CODE C

ANATOMICAL EXAMINATION

Public Health
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HUMAN TISSUE AND ORGAN DONATION ACT 2021

Code C: Anatomical Examination

Contents

Introduction to Cabinet Office's Code 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;

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

[1] See glossary.

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

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

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

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.

7B. For the purposes of this Code and the anatomy sector, these principles translate into actions which ensure that potential donors are given the information they need to make the best decisions requiring their consent.

It is also incumbent on regulated organisations to manage human material in accordance with expressed wishes, removing, storing, using and disposing material properly and respectfully.

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 Anatomy Code

9. Human bodies and body parts are used to teach students and to train surgeons and other healthcare professionals. PH, on behalf of CO, licenses and inspects organisations that carry out these activities in the Isle of Man. This is done to provide assurances to the public that bodies or tissue from the deceased are given with proper consent, and are managed appropriately. PH also provide advice and guidance to people whose work is covered by our regulatory framework.

Scope of this Code

10. This Code is primarily intended to guide those people whose work PH regulate, primarily through licensing and inspections, but it may be useful to members of the public, particularly potential donors and their relatives.

11. In addition to providing information on statutory and regulatory requirements, it also makes reference to the licensing Standards that PH-licensed organisations are expected to meet.

12. 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 CO's functions and informs the content of this and the other Codes.

Offences under the HTODA

13. The HTODA sets out a number of offences, for which the maximum penalty is three years imprisonment and/or a fine. In relation to the Anatomy sector, the offences are as set out below.

14. Section 12 of the HTODA makes it an offence to:

    a) remove organ or tissue from the deceased; and

    b) to store and use bodies, organs or tissue (i.e. material) for a purpose set out in Schedule 1 of the HTODA (a scheduled purpose),

    including when determining the cause of death where this is not by post mortem required by the Coroner, 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 do an activity, or that Section 1 of the HTODA does not apply.

15. Section 20(1) and (2) of the HTODA prohibit the following activities, except under the authority of a licence (the list below list is not exhaustive):

    a. the carrying out of an anatomical examination;

    b. the removal of organs or tissue from the body of a deceased person for use for scheduled purposes other than transplantation;

    c. the storage of an anatomical specimen; and

    d. the storage of the body of a deceased person, or organs or tissue which has come from a human body, for use for scheduled purposes.

16. To undertake an activity listed in section 20(2) without the authority of a licence from PH is an offence under section 24.

17. Sections 29 and 30 of the HTODA contain special provisions for anatomical specimens (and former anatomical specimens) to be lawfully held on unlicensed premises in certain circumstances and these are covered later in this Code.

Structure and navigation

18. As there are specific consent requirements for anatomical examination, the first part of this Code focuses on these.

19. The Code then sets out the relevant requirements and expectations for establishments licensed in the Anatomy sector, supported by good practice examples.

20. At the end of this Code, there is a section on the PH licensing Standards.

21. 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.

Providing information to potential donors

22. It is important that a person wishing to donate their body for anatomical examination is given all the information necessary to make an informed decision. This information should be made available in a variety of formats (electronic, written and oral) so that donors may choose which is most appropriate for them. Guidance may be provided for potential donors via the gov.im website.

23. Anatomy establishments should have a bequeathal booklet and body donation consent form.

Obtaining appropriate consent

24. Under the HTODA, appropriate consent for anatomical examination can only be given by individuals who choose to donate their body; consent cannot be given by someone else.

25. Documented and valid consent for anatomical examination given before XXXXX is treated as appropriate consent under the HTODA.

26. For consent for body donation to be valid under the HTODA, it must be in writing and:

    a. signed by the donor in the presence of at least one witness who attests their signature; or

    b. signed by a person at the direction of the donor, in their presence and in the presence of at least one witness who attests that person's signature.

26A. The HTODA accepts that it may not always be possible to obtain written consent from the individual who has chosen to donate their body or part of their body for anatomical examination, for example when a person with sufficient mental capacity is physically unable to write. In these circumstances, PH advises that:

    a. the potential donor has sufficient mental capacity to make the decision to donate their body for anatomical examination and is able to indicate their wish verbally or physically;

b. the person should sign their own name, state that they have signed at the direction of the donor and explain the circumstances of this direction;

c. the form should then be signed by the witness before being submitted to the receiving institution.

This procedure must occur prior to the donor's death. The consent form cannot be signed by the third party after death has occurred.

Example of good practice

A widower had a stroke that left him unable to communicate in any form, including in writing. Many years ago, when he was well, he expressed an interest in donating his body for medical teaching after his death but did not take the matter further. Now the man is dying and his daughter wants her father's wishes to be complied with. Given the lack of documented consent and the inability to assess mental capacity, there is no way to confirm that the man wishes to donate his body for anatomical examination. Therefore, the offer of donation must be declined by the anatomy facility.

27. Anyone wishing to donate their body, or part of their body, for anatomical examination should preferably use a consent form from the facility of their choice, which should be kept as part of the donation records.

28. Alternatively, individuals may also indicate their choice to donate their bodies for anatomical examination in their will. In this case, an individual should be encouraged to complete and return a consent form from the facility of their choice and to insert a copy in their will. The potential body donor should be made aware that, although a consent form does not have to be used in their will, to avoid confusion the wording of their consent should resemble the wording on the consent form provided by the establishment to which they wish to donate their body.

29. Medical school staff are sometimes faced with the challenge of deciding whether the consent given by potential donors, sometimes many years before their death, is valid if it contains wording inconsistent with terms used in the HTODA.

30. 'Anatomical examination' is not a term commonly used by the general public, and therefore it may not be used in written consent expressed in personal letters or wills. This means that medical schools can be put in a difficult position of deciding whether consent is valid or not when they receive written consent documents which use different terminology, such as 'use for medical research' or 'medical science'. Use of human tissue in research or training are purposes listed separately to 'anatomical examination' in the HTODA and therefore consent using these terms may raise issues about whether the donor intended their body to be used only in research projects or in training, rather than to teach anatomy through dissection. A donation may be declined in cases where the terminology used in the written consent is not clear.

31. When written consent includes terminology other than 'anatomical examination', and relatives or nominated representatives can confirm and will put in writing that use for the scheduled purpose of anatomical examination was what the donor had intended, then it is reasonable to accept the body for that purpose. Establishments should not accept donations for anatomical examination where there are factors in the form of the written consent itself which would appear to rule out teaching, studying or researching into the structure of the human body. Where there are no relatives or nominated representatives, or they were unaware of the donor's wishes, or hold

conflicting opinions and therefore cannot provide reliable clarification of the donor's intent, the consent remains ambiguous and establishments are advised to decline the donation.

32. It is essential that, where establishment staff have had to take a pragmatic and evidence-based decision, adequate records to demonstrate the rationale behind the decision are kept.

33. Where the validity of the consent to anatomical examination is questionable, and this guidance does not provide all the necessary clarification, further information and advice may be requested from PH.

34. Under the HTODA, appropriate consent is not needed for removal, storage and use of material from a deceased body for anatomical examination, if at least 100 years have elapsed since the date of the person's death.

34A. Appropriate consent is also not needed if the body has been imported (where that body was not exported with the intention to re-import to the Island); however the HTODA makes consent the fundamental principle underpinning the lawful storage and use of human tissue and so PH considers it good practice to ensure mechanisms are in place in the source country for obtaining consent.

35. The import and export of bodies or body parts is discussed in paragraphs 62-77 of this Code.

36. Omit

37. Storing and use of a body for anatomical examination is lawful provided that there is appropriate consent.

38. Omit.

39. Omit.

40. Omit.

Care of cadaveric material

41. During anatomical examination and storage, all parts of the body should be treated with due respect and consideration.

Example of good practice

A university anatomy establishment provides teaching to hundreds of healthcare students each year, some of whom attend from other universities.

The Designated Individual (DI) wants to ensure, to the best of their ability, that the dignity of deceased people is upheld. The DI acknowledges that physical supervision of all students at all times would be impossible but wants to put effective safeguards in place.

After thorough discussions with the establishment's staff, the DI puts a number of measures in place, including:

a) a review of the security of the premises;

b) a registration system, utilising a signing-in book so that the DI and other persons working under the PH-licence are aware of who is in the establishment at any given time. The reason for the visit should be recorded in the signing-in book, along with the name of the person under whose supervision the visitor will be;

c) revising the local Code of Conduct to reflect the requirements of the HTODA and this Code of Practice on Anatomical examination produced by PH;

d) a declaration to be signed by all relevant visitors to confirm that they have read and understood the local Code of Conduct;

e) prominent signs relating to important aspects of the local Code of Conduct.

The making and displaying of images

42. The making and displaying of images (including photographs, films and electronic images) falls outside the scope of the HTODA. However, PH requires DIs to put systems in place to ensure suitable practices are carried out.

43. Guidance on using visual and audio recordings in these instances may be found via the gov.im website.

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

Transfer or loan of cadaveric material

45. Omit.

46. Omit.

47. Omit.

48. Omit.

49. Omit.

50. Omit.

51. Omit.

52. Omit.

53. Omit.

54. Omit.

Documentation and record keeping

55. All places where anatomical examination is carried out should keep records in a permanent form for each body or body part in its possession (or in the possession of any other person authorised by the DI to hold the anatomical specimen). These records should be held on the premises where the donated body was first received, and on any other premises to which the body or body parts have been moved.

56. Records to support traceability are essential, particularly where material is difficult to label.

> **Example of good practice**
>
> Where plastination of specimens takes place, labelling may not be practically possible during the plastination process and so the co-plastination of parts that are indistinguishable from each other must be avoided, such as two normal hearts. A detailed record of each of the parts must be kept in a manner which allows full traceability of each part at every stage.

> **Example of good practice**
>
> If it is difficult to label small bones, establishments need to consider how they can ensure traceability, such as by colour-coding catalogued collections.

57. It has been concluded that records relating to body parts retained after anatomical examinations should be held on the premises in which the examination of the original anatomical specimen took place, and on any other premises to which the parts have been moved.

58. All records must be available for inspection and review.

Charging

59. Charges may be applied to cover the costs of transporting and embalming bodies and of preparing specimens for use at other establishments. These charges should fairly reflect the costs involved.

60. Donors should be told if their samples will or could be used for research involving the commercial sector. They should be given appropriate information on the range of activities and researchers which may be involved, and whether these include commercial establishments.

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

Import and export of bodies or body parts

Import

62. Bodies and body parts are imported into the Island for use in education or training relating to human health or for anatomical examination. The import and export of bodies, organs and tissue is not licensable under the HTODA. However, the storage and use of bodies, organ or tissue for education or training relating to human health or for anatomical examination is licensable.

63. The geographical scope of "import" and "export" according to the HTODA is as follows:

    a) "import" means import into the Island excluding a body, an organ or tissue which has already been exported from the Island with the expectation that it be re-imported into the Island[4];

    b) "export" means export from the Island.

64. Imported material should be obtained, used, handled, stored, transported and disposed of in accordance with the consent which has been obtained. Importers should satisfy themselves and be able to demonstrate to PH that, in the countries from which they seek to import tissue, the seeking of consent for the purpose to which the tissue is subsequently put is part of the process by which the material is obtained.

65. All persons or organisations wishing to import material (i.e. human bodies, body parts, organs and tissue) into the Isle of Man, should be able to demonstrate that either –

    a) the purposes for which they wish to import such material cannot be adequately met by comparable material available from sources within the Isle of Man; or

    b) there is for a particular purpose which justifies import of that material.

[4] For example, when a person has died on the Island, the export of the body off-Island for anatomical examination in a teaching hospital, and subsequent re-importation of the body to the Island for burial.

65A. Importers should assure themselves of the integrity of the material and that, as a minimum, it has been sourced with appropriate consent. They should be able to satisfy themselves and document the need for importing in terms of accessibility, quality, timeliness of supply, risk of infection, quality of service, cost effectiveness or scientific or research need. Such documentation should be available for inspection by PH.

66. The HTODA makes consent the fundamental principle underpinning the lawful storage and use of human bodies, body parts and tissue from the living or the deceased, for the purposes specified in the HTODA. The consent provisions of the HTODA do not apply, however, if the material has been imported (excluding where it was planned that an export would be re-imported). Nonetheless, PH considers it good practice to ensure mechanisms are in place in the source country for obtaining consent.

67. The HTODA makes it clear that bodies, organs and tissue are not to be exported and then re-imported simply to avoid the Act's consent requirements.

68. The import of fresh frozen bodies and body parts for the scheduled purpose of 'education and training relating to human health' is a common practice for some HTA-licensed establishments in the United Kingdom. Fresh frozen material is primarily used for surgical training. The benefit of using this material is that it provides healthcare professionals with opportunities to practice life-like surgical techniques and procedures without posing any risks to patients.

69. There are also potential health and safety risks associated with fresh frozen cadaveric material. As the suitability of donors from abroad has not been directly assessed by the DI, importing establishments should ensure that donors who have tested positive for HIV disease, hepatitis B, hepatitis C, tuberculosis, a transmissible spongiform encephalopathy (such as CreutzfeldtJakob Disease) and meningitis have been excluded from donation by the supplier in the source country. Donor testing should have been carried out by an accredited or licensed laboratory and all the donor information should have been reviewed and signed off before any specimen is considered available for release.

70. PH would expect a donor sheet to accompany any imported cadaveric material, confirming the low-risk status of the donor and including testing results.

71. PH expects DIs to assure themselves that all imported specimens are procured, wrapped and shipped appropriately to prevent accidental exposure and conform to the international standards for the transport of hazardous clinical material[5].

72. As fresh frozen cadaveric material will not have been subject to any chemical preservation, such as embalming, PH also expects establishments to adhere to two guidance documents published by the Health and Safety Executive (HSE):

    a) the first document, 'Controlling the risks of infection at work from human remains', concerns the handling of cadaveric material. Although it was published primarily for those in the funeral profession, it provides useful guidance on precautionary measures to be taken by anyone who has contact with human remains, and in particular deals with the risk of infection, including the sources, transmission and host of infection;

[5] Detailed requirements for the carriage of 'Dangerous Goods' are set out in the Technical Instructions approved and published by the International Civil Aviation Organisation (ICAO).

b) the second piece of HSE guidance is entitled 'Safe working and the prevention of infection in the mortuary and post mortem room'. Although it was published primarily for those working in a post-mortem examination room, it provides useful guidance on the handling, storage and examination of bodies and pathological specimens, including safe working practices, health surveillance and risk assessment.

73. If any specific requests were made by the deceased regarding disposal when consent was obtained, such requests must be carried out. This may include, for example, the return of material to the country of origin.

Export

74. Material to be exported should be obtained, used, handled, stored, transported and disposed of, in accordance with the consent which has been given, with due regard for safety considerations and with the dignity and respect accorded to human bodies, body parts and tissue provided for in the Codes of Practice under the HTODA. This includes providing donors with adequate information when obtaining consent, to the effect that their material may be exported for use abroad.

75. Documented agreements should be in place to ensure that human bodies, body parts and tissue to be exported from the Island are used in accordance with the consent which has been obtained. Material should be handled, stored, transported and disposed of, in a manner consistent with safety considerations, and with the dignity and respect accorded to human bodies, body parts and tissue provided for in the Codes of Practice under the HTODA.

76. Although the HTODA does not provide any prohibition or restriction on the import or export of human material, imports and exports from outside of England, Wales and Scotland must normally be declared to Isle of Man Customs and Excise.

Disposal

77. Processes should be in place to inform individuals, or their relatives, how bodies and tissue will normally be disposed of after use. Establishments should ensure that their employees are given the necessary training and support to help them identify and meet the expected range of needs and wishes of donors and their relatives.

78. Attitudes towards disposal may vary widely among cultures and religions. Staff should be sensitive to this, being aware that choices are for the individual or relative to make. Donors may wish to discuss the final disposition of their remains with relatives or others before making their choice.

79. Staff should be familiar with the establishment's arrangements, including what is available locally, and the options available to those wanting to make their own arrangements to dispose of tissue. Where appropriate, such information should be available in writing for people to take away with them. Staff should also be prepared to discuss who will be responsible for any associated costs.

80. All establishments should give particular consideration to the needs of individuals and families whose first language is not English. Any difficulties in communicating with the person concerned (for example because of language, literacy or hearing difficulties), and an explanation of how

these difficulties were overcome (such as through an independent translator), should be recorded.

It is good practice to retain tissue removed from the cadaver during dissection for disposal along with the body and 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.

81. 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.

    While the clinical waste route should be used as far as possible, 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.

82. 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.

83. 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.

84. 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

85. 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.

86. 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.

87. Omit.

PH Licensing Standards

88. In order to obtain a PH licence, the applicant must demonstrate that they and the relevant premises are suitable. PH will assess whether they can meet a number of standards (the general core Licencing Standards or the Post Mortem Licensing Standards as applicable), which were developed in consultation with representatives from the regulated sectors. These relate to the consent provisions of the HTODA and the regulatory requirements for governance and quality systems, traceability and premises. They reinforce the HTODA's intention that:

    a. consent is paramount in relation to activities involving the removal, storage and use of human tissue

    b. bodies of the deceased and organs and tissue removed from bodies are treated with respect

    c. the dignity of the person, whether living or deceased, is maintained.

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

90. 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 and that the conditions of the licence are complied with. By ensuring that the establishment is meeting PH's licensing Standards, the DI will be meeting their statutory responsibility.

91. 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 PH's licensing Standards (the general core Licencing Standards or the Post Mortem Licensing Standards as applicable), which reflect the guiding principles set out in Code A and provide the operational detail of how establishments should meet the requirements of the HTODA and the Codes of Practice.

92. PH's general core licensing Standards are grouped under four headings: Consent (C); Governance and quality systems (GQ); Traceability (T); and Premises, facilities and equipment (PFE). Under each of these headings, there are overarching statements, from which the Standards flow.

Consent (C)

93. Establishments meeting the consent standards will be able to demonstrate that their processes for seeking and gaining consent comply with the HTODA and the HTODA Codes of Practice. The Standards also cover the documentation and information used to support the establishment's

consent procedures, and ensure that staff involved in seeking consent are suitably trained and equipped for the task.

Governance and quality systems (GQ)

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

Traceability (T)

95. Establishments meeting the Traceability standards will be able to demonstrate full traceability for the human material for which they are responsible, from receipt to final disposal/disposition. CO inspectors will test this through traceability audits carried out on site and PH expect establishments to take a pro-active approach to assuring themselves of effective traceability throughout the lifetime of their licence. In addition, as the final traceability step, they will have established disposal arrangements which are in accordance with CO's Codes of Practice.

Premises, facilities and equipment (PFE)

96. Establishments meeting these Premises, Facilities and Equipment standards will be able to demonstrate that their premises and facilities are appropriate for their licensed activities and are safe, secure and clean. In addition, establishments will have systems for on-going monitoring to ensure all key quality specifications are maintained. The PFE Standards also cover equipment, ensuring that it is appropriate, and suitably maintained, and that it does not present an impediment to the staff using it.

97. The licensing standards which will be applicable to each sector from [insert date] and are included as an Annex to each of the relevant sector Codes on the website www.gov.im. The Standards are supported by comprehensive guidance notes.

Annex A

Legislative background and context

To be added at a later date.

Annex B

PH licensing Standards: Anatomy sector

Consent Standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's Codes of Practice
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice. b) Consent forms are available to those using or releasing organs or tissue for a scheduled purpose. c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice. d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HTODA and the HTODA's Codes of Practice. e) Language translations are available when appropriate. f) Information is available in formats appropriate to the situation.
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent
a) There is suitable training and support of staff involved in seeking consent. b) Records demonstrate up-to-date staff training. c) Competency is assessed and maintained.

Governance and quality system Standards
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities. b) There is a document control system. c) There are change control mechanisms for the implementation of new operational procedures. d) Matters relating to HTA-licensable activities are discussed at regular governance meetings, involving establishment staff. e) There is a system for managing complaints.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits covering licensable activities. b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
a) Qualifications of staff and all training are recorded; records showing attendance at training. b) There are documented induction training programmes for new staff. c) Training provisions include those for visiting staff. d) Staff have appraisals and personal development plans.

GQ4 There is a systematic and planned approach to the management of records
a) There are suitable systems for the creation, review, amendment, retention and destruction of records. b) There are provisions for back-up/recovery in the event of loss of records. c) Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).
GQ5 There are systems to ensure that all adverse events are investigated promptly
a) Staff are instructed in how to use incident reporting systems. b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice. b) Risk assessments are reviewed regularly. c) Staff can access risk assessments and are made aware of risks during training.

Traceability

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

a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.

b) A register of donated material, and the associated products where relevant, is maintained.

c) An audit trail is maintained, which includes details of when and where the bodies or tissue were acquired, the consent obtained, the uses to which any material was put, when and where the material was transferred, and to whom.

d) A system is in place to ensure that traceability of organs and tissue is maintained during transport.

e) Records of transportation and delivery are kept.

f) Records of any agreements with courier or transport companies are kept.

g) Records of any agreements with recipients of organs and tissue are kept.

T2 Bodies and human tissue are disposed of in an appropriate manner

a) Disposal is carried out in accordance with the HTA's Codes of Practice.

b) The date, reason for disposal and the method used are documented.

Premises, facilities and equipment standards

PFE1 The premises are secure and fit for purpose

a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose.

b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained.

c) There are documented cleaning and decontamination procedures.

PFE2 There are appropriate facilities for the storage of bodies and human tissue
a) There is sufficient storage capacity. b) Where relevant, storage arrangements ensure the dignity of the deceased. c) Storage conditions are monitored, recorded and acted on when required. d) There are documented contingency plans in place in case of failure in storage area.
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored
a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept. b) Users have access to instructions for equipment and are aware of how to report an equipment problem. c) Staff are provided with suitable personal protective equipment.

Glossary

To be added at a later date.