Code D

PUBLIC DISPLAY

Public Health
Cabinet Office | Cronk Coar, Noble's Hospital, Strang, Douglas, IM4 4RJ

HUMAN TISSUE AND ORGAN DONATION ACT 2021

Code D: Public Display

Contents

Introduction to the Cabinet Office 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 tissue or organ 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

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

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

3 (section 68: supplementary) of the HTODA. Separate guidance in the form of frequently asked questions is available on the gov.im website.[4]

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 public display sector, complying with these principles this means that bodies of the deceased, body parts or other human specimens should be

a) treated with respect in an environment that is safe and secure;

b) that the dignity of the deceased should be maintained at all times whilst they are being stored or are on display; and

c) any display of bodies of the deceased, body parts or other human specimens is in line with the consent given.

For specimens that are imported, it means that the country of origin should have a legal and ethical framework which includes consent and protects the interests of the deceased and their families.

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.

[4] Based upon: https://www.hta.gov.uk/guidance-professionals/regulated-sectors/research/analysis-dna-under-ht-act

Introduction to the Public Display Code

9. The display of human bodies, organs and tissue is not new to the Isle of Man (IOM), but it has primarily been carried out by establishments involved in medical education, medical training and public museums.

   The HTODA makes consent a legal requirement for the storage and display of human material where it is less than 100 years since the person's death. It also makes these activities subject to licensing by PH, where the material is from the body of a deceased person.

   This Code explains the consent and licensing requirements of the HTODA as they apply to public display, and includes practical advice to those involved in the public display of human material, whether on a permanent or temporary basis.

10. The activity of public display was not fully set out statute before the HTODA, although some controls were provided by the Human Tissue Act 1986. However, the Human Tissue Act 1986 did not set out general restrictions on the display of human bodies, organs or tissue.

11. A key principle underpinning the HTODA is that all human bodies and materials of human origin within its scope should be treated with respect and dignity. In relation to the public display of human material, this principle extends both to those showing the material, and to those viewing it.

12. Ethical issues raised by the display of human materials are explored in guidance provided via the gov.im website, which should be read by anyone involved in the display of human material. This acknowledges their unique status within museum collections and the special responsibilities placed on those who acquire and display them. The guidance referred to via the gov.im website may have a longer historical reach and deal with material collected before the period covered by the HTODA[5]. However, such guidance covers some areas of museum activity which are also affected by the HTODA, and CO advises anyone involved in the display of human material to refer to this guidance.

13. PH-licensed establishments in the public display sector form a diverse group. Examples of this may include:

    a. national museums that maintain largely static, permanent collections;

    b. charitable foundations dedicated to achieving improvements in human and animal health; and

    c. small specialist museums and organisations that stage temporary exhibitions.

14. The public display of human material and public engagement with human specimens in the areas of medicine and the humanities are becoming increasingly popular. As the interest of the public grows, museums are finding new roles for their collections and exploring novel ways of engaging with the public. This Code seeks to ensure that all those involved in activities that involve the public display of human material are aware of the statutory and regulatory requirements, as well as the guiding principles of consent, dignity, quality and honesty and openness, which should underpin the conduct of these activities.

15. CO recognises that many museums holding permanent collections are accredited under the Arts Council England's Museum Accreditation Scheme. These establishments must make sure that they meet all relevant legal, ethical and safety requirements, and have well established collections management procedures. The Accreditation Scheme includes standards on care

[5] i.e. for persons who died over 100 years ago.

and conservation, which satisfy many of the CO's requirements relating to the public display of human material. These establishments are also subject to the Museum Association's code of ethics and associated guidance.

Scope of this Code

16. Under the HTODA, public display of the body, tissue or organ of a deceased person and tissue or organ from a living person is a scheduled purpose for which consent is required. In some cases, it is also a licensable activity. Detailed information about scheduled purposes and licensable activities is explained in Annexes B and C.

17. The HTODA does not contain a definition of public display. CO considers public display to be 'an exhibition or display in which the body of a person, or tissue which has come from the body of a person, is used for the purpose of being exposed to view by the public'.

18. Public display may mean many things and the Code includes examples which illustrate situations that are, or are not, considered to be display to the public. In broad terms, it should be taken to mean events that are open to the public, whether by ticket sale or free access, regardless of the location and purpose of the venue and whether temporary or permanent. It includes static installations or exhibitions, as well as performance art or theatrical productions.

19. The HTODA includes hair and nails from the body of a deceased person within the scope of its definition of tissue, but not hair and nails from the body of a living person. Human material that has been modified in some way, or that is bound up with non-human materials, is also within scope, as are human body fluids or soft tissue used, for example, in the creation of an art work. This includes human cells used in the making of 'bioart'.

20. Throughout this guidance, examples are given to help establishments determine whether or not their activities fall within the remit of the HTODA.

21. The legal requirements of the HTODA and the guidance given in this Code do not apply in the case of bodies, or tissue or organs from such bodies, where:

    a. the person died before the HTODA came into force on [insert date here]; and

    b. at least 100 years have elapsed since the date of the person's death.

22. Nor do they apply to display for the purposes of:

    a. enabling people to pay their final respects to the deceased;

    b. display which is incidental to the deceased's funeral; or

    c. the display of bodies or tissue or organs displayed in a place of public religious worship and used for the purposes of religious worship or contemplation if there is a connection between the public display of the body or tissue or organ to that religious worship or contemplation.

23. The display of photographic or electronic images falls outside the scope of the HTODA. Therefore, this Code does not apply to broadcast or printed images.

    Guidance on the display of such images may be found via the gov.im website. Further guidance on images is provided in paragraphs 58-60.

24. *Omitted.*

Offences under the HTODA

25. The HTODA sets out a number of offences, for which the maximum penalty could be up to three years imprisonment and/or a fine. In relation to the Public Display sector, the offences are as set out below.

26. Section 12 (prohibition of activities without consent etc.) of the HTODA, along with other offences, makes it an offence to:

    a. remove, store or use tissue or organs from the deceased; or

    b. to store or use bodies for a purpose set out in section 7(1), (2) and (3) (authorisation of activities for schedule purposes),

    including when 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 other purpose.

    Section 12 of the HTODA also makes it an offence to falsely represent that there is appropriate consent to undertake an activity to which subsection (1), (2) or (3) of section 7 of the HTODA applies.

27. Section 20 (licensing requirements) of the HTODA prohibits the following activities relating to public display, except under the authority of a licence:

    a. the storage of the body of a deceased person, or a tissue or organ which has come from a deceased person, for use for scheduled purposes (which includes public display);

    b. the removal of a tissue or organ anfrom the body of a deceased person, for the purpose of public display; and

    c. the use of the body of a deceased person, or tissue or organ which has come from the body of a deceased person, for the purpose of public display.

28. To undertake an activity to which section 20 of the HTODA applies without the authority of a licence from PH is an offence under section 24 (breach of licence requirement).

29. It is not an offence to display tissue, tissue samples, organs, hair or nails from a living person on unlicensed premises, even if the person has since died[6].

30. However, it is an offence to display controlled material to the public on unlicensed premises, unless the display is to enable:

    a. people to pay their final respects to the deceased or incidental to a funeral; or

    b. the sale of controlled material by persons designated by the Department to lawfully engage in such activities.

31. Finally, it is not an offence to exhibit or broadcast images of the body of a deceased person or tissue or organs from the deceased.

Structure and navigation

32. The main body of the Code is divided into two main sections: consent and licensing. In each section, the requirements of the HTODA and any exemptions are explained. Thereafter,

[6]It may be helpful to have records indicating the origin of such materials to aid compliance with the requirements of the HTODA.

separate sections provide further guidance on particular issues relating to the public display of human material, such as the import and disposal of material.

33. Annex B explains the difference between licensable activities and scheduled purposes. This distinction has sometimes caused confusion.

34. Annex C provides flowcharts which summarise the licensing and consent requirements for public display of human tissue or organs from the living and the deceased.

35. A glossary is available at the end of the document. You can view, download and print copies of all the Codes from the gov.im website.

Consent

36. The HTODA and common law make consent a legal requirement for the removal, storage and use of tissue and organs which have come from a human body for scheduled purposes. Scheduled purposes are listed in Schedule 1 of the HTODA and include public display. Therefore, anyone removing, storing or using tissue or organs for the purpose of public display, whether from a deceased person or from a living person, must be satisfied that consent is in place.

37. The consent requirements of the HTODA are not retrospective. This means that establishments do not need to obtain consent for the storage or public display of bodies, tissue or organs that were already in their possession at the time the HTODA came into force on *[insert date here]*. Material held before this date is referred to as existing holdings[7].

> **Example**
>
> A surgeon has a private collection of preserved human body parts, tissue and organs thought to have come from the body of a deceased person, which they acquired early in their career and uses for teaching medical students.
>
> On retirement, they offers the specimens to a museum for public display. The museum has concerns that consent may not have been obtained appropriately for all specimens.
>
> As the consent requirements of the HTODA are not retrospective, the specimens can be treated as existing holdings and consent is not required for their display. However, a public display licence is required if the material came from people who died less than 100 years ago.

38. Where the person has died, consent must have been given by them in life for storage for public display or actual public display of their body, body parts, tissue or organs after death (whether an adult or a child). Their consent must be written and -

    a. signed by the person concerned in the presence of at least one witness who attests the signature, or

    b. signed at their direction in their presence and the presence of at least one witness who attests the signature.

    Alternatively, it can be stated in an adult's legally made will. Neither the relatives nor any other person can consent to the use of an individual's body after their death for public display. This applies whether the person is an adult or a child.

[7] Section 17 (existing holdings) of the HTODA.

39. Anyone organising a public display of bodies, tissue or organs that are not existing holdings must have the necessary assurance that valid consent has been given. They do not need to have taken or recorded the consent personally.

40. Although the displaying of photographic or electronic images falls outside the scope of the HTODA, CO believes that it is good practice for consent to be obtained for the making and subsequent display of such images.

Licensing

41. Licensing is one of the regulatory functions of PH, on behalf of CO. The HTODA lists among its licensable activities the storage and use, for the purpose of public display, of the body of a deceased person or tissue or organs which have come from the body of a deceased person. Therefore, a licence is required for the public display of bodies, tissue or organs from the deceased, but not from the living.

42. In considering whether to issue a licence for the public display of human material, PH will seek assurance that licensing standards are met by the establishment (see paragraphs 75-79). This will include ensuring that it has a clear policy on the behaviours, actions and attitudes demonstrated by staff and visitors, whether or not directed at the exhibits that might be considered to disregard the dignity of the deceased.

> **Example**
>
> An art gallery is staging an exhibition, which includes plastinated bodies in a variety of poses demonstrating the anatomy of the human body. The gallery usually offers its exhibition space as a venue for private functions such as birthday parties and wedding receptions. Reflecting its policy on the display of human material, it decides not to offer this service for the duration of the exhibition, out of respect for the deceased.

43. A licence is required regardless of the number of items that are on display and PH may take into account the number of items on display when setting licence fees, which are reviewed annually and set out on the gov.im website. A collection of items of the same type and known to have come from a single person can be counted as one item for the purpose of licensing.

> **Example**
>
> A music school displays the preserved hands of the school's founder, a famous pianist. The founder specifically asked for them to go on display in the school before he died in 1948. The music school has no plans to display any other human exhibits but wants to continue to display the hands, in line with the founder's wishes.
>
> For the purpose of PH licensing, the school has one exhibit of human material on public display.

44. The existing holdings exemption to the consent requirements of the HTODA referred to in paragraph 37 does not apply to the licensing requirement. This means that material less than 100 years old that was already in the possession of museums at the time the HTODA came into force on [insert date] is subject to licensing by the HTA.

Example

A museum is displaying a number of human skulls in an exhibition about the history of dentistry. The exhibition has been staged since the early 1970s and no additions have been made to the collection since 1987.

Although consent was given for many of the exhibits, there is no legal requirement under the HTODA for it to be in place. However, in accordance with the HTODA, a licence for storage for public display is required.

45. PH does not consider the display of bodies, tissue or organs to small groups of relevant professionals as part of a pre-determined programme of education and training to be public display.

Example

A hospital allows police officers that are dealing with scenes of crime to witness a post-mortem examination as part of their introduction to forensic medicine. The hospital is unsure whether it is required to have a PH licence for public display.

It is advised that a public display licence is not required as training involving the examination of bodies, which is delivered to the police or paramedics as part of their professional development[8], is not considered public display.

46. PH also does not consider the display of bodies, tissue or organs to students who are embarking on a career in healthcare to be public display. This includes where the students are invited to visit from a different establishment.

Example

Medical students beginning their first year of study are taken on a tour of the anatomy and pathology museum of a teaching hospital licensed by PH for anatomical examination.

As access to this museum is restricted to practitioners and medical students, the hospital's licences are sufficient and no additional licence is required for public display.

[8] Permission is required from the Coroner for coroner-authorised post-mortems further to rule 6(4) of the Coroner of Inquests Rules 1988 [SD 1988/0003]

47. Display of bodies, tissue or organs from bodies of the deceased, to members of the general public, for whatever reason, is considered to be public display.

> **Example**
>
> At a university open day for the general public, visitors are shown the lungs of a smoker and a non-smoker to demonstrate the effects of smoking.
>
> As members of the public are viewing the exhibits, a PH public display licence is required. The lungs were obtained after death from people who died after [insert date], so written and attested consent for public display is required from the individuals in life in order for the public display to lawfully take place.

48. Any individual or organisation displaying material of human origin should make sure that visitors are aware they will come across human remains, whose display may provoke an emotional or ethical response, particularly in the very young. Giving consideration to the format of the display to ensure that it is appropriate to the material being shown, and does not disregard the dignity of the deceased, may help promote a positive visitor experience.

> **Example**
>
> A city museum and art gallery is mounting an exhibition on death and the human experience. The exhibition is intended to provide an educational experience for visitors; stimulating a discussion on death and increasing their awareness of how individuals and different cultures respond to death.
>
> It holds a range of artefacts, all less than 100 years old, all from different areas of the world outside of the Isle of Man. These artefacts include a human jaw bone incorporated into a necklace from the Andaman Islands which was worn as a sign of mourning, human trophy skulls from Papua New Guinea, and a human skull with attached cattle horns from India, believed to prevent the deceased from hearing the voices of their relatives.
>
> To ensure that visitors get the most out of their visit to the exhibition, and are not alarmed by any of the exhibits, the museum has placed warning signs to alert visitors about the sensitive items on display and provided contextual information about each exhibit. There is also a notice which suggests that the exhibition is suitable for children over 14 years. There is a dedicated seating area which visitors can use for reflection, if the exhibition provokes an emotional response.

49. As noted earlier, storage for the purpose of public display or the actual public display of body parts, tissue or organs from the living do not require licensing. Neither is a licence needed for the continued storage or public display of that material should the person subsequently die.

> **Example**
>
> A human heart is on permanent display in a museum. The heart came from a patient who underwent a successful heart transplant and consented for her diseased heart to be displayed. A licence is not required, and will not be required for the continued display of the heart following the donor's death[9].

50. Bodies, tissue or organs from the deceased imported into the Isle of Man for public display are subject to licensing by PH.

51. The duration of the public display does not affect the requirement for licensing. Establishments that wish to exhibit human material must ensure that they have the necessary licences in place before they begin to store or exhibit the material.

> **Example**
>
> A temporary exhibit of several preserved human bodies sourced from an establishment in another country is displayed in a public museum in order to illustrate the physiology of athletes.
>
> The exhibition is for six months and the museum does not display any other human bodies, tissue or organs. A licence is required from PH and the establishment is advised to refer to the advice given in this Code on the import of human material.

52. Some museums hold material with no intention of ever putting it on public display. Instead, they keep it as part of a museum archive of items of historical interest or for ethnographic or anthropological research. In these cases, a licence is not required. If the establishment informs PH in writing of its intention never to display the material, PH will be satisfied that the retention of this material falls outside its remit. A licence should be sought if this position changes and there is subsequently an intention to display the material.

Material over 100 years old

53. The legislative requirements of the HTODA do not apply to bodies, tissue or organs if more than 100 years have elapsed since the date of the person's death. Consent is not, therefore, required for the public display of bodies or human material over 100 years old. Nor is a licence required.

54. Some museums hold collections where the age of the material is unknown. This may be because no documentary evidence, such as archival records, receipts or scientific evidence (such as carbon dating) is available. Where investigations are inconclusive and it is uncertain

[9] PH encourage records to be kept of such donations to ensure compliance with the requirements of the HTODA can be evidenced.

whether the material is over 100 years old or not, the earliest known acquisition date may be taken as an indicator of the age of the material.

55. There may be circumstances where the acquisition date is within the last 100 years, but there is good reason to believe that the material is more than 100 years old. In such cases, PH will accept a written statement of this from an independent and objective expert in the field. Where no acquisition date is available, a PH licence should be applied for.

> **Example**
>
> A national museum in the UK obtained a large number of preserved human organs from a hospital museum that has closed down. It has records which show that the hospital museum obtained the exhibits in the 1930s and 1940s.
>
> However, it believes that the donors died more than 100 years ago. As there are no records to confirm when the people died, the museum has sought advice from the Professor of Biological Anthropology at a well-respected academic institution.
>
> The professor stated in writing that, in their professional opinion, the specimens are more than 100 years old. It was accepted as evidence of the age of the specimens and advice was given by the UK regulator that no licence for public display is required.

Loans to other museums

56. The HTODA does not allow the loan of items or collections containing human material within the scope of the HTODA from a licensed establishment to a non-licensed establishment, except in the case of anatomical specimens (see the Code of Practice on Anatomical examination). Where tissue ororgans from a deceased person is to be stored or used in a public display, a licence is required by the establishment on whose premises the material is to be stored or displayed.

57. Where material is moved between licensed establishments, there should be a documented loan agreement, which sets out:

    a. the steps taken to ensure safe handling of the material;

    b. any environmental controls required; and

    c. procedures to deal with adverse events, such as damage to the material or a breach of security.

Photographic/electronic images

58. The display of photographic or electronic images falls outside the scope of the HTODA; therefore, a licence is not required for the public display of photographs containing images of bodies, body parts or other human tissue samples or for electronic images, for example on television.

> **Example**
>
> A small independent gallery is exhibiting the work of a photographic journalist who has spent several years taking photographs of the homeless and dispossessed in major cities around the UK. These include a small number of images of the bodies of homeless people who have died whilst living on the streets. The exhibition is not subject to licensing by PH and the consent provisions do not apply to the display of these images.

Example

A television production company plans to film a group of schoolchildren observing the dissection of a human body for a documentary on human anatomy. The filming of the programme and its subsequent broadcast on television are outside the remit of the HTODA.

However, the real time viewing of the dissection by the schoolchildren is considered by PH to be a public display and a licence is required.

In addition, the television production company is advised that as the body will be that of a person who died after the commencement of the HTODA, consent for their body to be used for public display will have to have been given by the person before they died.

59. If filming takes place on premises licensed by PH, the anonymity of subjects should be preserved. The number of people present at the filming should be kept to a minimum to ensure, as far as possible, the dignity of the deceased. The Coroner should be informed and their agreement sought if any bodies being filmed are under coronial jurisdiction.

60. The Designated Individual (DI) of the licensed establishment has a statutory duty to ensure that suitable practices take place on the premises. This includes ensuring that the bodies in their care are treated with dignity and respect. This responsibility must be understood and given due regard by anyone entering the premises, for whatever purpose, and should be reiterated to the film crew.

Import and export

61. The import and export of bodies or material of human origin, whether fresh, frozen, plastinated, dried or embalmed, is not a licensable activity under the HTODA. However, the storage of the material once it is imported may be licensable if this is for use for a scheduled purpose.

62. For the purposes of the HTODA, 'import' means import into the Isle of Man. 'Export' means export from the Isle of Man.

63. The guidance in this section does not apply to whole bodies or parts of bodies that are historical human remains, or human remains incorporated into artefacts, which are more than 100 years old.

Imported material

64. Given the importance of consent and its role in maintaining public confidence in the use of human bodies and body parts, CO considers that the same consent expectations should apply for imported bodies and body parts (as set out in paragraphs 37 to 40 in this Code) as for such material sourced domestically (within the Isle of Man), unless PH are satisfied that there are exceptional circumstances for not doing so.

65. Anyone removing, storing or using bodies or body parts imported for the purpose of public display should ensure that they have been sourced legally in the country of origin and the

person whose body or body parts are intended for public display has given consent for this purpose. Establishments should be confident in the validity and authenticity of the documentation they intend to rely on for assurance. Furthermore, when considering the import of material, establishments should give due regard to the guiding principles referred to earlier in this Code.

66. Good practice requires that effective and reliable processes should be in place for acquiring evidence of informed consent. This means that the importer should have implemented policies and/or Standard Operating Procedures (SOPs), which clearly set out how to obtain this evidence. This includes safeguarding the confidentiality of all information relating to consent. If a third party is importing the material, a Service Level Agreement (SLA) should be in place demonstrating that there is a record of consent in a suitable format.

67. It is CO policy that any individual or organisation wishing to import human bodies and material of human origin should be able to demonstrate that the purposes for which they wish to import such material cannot adequately be met by comparable material available from sources within the Isle of Man, or that it is for a particular purpose which justifies import. Importers should assure themselves of the integrity of the material and that, as a minimum, it has been sourced with appropriate consent.

68. Importers should therefore satisfy themselves that, in the countries from which they seek to import tissue or organs, the gaining of consent for the purpose to which the tissue or organs are subsequently used is part of the process by which the material is obtained. This involves ensuring that procedures are in place giving the necessary assurances.

69. The HTODA does not remove consent, licensing or any other requirements for bodies or tissue which are exported with a view to being re-imported. Any bodies, tissues or organs being transported in such a manner are not considered to be imported under the HTODA.

Exported material

70. When seeking consent, donors should be advised that their samples may be exported and used abroad. SLAs should be in place to ensure that human bodies and material of human origin to be exported from the Isle of Man are used in accordance with the consent which has been obtained. Material should be handled, stored and transported in a manner consistent with safety considerations, and with due regard to the dignity and respect that should be accorded to human bodies.

Disposal

71. Disposal of tissue and organs is one of the activities within the statutory remit of CO. Most establishments engaged in the public display of human material, particularly those that are accredited by Arts Council England under the Museums Accreditation Scheme, will have acquisition and disposal/deaccession policies that consider cultural issues, such as repatriation. Where this is not the case, the guidance on disposal in this code should be followed if material is to be disposed of.

72. The HTODA does not mandate any particular method of disposal, for example according to the type or size of the tissue or organ, and does not stipulate methods of disposal for

specific body parts. Instead, CO encourages staff at PH-licensed establishments to make decisions about the most suitable method of disposal in each case.

73. In cases where cremation is not possible, it is permissible to dispose of tissue, organs or body parts which have been displayed by incineration, provided they are disposed of separately from other clinical waste. PH-licensed establishments should have SOPs supporting the process for preparing, documenting and transporting specimens and body parts for incineration.

74. When seeking consent for use of their body, tissue or organs for public display, individuals should be informed how it is planned that tissue or organs will be disposed of after use and any options available.

75. Staff should be familiar with the establishment's arrangements for disposal. This includes what is available locally, basic legal requirements and the options available to those wanting to make their own arrangements to dispose of tissue or organs.

PH licensing Standards

76. 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 core Standards, 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 and organs;

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

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

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

78. Each licensed establishment is required to appoint a 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 premises are suitable 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.

79. When PH staff, or persons appointed by PH, undertake inspections of PH-licensed establishments, they will provide PH with evidence to make judgements about the suitability of the Licence Holder (LH), the DI, the practices taking place and the premises on which they take place. PH will do this by assessing the establishment's compliance with PH's licensing Standards, which reflect the guiding principles set out in Code A and provide the operational detail of how establishments should meet the requirements of the HTODA and the Codes of Practice.

80. PH's general 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. There are separate standards, set out in Code B, that apply to post-mortem premises.

Consent (C)

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

Governance and quality systems (GQ)

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

Traceability (T)

83. Establishments meeting these Standards will be able to demonstrate full traceability for the human material for which they are responsible, from receipt to final disposal/disposition. PH inspectors, or persons appointed by PH, will test this through traceability audits carried out on site and PH expects establishments to take a proactive approach to assuring themselves of effective traceability throughout the lifetime of their licence. In addition, as the final traceability step, they will have established disposal arrangements which are in accordance with PH's Codes of Practice.

Premises, facilities and equipment (PFE)

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

85. PH licensing Standards which are applicable to the Public Display sector are included at Annex D and on the gov.im website. The Standards are supported by comprehensive guidance notes.

Annex A

Annex A to be inserted at a later date.

Annex B

Scheduled purposes and licensing in the Public Display sector

1. To understand fully the requirements of the HTODA, knowledge of scheduled purposes and licensable activities is required.
2. The HTODA differentiates between scheduled purposes, for which consent is required, and activities for scheduled purposes, which are licensable. This is an important distinction, and one which sometimes causes confusion because not all purposes require both consent and a licence.

Scheduled purposes

3. There are three scheduled purposes which relate to the public display sector; consent is required to store or use bodies or tissue or organs for all of them:
    a. public display, which applies to tissue or organs from the living (excluding hair and nails) and deceased (less than 100 years old);
    b. research in connection with disorders or the functioning of the human body, which applies to tissue and organs from the living (other than hair and nails) and from the deceased (other than tissue and organs from a person who died over 100 years ago);
    c. education or training relating to human health, which applies to material from the deceased only (other than tissue and organs from a person who died over 100 years ago).
4. Note that only (a) requires consent from the person themselves; where the person has since died, their consent must be in writing and have been witnessed and attested. Where the person has died, consent for the scheduled purposes in (b) and (c) can be provided by the deceased person's nominated representative or relatives (those in a qualifying relationship to the deceased before they died; see Code A for more information).

Licensable activities

5. There are two licensable activities which are relevant to the public display sector:
    a. the storage of the body of a deceased person, or tissue or organs which have come from a human body, for use for scheduled purposes; and
    b. the use of the body of a deceased person or tissue or organs which have come from the body of a deceased person for the purpose of public display.
6. The *[IOM equivalent to the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006]*, exempt from licensing the storage of tissue or organs from a human body for use for public display, where the material is from a living person. That means that a licence is not required for the storage or public display of body parts, tissue or organs from the living.

Annex C Licensing and consent flowcharts

Flowchart to be inserted at a later date.

Licensing and consent requirements for public display of human tissue and organs from the living

Storage of and/or use of human tissue and organs from the living

1. Consent required? **YES**
    - Unless obtained before [insert date here]
2. Licence required? **NO**

Licensing and consent requirements for public display of human tissue and organs from the deceased

Storage of and/or use of human tissue and organs from the deceased

1. Consent required? **YES**
    - Unless obtained before [insert date here]; or
    - The person died before [insert date here] and 100 years have elapsed since their death
2. Licence required? **YES**
    - Unless the person died before [insert date here]and 100 years have elapsed since their death

Annex D

PH Licensing Standards: Public Display sector

Consent (C)

C1. Consent is obtained in accordance with the requirements of the Human Tissue and Organ Donation Act 2021 (HTODA) and as set out in its Codes of Practice.

a. If the establishment is required to seek consent, a process is in place which is in accordance with the requirements of the HTODA and its Codes of Practice, and records of consent are maintained.

b. If relevant, there is training for staff on how to seek consent for the public display of human material, which addresses the requirements of the HTODA and its Codes of Practice and records demonstrate attendance.

c. Where applicable, there are agreements with other parties to ensure that consent is sought in accordance with the requirements of the HTODA and its Codes of Practice.

C2. Information about the consent process and the activity for which consent is sought is provided.

a. There is written information about the consent process for those giving consent, which reflects the requirements of the HTODA and its Codes of Practice.

b. Standard operating procedures (SOPs) specify how information on consent is provided.

Governance and quality systems (GQ)

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

a. There are collections management policies and procedures, or equivalent, governing the storage and public display of bodies and human tissue and organs, which give due regard to the dignity of the deceased. These should include, as relevant to the establishment's activities:

   i. an overarching policy on the care and treatment of exhibits containing human tissue;

   ii. seeking consent for donation of bodies and human tissue and organs for public display;

   iii. specimen acquisition e.g. by bequest, exchange, loan or purchase from another individual or organisation nationally or internationally;

   iv. specimen preservation, monitoring and conservation;

   v. control of environmental conditions;

   vi. the management of sensitive material, such as foetal remains;

vii. transportation of specimens e.g. on loan to or return to other collections;

viii. the disposal/deaccession of specimens;

ix. storage contingency arrangements;

x. the creation, amendment, retention and destruction of records;

xi. the management of incidents and complaints.

b. There are procedures that govern the work of temporary staff and contractors, which ensure that they are sensitive to the special status of human remains and exhibits consisting of human material.

c. Regular governance meetings are held; for example, health and safety and risk management committees, that have agendas and minutes.

d. Policies and procedures are reviewed regularly and are version controlled.

GQ2. There is a documented system of audit.

There is a documented system of audit, which includes records of traceability and specimens.

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

a. There are clear reporting lines and accountability, with documented roles and responsibilities.

b. There is documented induction and training for staff, which includes the handling of human remains; attendance at training is recorded.

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. Systems ensure data protection, confidentiality and public disclosure (whistleblowing).

GQ5. There are systems to ensure that untoward incidents are investigated promptly.

a. There is a system for reporting and investigating serious untoward incidents.

b. Corrective and preventive actions are taken where necessary and improvements in practice are made.

GQ6. Risks associated with the establishment's practices and processes in relation to the storage and display of human material are assessed and monitored.

a. Risk assessments are documented.

b. Risk assessments set out steps taken to mitigate risks

c. Risk assessments are reviewed regularly

d. Staff can access risk assessments and are made aware of them in training

Traceability (T)

T1. A coding and records system facilitates traceability of bodies and human tissue and organs.

a. Bodies and human tissue and organs are traceable through a unique identification number or code.

b. The system of record-keeping should include the location of material at the establishment and may include a description or photographic record and details of any specialist storage conditions, shelf-life or contamination risk.

T2. Records of traceability are maintained.

a. Records of receipt, storage, transportation and delivery of bodies and human tissue and organs are maintained.

b. Disposal or de-accession records include the date, reason and method of disposal/deaccession.

c. Where applicable, disposal arrangements reflect specified wishes of the donor.

Premises, facilities and equipment (PFE)

PFE1. The premises and facilities are secure and safeguard the dignity of the deceased and the integrity of human tissue and organs.

a. Areas used for storage or public display provide an environment that is safe for staff and visitors and preserves the integrity of the material and the dignity of the deceased.

b. The establishment is clean, well maintained and subject to a programme of planned preventative maintenance.

c. Staff have access to the protective clothing, materials and equipment they need.

d. A documented risk assessment has been carried out of the premises to ensure that they are appropriate for the licensed activities.

e. There are policies in place to review and maintain the safety of staff and visitors.

f. The premises are secure with controlled access to bodies, human tissue and organs, and records.

g. Security measures include the use of lockable display areas and alarm systems.

PFE2. There are appropriate facilities for the storage of bodies and human tissue and organs.

a. Where chemicals are used for preservation, the area is adequately ventilated to control exposure.

b. Critical storage conditions are monitored and recorded.

c. There are systems to deal with emergencies.

d. There is a documented contingency plan for storage of bodies and human tissue and organs.

Glossary / definitions

To be inserted at a later date.