

## Standards and guidance



# Research Licensing Standards and Guidance

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Revision history .....	2
About the guidance documents .....	3
About the Standards.....	3
Consent (C).....	4
Governance and quality systems (GQ) .....	4
Traceability (T) .....	4
Premises, facilities and equipment (PFE) .....	4
HTA licensing standards .....	5
Consent standards.....	5
Governance and quality system standards .....	7
Traceability.....	14
Premises, facilities and equipment standards .....	15
Classification of the level of shortfall .....	18
Critical shortfalls.....	18
Major shortfalls.....	18
Minor shortfalls.....	19

## Revision history

<b>Version</b>	<b>Date</b>	<b>Changes</b>
1.0	23/01/2016	First version published

## About the guidance documents

1. The purpose of these guidance documents is to assist licensed establishments to meet the HTA's licensing standards. The documents contain additional information and examples of how to meet certain Standards.
2. These documents will be reviewed regularly to include additional guidance. In reviewing these documents we will take into consideration enquiries, inspection findings and additional examples of good practice.
3. For further guidance on meeting the HTA's standards, please contact the HTA either by:
  - a) Email: [enquiries@hta.gov.uk](mailto:enquiries@hta.gov.uk)
  - b) Telephone: 020 7269 1900

## About the Standards

4. In order to obtain an HTA licence, the applicant must demonstrate that:
  - a) the premises where the activity will take place are suitable; and
  - b) the proposed Designated Individual is a suitable person to supervise the activity.
5. As part of the application process, the HTA will assess whether the establishment can meet a number of licensing Standards. These were developed in consultation with representatives from the Research sector. These relate to the consent provisions of the Human Tissue Act 2004 (HT Act), governance and quality systems, traceability and premises.
6. The Standards 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.
7. The HTA works with establishments through its inspection process to help them comply with these Standards.
8. The 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)**

1. 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)**

2. 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)**

3. 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)**

4. 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.
5. 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.

## HTA licensing standards

### Consent standards

#### **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) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.
- b) Consent forms are available to those using or releasing relevant material for a scheduled purpose.

#### *Guidance*

*Legal requirements, such as the Data Protection Act 1998 and the common law duty of confidentiality, need to be considered in such circumstances.*

- 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.
- 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.
- e) Language translations are available when appropriate.
- f) Information is available in formats appropriate to the situation.

#### *General guidance*

*Consent is the fundamental principle of the Human Tissue Act 2004 and the HTA Codes of Practice A (Guiding principles and fundamental principles of consent) and E (Research) are the primary sources of guidance for compliance with this standard.*

*For health-related research in general i.e. not limited to that involving human tissue, the HRA provides resources such as template consent forms and participant information sheets.*

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

- a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice.

- b) Records demonstrate up-to-date staff training.
- c) Competency is assessed and maintained.

*General guidance*

*It is important that consent training is not considered a one-off event and that proficiency in seeking consent is upheld.*

*There is no set requirement for the frequency of consent training. Consent-seekers are expected to maintain awareness of current standards through reference to published guidance and relevant policies. Training may need to be updated when legislation has changed, new policies or practices have been implemented, different research activities are to be undertaken or a significant period of time has elapsed since research activities have been conducted.*

## 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

#### *Guidance*

*At a minimum, it is expected that most establishments will have standard operating procedures (SOPs) covering the following activities:*

- consent;*
- collection;*
- receipt;*
- labelling;*
- specimen preparation / preservation;*
- storage;*
- relevant transport arrangements;*
- cleaning and decontamination;*
- disposal.*

*More complex establishments, especially those releasing material, may need to cover more areas in their suite of documents.*

*A standard operating procedure (SOP) should be a clear and accurate representation of an existing procedure or process, preferably set out in the format of a stepwise guide. SOPs should be understandable to enable new staff to follow a procedure from beginning to end. They should be detailed enough to ensure uniformity between staff in the performance of a specific function and should be followed to the letter by all staff who have been appropriately trained.*

*People undertaking the processes should be involved in developing the SOPs to ensure that the written procedures reflect actual practices. Regular review of SOPs will help to prevent incremental departure from written processes with passing time and allow establishments to identify improvements. Establishments should introduce a system to record that staff have read and understood SOPs.*

*If human tissue is to be transferred between establishments, consideration must be given to minimise the likelihood of theft, damage or loss during transport. Some form of formal transfer arrangement, for example, as part of a Material*

*Transfer Agreement (MTA) should define how the human tissue is preserved, any potential contamination risks associated with it; and who is responsible for disposal, if applicable. We do not specify or endorse any particular format for MTAs; a number of template agreements are publically available and can be adapted to suit individual circumstances. Transportation procedures should also give sufficient detail to ensure the integrity of the tissue.*

- b) There is a document control system.

*Guidance*

*Governance documents should include:*

- *Revision history and version number*
- *'Effective from' date*
- *Review date (at least every three years)*
- *Pagination*
- *Author and reviewer names*

- c) There are change control mechanisms for the implementation of new operational procedures.

*Guidance*

*Change control mechanisms should take into account the risks of any planned changes, any validation required, any training required and how implemented changes will be reviewed.*

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

*Guidance*

*All staff working under the HTA licence should be aware of the governance arrangements in place, and they should be represented at governance meetings. Overall governance processes should be supported by regular meetings with staff at the establishment who are engaged in licensed activities. Formal meetings should be minuted and the actions should be noted and followed up. Documented minutes of meetings should be distributed to all relevant staff to help to ensure that they are aware of all important information relating to licensed activities at the establishment. National and local information relevant to activities should also be disseminated.*

- e) There is a system for managing complaints.

*General guidance*

*A formal quality management framework helps to establish minimum expectations for governance and quality systems, and facilitates continuous improvement.*

*The work of the staff at the establishment must be subject to a system of governance. This means that there should be clear reporting lines and accountability (particularly with regard to individual staff and the DI), documented roles and responsibilities.*

*Establishments are encouraged to have an over-arching quality document which provides an overview of the establishment's main purpose, organisation and structure and approach to governance and quality. This document should be accessible to all staff involved in licensed activities.*

*The HTA recommends that establishments adopt a harmonised approach to sample management as there are risks of varying practices where samples being stored for REC-approved projects are managed differently to samples subject to HTA's licensing standards.*

## **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

### *General guidance*

*Audits will demonstrate compliance with our standards and demonstrate whether establishments are meeting the requirements of their own systems.*

*A documented schedule of audits should be in place at each establishment.*

*Vertical audits of records and specimens will allow the establishment to assure itself that specimens and records are fully traceable from consent to disposal.*

*Records, including records of consent, should be audited regularly to ensure completeness, accuracy and legibility.*

*Audits should ideally include horizontal audits by staff involved in the processes, to ensure that SOPs accurately reflect actual practices and to identify areas for improvement. All audit findings and related corrective and preventative actions should be recorded to allow the establishment to demonstrate compliance with HTA standards and follow-up outstanding actions.*

*Audit processes can benefit from being undertaken by a person who is not normally involved in the activity at the establishment: a 'fresh eyes' view. Internal auditors should not be involved in auditing their own work.*

*Some establishments may be able to make use of existing in-house expertise*

or services.

### **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.

#### *General guidance*

*Training and induction packages help to ensure that staff are fully trained on all policies and procedures relevant to their work. Establishments should ensure that training and development plans are in place and that these are reviewed periodically.*

*Staff should be encouraged to attend professional meetings and training events to ensure that they keep abreast of good practices in their areas of expertise.*

### **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.

#### *Guidance*

*Documented records are used by establishments to evidence traceability and ensure a robust audit trail. In this context, traceability refers to the completeness of auditable information about every step in the pathway for the use of relevant material, from consent through to disposal, or the material has been used up entirely.*

*Documented procedures for the creation, review, amendment, retention and destruction of records are required to help to ensure that records are maintained appropriately. SOPs should detail the frequency of document review required to ensure that documents are regularly reviewed and updated as necessary.*

- b) There are provisions for back-up / recovery in the event of loss of records.

### *Guidance*

*Records may be in various formats, including paper based, electronic, or stored on recordable media.*

*A centralised system for the storage of records can help to ensure that records are regularly backed-up.*

- c) Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).

### *Guidance*

*Consideration must be given to other relevant legislation, including compliance with the Data Protection Act 1998 where tissue has been taken from the living, and compliance with professional guidelines where applicable.*

## **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.

### *General guidance*

*All establishments licensed by the HTA are required to have an internal system for reporting adverse events and, where necessary, instigating an investigation or root cause analysis.*

*Clearly assigning responsibilities for incident management is important. As the DI is responsible for licensed activities at the establishment, there should be a process in place to allow them to be made aware of adverse events so that proper investigation and reporting can take place. There should be an adverse incident SOP detailing how adverse incidents are logged, reported, addressed and monitored.*

*Although there is currently no requirement for establishments in the research sector to report adverse incidents to the HTA, if a DI has concerns about an adverse event, they are encouraged to contact us for further advice.*

*Relevant examples of adverse events include:*

- specimen loss;*
- missing or incorrect documentation;*
- security breach;*
- abnormalities in storage temperature readings;*

- *inappropriate disposal.*

### **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.

#### *Guidance*

*All establishments should identify the risks inherent in the key activities, and procedures should be developed in consideration of and to mitigate these potential risks where appropriate. Establishments may tend to focus risk assessments on health and safety issues which, in themselves, are not sufficient to meet our standards. DIs should also assess the risks associated with licensed activities. Documented risk assessments should include an evaluation of the level of the risk and, where appropriate, the mitigating actions identified and the level of residual risk remaining.*

*Risk assessments should include the risks relating to the premises, practices and procedures connected with licensed activities, including:*

- *receiving and/or storing specimens without appropriate consent documentation;*
- *storing or using human tissue after consent withdrawal;*
- *storage failure or other damage affecting human tissue quality for useful research;*
- *loss of human tissue;*
- *sample mix-up or loss of traceability;*
- *transport of specimens to and from the establishment ;*
- *security arrangements;*
- *incorrect disposal.*

- b) Risk assessments are reviewed regularly.

#### *Guidance*

*Risk assessments should be reviewed periodically (typically, every 1-3 years) and the actions to mitigate risks updated as necessary.*

*Risk assessments should also be reviewed following an incident.*

- c) Staff can access risk assessments and are made aware of risks during training.

#### *Guidance*

*By documenting risk assessments, staff are made aware of identified risks, which helps to prevent risks materialising and informs the development of*

*procedures and relevant documentation.*

## 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.

#### *General guidance*

*Where relevant, through their coding and records systems, HTA-licensed establishments should be able to demonstrate their awareness and ability to track ethical approval expiry dates and any relevant conditional agreements, such as consent opt-outs.*

### **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.

#### *General guidance*

*Establishments should carefully document disposal. Supporting procedures should detail the requirements for recording the details of disposal, including the date, reason and method. Records of disposal should be kept in order to provide a complete audit trail from donation through to disposal.*

## 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.

#### *Guidance*

*The establishment must be clean, well maintained and subject to a programme of planned preventative maintenance. Suitable environmental controls should be in place to avoid potential contamination.*

*Establishments should periodically review risk assessments of premises, facilities and equipment. This should ideally include an audit of the premises and equipment in order to identify areas requiring rolling maintenance, refurbishment or upgrade. This will help to ensure that remedial actions are implemented in a timely manner so that the premises, facilities and equipment remain fit for purpose.*

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

#### *Guidance*

*Security measures include the use of locks, alarm systems and protections against unauthorised access.*

*Establishments are expected to have policies in place to review and maintain the safety of staff, visitors and other relevant people e.g. students or donors.*

- c) There are documented cleaning and decontamination procedures

#### *Guidance*

*Documented cleaning and decontamination procedures should be supported by schedules*

### 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.

### *Guidance*

*Documented temperature monitoring allows establishments to easily visualise and identify when temperatures are out-of-range. It can also demonstrate temperature trends, to identify when storage conditions may be deteriorating and to alert staff to developing equipment failure. Temperature alarms should be regularly tested and manually challenged periodically to ensure that they are operating as expected.*

*Signs should be added to freezers to define alarm set points for the temperature ranges so that staff are visually reminded of minimum and maximum temperatures.*

*Where storage is critical, an appropriate remote temperature monitoring alarm and callout system may be required.*

*Checks and filling of liquid nitrogen dewars should be documented.*

*Where material can be stored at ambient/room temperature, this does not mean that storage conditions do not need to be monitored.*

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

### *Guidance*

*The establishment must have contingency arrangements in place should there be an emergency situation that renders the premises unusable for the storage of human tissue; this may need to be through a formalised arrangement with another HTA-licensed establishment for transfer of material.*

### *General guidance*

*Areas used for storage of human tissue for use in research must provide an environment that is safe for those working under the licence and preserves the integrity of the tissue.*

*Refrigerators, freezers and other vessels which contain human tissue should be appropriately labelled so that staff are aware of the necessity to maintain the quality, safety and security of such material and prevent mix-ups with other tissues.*

*Human tissue must be stored in such a way that it minimises the risk of contamination to those working under the licence. If necessary, the DI should work with health and safety personnel to implement environmental controls and appropriate equipment to reduce the risk of contamination.*

**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.

*Guidance*

*Equipment must be regularly maintained to ensure that it is suitable for use.*

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

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

*Guidance*

*There should be a system for renewing items that are no longer suitable through wear and tear.*

- c) Staff are provided with suitable personal protective equipment.

*Guidance*

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

## **Classification of the level of shortfall**

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and 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.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

### **Critical shortfalls**

A critical shortfall is:

- a shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions; or
- a combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

A critical shortfall may result in one or more of the following:

- a notice of proposal being issued to revoke the licence
- some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
- a notice of suspension of licensable activities
- additional conditions being proposed
- directions being issued requiring specific action to be taken straightaway

### **Major shortfalls**

A major shortfall is a non-critical shortfall that:

- poses a risk to human safety and/or dignity
- indicates a failure to carry out satisfactory procedures
- indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines
- has the potential to become a critical shortfall unless addressed; or

- is a combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

### **Minor shortfalls**

A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.