Cabinet Office

A: Guiding Principles and the Fundamental Principle of Consent

Code of Practice

Contents

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

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

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

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

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

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

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

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

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

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

    a) post-mortem examination;

    b) anatomical examination;

    c) public display of tissue from the deceased; and

    d) the removal and storage of human tissue for a range of purposes, including research, medical treatment, education and training.

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

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

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

[1] See glossary.

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;

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

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

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 website www.gov.im.[4]

8. This Code of Practice 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. The following principles should inform the actions of anyone undertaking activities within DHSC's remit under the HTODA:

    a) consent;
    b) dignity;
    c) quality; and
    d) honesty and openness.

9. 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 this Code

10. The Code is divided into three sections –

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

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

Section One - Guiding principles

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

12. **Consent** and the wishes of the donor, or where appropriate their nominated representatives or relatives[5], have primacy when removing, storing and using human tissue. This means –

    a) human tissue, or bodies of the deceased, should be used in accordance with the expressed wishes of donors or their nominated representatives or relatives;

    b) donors and their nominated representatives or relatives should be given the information they need to be able to make a decision that is right for them;

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

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

    a) the dignity of the donor should be respected at all times;

    b) there should be mechanisms in place to protect bodies and human organs and tissue from harm;

    c) the privacy of the individual should be maintained;

    d) the disposal of human tissue should be managed sensitively and the method of disposal should be appropriate to the nature of the material;

    e) disposal of human tissue or organs from the deceased should, where possible, be in line with their wishes, if known, or the wishes of the deceased person's relatives;

    f) where human tissue is imported, importers should endeavour to ensure that it is sourced from a country that has an appropriate ethical and legal framework.

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

    a) practitioners should be competent, have undertaken appropriate training and work with care in accordance with good practice and other relevant professional guidance;

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

b) practitioners' work should be subject to a system of governance that ensures the appropriate and safe storage and use of human tissue and which safeguards the dignity of the living or deceased;

c) premises, facilities and equipment should be clean, secure and subject to regular maintenance;

d) proper and accurate records and information should be maintained to ensure full traceability of human tissue and bodies of the deceased and donor tissue;

e) patient data should be held securely and confidentially.

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

a) communication with a donor, or person from whom consent is being sought, should be open, honest, clear and objective;

b) serious incidents involving human bodies and tissue should be subject to rigorous investigation to ensure that lessons are learned and the risk of reoccurrence is minimised;

c) establishments should adopt a policy of candour and transparency, as well as meeting their other, statutory and professional, duties of candour where appropriate[6];

d) discussions about medical investigation or treatment are kept entirely separate from discussions relating to consent for scheduled purposes;

e) establishments should be open and transparent in relation to arrangements for charging and reimbursement, where applicable.

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

[6] e.g. Manx Care (Duty of Candour Procedure) Regulations 2021 *[SD 2021/0069]*, as well as the associated Manx Care: Duty of Candour Procedure, Operational Policy of 1st April 2021.

Section Two - The fundamental guiding principle of consent

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

    a) the legal concept of consent;

    b) the activities for which consent is required;

    c) appropriate consent;

    d) valid consent;

    e) conditions on consent;

    f) duration of consent;

    g) withdrawal of consent.

The legal concept of consent

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

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

20. If appropriate and valid consent has been provided, then this is sufficient for an activity covered by the HTODA to proceed (subject to licensing and other legislative requirements having been met). Throughout this Code, references to consent should be taken to mean appropriate and valid consent.

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

22. Where a person with capacity has made the decision not to consent to an activity covered by the HTODA, then the activity must not proceed as there is no consent in place.

The activities for which consent is required

23. Consent under the HTODA relates to the purposes for which organs or tissues might be removed, stored or used. These purposes are set out in Schedule 1 (scheduled purposes) of the HTODA and are called scheduled purposes (see Annex B).

24. The HTODA does not require an activity for which consent has been given to proceed (see paragraph 21).

25. It is not a legal requirement for consent to be obtained for the disposal of material. However, it is good practice for disposal options to be given, and for the wishes of the donor or their relatives obtained during the process of seeking consent (see Code B: Post-mortem examination and Code C: Anatomical examination) to be respected, where possible.

26. In broad terms, the HTODA and the Codes of Practice require that consent must be in place to –

    a) store and use bodies of the deceased;

    b) remove, store and use tissue from the body of a deceased person;

    c) store and use tissue from the living.

27. Annexes B and C set out in detail the purposes for which consent is required under the HTODA.

28. Anyone removing, storing or using tissue in circumstances for which the HTODA requires consent, must be satisfied that consent is in place. CO has set standards on consent for those working in licensed establishments. The Standards and associated guidance include how the consent process should be governed, the information that should be provided to those from whom consent is sought and the training that staff should receive.

29. There are certain exceptions to the consent provisions set out in the HTODA in relation to the activities of coroners and the police. Further information can be found in Code B: Post-mortem examination. There are also other limited situations where consent may not be required (see Annex B).

Appropriate consent

30. The HTODA defines 'appropriate consent' by reference to the person who may give consent. This is broadly either the person concerned, their nominated representative (see paragraphs 79-85), or, in the absence of either of these, a person in a 'qualifying relationship' with them immediately before they died. In the case of anatomical examination and public display, consent can only be given, in writing, by the person concerned.

31. An adult may appoint one or more nominated representatives to carry out their wishes after death in relation to activities for which consent under the HTODA is required. An executor is not automatically classified as a nominated representative and would need to be specifically appointed to this role in line with the requirements of the HTODA.

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

    a) spouse or partner (including civil or same sex partner). The HTODA states that, for these purposes, a person is another person's partner if the two of them (whether of different sexes or the same sex) live as partners in an enduring family relationship;

    b) parent[7] or child (in this context a child may be of any age, but must be competent if under the age of 18, and means a biological or adopted child);

    c) brother or sister;

    d) grandparent or grandchild;

    e) niece or nephew;

    f) stepfather or stepmother;

    g) half-brother or half-sister;

    h) friend of long standing.

33. Consent is needed from only one person in the hierarchy of qualifying relationships and should be obtained from the person ranked highest. If a person higher up the list refuses to give consent, it is not possible to act on consent from someone further down the list. For example, if a spouse refuses but other relatives wish to give consent, the wishes of the spouse must be respected. However, the guidance in paragraphs 34 and 36 should be observed in line with this principle. If there is no one available in a qualifying relationship to make a decision on consent (and consent had not been indicated by the deceased person or a nominated representative), it is not lawful to proceed with removal, storage or use of the deceased person's body, organs or tissue for scheduled purposes.

34. While the HTODA is clear about the hierarchy of consent, the person giving consent should be encouraged to discuss the decision with other relatives. This may include people not on the list, for example, an aunt or uncle.

35. Relationships listed together, for example 'brother or sister', are accorded equal ranking, in which case it is sufficient to obtain consent from just one of them, provided they are ranked equal highest. For example, if the deceased person

[7] Refer to the glossary for the definition of a parent for the purposes of the HTODA.

has no spouse or partner, but has several children, the consent of only one child is required.

36. Where there is a conflict between those accorded equal ranking, this should be discussed sensitively with all parties, whilst explaining clearly that so far as the HTODA is concerned, the consent of one of those ranked equally in the hierarchy is sufficient for the procedure to go ahead. This does not mean that the consent of one person must be acted on, and a decision not to proceed may be made on the basis of the emotional impact that this would have on family and friends.

37. If those close to the deceased person object to the activity, for whatever purpose, when the deceased person (or their nominated representative) has explicitly consented, the healthcare professional should seek to discuss the matter sensitively with them. They should be encouraged to accept the deceased person's wishes and it should be made clear that they do not have the legal right to revoke valid consent (see also Code F: Donation of solid organs and tissue for transplantation).

38. The emphasis in these difficult situations should be placed on having an open and sensitive discussion with those close to the deceased where the process is explained fully to them.

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

Valid consent

40. For consent to be valid it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. The person should understand what the activity involves, any reasonable or variant treatment and, where appropriate, what the material risks are. In relation to organs, the test of materiality[8] is 'whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach a significance to it'.

41. Consent may be specific or it may be broader in its scope, sometimes referred to as 'generic consent'. Specific consent is given in relation to a defined project, treatment and/or use. Generic consent refers to a broader permission, where consent may, for example, be given to allow the storage and use of tissue for

[8] See: Montgomery v Lanarkshire Health Board (Scotland), 11th March 2015. Neutral citation number [2015] UKSC 11. https://www.supremecourt.uk/cases/uksc-2013-0136.html, checked 27th August 2024.

an as yet unknown research project. In practical terms, specific and generic consent may be sought at the same time, to derive the greatest benefit from valuable human tissue and organs donated for research.

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

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

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

Conditions on consent

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

46. The HTODA recognises that individuals have the autonomous right to give or refuse consent to the use of tissues or organs for scheduled purposes.

47. Whilst respecting this autonomous right, tissues or organs should not be removed, stored or used for a scheduled purpose under a form of consent which seeks to impose restrictions on the class of the beneficiary of the scheduled purpose. For example, a medical practitioner should not remove an organ for transplantation if the donor imposes a condition that the recipient of a transplanted organ must be a man, or must not be an alcoholic. This includes any restriction based on a beneficiary's sex, sexual orientation, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status (including characteristics protected under the Equality Act 2017). This position reflects Article 14 of the European Convention on Human Rights, as set out in the Human Rights Act 2001, and arises from the equality duty placed on CO, PH, DHSC and Manx Care by the Equality Act 2017.

48. Where any conditions attached to consent cannot be acted upon, the person who has attached the condition should be made aware of this and asked whether they are willing to put these conditions aside in order to allow the activity to proceed. It would be an offence to proceed with an activity for a scheduled purpose in the knowledge that a persisting condition on consent could or would not be fulfilled, as valid consent would not be in place. Only the person who has attached the condition to the consent can put the condition aside. For further information, see paragraph 24 of Code F: Part 2.

Duration of consent

49. Consent may differ in its duration. It may be enduring or time-limited.

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

Withdrawal of consent

51. Consent may be withdrawn at any time, whether it is generic or specific. Withdrawal should be discussed at the outset when consent is being sought. The practicalities of withdrawing consent and the implications of doing so should be made clear. Withdrawal of consent cannot be acted upon where tissue has already been used. In the case of organ donation from the deceased, consent cannot be withdrawn once the retrieval of the organ has commenced.

52. If someone gives consent for their tissue to be stored or used for more than one scheduled purpose and then withdraws consent for a particular scheduled

purpose, such as research, this does not necessarily mean that the sample or samples have to be removed or destroyed. However, the samples may no longer be stored or used for the particular purpose for which consent has been withdrawn. In addition, if someone withdraws consent for samples to be used in any future projects, this does not mean that information and research data should be withdrawn from any existing projects.

Section Three - Consent requirements

53. This section is divided into three parts –

    a) **Part 1**: General provisions;

    b) **Part 2**: Tissue from the deceased;

    c) **Part 3**: Tissue from the living.

Part 1: General provisions

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

    a) does the activity require consent and what, if any, exceptions to the consent provisions of the HTODA apply in this case?[9]

    b) has the appropriate person given consent? (paragraphs 78 – 94 and 113 – 134)

    c) has sufficient written (in paper or electronic format) or verbal information been provided for the person giving consent to make a properly considered decision? (paragraphs 95 – 99)

    d) how will the consent be given and recorded? (paragraphs 57 – 60);

    e) is written consent required? (paragraphs 102 – 104);

    f) is the consent needed for more than one purpose? (paragraphs 105 – 107);

    g) if a child is involved, are they competent to consent and have they expressed particular wishes or views? (paragraphs 87 – 94 and 128 – 134);

    h) if an adult lacks capacity to consent, how should the provisions of the Mental Health Act 1998 Code of Practice[10] [MH Act Code of Practice] be applied? (paragraphs 114 – 127).

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

56. The Mental Health Act 1998 (MH Act) and the MH Act Code of Practice makes provision with regard to the treatment of persons who are unable to make particular decisions for themselves as a result of a temporary or permanent

[9] Note that consent may not be required in all circumstances or by this Act, although other consent provisions may also apply. See table in Annex B.
[10] As of March 2011.

impairment or disturbance in the functioning of the mind or brain[11]. Establishments should take into consideration the MH Act, and the MH Act Code of Practice, when seeking consent.

Format of consent

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

58. Written consent, either in paper or electronic format, serves as evidence of consent, but a signature on a form does not of itself make the consent valid (see section on valid consent, paragraphs 40 – 44). Protocols should be in place to ensure that the consent process has been completed, that there is valid consent and that the decision has been properly recorded. Establishments seeking to update existing consent forms or develop new protocols should ensure that they comply with this Code and other relevant CO guidance.

59. When consent is obtained but it is not in writing, this should be clearly documented, for example in the patient's records where applicable. The record should detail when consent was obtained and the purposes for which the consent was given.

60. The NHS Organ Donor Register (ODR) operates throughout the UK and in the Island to allow people to record their wishes about organ donation. Further information on the ODR as a source of consent can be found in Code F: Donation of solid organs and tissue for transplantation.

Religion, belief and culture

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

Communication

62. Consent is valid only if proper communication takes place and the person has a reasonable understanding of what is being explained to them. Particular consideration should be given to the needs of individuals and families whose first language is not English. Any difficulties in communicating with the person

[11] n.b. paragraphs 15.18 to 15.23 of the MH Act Code of Practice.

interviewed, (for example, because of language, literacy or hearing difficulties) and an explanation of how these difficulties were overcome should be recorded.

63. Under the MH Act Code of Practice, efforts should be made to provide information that is appropriate in terms of culture and language when assessing capacity. The explanation should be appropriate to the level of the person's assessed ability. See chapter 15 of the MH Act code of practice for assessment of capacity and treatment of mentally incapacitated patients, for further information on persons who lack capacity to consent.

Use of documentation

64. Establishments should provide appropriate information on the activities for which they are seeking consent. The information might be in the form of leaflets or information sheets, or it might be contained within the consent form.

65. Patient information sheets should be provided about research projects; these are also usually required by ethics committees approving research projects. PH has issued guidance on developing model consent forms and information sheets for research establishments to use when seeking consent.

66. Many establishments have policies on consent that include the use of standard documentation. Such documentation should make reference to the HTODA and the roles of CO, PH, DHSC, Manx Care and NHSBT, and be reviewed to ensure that it is consistent with this Code.

67. Where appropriate, information should be available in a variety of languages and formats such as video, audio or Braille, and in line with other legislation, such as the Equality Act 2017. Wherever possible, professional translators trained in translating[12] for the bereaved and in maintaining confidentiality should be used.

Existing holdings

68. The consent requirements of the HTODA are not retrospective. This means it is not necessary to obtain consent for material that was already held for use for a scheduled purpose when the HTODA came into force on *[date as per appointed day order(s)].*

69. Although there are no statutory requirements to obtain consent for the storage or use of tissue that is an existing holding, this does not mean that all such human organs and tissue can be used freely and without regard to issues of consent or other ethical considerations as well as the requirements of

[12] A telephone translation service may be available within the Noble's Hospital. In addition, a list of interpreters, and guidance on the use of interpreters, is available on the Isle of Man Government Intranet. See: Cabinet Office Sharepoint page, Interpreters. http://sp16/sites/co/SitePages/Interpreters.aspx.

legislation that had effect prior to this date (e.g. the Human Tissue Act 1986 and the Human Organ Transplants Act 1993), subject to any transitional arrangements that may be put in place to give effect to the HTODA.

70. The views of the deceased person, or of their relatives, (if known) should be respected if the tissue is disposed of.

71. Under the HTODA, consent is not required for carrying out research on existing holdings of human organs and tissue. Ethical approval may be required for research involving existing holdings and reference should be made to the guidance produced by PH[13].

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

Use of images

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

74. CO endorses the guidance on images provided by the General Medical Council (GMC) in its publication "Making and using visual and audio recordings of patients"[14].

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

[13] For further information see Isle of Man Research Ethics Committee (IOMREC) webpage. https://www.gov.im/about-the-government/departments/cabinet-office/public-health/research-governance-and-regulation-rgr/isle-of-man-research-ethics-committee-iomrec/

[14] See: https://www.gmc-uk.org/-/media/documents/making-and-using-visual-and-audio-recordings-of-patients_pdf-58838365.pdf

Part 2: Tissue from the deceased

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

    a) anatomical examination;

    b) determining the cause of death;

    c) tissue, tissue blocks and slides resulting from a post-mortem examination are automatically kept as part the patients' medical records. (Tissue includes tissue sample, blood ((or any sample derived from blood)) or other body fluid).

    d) establishing after a person's death the efficacy of any drug or other treatment administered to them;

    e) obtaining scientific or medical information, which may be relevant to any person including a future person;

    f) public display;

    g) research in connection with disorders or the functioning of the human body;

    h) transplantation;

    i) clinical audit;

    j) education or training relating to human health;

    k) performance assessment;

    l) public health monitoring; and

    m) quality assurance.

77. Consent is not required for a coroner's post-mortem examination, nor for the retention of tissue samples (e.g. tissue blocks and slides as well as bodily fluid, blood and any sample derived from blood) created as a consequence of such a post-mortem. Once the Coroner has notified the DHSC (or Manx Care as the case may be) that such tissue samples are no longer required to be retained, such samples automatically form part of the medical record of the deceased person. The retention of organs following such a post-mortem will, however, require authorisation in accordance with section 58 to 62 (inclusive) of the HTODA.

77A. Other types of post-mortem examination may be authorised in accordance with the requirements of Part 4 of the HTODA. The use or retention of organs and tissue arising as a consequence of such post-mortems must also be authorised (see Code B: Post-mortem examination for further guidance).

Who may give consent?

Adults

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

Nominated representatives

79. If, prior to an adult's death, that adult had not decided to provide either –

    a. consent to allow the use of that adult's body, organs or tissue for a scheduled purposes; or

    b. refusal to allow the use of adult's body, organs or tissue for scheduled purposes,

    either generally or specifically, then their relatives should ask whether a nominated representative was appointed to take such a decision.

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

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

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

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

84. With respect to authorisations for post-mortem examination, the nomination may be disregarded if no one is able to give consent under it, or it is not reasonably practicable to communicate with the nominated representative

within the time available if the consent is to be acted upon[15]. In the event that a nomination is disregarded, consent may be given by a person in a 'qualifying relationship' (see paragraph 32) if there is no authorisation otherwise in force as granted by the person in question when they were alive[16]. For further information please see Code F: Donation of solid organs and tissues for transplantation.

85. Under the HTODA, children cannot appoint nominated representatives and therefore provisions related to seeking consent from nominated representatives do not apply.

Those in a qualifying relationship

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

Children

87. Under the HTODA, a child (except in the context of qualifying relationships) is defined as being under 18 years old[17]. The position of a child who, before they died, was competent to reach a decision and gave consent for one or more scheduled purposes after their death, is no different from that of an adult. In that circumstance the child's consent is sufficient for medical practitioners to make lawful under the HTODA the removal, storage or use of tissue for the specified scheduled purpose(s). Additional requirements may apply under other legislation.

88. The principle of 'Gillick competence' applies to the assessment of a child's competence to consent in these circumstances. In the Gillick case, the court held that a child was considered competent to give valid consent to a proposed intervention if they had sufficient intelligence and understanding to enable them to fully understand what was involved.

89. If a competent child consents to an activity, or activities, covered by the HTODA, that consent carries over into adulthood unless it is withdrawn. This is a principle of common law.

90. If a child did not make a decision, or was not competent to make a decision, before their death, the appropriate consent will be that of a person with

[15] See subsection (3) of section 47 (authorisation of post-mortem examination etc. by adult's nominee or person in qualifying relationship) of the HTODA.
[16] See section 46 (authorisation of post-mortem examination etc: adult) of the HTODA.
[17] n.b. Definition of "child" as per paragraph (2) of section 3 (interpretation) of the HTODA.

parental responsibility for the child. The consent of only one person with parental responsibility is necessary.

91. In some cases it may be advisable to establish with the person who had parental responsibility for the deceased child whether the child was competent to make the decision. A person who has parental responsibility will usually, but not always, be the child's parent (see the Children and Young Persons Act 2001 for the legal position). In any case where a child has consented to the use of their body or tissue, it is essential to discuss this with the child's relatives.

92. The issue should be discussed fully with relatives, and careful thought should be given as to whether to proceed if a disagreement arises between parents or other relatives. Any previously stated wishes of the deceased child should be considered, taking into account the child's age and understanding at the time of stating the wish. Further guidance is included in Code F: Donation of solid organs and tissue for transplantation and Code B: Post-mortem examination.

93. If there is no person with parental responsibility (for example, if the parents died at the same time as the child), then consent should be sought from someone in a qualifying relationship, (see section on qualifying relationships, paragraph 32). Under the HTODA children cannot appoint nominated representatives and therefore provisions related to seeking consent from nominated representatives do not apply.

94. For the anatomical examination or public display of tissue from a deceased child to take place, written (either by the child or at their direction) and witnessed consent is required from the child before they die. Those with parental responsibility at the time of the child's death cannot agree to the use of the child's body after death for these purposes.

Providing information about the process

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

96. Healthcare professionals and other suitably experienced people involved in seeking consent need to tailor the information they provide to each specific situation, considering the above advice and the *Montgomery*[18] case law. Some people may require in-depth detail, whereas others may prefer to give consent

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

having only had the basics of the procedure explained to them. The establishment's policy should set out a minimum amount of information to be provided in relation to each activity. Further information may be found in the sections on the duration of consent (paragraphs 49 – 50) and use of documentation (paragraphs 64 – 67).

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

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

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

99. Seeking consent from patients before death, or from those close to them after their death, requires sensitivity. This is especially true for donations for transplantation, post-mortem examinations and the retention of organs and tissue for research. Further guidance is set out in Code B: Post-mortem examination and Code F: Donation of solid organs and tissue for transplantation.

Disclosing information about the deceased

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

101. In certain circumstances it may be necessary to share sensitive information with the relatives if the results of the activity have the potential to affect them or other relatives. For further guidance see GMC guidance on confidentiality; good practice in handling patient information and the Department of Health and Social

Care guidance on confidentiality, which deals with disclosing information after a patient has died.

Written consent

102. Written, witnessed consent is always needed for anatomical examination and for public display of bodies or body parts (see Code C: Anatomical examination and Code D: Public display, for detailed guidance).

103. Written consent should be obtained wherever possible for all other activities involving the deceased. If verbal consent is obtained, this should be clearly documented in the patient's records (see paragraph 57 – 60).

104. Model consent forms are available for post-mortem and anatomical examination on the website www.gov.im. Consent forms are only one part of the consent process and should be completed after appropriate discussion and more detailed explanation, where necessary.

Seeking consent for multiple activities

105. When someone has died, healthcare professionals may wish to seek consent for more than one scheduled purpose. For example, if a post-mortem examination is to be carried out, some tissue samples could also usefully be obtained for research purposes. In this case, it would be necessary to seek consent for both activities. Anticipating and explaining the purpose for which tissue could be used will avoid the need for seeking consent on repeated occasions.

106. Where consent has been given for the use of organs or tissue after death for transplantation, separate consent is required for storage and use for research purposes. In such cases, the necessary consents should ideally be sought at the same time and recorded in the same place.

107. Unless the subject of a post-mortem investigation being conducted by a Coroner, the storage and use of post-mortem organs and tissue will require authorisation in accordance with the requirements of the HTODA. See below and paragraph 77 as well as Code B: Post-mortem examination.

Post–mortem consent

107A. Post-mortem examination in all its forms is important for informing relatives, healthcare professionals and other interested parties about the cause of death. It may also provide information about possible acquired or genetic diseases that may need treatment and care. More generally, post-mortem examination is considered by clinicians to be important in improving clinical care, maintaining clinical standards, increasing understanding of disease, identifying the spread of infectious diseases and supporting research and training.

107B. Further information on post-mortem consent requirements is set out in Code B: Post-mortem examination.

Part 3: Tissue from the living

108. Under the HTODA, consent is needed for storage and use of tissue from a living person for the following scheduled purposes[5]:

    a) obtaining scientific or medical information which may be relevant to any person including a future person;

    b) public display;

    c) research in connection with disorders, or the functioning, of the human body; and

    d) transplantation.

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

    a) in the course of diagnostic procedures, such as taking a blood or urine sample, tissue biopsy, cervical screening;

    b) in the course of treatment, such as removing tissue (organs, tumours) during surgery; and

    c) when removed specifically for the purpose of research.

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

111. To give consent, the individual should understand the nature and purpose of what is proposed and be able to make an informed decision. They should be told of any material or significant risks inherent in the way the sample will be obtained, how the tissue will be used and any possible risks or implications of its use, such as genetic tests. The test of materiality is set out in paragraph 40. If the person concerned is not a patient, and is volunteering samples purely for research, the general principles of providing appropriate information still apply (see paragraphs 40 – 44 on valid consent).

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

Who may give consent?

Adults who have capacity to consent

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

Adults who lack capacity to consent

114. The HTODA does not specify the criteria for considering whether an adult has capacity to consent. The MH Act and associated MH Act Code of Practice outlines the criteria to apply in Isle of Man.

115. This Code summarises the requirements of the MH Act and the MH Act Code of Practice. However, practitioners working with organs or tissue from an individual who may lack capacity must consider the MH Act and MH Act Code of Practice directly and should not rely solely on this Code.

116. Under the MH Act Code of Practice a person aged 16 and over is unable to make a particular decision if they cannot do one or more of the following things:

    a) take in and retain the information given to them that is material to the decision, especially as to the likely consequences of having or not having that treatment;

    b) believe the information;

    c) weigh up the information in the balance as part of the decision-making process;

117. Full guidance on how the MH Act and MH Act Code of Practice defines capacity and how it should be assessed is given in chapter 15 of the MH Act Code of Practice.

118. The provisions of the MH Act should be considered together with general principles governing capacity to consent to medical procedures. Guidance is available from the Office of Public Guardian website and in the MH Act Code of Practice.

119. The MH Act and the MH Act Code of Practice governs decision-making on behalf of children (aged 16 to 18) and adults who lack capacity if unable to make a decision in relation to a matter at the relevant time because of a mental disorder.

120. There are detailed provisions contained in the MH Act and the MH Act Code of Practice concerning decisions made on behalf of adults lacking capacity. All

decisions must be made in the person's best interests. Individuals providing care or treatment to a person have a legal duty to have regard to the MH Act and the MH Act Code of Practice when working with or caring for individuals who lack or may lack capacity to make decisions for themselves, as laid out in chapter 15 of the MH Act Code of Practice.

121. The MH Act Code of Practice premises that an individual is presumed to have capacity to make a treatment decision unless that person is –

    a) unable to take in and retain the information material to the decision, especially as to the likely consequences of not having the treatment; or

    b) is unable to believe the information

    c) is unable to weigh the information in the balance as part of a process of arriving at the decision.

    The assessment of that individual's capacity to make a decision is a matter for clinical judgement, guided by current professional practice and subject to legal requirements. An assessment should be in relation to a particular treatment proposal and should be assessed at the time the treatment is proposed as capacity is variable over time. It is the personal responsibility of any healthcare professional proposing to treat an individual to ensure their understanding of the current law and determine whether that individual has the capacity to give valid consent.

122. Individuals may sometimes temporarily be unable to make a decision, for example, if they are affected by delirium, shock, pain or drugs. It may therefore not be appropriate to seek consent at that time and, in some cases, it may be necessary to delay the decision until the person regains the capacity to make it, as laid out in the MH Act and the MH Act Code of Practice.

123. Some adults may have capacity to make decisions about some matters, but not others. The MH Act and the MH Act Code of Practice intends that care be taken to ensure that patients are given every opportunity, and support where needed to make their own decisions.

124. A person must not be treated as unable to make a decision unless all practicable steps to help them do so have been taken without success. Nor must they be treated as being unable to make a decision merely because they make an unwise decision.

125. The ability of adults with learning difficulties or with limited capacity to understand should not be underestimated. Where appropriate, someone who knows the individual well, such as a relative or carer, should be consulted, as they may be able to advise on or assist with communication.

126. *Omitted*.

127. Storage or use of tissue from adults who lack capacity to consent is permitted in certain circumstances specified in the HTODA and regulations made under that Act.

Children

128. The HTODA allows children to consent to activities for scheduled purposes if they are competent to do so (see paragraph 87 and section 9 of the HTODA).

129. Where the child has died and the child had not made a decision to give or withhold consent, the HTODA allows a person with parental responsibility for him or her immediately before he or she died to consent. Where the child is alive and has not made a decision and is either:

    a) not competent to do so; or

    b) competent to do so, but is unwilling to make that decision,

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

130. A person who has parental responsibility will usually, but not always, be the child's parent. The Children and Young Persons Act 2001 is the relevant legislation for establishing who has parental responsibility.

131. The HTODA is silent on how to assess a child's competence. The responsibility for assessing competence rests with the person seeking consent. The *Gillick* test (see paragraph 88) is considered to be the appropriate benchmark for assessing a child's competence.

132. Where there is any dispute between people with parental responsibility or any doubt as to the child's best interests, the matter should be referred to the Court for approval[19]. For further guidance on court approval in cases of potential donation, see Code F: Donation of solid organs and tissue for transplantation and Code G: Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation.

133. Where a child has capacity to consent, and agrees to the sharing of their information, it is good practice to consult the person (or people) who have parental responsibility for the child and to involve them in the process of the child making the decision. However, it should be emphasised that, if the child has capacity to consent, the decision to consent and to share their information must be the child's. It is also essential to make sure that a child has consented voluntarily and has not been unduly influenced by anyone else.

134. If a child does have the understanding or intelligence[20] to make a decision about whether to disclose their information to those with parental responsibility

[19] n.b. Section 40 (appointment by Court of acting nearest relative) of the MH Act.
[20] N.b. Paragraph 31.11 of the MH Act Code of Practice.

for them, you may only disclose information where it is in the best interests of the child.

135. Omitted.

136. Omitted.

137. Omitted.

138. Omitted.

HTODA powers to deem consent

139. Section 14 (power to dispense with need for consent) of the HTODA allows CO to dispense with the need for consent in certain circumstances, having regard to the circumstances in which the High Court may make an order further to regulations made under section 15(4) of the HTODA. Where tissue from a living person could be used to obtain scientific or medical information which may be relevant to another person or future person, CO has the power to deem consent to be in place where it is not reasonably possible to trace the person from whom the material came, or they have not responded to requests for consent to use of their material. This may be important where information could be obtained about the treatment and diagnosis of the other person.

140. This provision can only be used when the Department is satisfied –

    a) there is no reason to believe that the person has died;

    b) they are not known to have refused to consent or they lack capacity to consent;

    c) that it is either –

        i. not reasonably possible to trace the person from whose body the organ has tissue has come; or

        ii. reasonable efforts have been made to get the donor to decide whether or not to consent and a notice has been given to the donor of the application to deem consent.

    The Department may have regard to HTA guidance on the implementation of these provisions.

Fetal tissue

141. The law does not distinguish between foetal tissue (with the exception of embryos as defined by the Act) and other tissue from the mother. The definition of tissue includes all non-foetal products of conception (i.e. placenta, membranes, umbilical cord, amniotic fluid). Consequently, foetal tissue and non-foetal products of conception are subject to the same consent requirements under the HTODA as all other tissue from the living (see section on tissue from the living, paragraphs 108 – 112). However, because of the

sensitivity surrounding pregnancy loss, consent should always be sought, even where it might not be lawfully required.

142. It should be noted that the reference to foetal tissue within this Code does not include stillbirths (babies born dead after 24 weeks gestation) or neonatal deaths (babies or foetuses of any gestational age which are born showing signs of life and die before the age of 28 days). Seeking consent for the removal, storage or use of the tissue of babies from stillbirths or neonatal deaths should be handled in accordance with provisions for seeking consent for use of the tissue of the deceased (see paragraphs 76 – 77A). It is recommended that, whenever possible, the consent process for the examination of stillbirths and neonatal death involves the mother, and that, where appropriate, both parents are involved.

143. In the event of foetal tissue arising as a consequence of treatment provided further to the Abortion Reform Act 2019, regard must be had to any direction issued by the DHSC[21] with regard to the disposal of the products of conception. CO has published guidance on the disposal of pregnancy remains, which reflects the very sensitive nature of these.

CO Licensing Standards

144. In order to obtain a licence from PH, the applicant must demonstrate that they and the relevant premises are suitable[22]. PH will assess suitability against a number of core Standards, which were developed in consultation with representatives from the regulated sectors. These relate to the consent provisions of the 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.

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

146. 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

[21] Disposal of a Foetus Following Termination Directions 2019 *[GC 2019/0003]*, Department of Health and Social Care. Approved by Tynwald on 22nd May 2019 to come into effect on 24th May 2019.
[22] See [insert title of licensing regulations here].

the conditions of the licence are complied with and that other people to whom the licence applies are suitable to carry on the activity. By ensuring that the establishment is meeting the licensing standards set by CO, the DI will be meeting their statutory responsibility.

147. When CO staff (i.e. PH staff), or persons appointed by CO for this purpose, undertake inspections of licensed establishments, they make judgements about the suitability of the Licence Holder (LH), the DI, the practices taking place and the premises on which they take place. They do this by assessing the establishment's compliance with the licensing standards set by CO, which reflect the guiding principles set out in this Code and provide the operational detail of how establishments should meet the requirements of the HTODA and the other Codes of Practice.

148. The licensing standards set by CO are grouped under four headings: Consent (C), Governance and Quality Systems (GQ), Traceability (T), and Premises, Facilities and Equipment (PFE). Under each of these headings, there are overarching statements, from which the Standards flow.

Consent (C)

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

Governance and Quality systems (GQ)

150. Establishments meeting 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)

151. 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 we expect establishments to take a pro-active approach to assuring themselves of effective traceability throughout the lifetime of their licence. In addition, as the final traceability step, they will have established disposal arrangements which are in accordance with these Codes of Practice.

Premises, Facilities and Equipment (PFE)

152. Establishments meeting the 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.

    The licensing standards 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: Background, interpretation and guidance

Legislative background and context

1. Cabinet Office (CO) is the Department responsible for the operation of the general functions of the Human Tissue and Organ Donation Act 2021 (HOTDA) further to section 19 (general functions) of that Act.
2. Public Health (PH), as a part of CO, will assist in the day to day operation of these functions, including the issuing of licences further to section 20 of the HTODA.
3. The HTODA was introduced to improve the process with respect to the granting of consent for the donation of organs and human tissue, noting the Island's legislation no longer aligned with similar provisions in the UK [i.e. the Human Tissue Act 2004 (of Parliament)]. The HTODA revokes and replaces the Island's previous regulatory controls with respect to organs and human tissue (i.e. the Human Tissue Act 1986 and the Human Organ Transplants Act 1993) with new legislation which is, in part, aligned with UK regulatory controls.
4. The HTODA applies to the removal, storage and use of human organs and tissue for scheduled purposes[23], in accordance with a licence granted by PH as may be required from time to time.
5. The requirements of the HTODA[24] do not apply to activities involving bodies, or to an organ or tissue that comes from a person 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
6. The Human Tissue and Organ Donation (Persons who Lack Capacity to Consent and Transplants) Regulations **** (the Regulations) lay down the responsibilities of *[XXXXX]* in relation to the donation of transplantable material from living donors, including those who lack capacity to consent.
7. The European Union Tissue and Cells Directive 2004/23/EC (EUTCD) sets standards of quality and safety for the donation, obtainment, testing, processing, preservation, storage and distribution of human tissues and cells.
8. The standards set by the EUTCD are also prescribed in UK law via the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (of Parliament) ["Q&S Regulations UK"].
9. To align with these UK and EU standards, CO has made the Human Tissue and Organ Donation (Quality and Safety for Human Application) Regulations 20** ["Q&S Regulations"]. Establishments regulated under the Q&S Regulations

[23] Defined by the HTODA and explained in further detail in the glossary.
[24] n.b. sections 7(5) & (6), 18(5), 21(6), 42 and 68(2) of the HTODA.

should refer to the CO's *Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment*.

10. The European Union Organ Donation Directive 2010/53/EU (EUODD) sets quality and safety standards for organ donation and transplantation.

11. The standards set out by the EUODD have been transposed into UK law through The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (of Parliament) ["Q&S (Organs) Regulations UK"].

12. To align with these UK and EU standards, CO has made the Human Tissue and Organ Donation (Quality and Safety of Organs Intended for Transplantation) Regulations 20** ["Q&S (Organs) Regulations"]. Establishments licensed under the Q&S (Organs) Regulations should refer to CO's The Quality and Safety of Organs Intended for Transplantation: a documentary framework.

13. A deemed consent system for organ and tissue donation after death is operational in the Isle of Man. This does not have an impact on CO's, and PH on behalf of CO, regulation of living organ donation.

Status and use of the Codes of Practice

14. Throughout the Codes, the word 'must' applies to all legal requirements derived from primary and secondary legislation (for example, the legal requirement to hold a licence to store human tissue for use for a scheduled purpose) and the duty to abide by CO's licensing standards. We use the word 'should' when providing advice on how to meet these requirements.

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

Other advice and guidance

16. The Codes of Practice complement each other and should be read alongside other relevant advice and guidance, which is either referenced in the text or provided on the website www.gov.im.

17. The Codes of Practice may also refer to guidance which has been produced by a number of other organisations. CO is not responsible for the content of others' guidance, but does recommend that practitioners follow such guidance when they fall within its remit.

18. The Codes of Practice and other CO guidance should, however, be used as the definitive source of information within the remit of the HTODA or any other matters within CO's remit. If you are in any doubt, please contact PH or seek

your own legal advice. Regulated sectors should also keep up to date with other relevant legislation.

Annex B – Consent requirements for scheduled purposes

Table setting out consent requirements under the HTODA for scheduled purposes.

Scheduled purpose	Consent required for human tissue from the living			Consent required for human tissue from the deceased		
	Removal	**Storage**	**Use**	**Removal**	**Storage**	**Use**
Anatomical examination	N/A	N/A	N/A	✓	✓	✓
Determining the cause of death Adult and child over 12 **	N/A	N/A	N/A	✓**	✓**	✓**
Determining the cause of death Paediatric, Neonatal, Perinatal, Fetal, Stillborn ***	N/A	N/A	N/A	✓***	✓***	✓***
Establishing after a person's death the efficacy of any drug or other treatment administered to them**	N/A	N/A	N/A	✓**	✓**	✓**
Obtaining scientific or medical information about a living or deceased person which may be relevant to any person (including a future person)	X*	✓	✓	✓	✓	✓
Public display	X*	✓	✓	✓	✓	✓
Research in connection with disorders, or the functioning of the human body	X*	✓	✓	✓	✓	✓
Transplantation	X*	✓	✓	✓	✓	✓
Clinical audit	X*	X	X	✓	✓	✓
Education or training	X*	X	X	✓	✓	✓
Performance assessment	X*	X	X	✓	✓	✓
Public health monitoring	X*	X	X	✓	✓	✓
Quality assurance	X*	X	X	✓	✓	✓

✓ Consent is required under the HTODA.

X Consent is not required under the HTODA.

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

** Consent is not needed for post-mortems under coroner authority. Nor is consent required for the storage, as part of patients' medical records, of tissue, tissue blocks and slides resulting from a post-mortem examination, as these will be held automatically. (Tissue includes tissue sample, blood ((or any sample derived from blood)) or other body fluid).

*** Consent is needed for Paediatric, Neonatal, Perinatal, Fetal and Stillborn post-mortems carried out in England, NI. Due to the specialist nature of paediatric post-mortems these should be undertaken at paediatric pathology unit. This consent should cover removal, storage and/or use of material from the deceased for any scheduled purpose

Annex C – Consent requirements and good practice

Table setting out when consent is required and when it is recommended as good practice.

Activity (Consent may be sought for more than one activity at the same time)	Consent required	Consent recommended as good practice	Guidance	
			Code reference	Further guidance
Storage and/or use of tissue from the living for the scheduled purposes of: • obtaining scientific or medical information which may be relevant to any other person, now or in the future; • public display; • research; • transplantation	✓	N/A	Paragraph 109, 111 - 115	
Storage and/or use of tissue from the living for research, where the research is ethically approved and the tissue is non-identifiable to the researcher	X	✓	Paragraph 109, 111 - 115	
Storage and/or use of tissue from the living for the scheduled purposes of: • clinical audit; • education or training • relating to human health; • performance assessment; • public health monitoring; • quality assurance	X		Paragraph 109, 111 - 115	
Removal, storage and/or use of material from the deceased for any scheduled purpose	✓		Paragraph 76, 108 - 110	

Activity (Consent may be sought for more than one activity at the same time)	Consent required	Consent recommended as good practice	Guidance	
			Code reference	Further guidance
Diagnosis and treatment	X	Consent is required under the common law for removal of tissue from the living	Paragraph 109 – 112	Mental Health Act 1998 Code of Practice
Coroner's post-mortem	X	Consent is not required for tissue, tissue blocks and slides resulting from a post-mortem examination. These are automatically kept as part the patients' medical records. (Tissue includes tissue sample, blood ((or any sample derived from blood)) or other body fluid).	Code B: Post-mortem examination	Licensing standards and guidance The Cremation Regulations 2000 Coroner of Inquests Rules 1988[25] (as amended)

[25] GC 3/88 as amended by SD 0126/13.

Activity (Consent may be sought for more than one activity at the same time)	Consent required	Consent recommended as good practice	Guidance	
			Code reference	Further guidance
Hospital Consent Post-mortem (Adult & child over 12)	Consent/Authorisation is required for a Hospital Consent Post-mortem. Tissue blocks and slides resulting from a Hospital Consent post-mortem examination are automatically kept as part the patients' medical records. (Tissue includes tissue sample, blood ((or any sample derived from blood)) or other body fluid).		Code B: Post-mortem examination	Licensing standards and guidance Scotland Gov/Health consent/authorisation forms https://www.nn.nhs.scot/pathology/professional/post-mortem-forms/ The Cremation Regulations 2000 Coroner of Inquests Rules 1988 (as amended)
Hospital Consent Post-mortem (Paediatric, Neonatal, Perinatal, Fetal, Stillborn) Removal, storage and/or use of material from the deceased for any scheduled purpose	Consent is required for material resulting from a Paediatric, Neonatal, Perinatal, Fetal, Stillborn post-mortem examination.		Code B: Post-mortem examination	Licensing standards and guidance Human Tissue Authority The Cremation Regulations 2000

Activity (Consent may be sought for more than one activity at the same time)	Consent required	Consent recommended as good practice	Guidance	
			Code reference	Further guidance
				Coroner of Inquests Rules 1988 (as amended)
Criminal justice	X		Code B: Post-mortem examination	Section 38 (criminal justice purposes) of the HTODA
Making and displaying of images	X	✓	Paragraph 73 – 75	General Medical Council guidance on making and using visual and audio recordings of patients
Storage and/or use of existing holdings	X		Paragraph 68 – 72	