CODE E

RESEARCH

Public Health

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

HUMAN TISSUE AND ORGAN DONATION ACT 2021

Code E: Research

Contents

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

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

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

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

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

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

   e) securing publicity on or around 15th March of each year on the desirability of making tissue and organs 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 and organs from the deceased; and

   d) the removal and storage of human tissue and organs 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 a 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 tissues and organs as a consequence of these activities.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8. In combination, the Codes of Practice are intended to provide anyone undertaking activities with a reference source which gives practical advice on the minimum steps necessary to comply with the relevant legislation as well as CO and PH policy.

Introduction to the Research Code

The role of PH in regulating research under the HTODA

9. The type of research regulated by PH under the HTODA, on behalf of CO, usually takes the form of 'laboratory bench' research. PH ensures that tissue an organs for this type of research are removed and stored in an appropriate and well managed way.

10. PH licenses organisations for removal and storage for research in the Isle of Man. PH's licensing role in research is limited to licensing premises, such as tissue banks, to store tissue and organs from the living and the deceased. PH also license establishments, including establishments in the post mortem sector, for tissue to be removed from the deceased for research.

11. PH do not license the 'use' of tissue or organs for research or approve individual research projects or clinical trials.

However, CO may grant ethical approval for tissue and organs to be stored and used for research in connection with disorders of the human body, if that tissue or organ has been donated by a living person. CO support the operation of the independent Isle of Man Research Ethics Committee (IOMREC). Before granting such ethical approval, CO will always seek a recommendation from the IOMREC.

PH, and CO, may also work in partnership with other organisations with the aim of helping researchers to navigate and understand their regulated activities. CO and PH do this by discussing matters of joint relevance, sharing information, working together on answering enquiries and producing joint positions or guidance.

Scope of this Code

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

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

14. This Code should be read in conjunction with Code A: Guiding principles and the fundamental principle of consent, which sets out the principles which govern the conduct of activities within DHSC's remit and informs the content of this and the other Codes.

Offences under the HTODA

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

16. Section 12 (prohibition of activities without consent etc.) of the HTODA makes it an offence:

    a) to remove tissue or organs from the deceased; and

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

    including determining the cause of death, without appropriate consent (including that of the Coroner).

    Where there is consent to use material for one purpose, it may not be used for another purpose without appropriate consent for that purpose.

    Section 12 (prohibition of activities without consent etc.) of the HTODA also makes it an offence to falsely represent that there is appropriate consent to do an activity, or that Section 7 (authorisation of activities for scheduled purposes) of the HTODA does not apply.

17. Section 20(1) and (2) (licence requirement) of the HTODA prohibit the following activities in the research sector, except under the authority of a licence:

    a) the removal (otherwise than in the course of the carrying-out of an anatomical examination or the making of a post-mortem examination) of tissues or organs from the body of a deceased person for use for scheduled purposes other than transplantation; and

    b) 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.

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

19. The offence of non-consensual analysis of DNA and the exceptions to it are set out in section 68 (non-consensual analysis of DNA) of the HTODA and covered in detail later in this Code.

Structure and navigation

20. This Code begins with information about the research and range of human material within the remit of DHSC and regulatory function of CO. The Code then covers matters relating to tissue and organs from the living, and tissue and organs from the deceased.

21. The main body of the Code covers the consent and licensing requirements relevant to the research community and sets out the expectations for establishments licensed in the research sector, supported by good practice examples.

22. At the end of this Code, there is a section on PH licensing standards.

23. A glossary with terms specific to this Code is available at the end of the document. You can view, download and print copies of all the Codes from the gov.im website.

Tissue, organs and research

What is research?

24. The HTODA does not contain a definition of research, but for the purposes of what falls within DHSC's remit and CO's regulatory function, the following definition is applied:

    A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body. Research attempts to derive new knowledge and includes studies that aim to generate hypotheses, as well as studies that aim to test them or develop practical applications or new knowledge.

25. Omit.

What is meant by the terms tissue and organ?

26. The HTODA defines tissue, and thus organs, as *'material, other than gametes, which consists of or includes human cells'*. Tissue does not include hair or nails from living people, embryos outside the human body or any material which contains only cells created outside the human body; for example, cell lines.

27. The fundamental concept of the definition of tissue is that if a sample is known to contain even a single cell that has come from a human body, then the sample should be classified as tissue.

28. Omit.

Access to tissue and organs from the living

29. Tissue and organs from the living means tissue or organs (or both) taken while the person was alive, and this definition persists after their death.

30. Tissue that were taken from the living for diagnosis and subsequently stored in a diagnostic archive can be valuable for use in research in connection with the disorders, or the functioning of, the human body. Diagnostic tissue can only be released for research under the following circumstances:

    a) when, subject to any conditions applied, the person has given consent for use of their tissue in research (the preferable scenario); or

    b) when the tissue will be released to the researcher in a non-identifiable form and will be used in a project that has ethical approval by CO further to recommendation from the Isle of Man Research Ethics Committee (IOMREC), see paragraphs 65-69.

Example

A researcher wishes to use paraffin-embedded blocks of surgically removed thyroid tissue stored in the archives of a pathology department after its use for diagnosis.

As consent for the use of the donor's tissue for research was not originally sought from that person, it can only be released from the diagnostic archive if it does not identify that person and is used in a specific project that has been recommended by the IOMREC and approved by CO.

Example

A researcher requires whole blood for a research project.

They are able to access blood samples from a diagnostic archive in a hospital biochemistry laboratory, which have been stored for the intended purpose of diagnosis and screening.

Consent for the use of the samples for research was not obtained. The researcher can use these samples without the patients' consent, provided the samples are not identifiable to the researcher and the specific project has been recommended by the IOMREC and approved by CO.

31. Once tissue is released from a diagnostic archive for research, it must be stored on PH-licensed premises, unless it is for a specific project approved by the CO on the basis of a recommendation from the IOMREC, or where any of the exceptions described in paragraph 84 apply. Further information about diagnostic archives releasing tissue for research is covered in paragraphs 94-97 of this Code.

32. On rare occasions, tissue and organs may be removed from the living for transplantation and not used; for example, it may be surplus to clinical requirements and might otherwise be disposed of. Such tissue and organs can be used for research where consent is in place for that purpose, or where the tissue or organs will not be identifiable to the researcher and this material will be used in a specific project recommended by the IOMREC and approved by CO.

33. If a person has made known their objection to the use of tissue for purposes other than medical care, such as research, this must be respected.

34. Findings of potential medical importance to donors may be made while undertaking human tissue research, including 'incidental findings' beyond the aims of the research. There is no single approach for the feedback of such findings.

    Researchers are therefore encouraged to consider how they would manage such findings and should be able to demonstrate appropriate arrangements where these are relevant, reflecting these clearly in the information used to support the consent process.

    The Medical Research Council (MRC) and Wellcome Trust have published a framework on the feedback of health-related findings in research.

Access to tissue and organs from the deceased

35. The HTODA requires that removal of tissue or organs from the deceased for research within the scope of the HTODA must always take place under the authority of a PH licence. In other words, the specific removal premises must be licensed and a Designated Individual (DI) will be responsible for the removal activity.

36. Human tissue and organs removed from the deceased must only be retained for use in research, other than for anatomical examination, if:

    a) the human tissue has formed part of a person's medical record following a coroner-authorised post-mortem and the research is for the purposes of:

        i. Providing information about, or confirming the cause of death;

        ii. Investigating the effect and efficacy of any medical or surgical intervention carried out on the person

        iii. Obtaining information which may be relevant to the health of any other person (including a future person);

        iv. Audit; or

    b) appropriate consent has been explicitly given for that activity involving that human tissue or organ.

    You can find more information about appropriate consent in Code of Practice A and Code of Practice B, the latter of which specifically relates to post-mortem examinations.

37. Once tissue or organs from the deceased are stored for research this material must be held on PH-licensed premises, unless this material is being used in a specific project approved by, or pending ethical approval from CO, or where any of the exceptions described in paragraph 84 apply.

Research involving stillborn babies or infants who have died in the neonatal period

38. Obtaining consent for the removal, storage or use of the tissue or organs of babies from stillbirths or neonatal deaths should be handled in accordance with provisions for seeking consent for use of the tissue or organs of the deceased.

Consent

Obtaining consent

39. The giving of consent is a positive act. The HTODA requires that consent must be sought for the removal, storage and use of human tissue or organs for certain scheduled purposes, including research in connection with disorders, or the functioning, of the human body, subject to

    a) the exception set out in paragraph 36(a) above; and

    b) the exceptions set out later in this Code (see paragraphs 56 to 69).

40. Consent to treatment and examination (and the removal of tissue or organs from the living for research) is required by the HTODA and is also covered by the common law, the Mental Health Act 1998 (MH Act) and the MH Act Code of Practice where appropriate; these are not covered in this Code of Practice. Manx Care have policies in place for seeking consent to treatment and the legal position is set out in guidance accessible via the gov.im website.

41. Omit.

42. To give consent when alive, the individual (or the person with parental responsibility) 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 or organs will be used and any possible risks or implications of its use, such as genetic tests. Where consent was not given while the person was alive, their nominated representative or a relative may give consent (please see Code of Practice A for more information).

43. Establishments should also provide appropriate and clear information on the activities for which they are seeking consent. The information might be in the form of leaflets or information sheets, or might be contained within the consent form. Many establishments have policies on consent that include the use of standard documentation. Such documentation should make reference to the HTODA and the role of the relevant parties (e.g. CO, PH & NHSBT), and be reviewed to ensure that it is consistent with the relevant HTODA Codes of Practice.

44. Where appropriate, information should be available in widely spoken languages and in a variety of formats, such as video, audio or braille and in line with other relevant legislation, including the Equality Act 2017.

Example

Some researchers have provided information about their research study whereby the donor gives consent electronically. The study software allows information to be displayed in large font or listened to via audio play-back. The software allows donors to submit questions by email or via a dedicated contact number.

The patient information leaflet may be printed at the donor's request. The establishment also provides the information in hard copy to those who do not have computer access.

45. To facilitate the use of valuable human tissue and organs in research, donors should be advised of the potential value of giving their generic consent to future research. It is still important, however, that consent is valid. If the intention is to store the tissue or organs for an as yet unknown research purpose or as part of a research tissue bank then this should be explained, setting out the types of research that may be involved, any wider implications and the circumstances under which the tissue or organs will be disposed of.

46. 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 guidance on 'Conditions on consent' can be found in paragraphs 45-48 of Code A.

47. If identifiable tissue or organs are to be used for research, donors should be informed about any implications this may have. For example, they may be contacted by researchers, given feedback, or be asked for access to their medical records. Donors should be asked whether the consent they are giving is generic (for example, for use in any future research project), or specific (for one research project only). If it is the latter, detailed information about the research project should be provided, in line with good practice. Depending on the nature of the research, researchers may need to consider how they deal with a later loss of mental capacity by the donor. Certain safeguards, which are outlined in paragraph 54, need to be in place where the possibility of research involving adults who lack capacity is being explored.

48. To ensure transparency in areas of public concern, for example where research is known or is likely to involve the commercial sector, genetic testing or the use of human tissue or organs in animals, those facts should be included and discussed in the information used to support the consent process. Where there is an expectation that samples may be exported for use abroad, CO also advises that donors are provided with adequate information as part of the consent process.

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

50. Subject to the exceptions set out later in this Code, detailed consent must be obtained from employees or students who volunteer the use of their tissue or organs for research (see paragraph 53).

Example

Students on a sports science course are being asked to give a blood sample in order to take part in research into the link between stress and exercise. For the consent to be valid, the students must be given sufficient information so they can give their consent voluntarily, having made an informed choice about whether they want to participate in the research or not.

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 implications and practicalities of withdrawing consent should be made clear; for example, withdrawal of consent cannot be effective where tissue has already been used.

52. If a donor gives consent for their tissue or organs 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 a donor 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.

53. Research establishments may wish to seek consent to obtain the equivalent of 'healthy volunteer' blood, or other, samples from their own staff or students. A reliance on this mechanism of donation poses potential risks to staff or students who are also donors; for example, there is a risk of people feeling pressured or coerced to donate. At a minimum, in addition to meeting all other required regulatory standards, establishments that wish to obtain samples from their staff or students should put systems in place to ensure the following:

    a) a confidential coding system, so that donors cannot readily be identified by their colleagues;
    b) donors should be able to withdraw their consent at any time, without any reason, without their decision having any negative effect on their relationship with colleagues or their conditions of employment or enrolment;
    c) donors of samples with desirable biological characteristics should not be unfairly targeted;
    d) donation thresholds should be established, and donation quantities monitored, such that donors do not donate excessively;
    e) where donations are likely to be repeated, appropriate consent should either be sought afresh or reconfirmed, depending on whether the information needed to support the consent process has changed.

    In addition, establishments need to consider other risks, such as whether the lifestyle or medical history of the donor has changed since their previous donation. This may be important to protect both research staff (for example with regard to exposure to potential infectious risks) and donors (such as where their health status precludes donations).

    In consideration of these issues, establishments may wish to seek separate employment law or other legal advice when considering whether or not to involve their staff or students as donors.

54. Not all adults whose human tissue or organs may be used in research have the capacity to consent themselves. However, medical research involving adults who lack mental capacity can lead to innovations in healthcare which could substantially improve their health and quality of life, and that of others with similar conditions. It is therefore important that these adults are given the opportunity to possibly participate in such research.

    However, certain safeguards need to be in place to ensure that this vulnerable group are protected when they do participate in research. The IOMREC are required to review such research and more information about these arrangements can be found on the gov.im website.

    For detailed information about medical research involving adults who cannot consent, refer to guidance on the gov.im website; the MH Act and the associated MH Act Code of Practice; and the progress being made to implement the Capacity Act 2021 (of Tynwald).

55. It is important for those involved in research to be aware that, in addition to the consent provisions of the HTODA, they will need to adhere to other legal requirements such as the Data Protection Act 2018 and the common law duty of confidentiality.

Consent exceptions

56. The consent requirements of the HTODA are not retrospective. This means that legally it is not necessary to seek consent under the HTODA to store or use an 'existing holding' for a scheduled purpose. An existing holding is material from the living or deceased that was already held at the time the HTODA came into force on XXXDATEXXX.

57. Although there is no statutory requirement for consent for storage or use of tissue or organ that is an existing holding, it does not mean that all such human tissue and organs can be used freely and without regard to issues of consent or other ethical considerations. If practical, the consent of the participant should be sought and the views of the deceased person or of their relatives[4] (if known) must be respected.

58. Ethical approval may be required for research involving existing holdings and, as for any case where ethical review is being considered, reference should be made to the guidance published on the gov.im website.

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

60. It should be noted that consent is normally required to use identifiable patient data in research. In cases where researchers do not have consent to use identifiable patient data for research, they should refer to the IOMREC for ethical review. Obtaining consent may be preferable to developing complex systems for keeping samples unlinked.

61. Whatever the date the tissue or organ was donated for research, if more than 100 years have elapsed since a person's death, consent to undertake research on their tissue or organ is not required under the HTODA.

[4] 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.

62. In terms of research, the consent provisions of the HTODA do not apply to imported material. However, CO considers it good practice for there to be mechanisms in place to provide assurance that the tissue or organ has been obtained with valid consent. Specific guidance on import (and export) is set out later in this Code (see paragraphs 98-114).

63. There is a further statutory consent exception for the use and storage of human tissue and organs for research, where all of the following criteria apply:

    a) the tissue or organ is from a living person; and

    b) the researcher is not in possession, and not likely to come into possession of information that identifies the person from whom it has come; and

    c) where the material is used for a specific research project recommended by the IOMREC and approved by CO.

64. There may be occasions when a clinician involved in research may also have access to a secure database that would permit identification of a sample used in research and the identity of the patient whose material is being used. Providing the research material is not identifiable to the researcher (if it has been coded by a laboratory accession number, for example) and the researcher does not seek to link the sample to the patient, it will still be regarded as non-identifiable and the research will be permissible without consent if recommended by the IOMREC and approved by CO.

65. Ethical approval of research on human tissue must be applied for as described in the guidance available via the gov.im website. Ethical approval which qualifies for exemptions under the HTODA can only be recommended by the IOMREC and approved by CO.

66. Further information about the link between ethical approval and the licensing and consent exceptions is provided in Annex B.

67. Omit.

68. Omit.

69. The IOMREC can consider all applications relating to research involving the use of human tissue and organs, even where this is conducted outside the NHS.

Consent for DNA analysis and the offence of non-consensual DNA analysis

70. Anyone holding 'bodily material' without the qualifying consent of the person/s concerned, intending to analyse the DNA and use the results, may be breaking the law. Section 68 (non-consensual analysis of DNA) of HTODA, makes it an offence to analyse DNA without qualifying consent unless it is for an excepted purpose. On summary conviction the offence attracts a fine of up to £10,000 (level 5 on the standard scale) or a term of imprisonment of up to 12 months. On conviction on information the offence may be punished with a custodial sentence of up to 3 years.

71. 'Bodily material' differs from 'tissue' as it includes hair and nails from the living as well as the deceased. It also includes gametes (human sperm and eggs).

72. DNA itself (as opposed to tissue from which it originates) is not considered to be tissue under the HTODA. DNA storage and processing by the police is not subject to licensing noting the exception provided by section 38 (criminal justice purposes) and Part 2 of Schedule 3 to the HTODA.

73. In this section, the guidance also applies to RNA analysis where it is to be used to provide information about DNA.

74. The results of DNA analysis can be used for research without consent[5], providing the bodily material from which the DNA is extracted:

    a) is from a living person; and

    b) the researcher is not in possession, and not likely to come into possession of information that identifies the person from whom it has come; and

    c) the material is used for a specific research project which has received recommended for ethical approval by the IOMREC to the CO for approval

75. Although no offence will be committed in this situation, PH recommends that consent is sought where it is practical to do so. Information about ethical approval from the IOMREC is provided in paragraphs 65-69 and 86-88.

Example

A researcher is using the results of DNA analysis extracted from tissue biopsies from living people as part of a research project that has been recommended by the IOMREC and approved by CO. The researcher will not come into possession of any patient identifiable information. No offence will be committed if consent is not obtained.

76. If appropriate consent has previously been obtained to use samples for research under the HTODA, and there is a subsequent intention for the research to include the analysis of DNA, as long as the consent does not rule-out DNA analysis, then the original consent will suffice as 'qualifying' consent for use in the Isle of Man. However, where samples are being prospectively collected for research involving DNA analysis, it should be made clear to the donor that their bodily material will be used for this purpose.

77. The DNA analysis offence in the HTODA applies only to bodily material; however, it is possible to extract human DNA from acellular materials, such as serum, for analysis. It follows that the offence does not extend to acellular materials from which DNA can be extracted and analysed.

78. Even though an offence would not be committed, the use, without consent, of acellular material for DNA analysis for a purpose other than an excepted purpose, appears contrary to the purpose and intention of the DNA offence set out in the HTODA. As this does not fall within the scope of the HTODA or the regulatory function of PH, there was a concern that a regulatory gap existed.

79. Working together to address this concern, the HTA, HRA and Devolved Administrations have agreed a position on the regulatory oversight of proposed research using DNA extracted from acellular material. This position is supported by the CO.

[5] i.e. for an "excepted purpose" further to paragraph 9 (DNA analysis on anonymised basis for medical research) of Schedule 3 to the HTODA.

The ethical issues in the use of this material are the same as for those using bodily material and, therefore, it is expected that researchers intending to extract human DNA from acellular material for research analysis to submit their proposals for ethical review by the IOMREC if consent is not in place. Information about ethical approval from the IOMREC is provided in paragraphs 65-69 and 86-88.

Licensing

80. This section explains where, in the context of research, a licence from CO is needed and where exceptions to licensing requirements apply.

81. The storage of human tissue and organs for research, and its removal from the deceased, is licensed by PH. PH does not license the 'use' of tissue and organs for research and it does not have a role in approving individual research projects.

82. The HTODA does not define the term 'storage' and does not give any minimum or maximum term for storage of human tissue and organs for research.

83. As there is no set time period for storage, PH encourage researchers instead to consider whether they are actually storing material for research in the normal usage of that term; for example, to think about the context in which they plan to hold tissue and organs and their intention. Some examples are provided below to help clarify the concept of storage requiring a licence.

84. A licence to store tissue and organs for research within the scope of the HTODA is not required in the following circumstances:

    a) It is from a person who died prior to XXXDATEXXX and at least one hundred years have elapsed since their death[6].

    b) It is being held 'incidental to transportation'[7].

    This term is not defined in law but CO has interpreted this as the temporary holding of material in transit, while it is being conveyed from one place to another.

    It is considered the timeframe should only apply for a matter of hours or days, and no longer than a week. The intention of the wording of that interpretation is not to designate a seven-day exemption period, but rather to indicate that the material should be held for as short a period as possible. The focus is on hours or days, rather than one week.

Example

Skin biopsies for use in research are collected across a number of sites and batched before being sent to an establishment licensed by PH for storage for research. The multiple sites collecting the biopsies do not need to be licensed as the storage is pending transportation to a licensed establishment.

[6] This exemption from licensing is set out in the HTODA.
[7] (This exemption from licensing is set out in the HTODA).

c) It is being held whilst it is processed with the intention to extract DNA or RNA, or other subcellular components that are not tissue or organs (i.e. rendering the tissue acellular).

CO views this as analogous to the 'incidental to transportation' exception above. CO therefore takes the position that a licence is not required in these circumstances, providing the processing takes a matter of hours or days and no longer than a week. In summary, if there is no intention to use or store human cellular material for research, and the only holding of cellular material is temporary and for the purpose of obtaining material which does not contain cells, then no storage licence is required.

Example

A researcher wants to undertake a study looking into immunological responses to breast cancer. To do this clotted blood samples will be spun down to collect the serum. As the blood will be spun down within a matter of days and any residual cells disposed of to leave serum that is not tissue or organs, the blood does not need to be stored under a PH licence.

Further examples where a PH storage licence would not be required:

Example

An experiment is conducted over a 6 day period. Whole blood samples are provided by volunteers throughout the sample collection period. All the samples are made acellular by within 7 days, with only serum being stored for research.

Conclusion: There is no intention to use or store human cellular material for research, and the only holding of cellular material is temporary (a few days) and for the purpose of *obtaining research material which does not contain cells*. The serum is the material which will be stored for research, and this does not require a PH licence.

Example

A study has received approval from the CO, further to a recommendation from the IOMREC, where blood samples are taken during a clinical trial.

Conclusion: No PH licence is required to store samples for which such CO approval has been obtained (see paragraph 86).

e) Example where a PH storage licence would be required:

Blood samples from healthy volunteers are collected from two groups of participants as part of a research study over a two-day period. After each collection, the samples are stored in a refrigerator and then analysed for research, as a batch, once all have been collected. All samples are used and disposed of within seven days of the first collection. The project involves healthy volunteers and has not been recommended by the IOMREC and approved by CO.

Conclusion: Although the storage period is for only 2-3 days, tissue samples (whole blood) are being stored solely for the purpose of research within the scope of the HTODA; a PH storage licence is therefore required. Please note that even if the research destroys the cells, this does not alter the point that prior licensable storage of tissue for research would have taken place.

85. Imported tissue or organs stored for research should be treated in the same way as tissue or organs originating from participants in the Isle of Man. This means that the same exceptions to licensing apply. More information about imported material is provided later in this Code.

Ethical approval and its interaction with PH licensing

86. In addition to the exceptions above, there is a broader exception set out in *Human Tissue and Organ Donation (Ethical Approval, Qualifying Purposes and Transplantable Material) Regulations 2025*. These Regulations allow human tissue or organs held for a specific research project recommended by the IOMREC and approved by CO or, where approval is pending, to be stored on premises without a PH licence. An application for ethical approval is pending from the point it has been submitted until the decision has been communicated to the applicant.

87. CO advises researchers to consider the need for ethical approval before embarking on any research. A PH licence should not be viewed as an alternative to ethical approval by CO on the basis of a recommendation by the IOMREC.

88. While there is a relationship between ethical approval by CO on the basis of a recommendation by the IOMREC, and some of the requirements of the licensing requirements of the HTODA with regard to research, the need for ethical review of research should always be considered separately and in parallel with the legal requirement for a licence.

88A. Decisions about the need for ethical review are governed by institutional (e.g. local policies) and/or wider arrangements (e.g. the standard operating procedures of the IOMREC or legal requirements, such as the MH Act), and should be informed by potential ethical concerns raised by proposed research, whether or not the research involves human cellular material.

89. Once human tissue or organs are no longer being stored for a project approved by the CO on the basis of a recommendation by the IOMREC (or one where such approval is pending), these materials must be stored on PH-licensed premises if it is intended for a scheduled purpose. Where these materials are to be used for further research that does not have IOMREC approval, the research must be in accordance with the initial consent obtained or, if appropriate, further consent should be obtained. The need for further ethical review would also need to be considered as outlined in the previous paragraph.

90. Provided that the tissue or organs in the bank are stored on PH-licensed premises, the CO may give generic ethical approval, following a recommendation from the IOMREC[8], for a research tissue bank's arrangements for collection, storage and release of tissue and organs. Such research tissue banks need to be licensed because at least some of the tissue or organs being stored are not for specific projects holding CO approval.

[8] Subject to the IOMREC having the necessary knowledge and expertise to consider such an application.

Applications for ethical review of research tissue banks are voluntary. Subject to conditions, the bank's generic ethical approval extends to specific projects receiving non-identifiable tissue or organs from the bank. The tissue or organs do not then need to be stored on PH-licensed premises for the duration of the project; nor does the project need specific ethical approval.

If the research is not carried out in accordance with these requirements, specific project approval by the CO (on the basis of a recommendation by the IOMREC) will be required or, alternatively, the samples will need to be stored under a PH-licence. Information about the requirements governing the release of tissue or organs can be found on the gov.im website.

CO can also be a source of ethical advice to a bank on its arrangements for collecting, managing and distributing tissue or organs. In particular, CO can advise on informed consent and procedures for providing feedback to participants. Ethical approval for a research tissue bank offers additional assurance to end user researchers, donors and the public that its operations meet the highest ethical standards.

91. If the research tissue bank does not have broad ethics approval, human tissue or organs from the bank must be stored on PH-licensed premises unless a storage licensing exemption applies; for example, the researcher has obtained project specific approval from the CO on the basis of a recommendation from the IOMREC.

92. On completion of research using tissue or organs from a CO-approved research tissue bank, the individual researcher must transfer the tissue back to the bank or to an alternative PH-licensed establishment, apply for their own PH licence (unless there are existing local licensing arrangements which can be used to cover the further storage), apply for specific project approval by the CO or dispose of the human tissue or organ.

Example

A dental teaching hospital establishes a bank of human teeth to carry out research into tooth erosion, wear and hypersensitivity and control of dental plaque and staining. The teeth will be donated with consent from the donor after routine dental extraction. The hospital obtains a storage licence from PH as well as generic ethical approval to operate as a research tissue bank.

An individual researcher receiving teeth from the bank does not need to make further applications for project specific ethical approval or for a PH licence, provided the research project falls within the research aims, material disposal terms and terms of donor consent specified in the hospital's research tissue bank ethical approval. In this way, valuable human tissue and organs for research are controlled and made more accessible to a number of research projects.

93. Tissue or organs may need to be disposed of because, for example the consent does not permit its broad use for research, or (in rare instances) consent has been withdrawn. Further information about disposal can be found later in this Code (see paragraphs 127 – 130).

Diagnostic archives

94. Tissue or organs that are taken from the living for diagnosis and subsequently stored in a diagnostic archive can be a valuable research resource. Purely diagnostic archives do not need to be stored on PH-licensed premises as no licensable activity would be taking place.

    However, the HTODA clearly provides that the storage of tissue or organs for a 'scheduled purpose' must be on licensed premises. CO's position is that if a diagnostic archive releases tissue or organs for research occasionally upon request, its status as a diagnostic archive is clear.

    However, if there is an expectation that tissue or organs will be released on a regular basis, then it may cease to be a purely diagnostic archive, particularly where there are developed governance / decision-making structures and procedures for applying for tissue and organs.

95. Where a diagnostic archive functions as a resource for researchers as it invites applications for the release of samples, and/or in any way advertises the archive as a research resource, it is functioning as a research tissue bank. It must therefore be encompassed within the PH's licensing framework. This legal requirement stands, even where tissue and organs released from the archive will only ever be used as part of a specific project approved by on the basis of a recommendation by the IOMREC

96. Where the archive is on premises already licensed by PH for storage, providing the DI is willing to take responsibility for the governance of the archive, the licence can be extended in anticipation of the archive operating as a research tissue bank.

97. Where the archive is on premises not licensed by PH for storage, a new licence application will need to be submitted prior to the archive operating as a research tissue bank.

Import and export

98. The import and export of tissue and organs is not a licensable activity under the HTODA as long as it is to either –

    a) for the purposes of transporting to a premises in respect of which a licence is in force; or

    b) It is for the purposes of education, training or research.

    However, the storage of the material once it is imported may be licensable if this is for a scheduled purpose, such as research within the scope of the HTODA.

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

    a) 'import' means import into the Isle of Man;

    b) 'export' means export from the Isle of man.

100. Tissue and organs may be imported for use in research projects. A licence may not be needed to store this material in some cases where it is being kept for use in a research project that has been approved by CO on the basis of a recommendation by the IOMREC (see paragraphs 86-88). CO recommends that, wherever possible, the import and export of tissue and organs is conducted via PH's licensing regime, which involves a DI ensuring that premises are suitable for activities as authorised by the licence.

101. Imported material should be procured, used, handled, stored, transported and disposed of in accordance with the consent which has been obtained.

102. All persons or organisations wishing to import human bodies, body parts, tissue and organs into the Isle of Man should be able to demonstrate that:

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

    b) there is 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. They should be able to satisfy themselves and document the need for importing in terms of accessibility, quality, timeliness of supply, risk of infection, quality of service, cost effectiveness, or scientific or research need. Such documentation should be available for inspection by PH.

103. The HTODA makes consent the fundamental principle underpinning the lawful storage and use of human bodies, body parts, tissue and organs from the living or the deceased, for the purposes specified in the HTODA. The consent provisions of the HTODA do not apply, however, if the material has been imported. Nonetheless, CO considers it good practice to ensure mechanisms are in place in the source country for obtaining consent.

104. The importer should have in place, policies and/or SOPs which clearly set out the evidence indicating how informed consent was obtained, including safeguarding the confidentiality of all information relating to consent. If a separate organisation is importing the material, a documented agreement should be in place demonstrating that there is a record of consent in a suitable format.

105. Importers should satisfy themselves, with due assurance from their partners abroad, that any material intended for import is sourced consistently with the legal and ethical review requirements in the Isle of Man.

105A. When an establishment imports material into the Isle of Man for research, it is good practice for approval to be obtained from a research ethics authority or the local equivalent in the source country beforehand. Many countries have research ethics arrangements which operate to agreed standards. The ethical review in the source country may, in some cases, be considered to provide suitable assurances for the import of material into the Isle of Man.

106. If the importer of the material cannot ensure that ethical standards have been put in place, any potential risks of accepting such material should be carefully considered.

107. The supplier's record and other documentation of each consignment of imported human bodies, body parts, tissue and organs should be retained by the person undertaking the export for at least five years after disposal of the last item included in the consignment. The register maintained by the person undertaking the import should, similarly, be retained for at least five years after disposal of the last body item recorded in it.

108. Unless stipulated otherwise, the disposal arrangements for imported material should meet the requirements of the HTODA and these Codes of Practice; in other words, as though the material had been sourced from the Isle of Man.

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

110. Imports (and exports) of human tissue and organs other than to England, Wales and Scotland must normally be declared to HM Revenue and Customs.

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

112. It is the responsibility of the recipient country to ensure that, prior to export, the material is handled appropriately and that the required standards of that country have been met.

113. Documented agreements should be in place to ensure that human bodies, body parts, tissue and organs to be exported from the Isle of Man are used in accordance with the consent which has been obtained. Material should be handled, stored, transported and disposed of, in a manner consistent with safety considerations, and with the dignity and respect accorded to human bodies, body parts, tissue and organs in legislation and these Codes of Practice.

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

Xenotransplantation

115. Xenografts are cells, tissues or organs that are transplanted from one species to another. Human tissues, organs and cells are widely used in 'research in connection with disorders, or the functioning, of the human body' involving animal models.

    The use of human tissues, organs and cells in animals is not considered a method of storing human tissue, organs or cells and therefore does not require a storage licence.

    However, where human tissues, organs or cells are being stored for a scheduled purpose **before** they are transplanted into a recipient species, a storage licence may be required.

116. When consent is obtained for tissue, organs or cells to be used in research and it is known at the time of obtaining consent that this would involve the transfer of material to animal models, this should be explained to the individual and consent should be obtained for this.

    This is based on the requirement that for consent to be valid the individual should understand the nature and purpose of what is being proposed which includes how the tissue or organs will be used.

Interface between research, human application and clinical trials

Tissue, organs and cells, including stem cells and cell lines

117. The use of tissues, organs and cells in human application and clinical trials is a rapidly developing field. As the boundaries between research and human application are continually shifting, the potential for cross-over between the sectors is significant. To ensure that you are up to date with the regulatory requirements, you are advised to keep abreast of information provided on the gov.im website.

118. Human tissue and organs for research in vitro (i.e. will not be transplanted into humans) must be stored under a PH licence, subject to any exceptions that may be set out in the licensing section of this Code (see paragraph 84).

119. Tissue, organs or cells, including cell lines, which may be transplanted into humans, even where it is for research, will not be licensed by the PH.

120. Omit.

121. Omit.

122. Omit.

123. Omit.

Clinical trials

124. The storage of human tissue and organs as part of a clinical trial (where the material itself will not be used in human application) must take place on PH-licensed premises, subject to the exceptions set out in the licensing section of this Code (see paragraph 84).

125. Following the conclusion of a clinical trial, researchers may wish to store tissue and organs collected during the trial for research within the scope of the HTODA. Where there are plans to do this, researchers must have regard to the relevant consent and licensing requirements of the HTODA, as set out in this Code.

126. Establishments using tissues, organs or cells for human application as part of a clinical trial must be licensed under the *[Q&S Regulations]*. It is important to note that licensing under the *[Q&S Regulations]* still applies where tissue, organs or cells are used for human application as part of a clinical trial approved by CO upon a recommendation from the IOMREC.

Disposal

127. Processes should be in place to inform donors how their tissue and organs will be disposed of after use. The HTODA permits disposal of surplus tissue and organs as clinical waste.

128. CO recognises that what is sensitive and what is feasible at a local level needs to be taken into account. It is good practice for human tissue and organs to be bagged separately from clinical waste. It is not necessary for each tissue sample to be bagged and disposed of individually.

129. Establishments may have collections of existing holdings that are considered to be valuable for teaching or possible future research. They should review the usefulness of these collections on a regular basis and, where items are found not to be of value, they should be disposed of sensitively and respectfully, and the details documented.

130. Manx Care has issued separate guidance on the disposal of pregnancy remains, which may be accessed via the gov.im website.

PH Licensing Standards

131. 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 based on equivalent UK standards and after appropriate consultation. 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 organs and tissue removed from bodies, are treated with respect;

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

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

133. 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.

134. When PH staff undertake inspections of PH-licensed establishments, they make judgements about the suitability of the Licence Holder (LH), the DI, the practices taking place and the premises on which they take place. They do this by assessing the establishment's compliance with PH's Licensing Standards, 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 its Codes of Practice.

135. PH's Licensing Standards are grouped under four headings: Consent (C); Governance and Quality Systems (GQ); Traceability (T); and Premises, Facilities and Equipment (PFE). Under each of these headings, there are overarching statements, from which the standards flow. Separate standards for post-mortems are set out in Code B.

Consent (C)

136. Establishments meeting the consent standards will be able to demonstrate that their processes for seeking and gaining consent comply with the HTODA and its 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 System (GQ)

137. 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)

138. 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 will test this through traceability audits carried out on site and PH expect establishments to take a pro-active approach to assuring themselves of effective traceability throughout the lifetime of their licence. In addition, as the final traceability step, they will have established disposal arrangements which are in accordance with the HTODA's Codes of Practice.

Premises, Facilities and Equipment (PFE)

139. Establishments meeting these 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. 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.

140. PH Licensing Standards which will be applicable to the research sector from [XXXX] are included at Annex D and on the gov.im website. The standards are supported by comprehensive guidance notes.

Annex A

Legislative background and context

To be inserted later.

Annex B

Licensing and consent flowchart

To be inserted later.

Annex C

The link between ethical approval and the licensing consent exceptions for human tissue and organs in research

Flowchart be inserted later.

Annex D

HTA Licensing Standards: Research sector

Consent Standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue and Organ Donation Act 2021 (HTODA) and as set out in the HTODA's Codes of Practice
a) Consent procedures are documented and these, along with any associated documents, comply with the HTODA and the HTODA's Codes of Practice. b) Consent forms are available to those using or releasing tissue or organs for a scheduled purpose. c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HTODA and the HTODA's Codes of Practice. d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HTODA and the HTODA's Codes of Practice. e) Language translations are available when appropriate. f) Information is available in formats appropriate to the situation.
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent
a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HTODA and the HTODA's Codes of Practice. b) Records demonstrate up-to-date staff training. c) Competency is assessed and maintained.

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

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

Traceability

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

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

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

c) An audit trail is maintained, which includes details of: when and where the bodies, tissue and organs were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred and to whom.

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

e) Records of transportation and delivery are kept.

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

g) Records of any agreements with recipients of tissues or organs are kept.

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

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

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

Premises, facilities and equipment standards

PFE1 The premises are secure and fit for purpose

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

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

c) There are documented cleaning and decontamination procedures.

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

a) There is sufficient storage capacity.

b) Where relevant, storage arrangements ensure the dignity of the deceased.

c) Storage conditions are monitored, recorded and acted on when required.

d) There are documented contingency plans in place in case of failure in storage area.

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

a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept.

b) Users have access to instructions for equipment and are aware of how to report an equipment problem.

c) Staff are provided with suitable personal protective equipment.