CODE B

POST-MORTEM EXAMINATION

Public Health

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HUMAN TISSUE AND ORGAN DONATION ACT 2021

Code B: Post-mortem Examination

Contents

Introduction to Cabinet Office's Codes of Practice for the Human Tissue and Organ Donation Act 2021.

1. Section 19 of the Human Tissue and Organ Donation Act 2021 (HTODA) extended Cabinet Office's (CO) regulatory functions. These functions include –

   a) maintaining a statement of the general principles that CO believes should be followed when carrying-on activities, and functions in relation to them, under the HTODA;

   b) providing general oversight and guidance in relation to activities under the HTODA as CO considers appropriate;

   c) superintending, in relation to activities under the HTODA, compliance with Parts 2 and 3 of the HTODA and these Codes of Practice;

   d) providing to the public, and to persons carrying on activities under the HTODA, such information and advice as it considers appropriate about the nature and purpose of such activities; and

   e) securing publicity on or around 15th March of each year on the desirability of making organs and tissue available for the purposes of transplantation.

1A. Section 20 of the HTODA requires any person undertaking certain activities under the Act to, following an inspection, obtain a licence from CO.

Public Health (PH), as part of CO, have the delegated authority to undertake inspections, issue licences and advise CO on the undertaking of its other functions under the HTODA.

1AA. The types of activities PH will regulate on behalf of CO through licensing and inspection are –

   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.

1B. CO and PH will also regulate the Department of Health and Social Care's (DHSC) activities under the HTODA, which may be delegated by DHSC to Manx Care, or supported by National Health Service Blood & Transplant (NHSBT) as appropriate.

1BB. A comprehensive list of DHSC's activities under the HTODA are set out in section 18 (DHSC's remit) of that Act, but in summary they include –

   a) for either a scheduled purpose or for the purposes of UK legislation referenced by the HTODA, the obtainment[1], processing, testing, storage, distribution, removal, use, import, export and disposal of human tissue;

   b) for either a scheduled purpose or for the purposes of UK legislation applied by the HTODA, the donation, testing, characterisation, obtainment, preservation, transport, import, export, storage, transplantation and disposal of human organs;

[1] See glossary.

c) the disposal of an organ or tissue which has been removed from a person's body for medical treatment;

d) the carrying out of anatomical examination, and the making of post-mortem examinations undertaking of post-mortem and examinations, and the associated disposal of organs and tissues as a consequence of these activities.

2. Further information about the legislative background and context of the HTODA and its Codes of Practice is set out at Annex A.

3. This document is part of a suite of seven Codes of Practice produced by CO.

- **Code A**: Guiding principles and the fundamental principle of consent;
- **Code B**: Post-mortem examination;
- **Code C**: Anatomical examination (including import/export);
- **Code D**: Public display (including import/export);
- **Code E**: Research (including import/export);
- **Code F – Part 1**: Living organ donation;
- **Code F – Part 2**: Deceased organ and tissue donation;
- **Code G**: Donation of allogeneic bone matter and peripheral blood stem cells (PBSCs) for transplantation.

4. The Codes of Practice give practical guidance to professionals carrying out activities which lie within DHSC's and Manx Care's remit; CO's general functions under the HTODA; any secondary legislation made under that Act; and any UK legislation that is read as applied to the Island further to that Act (subject to any modifications made by an order under section 71 of the HTODA).

5. While the Codes of Practice will be of interest to members of the public, the Codes will be relevant to professionals carrying out activities under:

a) the *[IOM equivalent to UK's Human Tissue (Quality and Safety for Human Application) Regulations 20**[2]]*; and

b) the *[IOM equivalent to the UK's Quality and Safety of Organs Intended for Transplantation Regulations 20**[3]]*.

6. The Codes of Practice provide guidance on activities within the scope of CO's general functions under the HTODA. Whilst PH, and CO more generally, may offer advice on matters outside of those general functions, neither CO nor PH have any requirement under the HTODA in relation to the provision of such advice. CO and PH will endeavour to provide signposts to other agencies where issues arise that are beyond the reach of CO and PH.

7. The Codes of Practice do not include information about the analysis of DNA. This is because CO has no regulatory or statutory powers in relation to the non-consensual analysis of DNA, for which the provisions are set out in section 68 (non-consensual analysis of DNA) and Schedule 3 (section 68:

[2] SD 20**/****.
[3] SD 20**/****.

supplementary) of the HTODA. Separate guidance in the form of frequently asked questions is available on the website www.gov.im.

7A. Code A (Guiding principles and the fundamental principle of consent) contains information that is applicable to all establishments and professionals operating under the HTODA (including any UK legislation referenced by that Act, or secondary legislation made under that Act). It sets out the four guiding general principles on which the work of CO and PH under the HTODA is founded.

For the purposes of this Code and the post-mortem sector, giving effect to these principles 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, the Codes of Practice are intended to provide anyone undertaking activities with a reference source which gives practical advice on the minimum steps necessary to comply with the relevant legislation as well as CO and PH policy.

Introduction to the post-mortem examination code

9. Post-mortem examination in all its forms is important for informing relatives[4], 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 consent, or authority, of the Coroner of Inquests. These may occur when[5] –

- there is reason to believe that a deceased person died directly, or indirectly –
    - as a result of violence or misadventure or unfair means;
    - as a result of negligence or misconduct or malpractice on the part of others;
    - from any cause other than natural illness of disease for which that deceased person has been seen and treated by a registered medical practitioner within 28 days before their death; or
    - in such circumstances as may require investigations (including death as a result of the administration of an anaesthetic);
- the body of a deceased person has been found in a public place;
- an unexpected death has occurred and the cause of death is unknown;
- a death has occurred in suspicious circumstances; or
- a death has occurred in prison or police custody, or as a result of an injury caused by a constable in the performance, or purported performance of their duty.

In these circumstances the consent of the family is not required in these cases. Further to section 43 (consent of Coroner to post-mortem examination) of the HTODA, it is also an offence to conduct a post-mortem examination of the body of a deceased person under these circumstances without the consent of the Coroner of Inquests.

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.

[4] Throughout this Code, the term 'relatives' should be taken to mean those in a qualifying relationship to the deceased before they died as defined by section 5 of the HTODA. See also paragraph 64 of this Code.
[5] Note section 2(1) and (4) of the Coroner of Inquests Act 1987.

11. The CO's function is to ensure that post-mortem examinations are undertaken as authorised, or consented, by the Coroner of Inquests and on suitable premises licensed for that purpose, which is a statutory requirement under the HTODA.

    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 HTODA.

12. This Code, and the associated licensing standards, apply to those directly involved in performing post-mortem examinations – pathologists and anatomical pathology technologists (APTs). They may also inform the practice of others who are not subject to regulation by PH, such as the Coroner of Inquests authorising (or consenting to) 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. PH regulates, through its licensing and inspections process, establishments which carry out full, limited, and minimally invasive post-mortem examinations. This includes post-mortem examinations undertaken in emergency mortuaries. Further information on emergency mortuary licensing is available on the gov.im website, including the licensing standards that emergency mortuary facilities are expected to meet.

14. Omit

15. The licensing requirements 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 organs and tissue from the body of a deceased person and the storage and use of a body after death for the scheduled purposes defined in the HTODA, 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 HTODA and observing the good practice set out in the HTODA'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 HTODA 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 DHSC's remit and informs the content of this and the other Codes for PH's functions. Those involved in carrying out post-mortem examinations should also familiarise themselves with the licensing Standards on post-mortem examination.

Offences under the HTODA

20. The HTODA sets out a number of offences, for which the maximum penalty is imprisonment and/or a fine. In relation to the post-mortem sector, the offences are as set out below.

21. Section 12 of the HTODA makes it an offence to remove *organs, tissue sample, blood (or any material derived from blood) or other body fluid* from the deceased and to store and use bodies and *organs, tissue sample, blood (or any material derived from blood) or other body fluid* for a purpose set out in Schedule 1 of the HTODA (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 12 of the HTODA also makes it an offence to falsely represent that there is appropriate consent to undertake an activity, or that Section 1 of the HTODA 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 20(1) and (2) of the HTODA prohibit the following activities, except under the authority of a licence:

a) the making of a post-mortem examination;

b) the removal of organs or tissue from the body of a deceased person, (otherwise than in the course of an anatomical examination or a post-mortem examination) of an organ or tissue of which the body consists or which it contains, for use for a scheduled purpose other than transplantation; and

c) the storage of the body of a deceased person, or *organs, tissue sample, blood (or any material derived from blood) or other body fluid* which has come from a human body, for use for scheduled purposes.

23. To undertake an activity listed in section 20(2) without the authority of a licence from the HTODA is an offence under section 24. 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 post-mortem examinations are conducted under the authority of the Coroner of Inquests, 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 HTODA and storage. Finally, at the end of the Code there is a brief section explaining CO'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 gov.im website.

The coroner's post-mortem examination

28. Post-mortem examinations enable coroners to fulfil their statutory duty to hold inquests as required by section 7 of the Coroners of Inquests Act 1987. This Act, and the associated secondary legislation, empowers the Coroner of Inquests to authorise a post-mortem examinations as a consequence of this duty.

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 a Manx Care 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 Coroner of Inquests may notify any person or persons of a post-mortem examination and permit that person, or persons, to attend that examination. With this permission in place, post-mortem examination may be observed by healthcare professionals, police, paramedics and others as part of their training or for other purposes.

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. 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 gov.im website.

Defence post-mortem examinations

35. Defence post-mortem examinations may be conducted by any person considered competent to do so by the Courts. Otherwise, such examinations are subject to the same regulatory requirements of the HTODA 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 (Note: paragraph 41 is equally applicable in this circumstance). If new 'sub-samples' are created from the original samples (for example, new slides from tissue blocks), it is important that 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. Where such samples are held outside of the Island, they are subject to the regulatory controls of that jurisdiction.

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 form part of the medical records of the deceased person. 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.

38. Omit.

Retention of tissue with the authority of the Coroner

39. Under the Coroners of Inquests Rules 1988[6], the pathologist must notify the coroner in writing of any *material* (for this purpose, tissue and organs that are not tissue samples or bodily fluids) they have retained, which may be provided as part of the post-mortem report. The pathologist must set out why they believe the material being retained relates to the cause of death or the identity of the deceased. The pathologist may suggest various retention periods for the material. 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.

40. The coroner must provide information to the relatives (if any) –

- of *material* that has been retained, and
- that tissue samples may also have been retained separately as part of the medical record,

and how long that *material* will be retained and the options for dealing with the *material* once it is no longer required for the coroner's purposes.

41. A coroner's 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 HTODA.

42. Tissue samples may be taken at post-mortem examination, and also from deceased children under the sudden unexpected death in infancy protocols. Storage of tissue samples for use for a scheduled purpose can only take place on PH-licensed premises unless these are being held for criminal justice purposes[8], or have been sent to an off-Island specialist laboratory from PH-licensed premises and will be returned to PH-licensed premises following analysis or disposed of locally.

42A. The taking of samples from a deceased person for criminal justice purposes, or under the authority of the Coroner of Inquests, does not require consent. Where tissue samples

[6] GC 3/88 as amended by SD 0126/13 and SD 2025/****.
[7] [add reference as per Coroners of Inquests Rules 1988 (as amended).
[8] Subject to the requirements of section 38 (criminal justice purposes) of the HTODA.

are taken under the authority of the coroner of inquests *such samples will form part of medical records once they are no longer required for the purposes of the coroner of inquests.*

Valid consent from the deceased, or a nominated representative for the deceased, or a person in a qualifying relationship with the deceased, is required *to store or use these samples* for use for education, training or research when no longer required for criminal justice purposes

Valid consent from the deceased, or a nominated representative for the deceased, or a person in a qualifying relationship with the deceased, is required *to use these samples* for use for education, training or research when the coroner's authority ends.

Disposal or further retention following coroners' post-mortem examinations

43. Once the coroner's authority has ended, it is not lawful to use or store material or full-bodies, other than as a tissue sample as part of that person's medical record, for education, training or research without appropriate consent. Nor is it lawful to use or store organs or full-bodies for education, training or research without consent or a PH-licence[9]

44. The Coroners of Inquests Rules 1988 place an obligation on the coroner to inform the family of their disposal options for material, 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 HTODA.

45. 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. The Coroner has an obligation to give written notice to establishments once material is no longer required for the purposes of the functions of the Coroner. Establishments should have a policy that governs the disposal of such material when this is the decision of the relatives.

46. 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.

[9] Note: section 45 (removal during examination and retention of organs and other parts of a body) of the HTODA.

Example

An establishment has worked with the local coroner to produce an information leaflet about the relatives' options for disposal or retention of material (i.e. organs) following a post-mortem examination. This document reflects the establishment's disposal policy and associated restrictions.

It also provides information for relatives to help inform their decision about disposal. For example, explaining that the cremation of organs will 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.

47. 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.

48. Problems arise when relatives do not, or cannot, communicate their decision about what they wish to happen to such material. This creates uncertainty about the lawfulness of retention of material 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 an organ 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.

49. 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 organs unnecessarily and without consent. This includes organs sent for specialist examination.

50. Good communication between coroners and pathologists is essential to ensure that organs are not stored indefinitely without consent. PH recommends that a nominated person is identified to handle the communication 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 organ disposal or retention when the coroner's authority has expired. A model communication flowchart to support good communication between coroners and pathologists is contained in Annex B.

51. If the family does not, or cannot, communicate their decision about what they wish to happen to the organ or a full-body, the nominated person should advise the family that the pathology department will hold the material and bodies 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 material other than full bodies 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 material should be disposed of (see section on disposal of post-mortem tissue, paragraphs 135-146). The storage of full bodies after this 3 month period may also be subject to a storage fee from the establishment in question.

52. 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 material or dispose of a full-body, 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 material and the waiving of storage fees for full-bodies[10].

53. Sometimes, families express their wish for material or full-bodies 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 material indefinitely and that it will be disposed of within a certain period (see paragraph 47). Furthermore, fees may be charged or imposed for the storage of full-bodies.

[10] Note: Manx Care policy on the provision of burials and cremations.

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 retained material of full-bodies must not be used for education, training or research and, if material is disposed of, this should be done in an appropriate manner and records kept.

52A. Regard should also be given to the provisions of section 28 (burial or cremation) of the Social Services Act 2011, and associated Manx Care policies, with respect to the making of suitable arrangements to dispose of any full-bodies where it appears to Manx Care that no other suitable arrangements for the disposal of that full-body have been or are being made.

54. It is important that the family is informed of the potential benefit to them of material, tissue samples and full-bodies being retained and used for the purposes of education, training or research. For example, if the post-mortem research on tissue 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 material, tissue samples and full-bodies for education, training or research. Where the family decides that materials and tissue samples may be kept to be used for education, training or research, appropriate consent should be obtained in line with the provisions set out in Code A (see sections on nominated representatives and qualifying relationships).

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

Criminal investigations

56. 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 a pathologist who is working in 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.

Where it is not reasonably practicable for a Home Office-registered forensic pathologist to conduct the post-mortem in person, subject to the consent of the Coroner, the post-mortem may be conducted by a pathologist under the supervision of the Home Office-registered forensic pathologist .

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.

57. There are some exemptions in the HTODA 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 the Coroner of Inquests and the police, the section 38 exemptions of the HTODA apply.

58. Omit.

59. 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.

60. 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

61. 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.

62. 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.

63. 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 PH.

64. 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.

65. 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 HTODA 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 HTODA.

66. Those in a qualifying relationship are found in the HTODA in the following order (highest first):

a) spouse or partner (including civil or same sex partner). The HTODA 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.

67. Consent must be given before the post-mortem examination is undertaken to ensure proper compliance with the HTODA. 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.

68. Hospital staff should, when seeking consent for a hospital post-mortem examination, explain the significance of the qualifying relationship under the HTODA 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.

69. To support staff taking consent for hospital post-mortem examinations, the Designated Individual (DI)[11] 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, the DI should check whether the consent giver is the highest ranking person in the qualifying relationship[12].

[11] Note paragraph 161.

[12] Note provisions relating to qualifying relations in paragraph 64 of this Code, paragraph 32 of Code A and section 5 of the HTODA.

70. There may be situations where it may not be possible to seek consent from the person in the highest ranking qualifying relationship. The HTODA allows for this person to be omitted from the hierarchy if they cannot be located, decline 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.

71. Where there is no record of consent (i.e. from the patient's, the patient's nominated representative, or from a person in a qualifying relationship), or consent cannot be obtained, the post-mortem examination cannot proceed.

72. 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.

73. Written consent is preferable and model consent forms for a hospital post-mortem examination of an adult are available on the gov.im website. The forms are not prescriptive and may be adapted as necessary, provided they comply with the HTODA 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.

74. Omit.

75. Omit.

76. 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.

    Following a hospital post-mortem tissues and organs should be retained, returned or disposed of, as consented to by the family.

77. Separate consent should be obtained for the removal and future storage and use of organs and tissue (including blocks and slides) for education, training or research.

78. A signed copy of the consent form should be included in the deceased's medical record. A copy of the consent form should also be given to the person giving consent.

Religion and culture

79. 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?

80. 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
Trained clinicians are sometimes used 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, ongoing training can be managed effectively.

81. Whichever approach is taken, the hospital should have a named individual who can provide support and information to the relatives.

82. 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.

83. 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.

84. Before the discussion with relatives the responsible clinician should consider obtaining advice from a pathologist, or a suitably 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.

85. 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.

86. 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.

87. Consent may be given during the course of a telephone conversation, which should be followed up 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.

88. 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. It is recommended that this period should be 24 hours.

Who may give consent for hospital post-mortem examinations?

89. Appropriate consent in the HTODA 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.

90. 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.

91. 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.

92. Where the deceased is a child (for the purposes of the HTODA, 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).

93. 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.

94. Foetal 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. Guidance on the disposal of pregnancy remains is available from Manx Care.

95. Omit

96. 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 foetus 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

97. 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.

98. 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

99. 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.

100. 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 (including potential retention as part of the medical record of the deceased following a post-mortem); 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.

101. Relatives should be provided with factual information that may be taken away if they want it. There may be a need to produce information in different languages.

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

103. Relatives should also be provided with the name, telephone number and/or email address of a contact person (for example, a bereavement adviser) so they may ask further questions later. Ready access to general information, for example, via the 'Manx Care Bereavement Book' and through the 'Relatives Support Service', may also be helpful to them.

104. 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.

105. 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

106. 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.

107. 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.

108. 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.

109. 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.

110. Healthcare professionals must have regard to their duty of patient confidentiality and the provisions of the Data Protection Act 2018. 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 guidance issued by the General Medical Council's (GMC) on confidentiality, which deals with disclosing information after a patient has died.

111. 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.

112. 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.

113. 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

114. Staff involved with seeking consent should be trained in how to obtain consent and the establishment should hold training records to demonstrate this.

115. 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 HTODA.

> **Example**
>
> Establishments seeking to develop training might consider a web-based training module for staff. By working through the relevant sections of the HTODA 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, the potential for retention of post-mortem tissue as part of the deceased person's medical record, and what is documented and where. It might also reference the HTODA so that people know that seeking valid consent is a legal requirement, not just good practice.

116. 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.

117. 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 the Safeguarding Board[13].

Tissue or organ donation

118. Prior to their death, many people have made a decision to consent to organ or tissue donation. All efforts should be made to allow those who wish to donate organs or tissue

[13] Established further to the Safeguarding Act 2018, of Tynwald.

to do so, and explanations should be given where it is not possible. For further guidance, see the Code of Practice on Donation of solid organs and tissue for transplantation (i.e. Code F, Part 1: Living Organ Donation & Code F, Part 2: Deceased organ and tissue donation)

119. Organ retrieval will take place before a post-mortem examination. Tissue and organ 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.

120. If the coroner is investigating the reason for the deceased's death, agreement from the coroner will be required for any organs or tissue to be removed prior to the post-mortem.

121. For guidance on arrangements between coroners and SNODs (Specialist Nurses in Organ Donation) on taking steps for organ preservation, see the Code of Practice on donation of solid organs for transplantation (i.e. Code F, Part 1: Living Organ Donation & Code F, Part 2: Deceased organ and tissue donation).

Removal of post-mortem tissue for use for scheduled purposes

122. 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 criminal justice purposes further to section 68 of the HTODA. 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. PH 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.

123. 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.

    If the injury occurs as part of post-mortem examination authorised by the Coroner of Inquests, the Coroner may be invited to issue a notice for the purpose of section 55 (tissue sample becoming part of medical records of deceased person) of the HTODA to allow a tissue sample to be released to form part of the deceased person's medical records.

Further to section 56 (use of tissue sample which has become part of deceased's medical records) of the HTODA that tissue sample may then be tested to obtain information relevant to the health of the injured person.

Where a hospital post-mortem examination has been authorised in accordance with the requirements of sections 46 to 50 of the HTODA, consent should be sought from the person who granted the authorisation (either at the time the authorisation was granted or at the time of the injury) for consent to undertake testing of tissue samples of the deceased in the event of an injury during the post-mortem examination.

Where there is no immediate access to a family member, recent case law suggests that permission may be given by a judge[14].

Storage of bodies and tissues in blocks and slides, including existing holdings

124. 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.

125. 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.

126. 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.

127. Blocks and slides for use for education, training or research 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.

[14] . Montgomery v Lanarkshire Health Board (Scotland), 11th March 2015. Neutral citation number [2015] UKSC 11. https://www.supremecourt.uk/cases/uksc-2013-0136.html

128. These exemptions are contained within the *[Manx equivalent to HT Act (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006].*

129. Specific consent must be obtained to store and use organs, or use tissue stored as part of the medical record (including blocks and slides) for education, training or research.

130. An existing holding is material that was being stored for use for a scheduled purpose when the HTODA came into force on XXXDATEXXX. Existing holdings are not subject to the consent provisions of the HTODA, but must be stored on licensed premises.

131. If a premises 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 either appoint a person or 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.

132. 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.

133. 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.

134. 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 and organs

135. Dignified treatment and separate disposal are the minimum considerations when disposing of tissue and organs.

    Tissue and organs may be disposed of via the clinical waste route. In such circumstances the tissue and organs should be separated from other clinical waste and their disposal recorded by the licenced premises and the clinical waste handler in accordance with agreed procedures. This does not require each tissue or organ to be disposed of as a separate item.

    Small amounts of tissue, notably bodily fluids and tissue separated from the body as a consequence of a post-mortem, may be disposed of via a non-clinical waste disposal route.

136. Establishments must have a disposal policy and procedures which govern arrangements for respectful and sensitive disposal to ensure that each organ 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.

    These disposal policies and procedures should also set out arrangements for the suitably respectful and sensitive disposal of tissue samples, once the medical record of which they are a part of has been deleted or destroyed in accordance with Manx Care's retention policy.

137. 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 organs. 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.

138. 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.

139. Relatives may wish for organs to be reunited with the body before burial or cremation. Establishments should have a system of checking that any retained organ is accounted for before the body is released to the family. If there is an organ 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 organ 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 organ has been reunited with the body as requested.

140. 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.

141. If for any reason an organ 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.

142. The deceased person or their relatives may have expressed wishes for the tissue samples or organs to be retained for future education, training or research. If relatives have given consent to the use of tissue or the storage and use of organs for these purposes, they should be offered the option of allowing the establishment to dispose of the material after its use.

143. Relatives may enquire some time later about tissue or organs that were 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.

144. Suitable arrangements should be made with third parties carrying out specialist examination of tissue and organs. These should ensure that all tissue and organs are sent back to the originating establishment for retention (as part of the medical record for tissue) 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 (where required).

145. Where existing holdings include identifiable tissue or organs that have 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.

146. An establishment may contract the disposal of human tissue or organs to another establishment. The responsibility for compliance with the Codes of Practice and the HTODA 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

147. 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. PH encourages establishments to have a disposal policy that is made available to the public (see paragraph 136).

148. 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.

149. Relatives may want a funeral service of their choice to retrieve 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 other implications. These should be discussed sensitively with those involved.

150. If the deceased person has been buried or cremated and relatives ask for the remaining organs to be returned later, this material 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 organ; and

    c) with confirmation that the cremation or burial authorities have agreed in principle to accept the remains for disposal.

151. 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[15] and ensure that the recipient is aware of any hazards associated with the organ and its fixative, and can handle these appropriately.

152. Because of the potential health hazards, releasing organs directly to relatives for indefinite storage, while not prohibited, 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

153. Tissue and organs 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 foetal tissue.

154. PH recognises that circumstances vary and is mindful of the practicalities involved in securing separate incineration. Where practical, human tissue and organs that are to be incinerated should be bagged separately from other clinical waste. It is not necessary for each tissue sample, item of tissue, or organ to be disposed of individually.

Burial

155. An establishment wishing to bury tissue or organs 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.

[15] The relevant legislation includes, but is not limited to, the Burials Act 1986, the Cremation Act 1957 and the Cremation Regulations 2000; the Civil Registration Act 1984; the Public Health Act 1990.

Cremation

156. Cremation of human tissue from a deceased person is possible under Regulation 13 (body parts) of the Cremation Regulations 2000[16], 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.

157. Omitted.

158. Although it may be 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

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

Disposal of existing holdings

160. 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 PH.

[16] SD 613/00

PH Post-mortem licensing standards

161. In order to obtain a PH post-mortem licence, the applicant must demonstrate that they and the relevant premises are suitable. PH will assess whether they can meet a number of licensing standards, which were developed in consultation with representatives from the regulated sectors. These relate to the consent provisions of the HTODA and regulatory requirements. The standards cover the following areas:

    a) governance;

    b) authorisation process;

    c) dignity and respect for the deceased and people who have been bereaved;

    d) pathology examination and reporting;

    e) removal, retention, storage, handling, transportation and disposal of the body, embryos, foetuses, tissue blocks, glass slides or organs; and

    f) education and training.

159A. The standards follow the same format. Each standard includes:

- a statement of the level of performance to be achieved;
- a rationale providing reasons why the standard is considered important;
- a list of criteria describing the required structures, processes and outcomes;
- what to expect if you are a person receiving care;
- what to expect if you are a member of staff; and
- what standards mean of organisations, including examples of evidence of achievement.

Within the standards, all criteria are considered 'essential' or 'required' in order to demonstrate the standard has been met.

162. PH works with establishments through its inspection process to help them comply with these Standards.

163. Each licensed establishment is required to appoint a Designated Individual (DI) for their licence, who has a statutory responsibility under the HTODA 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 PH's post mortem licensing Standards, the DI should be complying with their statutory responsibility.

164. When PH staff undertake inspections of PH-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 all relevant PH licensing Standards; these could be the post-mortem licensing standards discussed here and/or other PH licensing standards discussed in the rest of the Codes of Practise.

PH's post mortem licensing standards consist of the following six standards:

Standard 1: Governance

Standard 2: Authorisation Process

Standard 3: Dignity and respect for the deceased and people who have been bereaved

Standard 4: Pathology examination and reporting

Standard 5: Removal, retention, storage, handling, transportation and disposal of the body, embryos, fetuses, tissue blocks glass slides or organs

Standard 6: Education and training

165. Omit

166. Omit

167. Omit

168. Omit

169. The PH's post mortem licensing standards which will be applicable to the post-mortem sector from XXDATEXX are included at Annex C and on the gov.im website. The Standards are supported by comprehensive guidance notes.

Annex A: Legislative background and context

To be added

Annex B: PH Communication flowchart for coroner's post-mortem (PM) examination

To be added

Annex C: PH Post Mortem Licensing Standards

Standard 1: Governance[17]

Standard statement

Manx Care has a governance structure in place for the safe, effective and person-centred management of hospital post mortem examinations and reporting.

Rationale

To promote public confidence in the post-mortem examinations process, Manx Care will demonstrate that hospital post mortem examinations are a continuation of clinical care, part of their governance structures and comply with legislation.

The HTODA outlines the legislative requirements for post-mortem examination, including staff responsible for taking authorisation and retention and disposal of tissue blocks, glass slides and organs. There are infection control procedures for hospital post mortem examinations, including reporting infection from the deceased.

Guidance is available from the Royal College of Pathologists on hospital post mortem examination record management and audit activities[18].

Criteria

1.1 Manx Care is responsible for ensuring there are safe, effective and person-centred systems in place for the management of post-mortem examinations as described by the HTODA.

1.2 Manx Care has policies and procedures in place for hospital post mortem service including:

(a) the consent process;

(b) identification of the deceased;

(c) removal, retention, storage, handling, transportation and disposal of the body, embryos, foetuses, tissue blocks, glass slides or organs;

(d) the identification, notification and management of infection control;

(e) communication between the requesting clinician and pathologist; and

(f) reporting and documentation requirements for the pathologist and for the deceased's medical records.

[17] Based upon Scottish Management of Hospital Post-mortem Examinations Standards

[18] Reference in Scottish Code - check any relevant to IOM.

1.3 Manx Care has processes in place to ensure the implementation, monitoring and audit of hospital post mortem examination protocols and practice.

1.4 Throughout the hospital post mortem examinations process, Manx Care has a designated individual or team:

a) as the point of contact for people who have been bereaved;

b) to ensure the completion of all appropriate forms; and

c) to co-ordinate communication between clinical staff and people who have been bereaved.

1.5 Manx Care uses data from hospital post mortem examinations to improve the service.

What does the standard mean for people who have been bereaved?
People who have been bereaved: - have access to information or support around post mortem examination and bereavement; - are assured that hospital post mortem service follow legislation and national guidance; and - have confidence that their feedback will be used to improve the service.
What does the standard mean for staff?
Staff have a knowledge of policies and procedures and an understanding of their roles and responsibilities in the hospital post mortem examination process.
What does the standard mean for the organisation?
Manx Care can demonstrate clear policies and procedures to ensure that hospital post mortem examinations are delivered in line with legislation and guidance, and are monitored and audited.
Practical examples of evidence of achievement: **(*NOTE: this list is not exhaustive*.)**
- Copies of locally agreed policies and procedures for hospital post mortem examinations, for example, infection control and authorisation processes; - Audit and monitoring of data, policy implementation and review; - Copies of completed pathology reports and medical records to demonstrate compliance with legislation and policies. - Organisational charts and contact details of local and national bereavement services;

- Copies of the nationally-agreed minimum dataset for hospital post mortem examination records[19];
- Data on organ/tissue retention and disposal recorded;
- Feedback on experience of the hospital post mortem examination process from people who have been bereaved and staff; and recording of how this is used for service improvement.

[19] Reference in Scottish Code - Check if relevant to IOM.

Standard 2: Authorisation process

Standard statement

Authorisation is obtained for all hospital post-mortem examinations in line with legislation and guidance.

Rationale

Authorisation for hospital post-mortem examination is a sensitive subject for both those requesting it and those granting it. Staff must understand the legal requirements for authorisation and the completion of any required authorisation forms[20].

The HTODA details the hierarchy of authorisation, including self-authorisation, and the role of relatives and nominated representatives[21]. Self-authorisation for hospital post-mortem examination can be given by individuals who wish to donate their brain or other organs for research and advancement in the understanding of disease. Research organisations receiving donations will work with the individual, relatives and pathologists to ensure wishes and preferences are documented.

Criteria

2.1 An authorisation form is completed following discussion with the authorising individual about the deceased's wishes and preferences.

2.2 Before the hospital post-mortem examination is undertaken, copies of the completed authorisation form, including self-authorisation, are:

a. given to the authorising individual or nominated representative;

b. given to the pathologist; and

c. retained in the deceased's medical record.

2.3 Copies of the completed authorisation form for hospital post-mortem examinations on embryos or foetuses should be retained in the mother's medical record.

2.4 Copies of the completed authorisation form for hospital post-mortem examinations on babies who have died should be retained in the baby's medical record.

2.5 Information about the hospital post-mortem examination and authorisation process is provided in an appropriate format to the authorising individual or people who have been bereaved.

[20] Reference in Scottish Code - check any relevance to IOM.
[21] Reference in Scottish Code - check any relevance to IOM.

What does the standard mean for people who have been bereaved?
People who have been bereaved are provided with information and support to make an informed decision about authorising a hospital post-mortem examination.
What does the standard mean for staff?
Staff: • understand their roles and responsibilities when communicating about the authorisation process and completing authorisation forms; and • ensure discussions with people who have been bereaved are conducted supportively and are accurately documented.
What does the standard mean for the organisation?
Manx Care undertakes regular monitoring of the authorisation process and records to provide assurance that authorisation takes place in line with legislation and guidance and that decisions are accurately documented.
Practical examples of evidence of achievement: **(*NOTE: this list is not exhaustive*.)**
- Copies of policies and procedures relating to the authorisation process, including procedure for refusal to authorise; - Copies of fully completed authorisation forms; - Results of audits of the authorisation process; - Information leaflets explaining the authorisation process; - Where there is feedback or complaints about the hospital post-mortem examination authorisation process from people who have been bereaved and from staff, this is used to improve services.

Standard 3: Dignity and respect for the deceased and people who have been bereaved

Standard statement

The deceased, and people who have been bereaved, are treated with dignity and respect, and in accordance with their wishes.

Rationale

The personal, spiritual, faith and cultural values and beliefs of the deceased and people who have been bereaved are to be respected. Care of the deceased is a continuation of clinical care and, as such, the deceased's wishes and those of people who have been bereaved are taken into account.

Criteria

3.5 The deceased and people who have been bereaved are treated with sensitivity and dignity, and their personal, spiritual, faith and cultural values, beliefs and wishes are respected.

3.2 People who have been bereaved are provided with:

a. information about the process and purpose of a hospital post-mortem examination;

b. information about the requirements of authorisation;

c. reasons for transportation;

d. information about the retention of organs for education and research;

e. an opportunity to speak with staff involved in the care of the deceased, including the pathologist, to discuss the hospital post-mortem examination and its finding;

f. a copy of the final hospital post-mortem examination report written in lay language within 30 working day of request; and

g. information or signposting to bereavement, spiritual, faith and cultural support available.

3.1 Staff who are involved in any aspect of the hospital post-mortem examination process are trained in conducting sensitive conversations, and have knowledge of spiritual, faith and cultural values and beliefs in accordance with any specific instructions of the deceased prior to death.

What does the standard mean for people who have been bereaved?
People who have been bereaved: • are informed about all aspects of the hospital post-mortem examinations and have the opportunity to discuss the deceased's and their own wishes and preferences; • are assured that the deceased are treated with dignity and respect; and • have access and signposting to bereavement support and further information on the hospital post-mortem examination process.
What does the standard mean for staff?
Staff: • treat the deceased with dignity and respect; • ensure that people who have been bereaved are fully involved, informed and supported during the hospital post-mortem examination process; and • understand their responsibilities to ensure communication with people who have been bereaved is effective and documented, where appropriate.
What does the standard mean for the organisation?
Manx Care has: • policies and procedures to support the personal, spiritual, faith and cultural values, beliefs and wishes of the deceased and people who have been bereaved; • information on the hospital post-mortem examination process; and referral pathways for bereavement and faith services.
Practical examples of evidence of achievement: **(*NOTE: this list is not exhaustive*.)**
• Access to support services such as healthcare chaplains, bereavement co-ordinators, translation service and bereavement support; • Information leaflets on hospital post-mortem examination, authorisation and bereavement; • How feedback has contributed to enhanced information and communication.

Standard 4: Pathology examination and reporting

Standard statement

The deceased, and people who have been bereaved, are treated with dignity and respect, and in accordance with their wishes.

Rationale

Hospital post-mortem examination, reporting and documentation requirements are clearly set out in legislation and guidance[22]. Hospital post-mortem examination reports are made available promptly to ensure discussion with relatives, GPs and clinical staff can take place as soon as possible.

There are circumstances in which completion and reporting of the hospital post-mortem examination will take longer due to the nature of the investigation, for example, neuropathy, cytogenetics, or if there is a risk of infection transmission to staff, for example, hepatitis B or Creutzfeldt Jakob disease[23]. Staff should inform people who are bereaved of any such delays whilst maintaining confidentiality of the deceased[24].

Criteria

4.1 Hospital post-mortem examinations, reporting and audit are carried out in line with the HTODA and guidance, for example, from the Royal College of Pathologists.

4.2 Protocols and procedures are in place to ensure correct identification of the deceased.

4.3 The requesting clinician accurately completes the relevant authorisation form.

4.4 The pathologist carrying out the hospital post-mortem examination is provided with:

a. a clinical summary, including the reason for a hospital post-mortem examination;

b. a copy of the authorisation form, which details the wishes of the deceased, people who have been bereaved or nominated representatives; and

c. timely access to the deceased's medical records.

4.5 The hospital post-mortem examination is carried out or supervised by a pathologist on the specialist register of the General Medical Council (GMC). Paediatrics, perinatal and neuropathology post-mortem examinations are carried out or supervised by a pathologist trained in these specific fields.

[22] Reference in Scottish Code - Check if relevant to IOM.
[23] Reference in Scottish Code - Check if relevant to IOM.
[24] Reference in Scottish Code - Check if relevant to IOM.

4.6 A hospital post-mortem examination is carried out by the facility conducting the hospital post-mortem examination within 3 working days of receipt of the completed authorisation form.

4.7 On completion of the hospital post-mortem examination and associated tests, the pathologist provides the requesting clinician and other staff with:

a. an initial report within 3 working days; and

b. a final report within 30 working days.

4.8 Where neuropathy, paediatric pathology and some specialist tests are required, the timescale for completion and reporting on hospital post-mortem examinations will be extended.

4.9 Where the hospital post-mortem examination or reports are necessarily delayed, this is documented in the medical and pathology records, and timeously communicated to staff and the people who have been bereaved.

4.1 A description of the histology, cytology and any other samples taken and the results are included in the final hospital post-mortem examination report.

What does the standard mean for people who have been bereaved?

People who have been bereaved are assured that:

- the hospital post-mortem examination will be carried out as soon as possible after death;
- the deceased will be treated with respect and dignity;
- the hospital post-mortem examination report, if requested, will be presented in lay language; and
- any delays in the hospital post-mortem examination or reporting are fully explained and discussed confidentially.

What does the standard mean for staff?

Staff:

- are trained to carry out the hospital post-mortem examination;
- understand their roles and responsibilities when communicating about the authorisation process and completing authorisation forms and the initial and final hospital post-mortem examination reports; and
- ensure discussions with people who have been bereaved and colleagues are accurately documented and timeous.

What does the standard mean for the organisation?
Manx Care has locally-agreed procedures for carrying out a hospital-post mortem examination.
Practical examples of evidence of achievement: **(*NOTE: this list is not exhaustive*.)**
• Copies of locally-agreed policies for hospital post-mortem examination. • Audit of medical and pathology records to monitor communication and documentation relating to hospital post-mortem examinations. • Audit of reporting times for initial and final hospital post-mortem examination reports. • Copies of initial and final hospital post-mortem examination reports to clinicians and other staff, for example, midwives and GPs.

Standard 5: Removal, retention, storage, handling, transportation and disposal of the body, embryos, foetuses. tissue blocks, glass slides or organs

Standard statement

The deceased, and people who have been bereaved, are treated with dignity and respect, and in accordance with their wishes.

Rationale

People who are bereaved are assured that all aspects of the hospital post-mortem examination process are undertaken with sensitivity and respect for the deceased (refer to Standard 3). Communication, particularly around removal, retention, transportation and disposal, is paramount and wishes for disposal are discussed fully.

Legislation and guidance provide the framework for the removal, retention, storage, transportation and disposal of the body, embryos, foetuses[25], tissue blocks, glass slides and organs[26]. Tissue blocks and glass slides are retained as part of the deceased's medical records[27].

Criteria

5.1 Manx Care has local policies and procedures in place for the removal retention, storage, handling, transportation and disposal of the body, embryos, foetuses, tissue blocks, glass slides or organs, which describe:

a. staff roles and responsibilities;

b. communication with people who have been bereaved and staff, including the reason for referral for specialist investigations; and

c. maintenance and audit of records relating to transportation, including details of dates, and the sending and receiving departments.

5.2 Records relating to the removal, retention, storage, handling, transportation and disposal of tissue or organs are maintained and audited in line with legislation and national guidance.

5.3 Tissue blocks and glass slides are retained as part of the deceased's medical record and in-line with retention requirements for the medical records of which they form a part.

5.4 For diagnostic cases, organs are retained for a maximum of 3 months after the final hospital post-mortem examination report is completed. Any delays are documented in the medical and pathology records.

[25] Reference in Scottish Code - Check if relevant to IOM.
[26] Reference in Scottish Code - Check if relevant to IOM.
[27] Reference in Scottish Code - Check if relevant to IOM.

5.5 The wishes of the deceased and people who have been bereaved are documented and include all aspects of the hospital post-mortem examination and disposal of the body, embryos, foetuses or organs.

5.6 When responsibility for organ disposal is delegated to the pathology department, the arrangements are carried out and documented in line with local protocols.

4.8 Manx Care has protocols in place which set out local arrangements for the disposal of embryos and foetuses, and these are documented in the medical and pathology records.

What does the standard mean for people who have been bereaved?
People who have been bereaved can be reassured that: • staff will fully discuss with them their preferences relating to removal, retention, storage, handling, transportation and disposal; • their decisions are fully communicated to staff and accurately documented; and • the procedures are carried out in line with legislation and guidance.
What does the standard mean for staff?
Staff have a knowledge of legislation, policies and procedures, and an understanding of their roles and responsibilities for the removal, retention, storage, transportation and disposal of the body, embryos, foetuses, tissue blocks, glass slides or organs.
What does the standard mean for the organisation?
Manx Care can demonstrate: • clear policies and procedures to ensure that the removal, retention, storage, handling, transportation and disposal of the body, embryos, foetuses, tissue blocks, glass slides or organs are carried out in line with legislation and guidance; and • those policies and procedures are monitored and audited for quality improvement.
Practical examples of evidence of achievement: **(*NOTE: this list is not exhaustive*.)**
• Copies of policies and procedures for removal, retention, storage, handling, transportation and disposal of the body, embryos, foetuses, tissue blocks, glass slides or organs. • Audit reports detailing, for example, how tissue blocks and glass slides are stored. • Agreed audit and monitoring processes of policy implementation and review for quality improvement.

- Copies of completed medical and pathology records to demonstrate compliance with policies.
- Copies of locally-agreed minimum data for hospital post-mortem examination records, for example, organ retention.

Standard 6: Education and training

Standard statement

The deceased, and people who have been bereaved, are treated with dignity and respect, and in accordance with their wishes.

Rationale

A range of staff, including anatomical pathology technologists, clinical, laboratory and porters are involved in the removal, retention, storage, handling, transportation and disposal of deceased individuals.

Training will cover the relevant procedures and legislation associated with, for example, the authorisation, process, organ retention and disposal, reasons for hospital post-mortem examination and referral to the Coroner of Inquests. Staff are also supported in developing communication skills[28].

Criteria

6.1 Manx Care implements an education programme, with input from pathologists for medical and nursing staff which includes:

a. reasons for, and aims of, hospital post-mortem examination and what it entails;

b. the authorisation process, including accurate completion of authorisation forms;

c. the death certification review system and issuing the medical certificate of cause of death;

d. communication skills, including explaining the content of the medical certificate of cause of death and authorisation;

e. understanding personal, spiritual, faith and cultural issues;

f. when, and how, to refer to the Coroner of Inquests; and

g. the ethical and medico-legal framework in which hospital post-mortem examination occurs.

6.2 The education and training needs of specialist practitioners, for example anatomical pathology technologists and pathologists, are aligned to professional development frameworks,

6.3 Staff are knowledgeable and trained in infection control procedures, including handling the deceased, notification of infection hazards, and the relevant legislation and regulations.

[28] Reference in Scottish Code - Check if relevant to IOM.

What does the standard mean for people who have been bereaved?
People who have been bereaved are reassured that staff are knowledgeable, skilled and appropriately trained to deliver a safe, effective and person-centred hospital post-mortem examination service.
What does the standard mean for staff?
Staff are supported to undertake training and educational activities to maintain their knowledge of hospital post-mortem examination including communication, legislative frameworks and professional competencies.
What does the standard mean for the organisation?
Manx Care has a systematic approach to identifying the education and training needs to staff involved in authorisation and hospital post-mortem examination appropriate to their roles and responsibilities.
Practical examples of evidence of achievement: **(*NOTE: this list is not exhaustive*.)**
• Assessment of education and training requirements, for example, training needs analysis. • Supervision and mentoring programme. • Issues and incidents from hospital post-mortem examinations used in learning and education. • Copies of educational programmes. • Use of national information and educational tools for staff, for example, support around death, bereavement following pregnancy loss and the death of a baby, and LearnPro modules[29].

[29] Reference in Scottish Code - Check if relevant to IOM.

Glossary

To be added