and openly, with every effort made to meet the family's requirements without compromising the clinical outcome. If the outcome is likely to be compromised, an explanation of how and why will be required.

## Who may seek consent for hospital post-mortem examinations?

78. It is usually the responsibility of the deceased person's clinician to raise the possibility of a post-mortem examination. This is because they will know the deceased's medical history and the unresolved aspects that merit investigation, and they are likely to have developed a relationship with the relatives. Those involved in seeking consent may include a member of the medical team involved in the care of the patient prior to their death and/or someone closely aligned to pathology, such as an APT or a specialist nurse. However, there may be several options for who actually discusses the post-mortem examination with the relatives and a team approach is common.

### Example

Some Trusts use trained bereavement officers or APTs to seek consent for post-mortem examination. They are supported by the treating clinicians and pathologists. By nominating a small number of trained people who are regularly involved with seeking consent for post-mortem examinations, the Trust can manage ongoing training effectively.

79. Whichever approach is taken, the hospital should have a named individual who can provide support and information to the relatives.
80. Responsibility for obtaining consent should not be delegated to untrained or inexperienced staff. Anyone seeking consent for hospital post-mortem examinations should have relevant experience and a good understanding of the consent procedure. They should have been trained in dealing with bereavement and in the purpose and procedures of post-mortem examinations. Ideally, they should have also witnessed a post-mortem examination.
81. Due to the very small number of hospital post-mortem examinations that are now carried out, staff seeking consent may not have the opportunity to undertake this task on a regular basis and therefore there is a risk it may not be undertaken effectively. The establishment should provide staff members with a documented consent procedure which ensures that the information provided to relatives and the manner in which consent is sought are consistent.
82. Before the discussion with relatives, the responsible clinician should consider obtaining advice from a pathologist, or a suitable, trained and experienced APT, on which tissue, if any, is likely to be retained, for how long and for what purpose. The pathologist undertaking the post-mortem examination should be available for a discussion with the relatives if they would like further information.

83. Healthcare professionals may recognise the need to obtain a swift decision in order to maximise the benefit from a hospital post-mortem examination. However, it is important that they do not convey to relatives any sense of being rushed. Before the post-mortem examination, relatives may want to spend as much time as possible with the family member who has died and it is important to try to ensure that they have this time. However, if more information or better results might be obtained from an early examination, this should be explained to the family.
84. The pathologist conducting the post-mortem examination may feel that conditions imposed by relatives call into question or limit the value of the post-mortem examination. In such cases, relatives should be advised of these limitations. If the pathologist believes that the investigation is likely to be inconclusive, they should still give consideration to proceeding if the family would like a post-mortem to take place. Pressure should not be exerted on them as this would render invalid any consent given.
85. Consent may be given over the 'phone or, after a telephone conversation, by email. In these cases, checks should be made to ensure that the appropriate person has consented (see paragraphs 64-71). The content of the telephone conversation should meet the requirements set out in paragraph 97-99 below and be documented. Pathologists must satisfy themselves that the consent was appropriate and valid before proceeding with a post-mortem examination.
86. Once a decision has been made to proceed with the post-mortem examination and consent has been given, the family should be given the opportunity to change their minds or to change the scope of the post-mortem examination. The time relatives have to reflect on their decision and the point up to which they may withdraw their consent should be clearly stated and should not be less than 12 hours. The HTA recommends 24 hours.

### **Who may give consent for a hospital post-mortem examination?**

87. Appropriate consent in the HT Act means:
  - a. the consent of the deceased person (if a decision to, or not to, consent was in place immediately before death);
  - b. where (a) above does not apply, the consent of a nominated representative appointed by the deceased person to deal with this issue;
  - c. where (a) and (b) above do not apply, the consent of someone in a qualifying relationship to the deceased person immediately before that

person died. More information on qualifying relationships and other aspects of consent is contained in Code A.

88. Whilst it is legal to carry out activities with the consent of the highest-ranking qualifying person (where no decision was made by the deceased person and there is no nominated representative), consideration should be given to the possibility of this causing distress and resentment in other family members if there is disagreement.
89. There may be situations when those close to the deceased person object to the post-mortem examination, when the deceased person (or their nominated representative) has explicitly consented. Although they do not have the legal right to veto or overrule the wishes of the deceased, the emphasis in these difficult situations should be on having an open and sensitive discussion with relatives to seek a resolution.
90. Where the deceased is a child (for the purposes of the HT Act, a person below the age of 18), consent may be given by them before they died, provided they are competent to reach a decision to consent; this is, however, rare in practice. After their death, consent can be given by a person with parental responsibility for them immediately before they died (a person who has parental responsibility will usually, but not always, be their parent). In the absence of a person with parental responsibility, a person in a qualifying relationship to them at that time can give consent (see paragraphs 32-33 of Code A).
91. In relation to the post-mortem examination of a baby or young child, the Stillbirth and neonatal death charity (Sands) has published detailed guidance on communication with women or couples regarding all areas of pregnancy loss, which may be found on the Sands website.
92. Fetal tissue is considered in law to be the mother's tissue, and therefore, tissue from the living. It is good practice to seek consent for the examination of pregnancy remains, regardless of gestational age. The HTA has produced guidance on the disposal of pregnancy remains, which is available on its website.
93. A post-mortem examination of a fetus or a stillborn baby cannot be authorised by the coroner. As the infant never lived, in law it has not died, and therefore the coroner has no jurisdiction. It is accepted practice in these cases for consent to be sought from the mother of the baby for examination of the fetus or baby.

94. Women who have been the victim of a violent attack which has resulted in the loss of their unborn child will have to give consent in order for an examination of their fetus to be carried out. In such cases, they will need expert support to help them decide whether or not to consent to the examination. A multi-agency approach, including liaison with the police, will be necessary.

### **Discussing the post-mortem with the family**

95. The way in which a post-mortem examination is discussed with the deceased person's relatives is extremely important. They should be 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 (for example, about the retention or donation of tissue);
  - d. privacy for discussion between family members, if applicable;
  - e. emotional or psychological support if they need and want it (support may be available from an organisation with which a relative is already in touch, particularly if they have been a long-term carer of the deceased person);
  - f. the opportunity to change their minds, within an agreed time limit.
96. Discussions should be face-to-face, if possible, so that all necessary issues and questions are addressed and all parties are clear about what is agreed. A comfortable, private room should be used.

### **What the discussion should cover**

97. Relatives should be offered full and clear information about:
- a. the purpose of the post-mortem examination;
  - b. the range of choices available to them;
  - c. the potential uses for any material retained; and
  - d. the disposal options.
98. Whilst putting the needs of relatives first, those providing the information should aim to include the following in the discussion:
- a. a basic explanation of what happens in a post-mortem examination, including the removal, storage and use of organs and tissue and the various purposes for which tissue might be kept; this should include

organs, parts of organs and tissue in various forms, such as frozen sections and samples held in paraffin wax after fixing and processing;

- b. details of where and when the post-mortem examination will take place;
- c. the benefits of a post-mortem examination, the questions to be addressed in this case and the possible outcome;
- d. the possible alternatives to a full post-mortem examination (making clear the limitations to these and the benefits of a full post-mortem examination);
- e. information about tests needed (such as histology, toxicology, genetic testing) and whether these might cause delays to determining the cause of death;
- f. an explanation of the need for any images to be made (including photographs, slides, X-rays and CT scans);
- g. when, to whom, and how the results of the investigation will be made available and explained;
- h. options for what will happen to any material removed (including tissue blocks and slides) after the post-mortem examination;
- i. the potential benefits of the continued storage or use of tissue and organs for the family and options for use for a scheduled purposes, such as research or teaching, and the potential storage period;
- j. whether there are particular uses which relatives would wish to exclude from any general consent given;
- k. the timing of burial or cremation so that, where possible, any material removed can be reunited with the body if relatives so wish;
- l. the time period in which they can change their mind.

99. Relatives should be provided with factual information that may be taken away if they want it. Consideration should be given to the demographics of the local community when producing printed information. For example, there may be a need to produce information in different languages.

100. At the end of the meeting, relatives should be provided with a record of the discussion and of the agreement reached.

101. Relatives should also be provided with the name, telephone number and/or email address of a contact person (for example, the hospital's bereavement adviser), so they may ask further questions later. Ready access to general information, for example, via a hospital website, may also be helpful to them.

102. When discussing the post-mortem examination or retention of tissue, some relatives may wish to know in considerable detail what will be done to the body. In such cases, the procedure should be explained honestly and fully, with

Careful use of language. Others will not want as much, or even any, detail and this should be respected. However, sufficient information should be provided to ensure that valid consent is in place.

103. Medical students, doctors and other healthcare professionals may wish to observe the post-mortem examination or a demonstration of the findings for educational purposes and to develop their professional skills. Relatives should be given the opportunity to object to observers being present. Anyone observing the post-mortem examination with the agreement of the relatives, must respect the confidentiality of information relating to the deceased person.

### Information to be given to relatives after a hospital post-mortem examination

104. Relatives should be told when the results are likely to be available. They should also be given the option of an appointment to discuss the results with the clinician responsible for the deceased person's care, the pathologist or other specialist clinician.

#### **Example**

In one Trust, where consent is delegated to specialist nurses, the family is offered the option of receiving the results in writing. The results letter is drafted by the nurse, and shared with the pathologist and clinician before the final version is sent to the person who gave consent. The letter contains details of how to contact the clinician for a meeting if there are any further questions.

105. Some relatives will not want to know the results of the post-mortem examination, or will not want to discuss them in detail. Their wishes should be respected. However, they should be offered the opportunity to discuss the results at a later date.
106. There may be occasions where the deceased person expressed a specific wish before death that information should not be shared with relatives. This should be respected as far as possible.
107. Care should be taken regarding the possible disclosure of information, which the deceased person may not have wished to be disclosed or which may have significant implications for other family members. For example, disclosure of genetic information or the presence of an infectious disease. Healthcare professionals will have to make a decision about whether it is appropriate to disclose medical history or any other sensitive information about the deceased

that the family may not be aware of, taking into account the deceased person's express wishes and the family's awareness of their medical history.

108. Healthcare professionals must have regard to their duty of patient confidentiality and the provisions of the Data Protection Act 1998. In certain circumstances, it may be necessary to share sensitive information with the family if the results of the post-mortem examination have the potential to affect them or other relatives. For further guidance, see the General Medical Council's (GMC) guidance on confidentiality and the Department of Health's guidance on confidentiality, which deals with disclosing information after a patient has died. See also the Welsh Government's guidance on confidentiality.
109. In general, information about deceased patients should be treated in confidence. However, the relatives' legitimate wish for relevant information should be met with proper care and sensitivity and subject to any expressed wishes of the deceased person and any legislative restrictions on disclosure.
110. Following pregnancy loss or the death of a baby, pathology results may raise issues which are important for the parents to discuss together, such as genetic conditions. These issues may require further discussion with other healthcare professionals, for example a genetic specialist. Parents should be offered the chance to have such a meeting. If they do not feel ready to take up that offer immediately, they should be given details of whom to contact if they would like to later or if they have any questions, along with information about local and national support organisations.
111. Subject to the agreement of the parent(s), the report should also be given to the deceased child's GP or treating clinician, and to the mother's GP in the case of a neonatal death or stillbirth.

### **Training and support for staff**

112. Staff involved with seeking consent should be trained in how to obtain consent and the establishment should hold training records to demonstrate this.
113. Training and support should be offered to others involved with liaising with relatives, such as coroners officers and APTs. Training should ensure that they have sufficient knowledge of bereavement management and the procedures involved in the post-mortem examination. It should also cover the statutory requirements of the HT Act.

### **Example**

Establishments seeking to develop training might consider a web-based training module for staff. By working through the relevant sections of the HT Act and the Code of Practice, they can ensure that the key issues are covered. The module might include sections on what constitutes appropriate and valid consent, who is able to seek consent and also give it (i.e. those in qualifying relationships), cultural/religious considerations, the provision of information about the post-mortem examination itself and the retention, storage and disposal of material, and what is documented and where. It might also reference the HT Act so that people know that seeking valid consent is a legal requirement, not just good practice.

114. Relatives may not always know what is traditional or customary within the community when a death occurs. They may wish for time to talk to other family and community members. However, each case and decision is an individual and personal one and should be treated as such. Trusts and coroners' services should ensure that staff are given the necessary training and support to identify and meet the widest possible range of needs and wishes.
115. Local joint protocols between healthcare establishments and their coroners may provide opportunities for considering training needs and development opportunities. These may need to be developed in liaison with other relevant bodies such as the police, local authority and Local Safeguarding Children Boards.

## **Tissue or organ donation**

116. Prior to their death, many people have made a decision to consent to organ or tissue donation and in certain circumstances their consent may be deemed. All efforts should be made to allow those who wish to donate organs or tissue to do so, and explanations should be given where it is not possible. For further guidance, see the Code of Practice F, part two: Deceased organ and tissue donation.
117. Organ retrieval will take place before a post-mortem examination. Tissue retrieval may take place prior to or following a post-mortem examination, depending on the tissues involved and any time restraints. To avoid contamination of the tissue to be donated for transplantation, it is preferable for the retrieval to precede the post-mortem examination.

118. If the coroner is investigating the reason for the deceased's death, agreement from the coroner will be required.
119. For guidance on arrangements between coroners and transplant coordinators on taking steps for organ preservation, see Code of Practice F, part two: Deceased organ and tissue donation.

### **Removal of post-mortem tissue for use for scheduled purposes**

120. Removal of tissue samples from the body of a deceased person for use for a scheduled purpose is an activity for which consent or authorisation from the coroner is required, and which must take place on licensed premises, unless the removal is for police purposes. Removal may take place in locations other than the mortuary, for example, in the A&E department in cases of sudden unexpected death in infancy, or in operating theatres where tissue is removed for use for research during a transplant operation, providing that the licence covers these areas. Establishments must ensure that they have the necessary licences in place to ensure that removal is not taking place in breach of statutory requirements. The HTA advises that a Person Designated is identified by the Designated Individual (DI) to oversee licensed activity taking place in areas other than the mortuary to ensure that there is awareness of and compliance with statutory and regulatory requirements in these areas.
121. Mortuary staff are at risk of sharps injury. There may be occasions when an injury occurs during a post-mortem examination and there is the possibility that the deceased had an infectious disease, which needs to be established urgently. Because testing for infection is unlikely to be a factor in the cause of death, the coroner cannot authorise the testing to take place. The legal requirements of the HT Act are that consent would need to be obtained from the appropriate person in the hierarchy or qualifying relationships for a sample to be tested to establish the presence of an infectious disease, so that post exposure prophylaxis (PEP) can be administered. Where there is no immediate access to a family member, recent case law suggests that permission may be given by a judge under 'inherent jurisdiction'.

### **Storage of bodies and tissue blocks and slides, including existing holdings**

122. The storage of bodies in mortuaries must preserve the dignity of the deceased. This means both that storage facilities must be fit for purpose and that practices relating to body storage must show respect for the deceased. For example, practices such as placing more than one body on a tray, placing bodies

unshrouded on trays, or storing bodies in unrefrigerated storage, should not take place.

123. Storage facilities must also provide for adequate security, which ensures bodies are safe from harm and breaches of confidentiality, and that risks of errors in identification are mitigated. Storage arrangements must be sufficient to meet demand, including at peak times. There must be effective contingency arrangements to ensure that capacity issues do not present an increased risk to bodies in storage, including in relation to long-term body storage and the storage of bariatric bodies.
124. Tissue blocks and slides may be useful for the purposes of audit, teaching, research and quality assurance. It may also be useful to keep them in case they are useful for future diagnosis of relatives.
125. Blocks and slides for use for scheduled purposes must be stored on licensed premises. Exceptions to this general rule are storage of tissue from the body of a deceased person for:
  - a. use for research which is ethically approved by a recognised research ethics committee or for which such approval is pending; or
  - b. the sole purpose is analysis for a scheduled purpose, excluding research, and the material has come from, and is to be returned to, a licensed premises following analysis.
126. These exemptions are contained within the HT Act (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.
127. The HT Act does not make any special exemptions from the consent requirements for storing blocks and slides. Nor does it envisage the storage of material for no purpose. Therefore, specific consent must be obtained to store and use tissue, including blocks and slides, for any of the scheduled purposes listed in the HT Act.
128. An existing holding is material that was being stored for use for a scheduled purpose when the HT Act came into force on 1 September 2006. Existing holdings are not subject to the consent provisions of the HT Act, but must be stored on licensed premises.
129. If an NHS Trust has collections of existing holdings that are considered by clinicians to be valuable for teaching, it should review the usefulness of the collection on a regular basis. Depending on the size and nature of the

collection, it may be appropriate to establish a group or committee with responsibility for overseeing the collection, and ensuring that the storage environment remains appropriate and that storage conditions are routinely monitored.

130. Where consent has been given for this use or the specimens are existing holdings, they should be made available for use in the education and training of clinicians. Where this means that they are removed from storage to unlicensed premises, there must be procedures in place that ensure proper care is taken of the specimen and that their removal and return to storage are documented.
131. Whole organs should be stored separately, not in batches. Storing them separately improves the opportunity for them to be used in education and training and enhances the process of classification. It also recognises the individuality of each specimen.
132. Specimens may be made available for photography and imaging, with a view to using the images for the purposes of education and training, and for research (see the Code of Practice on Research).

## **Disposal of post-mortem tissue**

133. Dignified treatment and separate disposal are the minimum considerations when disposing of post-mortem tissue. This means disposal should be carried out separately from clinical waste, but not that each tissue sample needs to be disposed of individually.
134. Establishments must have a disposal policy and procedures which govern arrangements for respectful and sensitive disposal to ensure that tissue is disposed of in accordance with the wishes of the deceased person or their relatives where possible. The establishment may wish to hold a simple but respectful ceremony and involve their bereavement and spiritual care services in the development of their disposal policy.
135. Staff should be familiar with disposal arrangements, including what is available locally, basic legal requirements and the options available to those wanting to make their own arrangements to dispose of tissue. Where appropriate, such information should be available in writing for people to take away with them. They may wish to discuss it with relatives or community members before making their choice.

136. Attitudes towards disposal may vary widely among cultures and religions. Staff should be sensitive to this, being aware that choices are for the individual to make. 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.
137. Relatives may wish for organs and tissue to be reunited with the body before burial or cremation. Establishments should have a system of checking that any retained tissue is accounted for before the body is released to the family. If there is tissue not accounted for, the establishment should have a clear procedure for the course of action to be followed. Efforts should be made to keep the relatives informed throughout the process.

**Example**

One establishment's procedure includes placing a written notice on the shroud of the deceased person if any tissue has been removed at post-mortem. This notice states the disposal wishes of the relatives. The member of staff who is responsible for releasing the body is required to check the records and ensure that tissue has been reunited with the body as requested.

138. Where an organ has been removed at post-mortem examination, the establishment may offer to store the body until the organ can be returned. This may not always be practical as there may be a long delay. In these cases, the consequences should be explained to relatives. Where a body is released without an organ, it is important that relatives are made aware that this is the case.
139. If for any reason retained tissue cannot be reunited with the body before it is released for burial or cremation, the establishment should have a procedure that ensures the relatives are informed and that there is prompt and appropriate disposal.
140. The deceased person or their relatives may have expressed wishes for the tissue samples to be retained for future use. If relatives have given consent to the storage of tissue, they should be offered the option of allowing the establishment to dispose of the material after its use.
141. Relatives may enquire some time later about tissue that was taken during post-mortem examination. It may be that tissue has been subsequently disposed of in accordance with this guidance. If this is the case, the relatives should be

given full information in a sensitive manner.

142. Suitable arrangements should be made with third parties carrying out specialist examination of tissue. These should ensure that all tissue is sent back to the originating establishment for disposal or return to the body, or that the third party is provided with instructions for disposal or a copy of the consent form for retention.
143. Where existing holdings include identifiable tissue that has been retained at post-mortem examination on a coroner's behalf to establish cause of death, the coroner's office must be consulted before disposal may take place. This is necessary to confirm that the coroner has satisfactorily completed their investigation into the case and is content for the material to be disposed of.
144. An establishment may contract the disposal of human tissue to another establishment. The responsibility for compliance with the Codes of Practice and the HT Act lies with the establishment contracting such services. It may therefore be advisable to have service level agreements (SLA) in place as part of this process.

### **Disposal options**

145. Currently, basic disposal options are incineration, cremation or burial. Establishments should make decisions locally about the most suitable methods of disposal in each case. They should be open about their processes so relatives have the information required to make an informed choice. The HTA encourages establishments to have a disposal policy that may be made available to the public (see paragraph 136).
146. Relatives may want to be reassured about the suitability of arrangements. They should be told what the establishment can provide and that any additional requirements will be at their own expense.
147. Relatives may want a funeral service of their choice to collect tissue or an organ after the release of the body and to make their own arrangements for cremation or burial. Second funerals and burials of this nature may have significant emotional and financial implications. These should be discussed sensitively with those involved.
148. If the deceased person has been buried or cremated and relatives ask for the remaining tissue to be returned later, this should be released:

- a. preferably to funeral service staff acting for those who have legitimate responsibility for the disposal of the body;
- b. with confirmation of the identity of the tissue or organ; and
- c. with confirmation that the cremation or burial authorities have agreed in principle to accept the remains for disposal.

149. Material may be released directly to relatives, but the proposed method of disposal must be lawful and safe. The establishment should be mindful of the relevant legislation<sup>3</sup> and ensure that the recipient is aware of any hazards associated with the tissue and its fixative, and can handle these appropriately.

150. Because of the potential health hazards, releasing tissue directly to relatives for its indefinite storage is not advisable. Establishments should make an assessment based on the risks involved and the possible consequences of releasing the material. Further guidance on disposal options is set out below.

## Incineration

151. Tissue removed from the deceased for use for scheduled purposes may be incinerated after use. Care should be taken to ensure that this method is appropriate to the nature of the tissue. For example, many establishments choose not to incinerate whole organs or fetal tissue.

152. The HTA recognises that local circumstances vary and is mindful of the practicalities involved in securing separate incineration. Where practical, human tissue that is incinerated should be bagged separately from clinical waste. It is not necessary for each tissue sample to be disposed of individually.

## Burial

153. An establishment wishing to bury tissue from the deceased should consult the local burial authorities to establish what level of service they can provide. If the establishment wishes to bury this material, and a service is not available locally, they may wish to contact other service providers further afield.

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<sup>3</sup> The relevant legislation is the Cremation (England and Wales) Regulations 2008 (as amended) and the Births and Deaths Registration Act 1953 (which cover cremation and incineration of body parts); The "Lists of Wastes" list established pursuant to the Commission Directive 2000/532/EC (as amended), the Lists of Wastes (England) Regulations 2005 (which include at Code 18 01 02 body parts and organs including blood bags and blood preserves) and wider background legislation including the Waste Framework Directive (75/442/EC), the Hazardous Waste Directive (91/689/EEC); Part II of the Environmental Protection Act 1990 and its subsidiary legislation, including the Waste (England and Wales) Regulations 2011/988 and the Hazardous Waste (England and Wales) Regulations 2005/894.

## **Cremation**

154. Cremation of human tissue from a deceased person is possible under Regulation 19 of Part 4 of the Cremation (England and Wales) Regulations 2008, which sets out the requirements that must be met. These include evidence that the samples were removed in the course of a post-mortem examination or a certificate that there is no reason for further inquiry or examination of the body parts.
155. The Cremation (England and Wales) Regulations 2008 do not apply to Scotland. It should also be noted that different cremation legislation applies in Northern Ireland and that responsibility for this legislation lies with the Department of the Environment (NI).
156. Although it is lawful to cremate tissue blocks, crematoria have discretion about what they may accept. Crematoria have particular concerns about material on glass slides because of health and safety issues.

## **Disposal of pregnancy remains**

157. Pregnancy remains of less than 24 weeks gestation are considered to be the mother's tissue. The HTA has issued separate guidance on the sensitive handling of pregnancy remains, which reflects the very sensitive nature of these.

## **Disposal of existing holdings**

158. Existing holdings, whether identifiable or unidentifiable, may be disposed of in line with the guidance in this code. If establishments need further advice on the disposal of existing holdings, they should contact the HTA.

## **HTA licensing standards**

159. In order to obtain an HTA licence, the applicant must demonstrate that they and the relevant premises are suitable. The HTA will assess whether they can meet 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.

160. The HTA works with establishments through its inspection process to help them comply with these Standards.

161. Each licensed establishment is required to appoint a Designated Individual (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 other persons to whom the licence applies are suitable persons to participate in the carrying on of the activities and that the conditions of the licence are complied with. By ensuring that the establishment is meeting the HTA's licensing Standards, the DI should be complying with their statutory responsibility.

162. 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.

163. 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)**

164. Establishment's 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)**

165. 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. The governance and quality systems Standards govern the practices taking place on licensed premises, and ensure that they preserve the dignity of the deceased and that the deceased are treated with respect.

## **Traceability (T)**

166. 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 the HTA expects establishments to take a proactive 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)**

167. Establishments meeting these Standards will be able to demonstrate that their premises and facilities are appropriate for the licensed activities taking place, that they are safe, secure and clean and that there are effective contingency arrangements in place. 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 or a risk to bodies.
168. The HTA's licensing Standards which will be applicable to the post-mortem sector from 2017 are included at Annex C and on the HTA website. The Standards are supported by comprehensive guidance notes.

## Annex A

### 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 purposes<sup>4</sup> 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 Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations), as amended, implemented into UK law the European Union Tissue and Cells Directive 2004/23/EC (EUTCD). The Q&S Regulations set out the standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells for human application. In their amended form following UK's exit from the European Union, the Q&S Regulations modify the requirements of the EUTCD as applied to Great Britain to reflect the departure from the EU, but the same standards continue to apply. Those modifications do not apply to Northern Ireland where the HTA remains the Competent Authority for the purposes of the EUTCD.
6. 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 and the requirements set out in Codes A and G.

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<sup>4</sup> Defined by the HT Act and explained in further detail in the glossary.

7. The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (the Q&S (Organs) Regulations) implemented into UK law the European Union Organ Donation Directive 2010/53/EU (EUODD). The Q&S (Organs) Regulations set quality and safety standards for organ donation and transplantation. In their amended form following UK's exit from the European Union, the Q&S (Organs) Regulations modify the requirements of the EUODD as they apply to Great Britain, but the same standards continue to apply. Those modifications do not apply to Northern Ireland where the HTA remains the Competent Authority for the purposes of the EUODD. Establishments licensed under the Q&S (Organs) Regulations should refer to the HTA's Quality and Safety of Organs Intended for Transplantation: a documentary framework and the requirements set out in Codes A and F (parts one and two).
8. 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. The Human Tissue (Scotland) Act 2006 (HT (Scotland) Act) and the Human Tissue (Authorisation) (Scotland) Act 2019 apply in Scotland.
11. The HTA assesses applications for living organ donation and donation of regenerative tissue 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.

### **Status and use of the Codes of Practice**

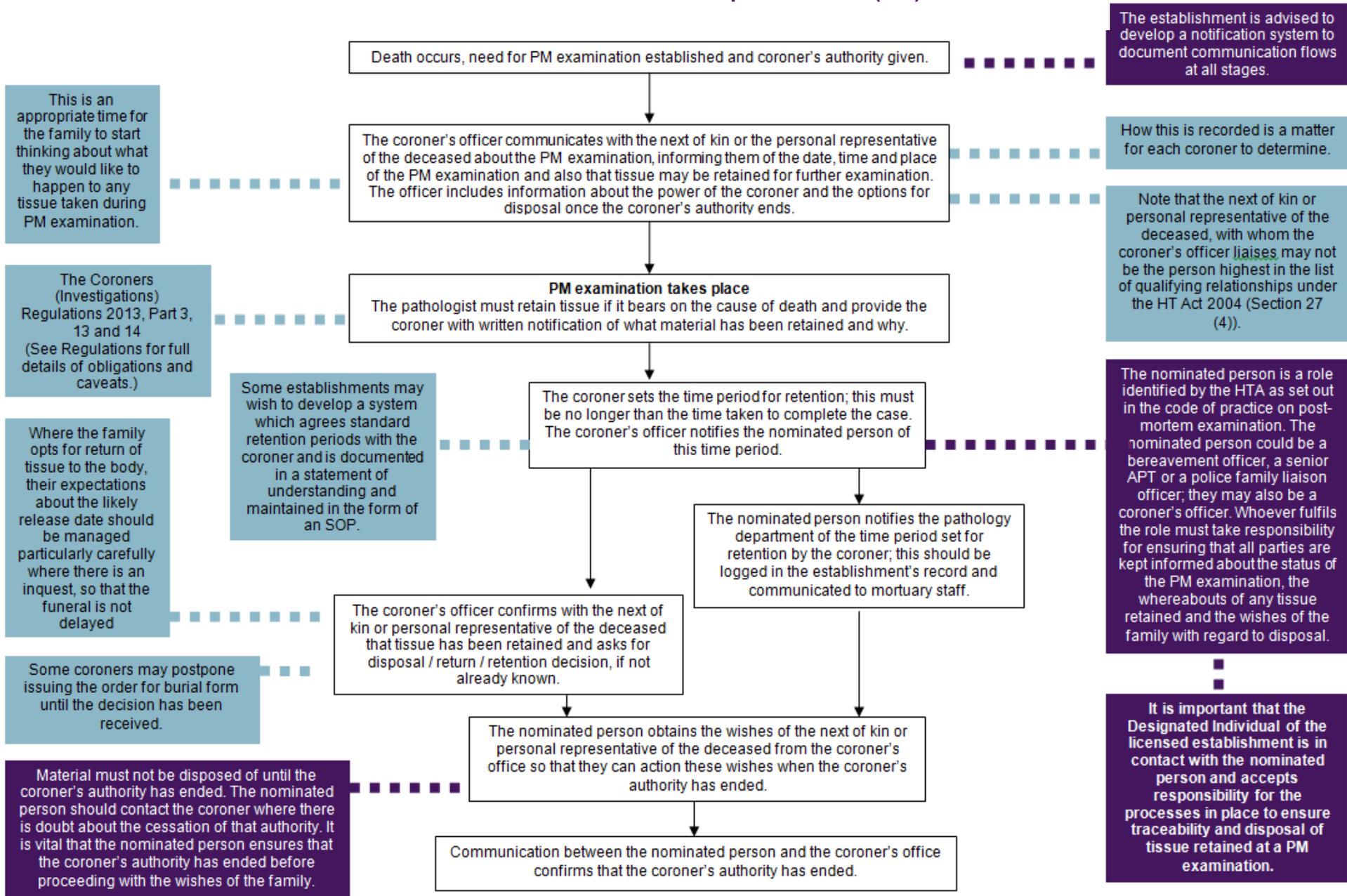
12. Throughout the Codes, the word '**must**' applies to all legal requirements derived from primary and secondary legislation (for example, the legal requirement to hold a licence to store human tissue for use for a scheduled purpose, the conditions of any licence and the requirements set out in any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

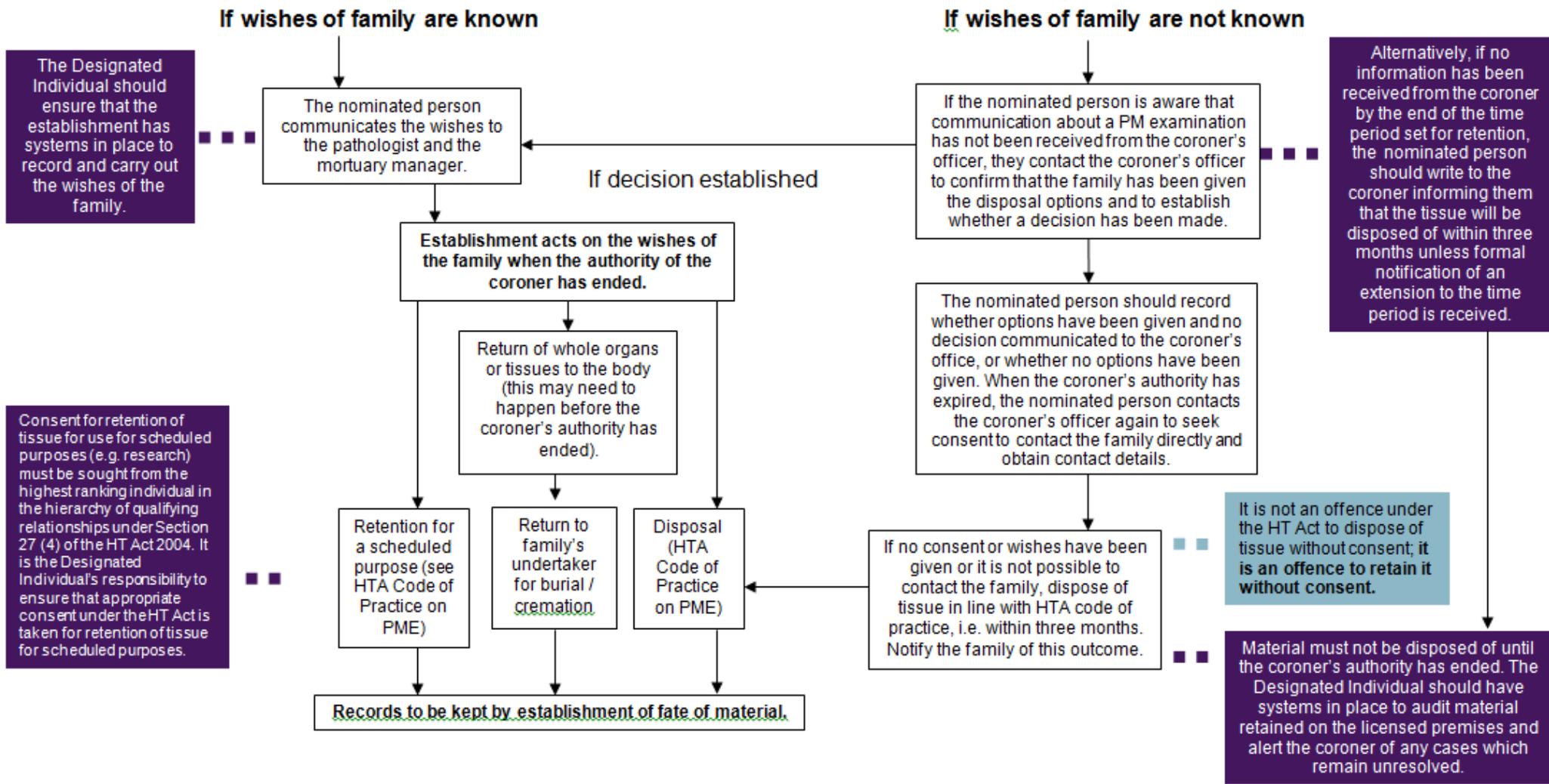
establishments are complying with legal requirements. Failure to follow a Code of Practice is not in itself a criminal offence under the HT Act, but the HTA will consider carefully any breach of a Code of Practice when considering whether there are grounds to take regulatory action.

### **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 it deals with matters within the scope of the HTA's 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.

## Annex B HTA communication flowchart for coroners' post-mortem (PM) examination





**Glossary**

**Nominated person:** a role defined by the HTA in the code of practice on Post-mortem examination

**Designated Individual:** the person who has statutory responsibility for ensuring compliance with the HT Act, HTA codes of practice and standards

**Scheduled purposes:** the purposes defined in Schedule 1 of the HT Act for which consent is required (subject to certain exemptions)

**Key**

- Action
- Information

## Annex C

### HTA licensing Standards: Post Mortem Sector

Consent
<b>C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice</b>
<p>a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice.</p> <p>b) There is a documented standard operating procedure (SOP) detailing the consent process.</p> <p>c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice.</p> <p>d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives.</p> <p>e) Where consent is sought for tissue to be retained for future use, information is provided about the potential uses to ensure that informed consent is obtained.</p> <p>f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds.</p> <p>g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided.</p>

**C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent**

- a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice.
- b) Records demonstrate up-to-date staff training.
- c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual.
- d) Competency is assessed and maintained.

**Governance and quality systems**

**GQ1 All aspects of the establishment's work are governed by documented policies and procedures**

- a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPATH. These include:
  - i. post-mortem examination, including the responsibilities of Anatomical Pathology Technologists (APTs) and Pathologists and the management of cases where there is increased risk;
  - ii. practices relating to the storage of bodies, including long term storage and when bodies should be moved into frozen storage;
  - iii. practices relating to evisceration and reconstruction of bodies;
  - iv. systems of traceability of bodies and tissue samples;
  - v. record keeping;
  - vi. receipt and release of bodies, which reflect out of hours arrangements;
  - vii. lone working in the mortuary;
  - viii. viewing of bodies, including those in long-term storage, by family members and others such as the police;
  - ix. transfer of bodies internally, for example, for MRI scanning;
  - x. transfer of bodies and tissue (including blocks and slides) off site or to other establishments;
  - xi. movement of multiple bodies from the mortuary to other premises, for example, in the event that capacity is reached;
  - xii. disposal of tissue (including blocks and slides), which ensures disposal in line with the wishes of the deceased person's family;

- xiii. access to the mortuary by non-mortuary staff, contractors and visitors;
- xiv. contingency storage arrangements.

- b) Procedures on evisceration ensure that this is not undertaken by an APT unless the body has first been examined by the pathologist who has instructed the APT to proceed.
- c) Procedures on body storage prevent practices that disregard the dignity of the deceased.
- d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use.
- e) There is a system for recording that staff have read and understood the latest versions of these documents.
- f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity.
- g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework.
- h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff.

#### **GQ2 There is a documented system of audit**

- a) There is a documented schedule of audits.
- b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these
- c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention.

**GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks**

- a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised.
- b) There are clear reporting lines and accountability.
- c) Staff are assessed as competent for the tasks they perform.
- d) Staff have annual appraisals and personal development plans.
- e) Staff are given opportunities to attend training courses, either internally or externally.
- f) There is a documented induction and training programme for new mortuary staff.
- g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures.

**GQ4 There is a systematic and planned approach to the management of records**

- a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.
- b) There are documented SOPs for record management which include how errors in written records should be corrected.
- c) Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).

**GQ5 There are systems to ensure that all untoward incidents are investigated promptly**

- a) Staff know how to identify and report incidents, including those that must be reported to the HTA.

- b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents.
- c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- d) Information about incidents is shared with all staff to avoid repeat errors.
- e) The establishment adopts a policy of candour when dealing with serious incidents.

**GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored**

- a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis.
- b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.
- c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register.

**Traceability**

**T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail**

- a) Bodies are tagged/labelled upon arrival at the mortuary.
- b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records).
- c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier.

- d) There is system for flagging up same or similar names of the deceased.
- e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises.
- f) There are procedures for releasing a body that has been in long term storage and is therefore not in the current register.
- g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings). The traceability system ensures that the following details are recorded:
  - i. material sent for analysis on or off-site, including confirmation of arrival
  - ii. receipt upon return to the laboratory or mortuary
  - iii. the number of blocks and slides made
  - iv. repatriation with the body
  - v. return for burial or cremation
  - vi. disposal or retention for future use.
- h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements.

**T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.**

- a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete.
- b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary.
- c) Disposal is in line with the wishes of the deceased's family.
- d) The method and date of disposal are recorded.

## **Premises, facilities and equipment**

### **PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue**

- a) The premises are clean and well maintained.
- b) There is demarcation of clear, dirty and transitional areas of the mortuary, which is observed by staff and visitors.
- c) There are documented cleaning and decontamination procedures and a schedule of cleaning.
- d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access).
- e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.

### **PFE2 There are appropriate facilities for the storage of bodies and human tissue**

- a) Storage arrangements ensure the dignity of the deceased.
- b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicted peaks of activity.
- c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs.
- d) Fridge and freezer units are in good working condition and well maintained.
- e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range.
- f) Temperatures of fridges and freezers are monitored on a regular basis.

- g) Bodies are shrouded or in body bags whilst in storage.
- h) There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.
- i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods.

**PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored**

- a) Items of equipment in the mortuary are in a good condition and appropriate for use:
  - i. fridges / freezers
  - ii. hydraulic trolleys
  - iii. post mortem tables
  - iv. hoists
  - v. saws (manual and/or oscillating)
- b) Equipment is appropriate for the management of bariatric bodies.
- c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually.
- d) Staff have access to necessary PPE.
- e) Where chemicals are used for preservation of tissue samples, there is adequate ventilation.
- f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if draught) are subject to regular maintenance and records are kept.

## Glossary

Term	HTA definition
Anatomical examination	Macroscopic examination by dissection for the purposes of teaching or studying, or researching into, the gross structure of the human body.
Anatomical Pathology Technologists (APTs)	Anatomical Pathology Technologists (APTs) assist pathologists carrying out post-mortem examination and carry out a wide range of tasks related to mortuary service delivery, including the receipt and release of bodies.
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.
Bariatric body	The body of an obese person that cannot be accommodated in standard mortuary refrigerated storage.
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 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>

Term	HTA definition
Coroner	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.
Coroner post-mortem examination	Carried out under the authority of the coroner, without consent being required from relatives, in order to assist coroners in carrying out their functions.
Cremation	The use of burning to reduce part or whole deceased human bodies to basic chemical compounds in the form of ashes. Cremation is used as an alternative to burial and is often associated with a religious and/or spiritual ritual. Cremation takes place within a registered crematorium under the oversight of a Registrar, and the relatives of the deceased may be present. Cremation is regulated in England and Wales by a permit issued by Local Authority Regulators and in Scotland by SEPA, as required by the Secretary of State's Guidance for Crematoria PG5/2(12).
Deemed consent	Deemed consent means that all individuals over 18 in England, Wales or Northern Ireland will be considered to have agreed to become an organ and tissue donor after their death, unless they made a decision not to donate their organs and/or tissue (i.e., they have opted out; they have nominated a representative to make a decision on their behalf after death about whether to donate; or are excluded from deemed consent). Deemed consent does not apply to people who lack mental capacity for a significant period before their death, children under 18 and people not ordinarily resident in the jurisdiction in which they have died for at least 12 months immediately before their death.
Defence post-mortem examinations	If a death is thought to have occurred as a result of criminal activity, then the post-mortem examination will be undertaken by a Home Office-registered forensic pathologist. In such circumstances, the legal defence team (for example the barrister or solicitor of the accused person) can request a second post-mortem examination, sometimes known as a defence post-mortem examination.

Term	HTA definition
Designated Individual (DI)	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.
Diagnosis	The identification of the nature of an illness or other problem.
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.
Full post-mortem examination	A full post-mortem examination involves opening the chest, abdominal and skull cavities to remove and examine the internal organs. After the organs have been examined, the pathologist returns the organs to the body. Body fluids or small pieces of tissue may be kept for further testing to determine the cause of death.
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's website.</p>

Term	HTA definition
Home Office-registered forensic pathologist	<p>Home Office-registered forensic pathologists undertake post-mortem examinations where homicide is suspected. They work within regional group practices, which are independent of the police, coroners and the Home Office.</p> <p>For further information see government crime and police guidance Forensic pathology: role within the Home Office.</p>
Hospital post-mortem examination	Carried out with appropriate consent from relatives to gain a fuller understanding of the deceased person's illness or the cause of death, and to enhance future medical care.
HTA Reportable Incident (HTARI)	A serious incident in the post mortem sector which falls within the classifications defined by the HTA and about which the HTA must be notified. Further information can be found on the HTA's website.
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.
Incident	An event or circumstance that could have resulted, or did result, in unnecessary damage, loss or harm.
Incineration	A process used to destroy human body parts. Incineration of human tissue as clinical waste is normal practice and is subject to separate regulation. Incineration does not usually have any associated ceremony. Technically, cremation and incineration are similar processes, both using burning to reduce part or whole deceased human bodies to basic chemical compounds in the form of ashes.
Licensed premises	Where the licensed activity takes place.
Licensing	<p>A number of activities can only be carried out when an establishment is licensed under the HT Act by the HTA.</p> <p>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.</p>

Term	HTA definition
Limited post-mortem examination	Post-mortem examinations may be limited to particular areas of the body, such as the head, chest or abdomen. Where the post-mortem examination is limited because of the consent given by relatives, the removal and examination of organs and tissue must be with the scope of the consent given.
Minimally invasive post-mortem examination / autopsy	These include post-mortem examinations in which needle biopsies through the skin are taken to sample internal organs and tissues, and examinations that use an endoscope or laparoscope to provide internal access to the gastrointestinal tract and the abdominal cavity. Needle autopsies are undertaken for only the most limited of examinations, for example when the body poses an increased risk of serious infection, or when there is neither the time nor conditions needed for a complete post-mortem examination. Endoscopic post-mortem examinations require specialist equipment and expertise; they have been used in cases in which consent for a more complete post-mortem examination has not been obtained.
Neonatal death	A foetus of any gestational age which is born alive and dies before the age of 28 days.
NHS Trust, including NHS Foundation Trusts	An NHS organisation, including NHS Foundation Trusts, comprising of hospitals which generally serve a geographical area or a specialised function.
Nominated representative	A person appointed by a person to represent them after their death for the purposes of activities under the HT 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
Paraffin-embedded blocks	Blocks of paraffin wax in which small pieces of tissue are fixed. The blocks can be cut into thin slices for microscopic examination.
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.
Pathology	The science of the causes and effects of diseases.
Peripheral blood stem cells (PBSCs)	Peripheral blood stem cells are the source of all blood cells. They are found in the bloodstream and are formed in bone marrow. They receive signals that direct them to differentiate into all the cell types found in blood (red cells, white cells or platelets). They can be mobilised from the bone marrow into the blood stream by giving a drug, and collected with an apheresis machine.
Person Designated (PD)	A person working under an HTA licence acting under the direction of the Designated Individual.
Post-mortem cross sectional imaging	Post mortem computed tomography (PMCT) or post mortem magnetic resonance (PMMR), which may be used instead of, or as an adjunct to post-mortem examination, to determine the cause of death. It provides a three-dimensional image of the patient's internal organs and structure, particularly of the soft tissues.
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.
Pregnancy remains	The term used by the HTA to refer to foetal tissue or products of conception resulting from pregnancy loss or termination of pregnancy, regardless of gestation. The term does not apply to stillbirths (babies born dead after the 24th week of pregnancy) and neonatal deaths.

Term	HTA definition
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 HT Act.
Relevant material	Defined by the HT Act as material other than gametes, which consists of, or includes, human cells. In the HT 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.
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.

Term	HTA definition
Scheduled purpose	<p>Under the HT Act, consent must be obtained to remove, store or use bodies or relevant material for scheduled purposes. The licensing requirements of the HT 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"> <li>• 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.</li> <li>• Part 2: Purposes requiring consent: Deceased persons – clinical audit, education or training relating to human health, performance assessment, public health monitoring, quality assurance.</li> </ul>
Service Level Agreement (SLA)	<p>A formal agreement that sets out the roles and responsibilities of two parties. An SLA cannot be used to provide a third party that is not licensed by the HTA with the authority to undertake licensable activities on behalf of a licensed establishment, only a Third Party Agreement (TPA) may be used for that purpose. Neither is it sufficient for governing the supply of goods or services which may affect the quality or safety of tissues and cells.</p> <p>If two establishments are licensed by the HTA and one undertakes licensable activities on behalf of the other, an SLA setting out roles and responsibilities is sufficient to document the working relationship between the two licensed establishments.</p>

Term	HTA definition
Standard operating procedure (SOP)	A document that sets out the established process to be followed to complete a task.
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.
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.