

## Code of Practice and Standards



# Code E: Research

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## Introduction to the Human Tissue Authority Codes of Practice

1. The Human Tissue Authority's (HTA) regulatory remit is defined in the Human Tissue Act 2004 (HT Act). The HTA regulates the following activities through licensing:
  - 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.
2. The HTA also assesses applications for organ, bone marrow and peripheral blood stem cell (PBSC) donations from living people.
3. Further information about the legislative background and context of the HTA and its Codes of Practice (including geographic coverage) is set out at Annex A.
4. This document is part of a suite of seven Codes of Practice produced by the HTA. The Codes give practical guidance to professionals carrying out activities which lie within the HTA's remit under the HT Act and Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (the Regulations). They will also be of interest to members of the public.
5. The HTA Codes of Practice provide guidance on activities within the scope of the HTA's remit. Whilst the HTA may offer advice on matters outside its remit, it has no power to act in relation to these and will endeavour to provide signposts to other agencies where issues arise that are beyond its regulatory reach.
6. HTA Code A: Guiding principles and the fundamental principle of consent contains information that is applicable to all establishments and professionals operating under the HT Act and the Regulations. It sets out the following four guiding principles, which should inform the actions of anyone undertaking activities falling within the remit of the HTA:
  - a) consent;
  - b) dignity;
  - c) quality; and
  - d) honesty and openness.
7. With regard to 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, Code A and this Code aim to provide anyone undertaking activities relevant to this sector with a reference source which gives practical advice on the minimum steps necessary to comply with the relevant legislation and HTA policy.

## Introduction to the Research Code

### The role of HTA in regulating research under the Human Tissue Act 2004

9. The type of research regulated by the HTA under the HT Act usually takes the form of 'laboratory bench' research. HTA ensures that tissue for this type of research is removed and stored in an appropriate and well managed way.
10. The HTA licenses organisations for removal and storage for research in England, Wales and Northern Ireland. Our licensing role in research is limited to licensing premises, such as tissue banks, to store tissue from the living and the deceased. We also license establishments, including establishments in the post mortem sector, for tissue to be removed from the deceased for research.
11. We do not license the 'use' of tissue for research or approve individual research projects or clinical trials. Neither do we have a role in the ethical approval of research. We do, however, work in partnership with other organisations with the aim of helping researchers to navigate and understand their regulated activities. We 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 we regulate, primarily 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 HTA licensing Standards that HTA-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 the HTA's remit and informs the content of this and the other Codes.

## Offences under the HT Act

15. The HT Act sets out a number of offences, for which the maximum penalty is three years imprisonment and/or a fine. In relation to the Research sector, the offences are as set out below.
16. Section 5 of the HT Act makes it an offence to remove relevant material from the deceased and to store and use bodies and relevant material for a purpose set out in Schedule 1 of the HT Act (a scheduled purpose), including determining the cause of death, without appropriate consent. Where there is consent to use material for one purpose, it may not be used for another purpose without appropriate consent for that purpose. Section 5 of the HT Act also makes it an offence to falsely represent that there is appropriate consent to do an activity, or that Section 1 of the HT Act does not apply. A person does not commit an offence if they reasonably believed that appropriate consent was in place, or that the activity carried out was not one that required consent.
17. Section 16(1) and (2) of the HT Act 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 relevant material 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 relevant material which has come from a human body, for use for scheduled purposes.
18. To undertake an activity listed in section 16(2) without the authority of a licence from the HTA is an offence under section 25(1). A person does not commit an offence if they reasonably believe the activity they are carrying out is not licensable, or that they are acting under the authority of a licence.
19. The offence of non-consensual analysis of DNA and the exceptions to it are set out in section 45 of the HT Act 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 the HTA. The Code then covers matters relating to tissue from the living and tissue 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 our Research sector, supported by good practice examples.

22. At the end of this Code, there is a section on the HTA 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 HTA's website.

## Relevant material and research

### What is research?

24. The HT Act does not contain a definition of research, but for the purposes of what falls within the HTA's remit, we endorse the following definition:

*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. The HTA also endorses the definition provided by the Department of Health and the Welsh Assembly Government, which is as follows:

*Research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods.*

### What is relevant material?

26. The HT Act defines relevant material as 'material, other than gametes, which consists of or includes human cells'. Relevant material 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 relevant material 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 relevant material.

28. To supplement the HTA's website information about relevant material, [a list has been produced](#) to provide stakeholders with further guidance on whether specific materials fall within the definition of relevant material under the HT Act.

## Access to tissue from the living

29. Tissue from the living means tissue taken while the person was alive, and this definition persists after their death.
30. Tissue that was 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 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 approval by a recognised Research Ethics Committee (REC). For more information on recognised RECs, 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 their tissue for research was not originally sought from the patient, it can only be released from the diagnostic archive if it does not identify the patient and is used in a specific project that has been approved by a recognised REC.

### Example

A researcher requires whole blood for a research project. She is 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 her and the specific project has been approved by a recognised REC.

31. Once tissue is released from a diagnostic archive for research, it must be stored on HTA-licensed premises, unless it is for a specific project approved by a recognised REC, or where any of the exceptions described in paragraph 84 apply. Further information about diagnostic archives releasing tissue for research is available on the HTA's website and is covered in paragraphs 94-97 of this Code.

32. On rare occasions, tissue 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 can be used for research where consent is in place for that purpose, or where the tissue will not be identifiable to the researcher and it will be used in a specific project approved by a recognised REC.
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 from the deceased

35. The HT Act requires that removal of tissue from the deceased for research within the scope of the HT Act must always take place under the authority of a HTA 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 removed from the deceased must only be retained for use in research if appropriate consent has been given. You can find more information about appropriate consent in Code of Practice A and Code of Practice B, which is about post-mortem examinations.
37. Once tissue from the deceased is stored for research it must be held on HTA-licensed premises, unless it is being used in a specific project approved by a REC (or where approval is pending), 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 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.

## Consent

### Obtaining consent

39. The giving of consent is a positive act. The HT Act requires that consent must be sought for the removal, storage and use of human tissue for certain scheduled purposes, including research in connection with disorders, or the functioning, of the human body, subject to the exceptions set out later in this Code.
40. Although the HT Act deals with removal of tissue from the deceased, consent to treatment and examination (and the removal of tissue from the living for research) is covered by the common law and the [Mental Capacity Act 2005](#) (MC Act) where appropriate; these are not covered in this Code of Practice. Trusts should have local policies in place for seeking consent to treatment and the legal position is set out in the Department of Health's guidance.
41. Guidance for healthcare professionals in Wales is available in the Welsh Assembly Government's Reference guide to consent for examination and treatment. The MC Act does not apply in Northern Ireland; the Department of Health (Northern Ireland) published its own reference guide to consent for examination, treatment or care in 2003. This guidance is based on mental health and capacity case law.
42. To give consent, 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 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 HT Act and the role of the HTA and be reviewed to ensure that it is consistent with the relevant HTA 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 2010.

#### **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 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 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 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 is 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. 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 on 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 in animals, these should be covered in the information used to support the consent process. Where there is an expectation that samples may be exported for use abroad, the HTA 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. The HTA 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, consent must be obtained from volunteers, for example, employees or students, to use their tissue for research.

**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 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 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 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. Specialist RECs are required to approve such research and more information about these arrangements can be found on the Health Research Authority's (HRA) website. For detailed information about medical research involving adults who cannot consent, refer to the guidance on the HRA's website and [MC Act](#) and associated [Code of Practice](#).

55. It is important for those involved in research to be aware that, in addition to the consent provisions of the HT Act, they will need to adhere to other legal requirements such as the Data Protection Act 1998 and the common law duty of confidentiality.

### Consent exceptions

56. The consent requirements of the HT Act are not retrospective. This means that legally it is not necessary to seek consent under the HT Act 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 HT Act came into force on 1 September 2006.
57. Although there is no statutory requirement for consent for storage or use of tissue that is an existing holding, it does not mean that all such human tissue 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<sup>1</sup> (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 produced by the HRA.
59. Although existing holdings are exempt from the consent provisions in the HT Act, the HTA'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 HRA. Obtaining

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<sup>1</sup> 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 HT Act.

consent may be preferable to developing complex systems for keeping samples unlinked.

61. Whatever the date the tissue was donated for research, if more than 100 years have elapsed since a person's death, consent to undertake research on their tissue is not required under the HT Act.
62. In terms of research, the consent provisions of the HT Act do not apply to imported material. However, the HTA considers it good practice for there to be mechanisms in place to provide assurance that the tissue 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 for research, where all of the following criteria apply:
  - a) the tissue 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 approved by a recognised REC.
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 approved by a recognised REC.
65. The HTA's remit does not include ethical approval of research on human tissue, which must be applied for as described in the guidance available from the HRA. Ethical approval which qualifies for exemptions under the HT Act can only be given by a recognised REC, which is either:
  - a) a REC recognised or established by, or on behalf of, the HRA under the Care Act 2014 or any other group of persons which assesses the ethics of research involving individuals and which is recognised for that purpose by, or on behalf of, the Welsh Ministers or the Department of Health in Northern Ireland; or
  - b) an ethics committee recognised by United Kingdom Ethics Committee Authority (UKECA) to review clinical trials of investigational medicinal

products under the Medicines for Human Use (Clinical Trials) Regulations 2004.

66. Further information about the link between ethical approval and the licensing and consent exceptions is provided in Annex B.
67. For the purposes of the HT Act, recognised RECs include all RECs within the Research Ethics Service of the four UK countries (although the HTA does not license storage of tissue for research in Scotland). Within the UK Research Ethics Service, the term 'favourable opinion' is used to mean ethical approval. Details of all recognised committees and general information about ethical approval can be found on the HRA's website. The HRA is the regulator responsible for ethical review arrangements in health research.
68. A university ethics committee is not, for the purpose of the consent exception, considered to be a recognised REC. Therefore, consent is still required for tissue to be used in a research project approved by a university ethics committee, even if it uses tissue from the living and the researcher is not in possession, and not likely to come into possession, of information identifying the participant.
69. Recognised RECs can consider all applications relating to research involving the use of human tissue, 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. It is an offence to analyse DNA without qualifying consent unless it is for an excepted purpose. The offence attracts a fine, a term of imprisonment of up to three years, or both. Although the HT Act does not generally apply to establishments in Scotland, the offence of non-consensual analysis of DNA applies to the whole of the UK, including Scotland.
71. 'Bodily material' differs from 'relevant material' 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 the bodily material from which it originates) is not considered to be relevant material under the HT Act. Its storage is therefore not subject to licensing.

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, 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 ethical approval from a recognised REC.
75. Although no offence will be committed in this situation, the HTA recommends that consent is sought where it is practical to do so. Information about ethical approval from recognised RECs 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 approved by a recognised REC. 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 HT Act, 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 England, Wales and Northern Ireland. 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 HT Act 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 HT Act. As this does not fall within the scope of the HT Act or the remit of the HTA, 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. The ethical issues in the use of this material are the same as for those using bodily material and, therefore, the HRA and the Devolved Administrations expect researchers intending to extract human DNA from acellular material for research analysis to submit their proposals for ethical review by a recognised REC.

## Licensing

80. This section explains where, in the context of research, a licence from the HTA is needed and where exceptions to licensing requirements apply.
81. The storage of human tissue for research, and its removal from the deceased, is licensed by the HTA. The HTA does not license the 'use' of tissue for research and it does not have a role in approving individual research projects.
82. The HT Act does not define the term 'storage' and does not give any minimum or maximum term for storage of human tissue for research.
83. As there is no set time period for storage, we 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 relevant material and their intention. We provide some examples below to help clarify the concept of storage requiring a licence.
84. A licence to store relevant material for research within the scope of the HT Act is not required in the following circumstances:

- a) It is from a person who died prior to 1<sup>st</sup> September 2006 and at least one hundred years have elapsed since their death.**

This exemption from licensing is set out in the HT Act.

- b) It is being held 'incidental to transportation'.**

This exemption from licensing is set out in the HT Act. This term is not defined in the law and the HTA has interpreted this as the temporary holding of material in transit, while it is being conveyed from one place to another. We consider the timeframe for this to be 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 HTA 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.

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

The HTA views this as analogous to the incidental to transportation exception above. The HTA 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 relevant material, the blood does not need to be stored under a HTA licence.

### **d) Further examples where a HTA storage licence would not be required:**

#### **Example 1**

A whole blood sample is taken and this is then immediately sampled for blood lactate levels in the plasma, then the sample is disposed of about five minutes following the sample being taken.

*Conclusion: No storage of relevant material for research would be taking place.*

## **Example 2**

A whole blood sample is taken and this is then immediately processed for various tests that day, some of which includes testing directly on the cells themselves. All samples are disposed of when the tests are complete, later that day.

*Conclusion: No storage of relevant material for research would be taking place.*

## **Example 3**

A whole blood sample is taken and made acellular immediately, and only serum is retained for research.

*Conclusion: No storage of relevant material for research would be taking place.*

## **Example 4**

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 day 7, 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 HTA licence.*

## **Example 5**

A study has received approval from a recognised REC where blood samples are taken during a clinical trial.

*Conclusion: No HTA licence is required to store samples for which REC approval has been obtained (see paragraph 86).*

### **e) Example where a HTA 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 approved by a recognised REC.

*Conclusion: Although the storage period is for only 2-3 days, relevant material samples (whole blood) are being stored solely for the purpose of research within the scope of the Act; a HTA 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 relevant material for research would have taken place.*

85. Imported tissue stored for research should be treated in the same way as tissue originating from participants in England, Wales or Northern Ireland. 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 HTA licensing**

86. In addition to the exceptions above, there is a broader exception set out in the HT Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006. These Regulations allow human tissue held for a specific research project approved by a recognised REC (or where approval is pending) to be stored on premises without a HTA licence. An application for ethical approval is pending from the point it has been submitted until the decision of the committee has been communicated to the applicant.
87. The HTA advises researchers to consider the need for ethical approval before embarking on any research. A HTA licence should not be viewed as an alternative to ethical approval by a recognised REC.
88. While there is a relationship between ethical approval from a recognised REC and some of the requirements of the HT Act with regard to research, the need for ethical review should be considered separately and in parallel with the legal requirement for a licence. Decisions about the need for ethical review are governed by institutional (e.g. local policies) and/or wider arrangements (e.g. the GAfREC framework or legal requirements, such as the Mental Capacity Act 2005), 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 is no longer being stored for a project approved by a recognised REC (or one where such approval is pending), it must be stored on HTA-licensed premises if it is intended for a scheduled purpose. Where it is to be used for further research that does not have recognised REC 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. The HTA and the HRA's Research Ethics Service (HRA RES) have agreed a position whereby its RECs can give generic ethical approval for a research tissue bank's arrangements for collection, storage and release of tissue, providing the tissue in the bank is stored on HTA-licensed premises. Such research tissue banks need to be licensed because at least some of the tissue being stored is not for specific projects holding REC approval. The banks are also required to work under HRA RES Standard Operating Procedures (SOPs). Applications for ethical review of research tissue banks are voluntary. Subject to conditions, the bank's ethical approval extends to specific projects receiving non-identifiable tissue from the bank. The tissue does not then need to be stored on HTA-licensed premises for the duration of the project; nor does it need project specific ethical approval. If the research is not carried out in accordance with these requirements, specific project approval by a recognised REC will be required or, alternatively, the samples will need to be stored under a HTA licence. Information about the requirements governing the release of tissue can be found on the HRA website. The RECs are also a source of ethical advice to the bank on its arrangements for collecting, managing and distributing tissue. In particular, the RECs 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 from the bank must be stored on HTA-licensed premises unless a storage licensing exemption applies; for example, the researcher has obtained specific project approval by a REC.
92. On completion of research using tissue from a REC-approved research tissue bank, the individual researcher must transfer the tissue back to the bank or to an alternative HTA-licensed establishment, apply for their own HTA licence (unless there are existing local licensing arrangements which can be used to cover the further storage), apply for specific project approval by a REC or dispose of the human tissue.

### **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 the HTA 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 HTA 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 ethics approval. In this way, valuable human tissue for research is controlled and made more accessible to a number of research projects.

93. Tissue 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.

### **Diagnostic archives**

94. Tissue that is 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 HTA-licensed premises as no licensable activity would be taking place. However, the HT Act clearly provides that the storage of tissue for a 'scheduled purpose' must be on licensed premises. The HTA's position is that if a diagnostic archive releases tissue for research occasionally upon request, its status as a diagnostic archive is clear. However, if there is an expectation that tissue 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.
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 HTA's licensing framework. This legal requirement stands, even where tissue released from the archive will only ever be used as part of a specific project approved by a NHS REC.
96. Where the archive is on premises already licensed by the HTA 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 the HTA 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 relevant material is not a licensable activity under the HT Act. 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 HT Act.
99. The geographical scope of 'import' and 'export' according to the HT Act is as follows:
- a) 'import' means import into England, Wales or Northern Ireland from a place outside England, Wales and Northern Ireland;
  - b) 'export' means export from England, Wales or Northern Ireland to a place outside England, Wales and Northern Ireland.
100. Tissue 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 a recognised REC (see paragraphs 86-88). The HTA recommends that, wherever possible, the import and export of tissue is conducted via the HTA 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 and tissue into England, Wales and Northern Ireland should be able to demonstrate that the purposes for which they wish to import such material cannot be adequately met by comparable material available from sources within those countries, or is for a particular purpose which justifies import. Importers should assure themselves of the integrity of the material and that, as a minimum, it has been sourced with appropriate consent. 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 the HTA.

103. The HT Act makes consent the fundamental principle underpinning the lawful storage and use of human bodies, body parts and tissue from the living or the deceased, for the purposes specified in the HT Act. The consent provisions of the HT Act do not apply, however, if the material has been imported. Nonetheless, the HTA 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 England, Wales and Northern Ireland. When an establishment imports material into England, Wales and Northern Ireland 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 England, Wales and Northern Ireland.
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 and tissue 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 HT Act and the HTA's Codes; in other words, as though the material had been sourced from England, Wales and Northern Ireland.

109. If any specific requests were made by the deceased regarding disposal when consent was obtained, such requests must be carried out. This may include, for example, the return of material to the country of origin.
110. Imports (and exports) of human tissue 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 and tissue provided for in Codes in England, Wales and Northern Ireland. 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 and tissue to be exported from England, Wales and Northern Ireland are used in accordance with the consent which has been obtained. Material should be handled, stored, transported and disposed of, in a manner consistent with safety considerations, and with the dignity and respect accorded to human bodies, body parts and tissue in legislation and in Codes in England, Wales and Northern Ireland.
114. The HT Act makes it clear that bodies and relevant material 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 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 and cells in animals is not considered a method of storing human tissue or cells and therefore does not require a storage licence. However, where human tissues and 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 and/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 will be used.

## Interface between research, human application and clinical trials

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

117. The use of tissues 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 by the HTA via the e-newsletter and website.
118. Human tissue for research *in vitro* (i.e. will not be transplanted into humans) must be stored under a HTA licence, subject to the exceptions set out in the licensing section of this Code (see paragraph 84).
119. Tissue or cells, including cell lines, which may be transplanted into humans, even where it is for research, must be licensed by the HTA under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations). For detailed information about the licensing requirements, see the HTA's website or contact a member of HTA staff.
120. Tissues and cells for transplantation into patients, including stem cells and cell lines, are regulated by three regulatory bodies for human application:
- a) the HFEA regulates the creation and use of embryos in the derivation of embryonic stem cell lines. The HFEA's remit ceases at the point the embryo is dissociated, at which point the HTA's remit begins;
  - b) the HTA regulates the procurement, testing, processing, storage, distribution and import/export of tissues and cells, including cell lines, intended for human application;
  - c) the Medicines and Healthcare products Regulatory Agency (MHRA) regulates when a cell therapy is deemed to be a Medicinal Product (MP) or Investigational Medicinal Product (IMP).

121. Researchers planning to work with tissue and cells with a reasonable expectation that those cells will be used in patients, should contact the MHRA for a decision as to whether the product could be a MP or an IMP.
122. Treatments classed as MPs or IMPs are regulated by the HTA only for procurement and testing of tissue. The subsequent steps are regulated by the MHRA. If a treatment containing human tissue or cells is not considered an MP or IMP by the MHRA, it will be regulated entirely by the HTA under the Q&S Regulations.
123. The HTA has produced statements in conjunction with the MHRA and HFEA, which explain our regulatory remits in regulating stem cells and Advanced Therapy Medicinal Products (ATMPs). A regulatory route map is also available on the HTA's website.

## Clinical trials

124. The storage of human tissue as part of a clinical trial (where the material itself will not be used in human application) must take place on HTA-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 relevant material collected during the trial for research within the scope of the HT Act. Where there are plans to do this, researchers must have regard to the relevant consent and licensing requirements of the HT Act, as set out in this Code.
126. Establishments using tissues 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 or cells are used for human application as part of a clinical trial approved by a United Kingdom Ethics Committee Authority (UKECA) - recognised ethics committee.

## Disposal

127. Processes should be in place to inform donors how their tissue will be disposed of after use. The HT Act permits disposal of surplus tissue as waste.
128. The HTA recognises that what is sensitive and what is feasible at local level needs to be taken into account. It is good practice for human tissue 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. The HTA has issued separate [guidance on the disposal of pregnancy remains](#), which is available on our website.

## HTA licensing Standards

131. In order to obtain a HTA licence, the applicant must demonstrate that they and the relevant premises are suitable. The HTA will assess whether they can meet a number of core Standards, which were developed in consultation with representatives from the regulated sectors. These relate to the consent provisions of the HT Act and the regulatory requirements for governance and quality systems, traceability and premises. They reinforce the HT Act'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.
132. The HTA works with establishments through its inspection process to help them comply with these Standards.
133. Each licensed establishment is required to appoint a Designated Individual (DI) for their licence, who has a statutory responsibility under the HT Act 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 the HTA's licensing Standards, the DI will be meeting their statutory responsibility.
134. When HTA staff undertake inspections of HTA-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 HTA'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 HT Act and the Codes of Practice.

135. The HTA'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.

### **Consent (C)**

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

### **Governance and quality systems (GQ)**

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. HTA 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 the HTA'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. The HTA licensing Standards which will be applicable to the Research sector from April 2017 are included at Annex D and on the HTA website. The Standards are supported by comprehensive guidance notes.

## Annex A

### Legislative background and context

1. The Human Tissue Authority (HTA) is the regulator for human organs, tissues and cells. The HTA was established by the Human Tissue Act 2004 (HT Act) in 2005, following the discovery of establishments removing and retaining human organs and tissue without consent. The HT Act addressed this issue and brought together other existing laws that related to human tissue and organs.
2. The HT Act applies to the removal, storage and use of human organs and tissue for scheduled purposes<sup>2</sup> in England, Wales and Northern Ireland, with the exception of the provisions relating to the use of DNA, which also apply to Scotland.
3. Under section 14(3) of the HT Act, the HT Act and the guidance given in the Codes of Practice do not apply to bodies or relevant material where:
  - a) the person died before the HT Act came into force on 1 September 2006; and
  - b) at least 100 years have elapsed since the date of the person's death.
4. The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (the Regulations) lay down the responsibilities of the HTA in relation to the donation of transplantable material from living donors, including those who lack capacity to consent.
5. The HTA is the Competent Authority in the UK for the implementation of the European Union Tissue and Cells Directive 2004/23/EC (EUTCD). The EUTCD sets standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.
6. The requirements of the EUTCD are transposed into UK law via the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations). With the exception of Code A: Guiding principles and the fundamental principles of consent, the Codes of Practice do not provide guidance on complying with the requirements of the EUTCD. Establishments licensed under the Q&S Regulations should refer to the HTA's Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment.
7. The HTA is the Competent Authority in the UK for the implementation of the European Union Organ Donation Directive 2010/53/EU (EUODD), which sets

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<sup>2</sup> Defined by the HT Act and explained in further detail in the glossary.

quality and safety standards for organ donation and transplantation. The requirements set out by the EUODD have been transposed into UK law through The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (the Q&S (Organs) Regulations) and The Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014. With the exception of Code A: Guiding principles and the fundamental principles of consent, the Codes of Practice do not provide guidance on complying with the requirements of the EUODD. Establishments licensed under the Q&S (Organs) Regulations should refer to the HTA's The Quality and Safety of Organs Intended for Transplantation: a documentary framework.

8. On 1 December 2015 a deemed consent system for organ donation after death became operational in Wales, as a result of the implementation of the Human Transplantation (Wales) Act 2013. This legislation relates to donation of organs and tissue from the deceased, and as such does not have an impact on the HTA's regulation of living organ donation. These Codes of Practice do not apply to organ and tissue donation from the deceased in Wales; the HTA has published a Code of Practice on the Human Transplantation (Wales) Act 2013 for establishments in Wales who work under the deemed consent for deceased organ donation system.

## **Scotland**

9. The HTA's remit does not extend to Scotland, and therefore the HTA's Codes of Practice do not apply to establishments in Scotland.
10. A separate piece of legislation, the Human Tissue (Scotland) Act 2006 (HT (Scotland) Act), applies to Scotland. The HTA's remit in Scotland is described in a letter titled [Human Tissue \(Scotland\) Act 2006: A guide to its implications for NHS Scotland](#), which the Scottish Health Department letter issued on 20 July 2006<sup>3</sup>.
11. The HTA assesses applications for living organ donation and donation of bone marrow and PBSCs on behalf of Scottish Ministers who delegated this responsibility to the HTA. The law in Scotland is significantly different from that in the rest of the UK, so this code does not apply in Scotland. Guidance for practitioners in Scotland is available [here](#).

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<sup>3</sup> Ref: NHS HDL (2006) 46.(updated 2017)

## Status and use of the Codes of Practice

12. 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, the conditions of any licence and the requirements set out in any directions issued by the HTA). It also applies to the duty to abide by the HTA's licensing standards. We use the word '**should**' when providing advice on how to meet these requirements.
13. Establishments are expected to follow the guidance contained in the Codes. Observance of the guidance is one of the ways in which the HTA assesses that establishments are complying with legal requirements. Failure to follow a Code of Practice is not in itself a criminal offence under the HT Act, but the HTA will consider carefully any breach of a Code of Practice when considering whether there are grounds to take regulatory action.

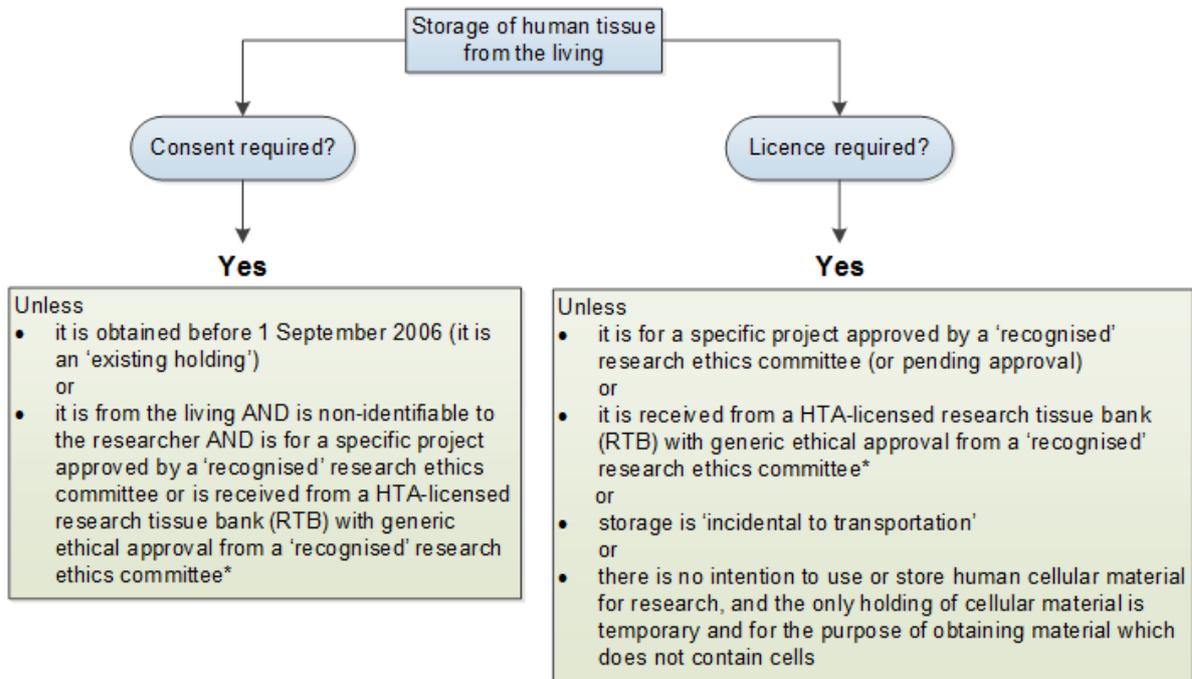
## Other advice and guidance

14. 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 HTA's website. The Codes of Practice may also refer to guidance which has been produced by a number of other organisations. The HTA is not responsible for the content of others' guidance, but does recommend that practitioners follow this guidance when they fall within its remit. Guidance that has been produced in collaboration with the HTA will appear on our website.
15. The HTA's Codes of Practice and other HTA guidance should, however, be used as the definitive source of information for issues within our remit. If you are in any doubt, please contact the HTA or seek your own legal advice. Regulated sectors should also keep up to date with other relevant legislation.

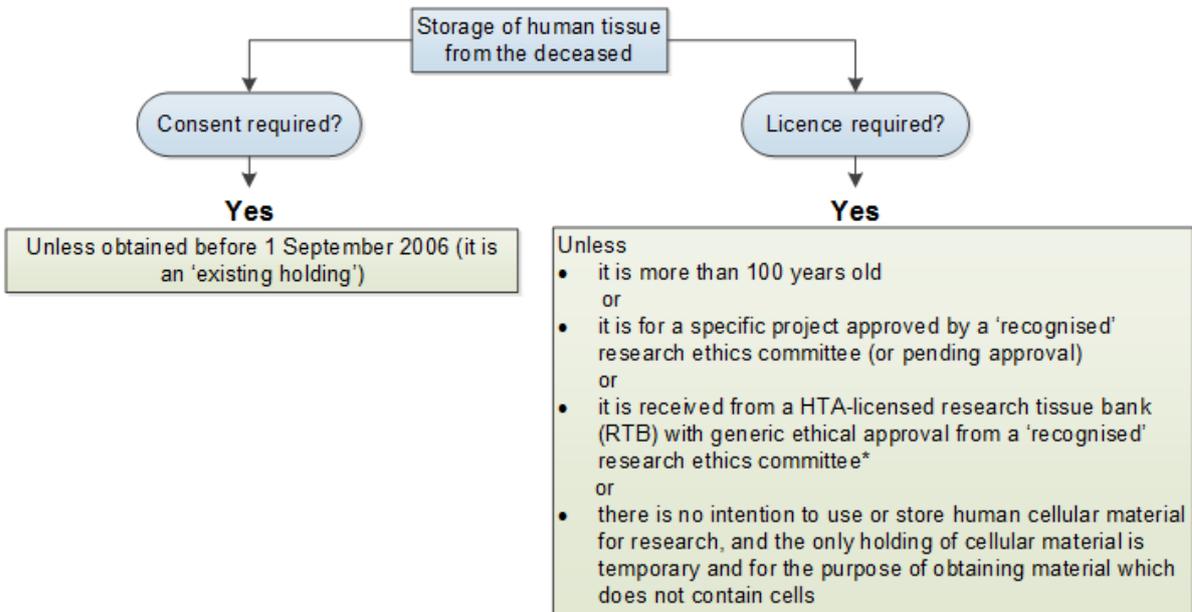
## Annex B

### Licensing and consent flowchart

#### Licensing and consent requirements for human tissue for research from the living



#### Licensing and consent requirements for human tissue for research from the deceased



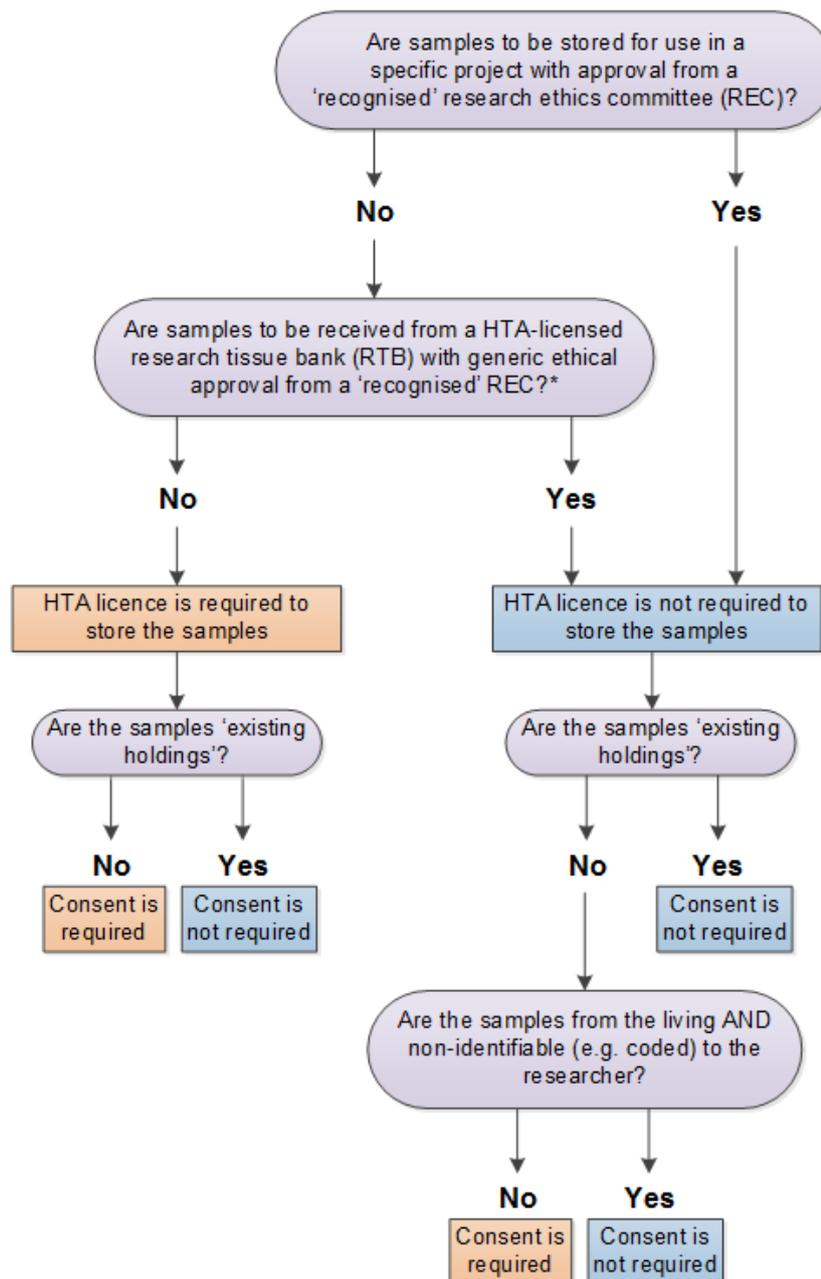
\*Please note the following for both flowcharts:

- Some RTBs require external researchers to obtain project-specific approval from a recognised research ethics committee.
- RTBs need to be covered by a HTA licence because at least some of the tissue being stored is not for specific projects holding approvals from recognised research ethics committees.

## Annex C

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

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



\*Please note the following:

- Some RTBs require external researchers to obtain project-specific approval from a recognised research ethics committee.
- RTBs need to be covered by a HTA licence because at least some of the tissue being stored is not for specific projects holding approvals from recognised research ethics committees.

## Annex D

### HTA licensing standards: Research sector

Consent standards
<b>C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's Codes of Practice</b>
<ul style="list-style-type: none"><li>a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.</li><li>b) Consent forms are available to those using or releasing relevant material for a scheduled purpose.</li><li>c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice.</li><li>d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice.</li><li>e) Language translations are available when appropriate.</li><li>f) Information is available in formats appropriate to the situation.</li></ul>
<b>C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent</b>
<ul style="list-style-type: none"><li>a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice.</li><li>b) Records demonstrate up-to-date staff training.</li><li>c) Competency is assessed and maintained.</li></ul>

## Governance and quality system standards

### **GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process**

- a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities
- b) There is a document control system.
- c) There are change control mechanisms for the implementation of new operational procedures.
- d) Matters relating to HTA-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 licensable activities
- b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these

### **GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills**

- a) Qualifications of staff and all training are recorded, records showing attendance at training.
- b) There are documented induction training programmes for new staff.
- c) Training provisions include those for visiting staff.
- d) Staff have appraisals and personal development plans.

**GQ4 There is a systematic and planned approach to the management of records**

- a) There are suitable systems for the creation, review, amendment, retention and destruction of records.
- b) There are provisions for back-up / recovery in the event of loss of records.
- c) Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).

**GQ5 There are systems to ensure that all adverse events are investigated promptly**

- a) Staff are instructed in how to use incident reporting systems
- b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.

**GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored**

- a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.
- b) Risk assessments are reviewed regularly.
- c) Staff can access risk assessments and are made aware of risks during training.

## Traceability

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

- a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.
- b) A register of donated material, and the associated products where relevant, is maintained.
- c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired 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 relevant material 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 relevant material are kept.

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

- a) Disposal is carried out in accordance with the HTA's Codes of Practice.
- b) The date, reason for disposal and the method used are documented.

## Premises, facilities and equipment standards

### **PFE1 The premises are secure and fit for purpose**

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

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

c) There are documented cleaning and decontamination procedures

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

a) There is sufficient storage capacity.

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

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

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

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

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

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

c) Staff are provided with suitable personal protective equipment.

## Glossary

Term	Definition
Advanced Therapy Medicinal Products (ATMPs)	Medicinal products which are prepared industrially or manufactured by a method involving an industrial process. ATMPs are innovative, regenerative therapies which combine aspects of medicine, cell biology, science and engineering for the purpose of regenerating, repairing or replacing damaged tissues or cells. ATMPs fall into three categories: Gene Therapies; Somatic Cell Therapies; and Tissue Engineered Products.
Anatomical examination	Macroscopic examination by dissection for the purposes of teaching or studying, or researching into, the gross structure of the human body.
Appropriate consent	Defined in the HT Act by reference to the person who may give consent. This is broadly either the consent of the person concerned, their nominated representative or (in the absence of either of these) that of a person in a qualifying relationship to them immediately before they died.
Biopsy	A medical procedure that involves taking a small sample of human tissue so it can be examined under a microscope.
Bodily material	Bodily material is material which has come from a human body and consists of or includes human cells. It is a broader definition than 'relevant material', as it includes hair and nails from the living as well as from the deceased and gametes (human sperm and eggs). The provisions of the HT Act 2004 in relation to the analysis of DNA apply to bodily material.
Bone marrow	A spongy tissue found in the hollow centres of some bones. It contains specialist stem cells, which produce the body's blood cells.
Cells	Individual human cells or a collection of human cells that are not bound by any form of connective tissue.
Clinical trial	A type of clinical research that compares one treatment with another. It may involve people with specific medical conditions or healthy volunteers, or both.

Term	Definition
Clinical waste	<p>The Controlled Waste Regulations 1992 define clinical waste as any waste which consists wholly or partly of: human or animal tissue; blood or other body fluids; excretions; drugs or other pharmaceutical products; swabs or dressings; or syringes, needles or other sharp instruments which, unless rendered safe, may prove hazardous to any person coming into contact with it.</p> <p>Clinical waste also refers to any other waste arising from medical, nursing, dental, veterinary, pharmaceutical or similar practice, investigation, treatment, teaching or research, being waste which may cause infection to any person coming into contact with it.</p>
Designated Individual (DI)	The person named on a licence issued by the HTA, under whose supervision licensed activities are carried out. The DI has a statutory responsibility to ensure that those carrying out licensed activities, and their practices, are suitable, and that the conditions of the licence are met.
Diagnosis	The identification of the nature of an illness or other problem.
Diagnostic archive	Samples used for diagnosis may be stored in an archive to benefit the person's medical care. These samples can also be valuable resources for health research.
DNA	<p>DNA stands for deoxyribonucleic acid. DNA is found in the nucleus of all cells, and contains the genetic information for the development and working of living organisms including human beings. The study of DNA is used in forensics, gene therapy, relationship (including paternity) testing and bioinformatics.</p> <p>Find out more information about the HTA's role with regards to DNA on the HTA's website.</p>
Donation	The act of giving human tissue, cells, organs or part organs for a scheduled purpose, either during life or after death.
Donor	Every human source, whether living or deceased, of tissue, cells, organs or part organs.
Existing holding	Material from the living or deceased that was already held for use for scheduled purposes when the Human Tissue Act 2004 came into force on 1 September 2006.
Export	The movement of human tissue from England, Wales or Northern Ireland to a place outside England, Wales and Northern Ireland.

Term	Definition
Human application	In relation to tissue or cells, human application means use on or in a human recipient, including use in applications situated or occurring outside the body, but not including use when tissue and cells are removed from and applied in the same person within the same surgical procedure.
Import	The movement of human tissue into England, Wales or Northern Ireland from a place outside England, Wales and Northern Ireland.
In vitro	Human tissue or cells made to occur in a laboratory vessel or other controlled experimental environment, rather than within a living organism or natural setting.
Investigational Medicinal Product (IMP)	A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial. This includes products that already have marketing authorisation, but are used or assembled (formulated or packaged) in a way different from the authorised form, or when they are used for an unauthorised indication, or when they are used to gain further information about the authorised form.
Licensed premises	Where the licensed activity takes place.
Licensing	A number of activities can only be carried out when an establishment is licensed under the Human Tissue Act by the HTA. Organisations whose activities involve the removal, storage or use of relevant material may need to work under a HTA licence. All establishments working under a HTA licence must work to specified Standards set by the HTA.
Medicinal Product (MP)	Any substance or combination of substances which: a) is presented as having properties for treating or preventing disease in human beings; and/or b) may be used in, or administered to, human beings, either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.
Neonatal death	A foetus of any gestational age which is born alive and dies before the age of 28 days.
Non-Departmental Public Body (NDPB)	A body which has a role in the processes of national government, but is not a government department or part of one, and which accordingly operates to a greater or lesser extent at arm's length from ministers.

Term	Definition
Organ	Defined by the Human Tissue Act (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, as amended, as a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with a significant level of autonomy. Part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirement of structure and vascularisation.
Paraffin-embedded blocks	Blocks of paraffin wax in which small pieces of tissue are fixed. The blocks can be cut into thin slices for microscopic examination.
Parental responsibility	A person who has parental responsibility will usually, but not always, be the child's parent. The category of persons with parental responsibility is as set out in the Children Act 1989.
Pathology	The science of the causes and effects of diseases.
Peripheral blood stem cells (PBSCs)	Peripheral blood stem cells are the source of all blood cells. They are found in the bloodstream and are formed in bone marrow. They receive signals that direct them to differentiate into all the cell types found in blood (red cells, white cells or platelets). They can be mobilised from the bone marrow into the blood stream by giving a drug, and collected with an apheresis machine.
Post-mortem examination	Dissection and examination of a body after death, principally in order to determine the cause of death or the presence of disease processes.
Practitioner	A person working with relevant material in an establishment licensed by the HTA.
Pregnancy remains	The term used by the HTA to refer to foetal tissue or products of conception resulting from pregnancy loss or termination of pregnancy, regardless of gestation. The term does not apply to stillbirths (babies born dead after the 24th week of pregnancy) and neonatal deaths.
Procurement	The processes by which tissues and cells are made available, including the physical act of removing tissue and the donor selection and evaluation.

Term	Definition
Recognised Research Ethics Committee (REC)	<p>This can be either</p> <ul style="list-style-type: none"> <li>a) a REC recognised or established by, or on behalf of, the HRA under the Care Act 2014 or any other group of persons which assesses the ethics of research involving individuals and which is recognised for that purpose by, or on behalf of, the Welsh Ministers or the Department of Health in Northern Ireland; or</li> <li>b) an ethics committee recognised by United Kingdom Ethics Committee Authority (UKECA) to review clinical trials of investigational medicinal products under the Medicines for Human Use (Clinical Trials) Regulations 2004.</li> </ul>
Relatives	<p>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 HT Act.</p>
Relevant material	<p>Defined by the HT Act as material other than gametes, which consists of, or includes, human cells. In the HT Act, references to relevant material from a human body do not include: (a) embryos outside the human body, or (b) hair and nail from the body of a living person. See policy guidance on how to apply this definition on the HTA's website.</p>
Research	<p>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.</p>
Research tissue bank	<p>This term can encompass any collection of human tissue of any size being stored for research. Further information can be found on the HTA's website.</p>

Term	Definition
RNA	<p>'RNA' stands for 'ribonucleic acid'. In human cells, RNA can be made from DNA (see Glossary definition for 'DNA'). The structure of the RNA can be used to predict the structure of the DNA from which it is made. Analysing the RNA can therefore be a way of analysing DNA.</p>
Scheduled purpose	<p>Under the HT Act, consent must be obtained to remove, store or use bodies or relevant material for scheduled purposes. The licensing requirements of the HT Act also refer to the scheduled purposes. Scheduled purposes are divided into those which apply generally, and those which apply to the deceased only.</p> <ul style="list-style-type: none"> <li>• Part 1: Purposes requiring consent: General – anatomical examination; determining the cause of death; establishing after a person's death the efficacy of any drug or other treatment administered to him; obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person); public display; research in connection with disorders; or the functioning; of the human body, transplantation.</li> <li>• Part 2: Purposes requiring consent: Deceased persons – clinical audit, education or training relating to human health, performance assessment, public health monitoring, quality assurance.</li> </ul>
Standard Operating Procedure (SOP)	<p>A document that sets out the established process to be followed to complete a task.</p>

Term	Definition
Stem cell	A precursor cell that can develop into more than one kind of cell. For example, early bone marrow cells can develop into red blood cells, white blood cells or platelets.
Stillbirth / stillborn	A stillbirth is defined under section 41 of the Births and Deaths Registration Act 1953 as ‘where a child issues forth from its mother after the 24 week of pregnancy, and which did not at any time after being completely expelled from its mother, breathe or show any signs of life’.
Surplus tissue	The term ‘surplus tissue’ refers to material which consists of or includes human cells and which has come from a person’s body in the course of his receiving medical treatment, undergoing diagnostic testing, or participating in research, as well as to relevant material which has come from a human body, and ceases to be used, or stored for use, for a purpose specified in Schedule 1. The HT act makes provision for surplus tissue to be dealt with as waste.
Tissue	Any and all constituent part/s of the human body formed by cells.
Transplantation	An implant of an organ or part organ, tissue or cells either from and into the same body or from one person to another.
Valid consent	Consent which has been given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. Valid consent is explained in detail in Code A: Guiding principles and the fundamental principle of consent.
Xenografts	Xenografts are cells, tissues or organs that are transplanted from one species to another.