HTA
Human Tissue Authority

HTA guidance on consent and licensing for removing samples from the deceased for testing

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Contents

Overview

The Human Tissue Authority (HTA) was established under the Human Tissue Act 2004 (HT Act). The HTA licenses a number of activities in England, Wales and Northern Ireland[1], and regulates establishments carrying out these activities.

Removing samples from the deceased for testing can only take place with appropriate consent or authority, and on HTA licensed premises.

We have a system to license facilities conducting this activity. HTA licences for this activity are for a fixed term of 12 months. You can apply to the HTA to revoke the licence, at any point.

This document provides guidance on the consent and licensing requirements of the HT Act for this activity and information about how to apply for an HTA licence.

This guide is presented in three sections:

- Part 1 – Licensing and consent requirements of the HT Act
- Part 2 – Applying for an HTA licence
- Part 3 – HTA licensing standards and guidance

Contact the HTA if:

- bodies may be stored on your premises for any other purpose(s) beyond your normal requirements; or

- the sample(s) may be stored on your premises for more than seven days before being sent for testing.

In these cases, a licence for storage may also be required.

For general enquiries and advice:

Please call 020 7269 1900 or email enquiries@hta.gov.uk.

[1] Please note that the HTA does not license this activity in Scotland. In Scotland, the Human Tissue (Scotland) Act 2006 applies. Some provisions in the HT Act related to DNA analysis also cover Scotland.

Part 1 – Legal requirements of the Human Tissue Act 2004

The HTA works within the statutory framework imposed by the HT Act. The HT Act sets out requirements for consent and licensing of activities for certain purposes – called scheduled purposes. Information about the scheduled purposes is on the HTA website[2]. Removing samples from the body of a deceased person for a scheduled purpose is a licensed activity in the HT Act. This activity must only take place with appropriate consent or authority and on HTA licensed premises.

For the purposes of the HT Act, samples include anything that is made of, or includes, human cells other than gametes (eggs and sperm). If a sample is known to contain a single cell from a human body, then the sample is relevant material. This includes nose and throat swabs, muscle and skin biopsies, blood samples, tissues and organs. There is more information about relevant material on the HTA website[3].

This part of the guide provides summary information on the consent and licensing requirements of the HT Act for removing samples from the deceased for testing.

Contact the HTA if you require further guidance on the requirements of the HT Act.

[2] Information on the HT Act and scheduled purposes: www.hta.gov.uk/sites/default/files/HTA%20%2807-17%29%20Public%20Guide%20to%20HT%20Act.pdf
[3] Relevant material: www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004

Consent requirements

The HT Act requires that appropriate consent is in place to remove, use and store samples from the deceased for a scheduled purpose.

This means that you must have consent to obtain a sample from the body of a deceased person for testing, and to store and use the sample. Where consent from an appropriate person has not been given, the activities cannot proceed.

The only exception to the requirement for consent is if the activity is conducted under authority of the coroner or police. They will tell you whether they authorise the activity.

Who may give consent

Appropriate consent is defined in the HT Act in terms of who may give consent.

Where the deceased person is an adult, appropriate consent means:

a) the consent of the deceased person (if a decision to, or not to, consent was in place immediately before death);

b) where (a) above does not apply, the consent of a nominated representative appointed by the deceased person to deal with this issue;

c) where (a) and (b) above do not apply, the consent of a person in a qualifying relationship to the deceased person immediately before they died.

Where the deceased person is a child, appropriate consent means:

a) the consent of the child if a decision to, or not to, consent was in place immediately before death (provided they were competent to reach a decision);

b) where (a) above does not apply, the consent of a person with parental responsibility for them immediately before they died (a person who has parental responsibility will usually, but not always, be their parent);

c) where (a) and (b) above do not apply, the consent of a person in a qualifying relationship to the deceased child immediately before they died.

A child is defined in the HT Act as being under 18 years old (except in the context of qualifying relationships).

Qualifying relationships

Qualifying relationships are ranked in the HT Act in the following order (highest first):

a) spouse or partner (including civil or same sex partner) – a person is considered a partner if the two of them (whether of different sexes or the same sex) live as partners in an enduring family relationship.

b) parent or child (in this context a child may be of any age, but must be competent if under the age of 18, and means a biological or adopted child)
c) brother or sister
d) grandparent or grandchild
e) niece or nephew
f) stepfather or stepmother
g) half-brother or half-sister
h) friend of long standing.

Consent is needed from only one person in a qualifying relationship and should be obtained from the person ranked highest. If a person higher up the list refuses to give consent, it is not possible to act on consent from someone further down the list.

Relationships listed together, for example ‘brother or sister', are accorded equal ranking, in which case it is sufficient to obtain consent from just one of them.

A person may be omitted from the hierarchy if they cannot be located, decline to deal with the matter or are unable to give valid consent (for example, because they are a child or lack capacity to consent). In such cases, the next person in the hierarchy would become the appropriate person to give consent.

Whilst the HT Act is clear on the hierarchy of relationships, there may be situations where relatives disagree on giving consent. There are procedures and advice on dealing with these conflicts in HTA Code of Practice A (paragraphs 30-39)[4].

[4] HTA Codes of Practice: www.hta.gov.uk/hta-codes-practice-and-standards-0

Seeking consent

Protocols should be in place to ensure that the consent process has been completed, that there is valid consent and that the decision has been properly recorded. Staff seeking consent should be trained in seeking consent and should have a good understanding of the procedure for seeking consent.

For consent to be valid it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity. Full and clear information should be provided about the purpose for which consent is being sought. The person giving consent should have the opportunity to discuss the issue fully, ask questions and make an informed choice.

Staff seeking consent should explain the significance of the qualifying relationship to the family and make enquiries about who is the person in the highest ranking qualifying relationship to ensure that consent is sought from the appropriate person. This should be documented in the record of consent.

Consent may be expressed in various ways and does not necessarily need to be in writing; however, a record should be made of the consent given. The record should detail when consent was obtained and the purposes for which the consent was given. Consent may be given on the telephone or, after a telephone conversation, by email – in these cases, the content of the telephone conversation should be documented. The record of consent should be included in the deceased's records and a copy should also be given to the person giving consent.

Consent may be withdrawn at any time. Withdrawal should be discussed at the outset when consent is being sought. The practicalities of withdrawing consent and the implications of doing so should be made clear.

Further information on consent is provided in HTA Codes of Practice A and B[5].

[5] HTA Codes of Practice A and B: www.hta.gov.uk/hta-codes-practice-and-standards-0

Licensing requirements

In the HT Act, removing samples from the body of a deceased person for a scheduled purpose is a licensed activity and must only take place on HTA licensed premises. This means that you must only remove a sample from the body of a deceased person for this purpose at premises that are licensed by the HTA. The relevant licence must be in place before the activity is undertaken.

The only exception to the licensing requirements is if the activity is conducted under authority of the police.

Information about HTA licences

HTA licences are premises specific. Licences for removing relevant material from the deceased for testing are for a fixed term of 12 months. You can apply to the HTA to revoke the licence, at any point. Contact the HTA for information on licensing fees.

Satellite sites

An HTA licence may cover several sites – as a hub and satellite sites. Each premises must be named on the licence as a separate site.

Licensable activities at all sites covered by the HTA licence should be under the same governance arrangements and supervised by the same Designated Individual (DI).

Licence roles

Designated Individual

The DI has a key role to play in implementing the requirements of the HT Act. They are the person under whose supervision the licensed activity is authorised to be carried out. They have the primary legal responsibility under section 18 of the HT Act to secure:

- that suitable practices are used in undertaking the licensed activity;
- that other persons working under the licence are suitable; and,
- that the conditions of the licence are complied with.

The HT Act is not prescriptive about who should act as the DI. Consider the following points when nominating a suitable person. They should:

- have some supervisory responsibility over other persons working under the licence;
- be in a senior enough position to be able to instigate change; and,

- not be too far removed from the operational aspects of the licensable activities for which they are responsible, thus ensuring that suitable practices are taking place under that licence.

Organisations may wish to consider one of the following individuals to be the DI:

- Director
- Regional Manager
- Facility Manager

Persons Designated

The HT Act allows the DI to designate persons on their licence, with their agreement. Persons Designated (PDs) can support the DI in overseeing licensable activities.

Organisations may wish to consider the following individuals to be PDs on the licence:

- Facility Manager (if not the DI)
- Funeral Directors or Operations staff

Licence Holder contact

The role of Licence Holder (LH) does not impose the duties that are expected of the DI; however, it is important to note that they have the right to apply to the HTA to vary the licence. This enables them to substitute another person as the DI when the DI is unable to oversee the licensable activity. The HTA prefers the LH to be a corporate body. Please note that different people should be assigned to each of the licence roles. More information on HTA licences and these roles is available on the HTA website[6].

[6] Information for DIs and named contacts: www.hta.gov.uk/useful-information-dis-and-named-contacts-0

HTA licensing standards

Licensed establishments are required to meet the HTA licensing standards.
Part 3 of this guide provides information on the licensing standards for the activity of removing samples from the deceased for testing.

HTA Reportable Incidents (HTARIs)

We require establishments licensed in this sector to notify the HTA of serious incidents and near-miss incidents that may affect the dignity of the deceased and damage public confidence.

Incidents that are required to be reported to the HTA are termed 'HTA Reportable Incidents' (HTARIs). The types of incidents that should be reported to the HTA include:

- Accidental damage to a body
- Loss of a sample
- Disposal or retention of a sample against the express wishes of the family
- Removal of a sample from the body without authorisation or consent
- Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence

Further details of the incident categories are in the HTARI guidance document.
Establishments must notify the HTA of incidents or near-miss incidents **within five working days** of the incident occurring or being discovered.

DIs are responsible for ensuring the HTA is notified of HTARIs and near-miss HTARIs in areas covered by the HTA licence. The DI or a PD on the licence should submit notification of an incident or near-miss incident to the HTA through the HTA Portal.

There is further information about reporting and managing HTARIs and near-miss incidents on the HTA website[7].

[7] Information on HTARIs: www.hta.gov.uk/policies/post-mortem-hta-reportable-incidents-htaris

Part 2 – Applying for a HTA licence

Submit a HTA licence application

To apply for a HTA licence, submit the following documents to the HTA:

- **Completed** HTA licence application form
- **Relevant procedures and policies for licensed activities**
- **Risk assessment(s) of licensed activities**

Submit the completed application form and supporting documents to:
licensing.enquiries@hta.gov.uk

For urgent applications, call the HTA on:
020 7269 1900

HTA licence application form

The information provided in the application form will help to inform the HTA's licensing decision. It is important to provide as much information as possible on the form. This will assist the prompt assessment of the licence application by the HTA.

Any incorrect or misleading information provided in an application could lead to revocation of a licence granted.

The licence application form has five sections:

- Section 1 – Establishment information
- Section 2 – Satellite site application (where applicable)
- Section 3 – Application to be Designated Individual
- Section 4 – Application to be Licence Holder (individual or corporate)
- Section 5 – Compliance with HTA licensing standards

Section 1 – Establishment information

HTA licences are premises specific. The licence application must specify the premises where the activities are to take place.

Where licensable activities are undertaken at different locations, one location may be the hub premises and the additional location(s) may be the satellite site(s). In this case, the satellite site section of the application form should also be completed – section 2.

Parent organisation

Provide the name of the parent organisation; for example, this may be the funeral organisation, Local Authority or the Local Resilience Forum.

Synopsis information

Provide a detailed synopsis of the arrangements for the facility. This should include the following information:

- The activities that will take place at the licensed premises;
- What samples will be taken;
- Who will be taking the samples;
- Whether you will be storing bodies for other purpose(s) outside your normal requirements;
- What is the maximum time samples will be on your premises before being sent off-site for analysis;
- How your facility relates to, or interacts with, other establishments, for example links with other establishments for testing.

Please refer to Part 1 of this document for information on licence contact roles.

Contact the HTA if:

- bodies may be stored on your premises for any other purpose(s) beyond your normal requirements; or
- the sample(s) may be stored on your premises for more than seven days before being sent for testing.

In these cases, a licence for storage may also be required.

Proposed Persons Designated (PDs) for the hub site

Provide details of PDs for the hub site.

Section 2 – Satellite sites

Where licensable activities are at different locations, a licence application can be made for a hub and satellite(s) site. Each premises where licensable activities will be conducted must be named on the licence as a separate site.

If a satellite site is required, complete the satellite site section of the application form for each satellite site and submit this as part of the licence application. The satellite application section of the form must be completed by the DI or the LH.

Information about the satellite site

Provide information of how the satellite site links to governance of the hub site, how the satellite site facility will be used, and relevant further information.

Persons Designated at the satellite site

There must be a primary PD at each satellite site, who can help to direct licensable activities at the site and who is accountable to the DI.

Provide details of the primary PD and any additional PDs for the satellite site.

Section 3 – Application to be Designated Individual

The DI application must be completed by the DI.

If the person is already a DI for another HTA licence, it is not necessary for information to be provided on this application form about education and/or professional qualifications, membership of relevant professional bodies and details of experience.

Lines of responsibility between the DI and any persons working under the licence

Describe the relationship between the DI, PDs and those working under the licence, as well as the DI's position in the overall governance structure.

The HTA must be satisfied that the DI is able and willing to supervise the licensed activities. The DI should have some supervisory responsibility over other persons working under the licence and be in a position to be able to instigate change.

Involvement in ensuring that staff who will work under the licence are appropriately qualified and trained in techniques relevant to their work and that they are continuously updating their skills

The DI must ensure suitable practices are carried out by those undertaking licensed activities; staff training is an important part of this.

Describe the DI's role in ensuring that staff working under the authority of a licence are suitably qualified and trained.

Involvement in governance and quality management activities within the establishment

The DI should not be too far removed from the operational aspects of the licensed activities for which they are responsible, thus ensuring that suitable practices are taking place under that licence.

Describe details of how the DI will be involved in and ensure appropriate activities are taking place, including those that they may not have direct oversight of. This should include details of meetings with staff undertaking licensed activities.

Explain why you think you are suitable for the role of DI

Provide any further supporting information of suitability for the role of DI.

Declaration

The proposed DI must read and acknowledge each statement in this section.

Section 4 – Application to be Licence Holder or Corporate Licence Holder

Either the 'Application to be Individual Licence Holder' or 'Application to be Corporate Licence Holder' sections of the form should be completed.

The HTA prefers the LH to be a corporate body, where possible (section 4ii).

Establishments applying as a corporate body should provide the contact name of an individual who will act as a representative for the corporate body – the Licence Holder contact. This individual should be more senior than the DI, in order to substitute the DI where necessary.

Declaration

The proposed Licence Holder contact or Corporate Licence Holder contact must read and acknowledge each statement in this section.

Section 5 – HTA licensing standards

As part of the licence application process, the HTA will assess whether the establishment can meet the HTA licensing standards. Guidance on how the licensing standards may be met is provided in Part 3 of this document.

Assess compliance with the HTA licensing standards by indicating for each standard:

- Standard not met
- Standard met
- N/A – Not applicable

Describe how each standard is met by providing details for each section in red font on the applicable form. If you are submitting documented procedures or procedures that describe the information requested in these sections, please list the document name and sections of the document where the information is detailed.

If a standard is not met, describe what will be done to rectify this and the timeframe for completing these actions.

Where a standard is not applicable, describe why the standard is not applicable to your establishment. Please note that, other where specifically indicated, only the standards applicable to the licensed activity of removing samples from the deceased for testing are included on the application form.

Contract the HTA if you require further information or guidance about the licence application form or the HTA licensing standards.

Relevant procedures and policies

Our licensing standards require that there are documented procedure and policies for processes related to the proposed licensed activities. Documented procedures should set out the process to be followed to complete a task. They should include sufficient details of the process for staff to follow.

Where documented procedures and policies are submitted with the application, please provide information on the licence application form of the document name and sections of the document where the relevant information for each standard is described.

Risk assessment(s) of licensed activities

Risk management is an essential part of good governance. Our licensing standards require that there are risk assessments of the establishment's practices and processes related to licensed activities. All procedures related to licensed activities should be risk assessed. This should include assessment of risks to the deceased and of undertaking

licensed activities, as well as actions to mitigate the identified risks. The HTARI categories provide a good basis for considering the types of risks.

Effective risk assessments identify the risk, the causes and potential effects. They consider what can be done to prevent the risk from materialising, how the solution will be implemented, who will be responsible for completing any actions and the time scales for completion. Risk assessments should be reviewed regularly.

As part of the licence application, we require documented risk assessments of the licensed activities planned to be undertaken at the establishment. These can be in any appropriate format. We have produced an example risk assessment template to assist establishments with documenting risk assessments of proposed licensed activities.

Assessment of an HTA licence application

When we receive an application for an HTA licence, we will contact the DI to confirm that we have received the application and to discuss the next steps.

As part of the licence application process, we will usually arrange a telephone interview with the DI to discuss the licence application and the arrangements for licensed activities at your establishment. We may request additional information and conduct a visual inspection of the facility.

The following requirements need to be met before a licence can be issued:

- We must have received a licence application form
- We must be satisfied that the proposed DI is a suitable person
- We must be satisfied that the proposed LH is a suitable person/entity
- We must be satisfied that the premises are suitable
- The licence and conditions must be acknowledged in writing by the DI and LH

Shortfalls

Where we assess that not all of the applicable standards are met, the level of the shortfall will be classified as ‘Critical’, ‘Major’ or ‘Minor’. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

Corrective and preventative action plans

In some cases, depending on the classification of the shortfalls, we may issue a licence offer with a corrective and preventative action (CAPA) plan to address the shortfalls. This is based on the HTA's assessment of risk of harm and, or a breach of the HT Act or associated Directions.

We will agree a CAPA plan with the establishment of the actions the establishment needs to take to address the shortfalls. The CAPA plan will include the deadlines for the actions to be completed and evidence that should be submitted to the HTA.

Granting an HTA licence

If the HTA assesses the establishment as suitable to be licensed, we will issue a licence offer. There is a statutory 28 day period for the DI and LH to acknowledge a licence offer. Licensable activities can commence once the HTA confirms receipt of the written acknowledgments from the DI and LH. A substantive licence will then be issued. There is a list of licensed establishments on the HTA website.

The relevant licences must be in place before licensable activities commence.

Representations process

The applicant has the right to ask the HTA to reconsider a licensing decision, provided they give written notice within 28 days of being notified of the original decision. This is in the form of representations. Further information is provided on the HTA website[8].

[8] Representations process: www.hta.gov.uk/policies/how-challenge-hta-licensing-decision

Part 3 – HTA licensing standards and guidance

Licensed establishments are required to meet the HTA licensing standards. These were developed in consultation with representatives from the Post Mortem sector.

The standards reinforce the intention of the HT Act that:

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

b) bodies of the deceased and samples removed from bodies are treated with respect; and

c) the dignity of the person is maintained.

The standards are grouped under four headings: Consent (C); Governance and quality systems (GQ); Traceability (T); and Premises, facilities and equipment (PFE).

Consent (C)

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)

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. The governance and quality systems standards govern the practices taking place on licensed premises, and ensure that they preserve the dignity of the deceased and that the deceased are treated with respect.

Traceability (T)

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. The HTA expects 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)

Establishments meeting these standards will be able to demonstrate that their premises and facilities are appropriate for the licensed activities taking place, that they are safe, secure and clean and that there are effective contingency arrangements in place. In addition, establishments will have systems for ongoing 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 or a risk to bodies.

HTA licensing standards and guidance for removing samples from the deceased for testing

The licensing standards are detailed here, as they apply to facilities removing samples from the deceased for testing. Licensing standards that are not applicable to this activity are not included in this document. This section also includes guidance to assist establishments to meet the licensing standards.

Contact the HTA if you require further information or guidance.

Consent

The HTA standards for consent apply to removal activity, unless it is conducted under coronial or police authority.

C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's Codes of Practice

a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice.

Guidance

The policy should include information on who can give consent for removal of relevant material from the deceased and the storage and use of samples. References to the 'Next of Kin' should be avoided. The HTA's Codes of Practice provide information on the consent requirements of the HT Act.

b) There is a documented standard operating procedure (SOP) detailing the consent process.

Guidance

This should include:

- *who is able to seek consent and what training they should receive;*
- *who can give consent for removal of relevant material from the deceased and the storage and use of samples (references to the 'Next of Kin' should be avoided);*
- *what information should be provided to those giving consent removal of relevant material from the deceased and the storage and use of samples;*
- *the process to manage cases where consent is withdrawn for removal, storage and use of samples.*

HTA Code of Practice B contains guidance for establishments on seeking consent.

c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's Codes of Practice.

Guidance

Information should include who can give consent for removal of relevant material from the deceased and the storage and use of samples. References to the 'Next of Kin' should be avoided. The HTA's Codes of Practice provide information on the consent requirements of the HT Act.

Information on consent should be available in different languages and formats, or there should be access to interpreters/translators. Family members should be given the opportunity to ask questions.

d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives.

e) Where consent is sought for tissue to be retained for future use, information is provided about the potential uses to ensure that informed consent is obtained.

f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds.

Guidance

The time relatives have to reflect on their decision and the point up to which they may withdraw consent should be clearly stated. The timeframe should be discussed with the family and documented. There should be procedures to manage cases where consent is withdrawn for the removal, storage and use of samples.

g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided.

Guidance

The consent forms should record the consent given for removal of relevant material and for the storage and use of samples.

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent

a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's Codes of Practice.

Guidance

Anyone seeking consent for removal of relevant material and storage and use of samples should have relevant experience and a good understanding of the consent procedure.

b) Records demonstrate up-to-date staff training.

Guidance

There should be a system to ensure that only staff who have up-to-date training seek consent (unless they are accompanied by a trained individual).

c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual.

d) Competency is assessed and maintained.

Guidance

There should be a system to ensure that only staff who have been competency assessed seek consent (unless they are accompanied by a trained individual).

Governance and quality systems

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

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath. These include:

i. systems of traceability of bodies and samples;

ii. record keeping;

iii. lone working in the mortuary;

iv. transfer of bodies and samples off site or to other establishments;

v. disposal of samples, which ensures disposal in line with the wishes of the deceased person's family;

vi. access to the mortuary by non-mortuary staff, contractors and visitors.

Guidance

Documented policies and procedures should reflect the requirements of the HT Act and the HTA's Codes of Practice. They should also reflect other relevant legislation and guidance. This includes the Health and Safety Executive's document: 'Managing infection risks when handling the deceased' (HSG283, published July 2018). Individual SOPs for each activity are not required. Some SOPs will cover more than one activity.

d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use.

e) There is a system for recording that staff have read and understood the latest versions of these documents.

Guidance

This includes all staff who undertake licensed activities.

f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity.

g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework.

Guidance

There should be an identified Persons Designated in each area of the establishment where licensed activities take place.

The Designated Individual has a duty to ensure that suitable practices are carried out by those working under the licence, that the other persons to whom the licence applies are suitable persons to participate in the carrying on of those activities and that the conditions of the licence are complied with.

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff.

Guidance

The DI should have regular debriefs with the team undertaking licensed activities.

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

a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised.

Guidance

This includes all staff who are involved in removal of samples from the deceased and handling and sending samples off-site.

b) There are clear reporting lines and accountability.

c) Staff are assessed as competent for the tasks they perform.

Guidance

This includes all staff who are involved in removal of samples from the deceased and handling and sending samples off-site.

Assessment of competence should include the standard of APTs' reconstruction work.

f) There is a documented induction and training programme for new mortuary staff.

Guidance

This will be specific to each facility and staff should be familiar with processes before starting work.

g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures.

Guidance

The qualifications of staff should be checked prior to them commencing work in the mortuary and their competency to undertake each task should be assessed.

Contractors, visiting and temporary staff and funeral service staff bringing bodies out of hours should be required to read relevant SOPs and sign to confirm their understanding.

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

a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.

Guidance

Records include consent records, sample request forms and records of transfer of samples sent elsewhere for testing.

b) There are documented SOPs for record management which include how errors in written records should be corrected.

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

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

a) Staff know how to identify and report incidents, including those that must be reported to the HTA.

Guidance

HTA reportable incidents (HTARIs) and near-miss HTARIs must be reported within five working days of the incident occurring of being discovered. Establishments must not wait until any internal review or investigation is complete before notifying the HTA of the HTARI. Designated Individuals and Persons Designated should register for an HTA Portal account, to ensure that HTARIs can be reported to the HTA within the required timescale. Refer to the HTA website for further information on HTARIs and reporting requirements.

The HTARI reporting requirements and process for reporting incidents should be documented in a standard operating procedure.

All staff involved in licensable activities should be aware of the HTARI reporting requirements and procedure.

Incidents that do not fall within the HTARI reporting requirements should be reported and investigated internally.

b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents.

c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.

d) Information about incidents is shared with all staff to avoid repeat errors.

e) The establishment adopts a policy of candour when dealing with serious incidents.

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

a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis.

Guidance

Risk assessments should be at regular intervals and when circumstances change. Staff should be involved in the risk assessment process and should be aware of the risks associated with the activities they undertake.

Risks to the dignity and integrity of bodies and stored samples should be covered. This should include risks to the security of the facility. The HTARI categories provide a good basis for risk assessments.

b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Guidance

Relevant staff should have knowledge of risks and the control measures that have been taken to mitigate them.

c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register.

Traceability

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

a) Bodies are tagged/labelled upon arrival at the mortuary.

Guidance

Processes should also be in place the all bodies are labelled upon arrival at the facility. The condition and labelling of bodies should always be checked and their

identity confirmed. Identification labels should be attached to the body. Body bags and shrouds should not be labelled in place of labels attached to the body.

Refer to standard T1(c) for further details of the requirements for labelling of bodies and samples.

b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records).

Guidance

The tracking system should include bodies and samples removed from the deceased.

c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier.

Guidance

This licensing standard aims to ensure that identification procedures are robust. Any deviation from documented procedures should be considered on a case-by-case basis, escalated internally (for example, to the facility manager and, or Designated Individual) and documented.

Bodies should be identified using a minimum of three identifiers attached to the body that can be used to check the identification of the deceased. Age is not considered to be robust as an identifier; date of birth should be used wherever possible. First name and last name are considered to be one identifier.
Where there are fewer than three identifiers on a body, enquiries should be made to obtain a minimum of three identifiers. It is good practice to obtain this information in writing and keep it with the deceased's record. The additional identifiers should be added to existing or additional identification bands on the body.

Identification for removal of samples from the deceased: A minimum of three identifiers of the deceased on the body should be checked against the consent or authority documentation prior to removing the sample from the body. Any discrepancies in the identifiers should be thoroughly investigated and documented before the proceeding with removal of relevant material from the body.

e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises.

Guidance

Mortuary white boards containing the names of the deceased give potential for error if wiped clean (such as when visitors attend for reasons of confidentiality), and should not be relied upon as the sole source of information about the locations of bodies.

Fridge/freezer failures that require bodies to be moved temporarily whilst repairs take place present a risk to traceability. Full identification checks should be made when bodies are placed back into normal storage.

Checks should be made to ensure that identification bands on bodies are accessible when bodies are transferred into freezer storage.

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings). The traceability system ensures that the following details are recorded:

i. material sent for analysis on or off-site

ii. disposal or retention for future use.

Guidance

When material is sent for analysis on or off-site, records should clearly indicate the type and quantity of the samples. Consent information which covers retention/disposal of tissues should be made available to the other site, as appropriate.

h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements.

Premises, facilities and equipment

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue

a) The premises are clean and well maintained.

Guidance

Floors, walls and work surfaces should be of non-porous construction and free of cracks and chips. The premises should be subject to a programme of planned preventative maintenance, which ensures that the premises, facilities and equipment remain fit for purpose.

b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors.

c) There are documented cleaning and decontamination procedures and a schedule of cleaning.

Guidance

There should be records of cleaning and decontamination.

d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access).

Guidance

Relatives who visit for a viewing should not be able to access the body store area.

e) Security arrangements protect against unauthorised access and ensure oversight of visitors and contractors who have a legitimate right of access.

Guidance

Consideration should be given as part of the planning process in order to ensure dignity of the deceased and reduce the risk of media intrusion.

Swipe card access lists should be reviewed regularly. Staff and authorised visitors and contractors should be aware of the establishment's security arrangements.

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

a) Items of equipment in the mortuary are in a good condition and appropriate for use.

Guidance

Equipment should be made of material that is easy to clean, impervious, non-rusting, non-decaying and non-staining.

b) Equipment is appropriate for the management of bariatric bodies.

Guidance

The 'safe working load' of equipment should not be exceeded.

d) Staff have access to necessary PPE.

Guidance

Refer to the Health and Safety Executive's document: 'Managing infection risks when handling the deceased' (HSG283, published July 2018) and guidance from Public Health England for PPE requirements.

e) Where chemicals are used for preservation of tissue samples, there is adequate ventilation.

f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept.

Guidance

Relevant staff should be notified of servicing and have access to service records.

Further information

The following links to the HTA website are referenced in this guidance document:

- Licence application form
- Example risk assessment
- HTA Codes of Practice A and B
- Information on HTA Reportable Incidents
- Information on relevant material
- Information for DIs and named contacts
- Representations process

Please refer to the glossary in Appendix 1 for the definition of commonly used terms.

Appendix 1 – Glossary

Term	HTA definition
Code of Practice	The HTA Codes of Practice aim to provide anyone undertaking licensable activities with a reference source which gives practical advice on the minimum steps necessary to comply with the relevant legislation and HTA licensing standards. The Codes of Practice are available on the HTA website.
Coroner	Coroners are independent judicial office holders, appointed by a local council. They investigate deaths that have been reported to them if it appears that the death was violent or unnatural, the cause of death is unknown or the person died in prison, police custody, or another type of state detention. In these cases, coroners must investigate to find out, for the benefit of bereaved people and for official records, who has died and how, when, and where they died. As part of their duties, coroners authorise post-mortem examinations and conduct inquests.
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.
HTA Reportable Incident (HTARI)	A serious incident in the post mortem sector which falls within the classifications defined by the HTA and about which the HTA must be notified. Further information can be found on the HTA website.
Licence Holder (LH)	The person who holds a licence and is responsible for the payment of any fees charged by the HTA. The LH can be a corporate body. Where the applicant is not the proposed DI, the HTA must be satisfied that the applicant is a suitable person to be the holder of the licence.
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 HT Act by the HTA. Organisations whose activities involve the removal, storage or use of relevant material may need to work under an HTA

	licence. All establishments working under an HTA licence must work to specified licensing standards set by the HTA.
Persons designated (PD)	A person working under an HTA licence acting under the direction of the Designated Individual.
Relevant material	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 website.
Scheduled purpose	Under the HT Act, consent must be obtained to remove, store and use bodies or relevant material for scheduled purposes. The licensing requirements of the HT Act also refer to the scheduled purposes.
Standard operating procedure (SOP)	A document that sets out the established process to be followed to complete a task.