Site visit inspection report on compliance with HTA minimum standards

King's College London

HTA licensing number 12522

Licensed under the Human Tissue Act 2004 for the

- **storage of relevant material which has come from a human body for use for a scheduled purpose**

22 March 2017

Summary of inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Although the HTA found that King's College London (the establishment) had met the majority of the HTA standards, one major shortfall and four minor shortfalls were found. The major shortfall was in relation to the suitability of the liquid nitrogen storage area (standard PFE1). The minor shortfalls were in relation to: consent documentation (standard C1); training in seeking consent (standard C3); sample traceability (standard GQ6); and disposal records (standard D2).

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual (DI), Licence Holder, premises and practices are suitable.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004 (HT Act). They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licenses against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

King's College London (the establishment) is licensed by the HTA under the HT Act for the storage of relevant material which has come from a human body for use for a scheduled purpose. This licence applies to the campus at St Thomas' Hospital.

The establishment has been licensed by the HTA since September 2008. This report describes the second, routine site visit inspection of the establishment in March 2017.

The establishment stores human samples for use for the scheduled purpose of 'research in connection with disorders, or the functioning, of the human body'. Researchers are required to obtain approval from the DI to store samples under the licence. The DI and Persons Designated (PDs) maintain oversight of all samples stored under the licence. Each research group storing samples under the licence has at least one PD. Each group has laboratory-specific standard operating procedures (SOPs), which are in accordance with the establishment's overarching SOPs for activities conducted under the licence.

All University staff and students working under the licence are required to register and complete the establishment's human tissue training programme upon commencing work under the licence and at three-yearly intervals thereafter. The establishment does not require clinical Consultant staff seeking consent for storage and use of samples under the licence to complete this human tissue training programme (see shortfall for standard C3).

The establishment requires that all samples transferred to or from the establishment under the HTA licence are either: part of a study approved by a recognised research ethics committee (REC); or, subject to a material transfer agreement confirming that consent has been obtained for the storage and use of the samples in accordance with the requirements of the HT Act. Principal Investigators for each group are required to keep records of the transfer of samples to and from the establishment under the HTA licence.

Samples are stored under the licence in -80°C freezers or liquid nitrogen storage tanks. Storage temperatures are continuously monitored and there are automated alarms with call-out notification procedures in the event of a deviation from the set acceptable temperature ranges. The establishment conducts periodic tests of the temperature alarm call-out systems. Temperature alarms and freezers are serviced regularly. The establishment has contingency arrangements for storage in the event of equipment failure.

All samples stored under the licence are assigned a unique identification number or name, which is used to track sample receipt, storage, use, distribution and disposal. The establishment uses electronic databases to provide traceability of samples. Each research group is responsible for maintaining traceability records for their sample collections. The DI conducts regular audits, including of sample traceability.

The establishment disposes of human samples by incineration. Samples are bagged separately from other waste. Records of disposal are kept by each research group.

At the time of the inspection, samples were being stored under the licence for six research groups. All samples stored under the licence are obtained from living people.

Cardiology Research Group – there are seven collections of heart tissue samples stored under the licence by the Cardiology Research Group. These samples are from patients who underwent surgical procedures involving the heart or donated their hearts for organ transplantation. These samples have been received from third party organisations. Some of these samples have been imported or are ‘existing holdings’ (material that was already held for use for a scheduled purpose when the HT Act came into force on 1 September 2006).

Coeliac Research Group – a collection of intestinal biopsy samples are being stored under the licence for a Coeliac Research Group previously based at the establishment. These samples are all existing holdings. The establishment is not currently using these samples and does not have clear plans to use these samples in the future. The HTA has advised the establishment on the arrangements for the storage of these samples (see advice item 15).

Imaging Sciences and Biomedical Engineering Group – this group receives leukocyte cones under an agreement with a third party organisation. The research group extracts peripheral blood mononuclear cells (PBMCs) from these preparations and stores the PBMC samples.

Women’s Health Maternal and Foetal Research Unit – two sample collections are stored under the licence by this research group. These collections include saliva and buffy coat cell samples. The samples are obtained from patients attending clinics at the establishment or are transferred to the establishment from third party organisations.

Women’s Health Pregnancy Research Group – samples stored by this research group are part of a research tissue bank (RTB): the Registry of Autoimmune Rheumatic Diseases. The RTB has received ethical approval from a recognised REC, including extension of the ethical approval to projects receiving non-identifiable samples from the RTB. Samples are collected from patients attending clinics at the establishment’s partner hospitals. Consent for the storage and use of samples is sought by clinical staff. Samples stored under the licence for this research group are whole blood samples.

Thrombosis, Haemostasis and Vascular Biology Research – samples stored by this research group are part of a REC-approved RTB: the Antiphospholipid Antibodies Biobank. Samples are collected from patients attending clinics at the hospital. Consent for the storage and use of samples is sought by clinical staff working at the establishment. Samples stored under the licence for this research group are whole blood samples, which are being stored pending processing to extract DNA. Storage of these blood samples is subject to the HT Act licensing requirements because they are stored for more than one week prior to processing.

The establishment also stores human samples that have been processed to render them acellular. The establishment has SOPs for sample processing to ensure that samples are rendered acellular. Acellular samples are not subject to the HT Act licensing requirements.

The establishment also stores samples of relevant material for use for research projects which have received approval from a recognised REC, thereby exempting storage of these samples from the HT Act licensing requirements. Principal Investigators at the establishment maintain oversight of REC approval to ensure that where approval expires, or samples are stored outside the terms of the approval, relevant material is stored under the licence.

The inspection timetable was developed in consideration of the activities conducted under the licence, compliance update information and discussions with the DI. The inspection included visual inspection of the areas where samples are stored under the licence, sample traceability audits, review of documentation and interviews with staff working under the licence.

Audits of sample traceability were conducted for each of the six research groups with samples stored under the licence. These audits included forward and reverse audits between samples and traceability records for each collection and included disposal records where samples have been disposed of. These audits comprised:

- 17 samples and nine disposed samples for the Cardiology Research Group, including transport details and agreements with supplying organisations;
- six samples for the Coeliac Research Group;
- four samples and 13 disposed samples for the Imaging Sciences and Biomedical Engineering Group;
- four samples from the Women's Health Maternal and Foetal Research Group, including transport details for two samples and consent forms for two samples;
- four samples for the Women's Health Pregnancy Research Group (Registry of Autoimmune Rheumatic Diseases), including consent forms; and
- two samples for the Thrombosis, Haemostasis and Vascular Biology Research Group, (Antiphospholipid Antibodies Biobank), including consent forms.

These audits revealed anomalies in traceability for four samples stored by the Cardiology Research Group (see shortfall against standard GQ6). Full sample traceability was demonstrated in the audits of the samples stored by the other five research groups.

These audits also identified anomalies with five out of seven consent forms reviewed for the Registry of Autoimmune Rheumatic Diseases, where signatures were on the wrong sections of the form (see Advice, item 2). This is in addition to the findings of the establishment's internal audits of all of the consent forms for this RTB, which identified seven consent forms where the tiered consent statements were not completed (see shortfall against standard C1). The establishment has logged this as an incident and reported this to the REC. Samples from these participants have been quarantined to ensure that they are not used without appropriate consent.

The establishment's audits revealed two consent forms for the Antiphospholipid Antibodies Biobank could not be located. Consent has been re-sought (see Advice, item 1).

Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Consent

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the Code of Practice.	Women's Health Pregnancy Research Group (Registry of Autoimmune Rheumatic Diseases) The establishment's internal audit of all of the consent forms for this RTB identified seven consent forms where the tiered consent statements were not completed. The establishment cannot therefore provide evidence that consent was sought in accordance with the requirements of the HT Act for storage and use of the samples from these seven participants. Although these samples are quarantined and are not available for use in research, there is a risk that these samples are being stored without appropriate consent. *See Advice, item 1.*	**Minor**
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	Women's Health Pregnancy Research Group (Registry of Autoimmune Rheumatic Diseases) The establishment could not provide evidence that a member of staff seeking consent for storage and use of samples under the licence had received suitable training in seeking consent and the requirements of the HT Act. Although this staff member had completed a training course one week prior to the inspection, they had been seeking consent for storage of samples under the licence for a number of years. This staff member was also not aware of the establishment's SOP for seeking consent. The importance of training in the consent requirements of the HT Act and the establishment's local consent seeking procedures is emphasised by the incident relating to the consent forms for this RTB, which relates to consent sought by this staff member (refer to shortfall against standard C1). *See Advice, items 1 and 2.*	**Minor**

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	<u>Cardiology Research Group</u> Audits performed during the inspection highlighted issues that the establishment needs to address to strengthen tissue traceability for samples stored by the Cardiology Research Group. These anomalies were: • one sample in storage was incorrectly recorded on the sample database as having been used to destruction; • one sample recorded on the sample database could not be located in storage (the establishment believe that this sample has in fact been used to destruction); and • two sample labels could not be reliably deciphered, meaning that traceability of these two samples could not be assured. The establishment's internal audits of sample traceability have also revealed a number of discrepancies with sample traceability for samples stored by this group. *See Advice, item 7.*	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE1 The premises are fit for purpose.	<u>Liquid nitrogen storage area</u> The establishment's arrangements for liquid nitrogen storage could pose a risk to the health and safety of staff. • The liquid nitrogen storage tanks and pressurised vessels are located in a corridor area. It is not possible to restrict access to the area to only personnel needing to access these storage tanks. • This storage area is located underneath a ceiling access point to a loft area and is obstructing access to an electrical plant cupboard. This means that the storage tanks and pressurised vessels have to be moved to the main corridor area when access to either of these service areas is required. • The ceiling of this area is in a poor condition.	**Major**

	• Although there is an oxygen monitor in this area of the corridor, there is no procedure to ensure that all personnel with access to the corridor, including security staff, are aware of what the alarm is for and what actions to take in the event of the alarm sounding. • There is no documented risk assessment of the safety of this corridor area and its suitability, or not, for the storage of liquid nitrogen tanks, including pressurised vessels. The DI has taken steps to try to relocate this liquid nitrogen storage facility to a more suitable area within the establishment, but this has not been achieved to date.	

Disposal

Standard	Inspection findings	Level of shortfall
D2 The reasons for disposal and the methods used are carefully documented.	The establishment's SOP for disposal does not include details that the date, method and reason for disposal must be recorded. Although some research groups storing samples under the licence do record the date, method and reason for disposal in laboratory notebooks or using a 'Disposal Log' form, this is not consistently done by all groups storing samples under the licence. *See Advice, item 14.*	**Minor**

Advice

The HTA advises the DI to consider the following to further improve practices:

No.	Standard	Advice
1.	C1	Several research groups have introduced checks on consent forms at the point that samples are received into the laboratory for storage. The DI is advised to formalise these checks and extend them to all samples to be stored under the licence where the establishment has been responsible for obtaining consent. This will help to ensure that all consent forms are present and completed correctly. This will also help to identify whether any preventative actions may be required where issues with consent forms are identified; for example, additional training requirements for those seeking consent.

2.	C1	Given the number of discrepancies identified in completion of consent forms for the Registry of Autoimmune Rheumatic Diseases RTB, the DI is advised to review this consent form to ensure that it is clear. This may include making the boxes, to initial for the tiered consent statements, larger and with a thicker outline, and amending the layout of the spaces for the participant, researcher and consent seeker to sign. The DI is reminded that any proposed modifications to this consent form must be approved by the REC since these forms are part of the REC-approved RTB.
3.	C2	The establishment's consent forms and participant information sheets provide information that participants can withdraw their consent for the storage and use of samples. The DI is advised to consider including central details for the establishment on this documentation, in addition to the lead researcher's contact details. This will help to ensure that participants are able to withdraw their consent even if the lead researcher has left the establishment.
4.	GQ2	The DI is advised to ensure that all documents relating to activities conducted under the licence are subject to the establishment's document control procedures. In particular, the DI is advised to consider the following advice. • Where documents are reviewed, the document version number should be updated so that it is clear that the document is a new version. Documents should include details of the author and reviewer. • Where SOPs include forms as an appendix, the DI is advised to consider including a link to the form instead. This will help to ensure that forms printed for completion contain the correct document control information and not that of the SOP from which they were printed. • Where sample traceability databases are printed, the printed document should detail the date of printing so that it is clear whether it is the most up-to-date version of the database. • Where local copies of sample traceability databases are kept, the procedures for this should be reviewed to ensure that there is a robust system for ensuring that the most recent version of the database is in use. All sample traceability databases should be stored securely and with appropriate systems for backup. • The use of the handwritten freezer maintenance record book should be reviewed to ensure that it provides a robust record of freezer maintenance and servicing. Use a formal maintenance record form should be considered.
5.	GQ2	The DI is advised to ensure that audit reports are documented in a clear manner to ensure that it is clear what corrective and preventative actions are required, and the responsibility and timeframes for completion of these. The DI is also advised to ensure that these reports contain sufficient details. For example, where the findings relate to a specific freezer, liquid nitrogen tank or temperature probe, the identification number of the affected equipment should be recorded in the report. This will help the establishment to identify trends in audits, which will in turn help to inform appropriate corrective and preventative actions.

6.	GQ5	The establishment's overarching SOPs do not include performing checks that organisations to which samples under this licence are distributed to are HTA-licensed, as appropriate. The DI is advised to ensure that checks are undertaken before samples are distributed to other organisations to ensure that they are HTA-licensed, as appropriate.
7.	GQ6	The establishment should review the use of handwritten sample labels to ensure that they provide an appropriate and reliable means for sample identification. This is particularly important where labels on small vials are handwritten, meaning that it can be difficult to decipher the labels, which may result in compromised sample traceability.
8.	GQ7	The DI is advised to review the adverse events SOP to include examples of adverse events that should be reported via the establishment's internal procedures. Examples of adverse events include, but are not limited to: • consent not sought in accordance with the HT Act requirements; • sample used not in line with consent given; • specimen loss; • missing or incorrect documentation; • security breach; • abnormalities in storage temperature readings; and • inappropriate disposal. The DI is advised to remove from this SOP the statement that all adverse events must be notified to the HTA. There is no requirement for establishments in the research sector to report adverse events to the HTA. The DI is advised that if they have concerns about an adverse event, they are encouraged to contact the HTA for further advice. The DI is also advised to ensure that all staff working under the licence are aware of the procedure for reporting adverse events.
9.	GQ7	The DI is advised to ensure that adverse event reports are documented in a clear manner and contain sufficient details. These reports should document clearly what corrective and preventative actions are required, and the responsibility and timeframes for completion of these. Where the findings relate to a specific sample collection or item of equipment, these details should be recorded in the report. This will help the establishment to identify trends in adverse events, which will in turn help to inform appropriate corrective and preventative actions.

10.	GQ8	The DI should ensure that the documented risk assessments for each research group cover the following risks, as appropriate: • receiving and / or storing samples without appropriate consent; • storing or using samples after consent withdrawal; • sample mix-up or loss of sample traceability; • transport of samples to and from the establishment; • storage and security arrangements; and • incorrect disposal. Risk assessments should be reviewed periodically and following an adverse event or procedural changes. This will help to ensure that risk assessments cover all of the risks associated with the activities undertaken, that assessments of risks are appropriate and further mitigating actions are considered, as required. The DI should review the risk register relating to undertaking licensed activities to ensure that where mitigating actions have been identified it is clear whether actions have been implemented or the timescale for completion.
11.	PFE2	The establishment is advised to ensure that all staff have access to and wear appropriate personal protective equipment (PPE). Whilst PPE was available at the establishment, staff accessing storage areas did not always wear this.
12.	PFE3	The DI is advised to ensure that all storage vessels are labelled as storing samples under the licence and the details of who to contact in the event of any problems. This will help to raise awareness that samples are stored under the licence in these vessels and ensure that any incidents or alarms are responded to appropriately. The DI is advised to ensure that freezers and liquid nitrogen tanks containing samples stored under the licence have unique identification numbers. This will help the establishment to analyse trends in storage temperatures and equipment failures (also refer to Advice, items 5 and 13).
13.	PFE3	The DI is advised to formalise the analysis of storage temperature records to identify trends. This may help the establishment to identify deterioration of freezers to potentially avoid future freezer breakdown. This is particularly important as, although they are regularly serviced, a number of the establishment's -80°C freezers may be nearing the ends of their working lives.
14.	D2	The DI should review the overarching disposal SOP to include details of the requirement to record the date, method and reason for disposal of samples stored under the licence. Some research groups storing samples under the licence use a 'Disposal Log' form to record the details of disposal. The DI may wish to implement the use of this form across all groups storing samples under the licence. Additional fields in sample traceability databases, to record disposal details (including date, method and reason for disposal), may also provide an effective system for ensuring that these details of disposal are consistently recorded.

15.	N/A	The DI is advised to consider the long-term fate of the collection of samples stored for the Coeliac Research Group previously based at the establishment. The samples are not being used currently and the establishment has no clear plans to use these samples in the future. The DI is reminded that if these samples are sent off-site then records of sample distribution must be kept and there must be an appropriate agreement in place with the organisation receiving the samples. The DI should ensure that the organisation to which the samples are sent is aware of the HT Act licensing requirements in relation to these samples. Although these samples are existing holdings, meaning that they are exempt from the consent requirements of the HT Act, they are subject to the licensing requirements of the HT Act. The DI is advised to contact the HTA for further advice on this matter, if this is required.
16.	N/A	A copy of the licence is displayed in the building's central entrance area. The DI is asked to display copies of the licence in each of the areas of the premises where samples are stored under the licence. This may help to raise awareness that samples are stored under the licence in these areas.

Concluding comments

This report outlines the second site visit inspection of this establishment. Although one major shortfall and four minor shortfalls were identified, a number of areas of good practice were observed.

The DIs of the research licences held by King's College London collaborate on HTA licence matters, including joint governance meetings and undertaking audits of each other's licences. This helps to raise awareness of common issues and areas of good practice.

Staff at the establishment demonstrated that they strive towards continual improvement of practices, and were open to the advice offered by the HTA during the inspection. The DI works hard to ensure compliance with the HTA's licensing standards. She demonstrated a good knowledge of the requirements of the HT Act and of the HTA's Codes of Practice.

The DI has nominated PDs on the basis of their roles working under the licence and has ensured that the PDs include a number of Principal Investigators and staff overseeing the management of samples under the licence. The PDs demonstrated willingness to work with the DI to ensure compliance with the HTA's licensing standards.

Several research groups storing samples under the licence have developed well-considered sample traceability systems. The Women's Health Maternal and Foetal Research Group have implemented a barcoding sample traceability system, including use of colour-coded sample vials to easily identify sample types. The Imaging Sciences and Biomedical Engineering Group have implemented a simple database for sample traceability using unique identification numbers for each sample and supported by use of colour-coded vials to assist with organising samples for each donation.

The establishment identified there was a risk of failed traceability for samples stored for the Coeliac Research Group after the Principal Investigator for this study left the establishment. The DI, with a member of the technical team, undertook a complete audit of traceability for these samples. Although this identified two discrepancies with sample traceability, these have been resolved on the database and full sample traceability was demonstrated during the inspection team's audit of this collection.

There are a number of areas of practice that require improvement, including one major shortfall and four minor shortfalls. The HTA has given advice to the DI with respect to consent, governance and quality systems, premises, facilities and equipment and disposal standards.

The HTA requires that the DI addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 19 April 2017

Report returned from DI: 28 April 2017

Final report issued: 28 April 2017

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 03 May 2019

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

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 code of practice
• Consent forms comply with the HTA's Code of Practice • Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose • If the establishment obtains consent, a process is in place for acquiring consent in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Where applicable, there are agreements with third parties to ensure that consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Consent procedures have been ethically approved
C2 Information about the consent process is provided and in a variety of formats
• Standard operating procedures (SOPs) detail the procedure for providing information on consent • Agreements with third parties contain appropriate information • Independent interpreters are available when appropriate • Information is available in suitable formats, appropriate to the situation • Consent procedures have been ethically approved
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• Standard operating procedures (SOPs) detail the consent process • Evidence of suitable training of staff involved in seeking consent • Records demonstrate up-to-date staff training • Competency is assessed and maintained

Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process
• Policies and procedures are in place, covering all activities related to the storage of relevant material for research in connection with disorders, or the functioning, of the human body • Appropriate risk management systems are in place

- Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes
- Complaints system

GQ2 There is a documented system of quality management and audit

- A document control system, covering all documented policies and standard operating procedures (SOPs).
- Schedule of audits
- Change control mechanisms for the implementation of new operational procedures

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

- Qualifications of staff and training are recorded, records showing attendance at training
- Orientation and induction programmes
- Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training
- Training and reference manuals
- Staff appraisal / review records and personal development plans are in place

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

- Documented procedures for the creation, amendment, retention and destruction of records
- Regular audit of record content to check for completeness, legibility and accuracy
- Back-up / recovery facility in the event of loss of records
- Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)

GQ5 There are documented procedures for distribution of body parts, tissues or cells

- A process is in place to review the release of relevant material to other organisations
- An agreement is in place between the establishment and the organisation to whom relevant material is supplied regarding the tracking and use of material and eventual disposal or return

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- There is an identification system which assigns a unique code to each donation and to each of the products associated with it
- An audit trail is maintained, which includes details of when and where the relevant material was acquired, the consent obtained, the uses to which the material was put, when the material was transferred and to whom

GQ7 There are systems to ensure that all adverse events are investigated promptly
• Corrective and preventive actions are taken where necessary and improvements in practice are made • System to receive and distribute national and local information (e.g. HTA communications)
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately
• Documented risk assessments for all practices and processes • Risk assessments are reviewed when appropriate • Staff can access risk assessments and are made aware of local hazards at training

Premises, facilities and equipment standards
PFE1 The premises are fit for purpose
• A risk assessment has been carried out of the premises to ensure that they are appropriate for the purpose • Policies in place to review and maintain the safety of staff, authorised visitors and students • The premises have sufficient space for procedures to be carried out safely and efficiently • Policies are in place to ensure that the premises are secure and confidentiality is maintained
PFE 2 Environmental controls are in place to avoid potential contamination
• Documented cleaning and decontamination procedures • Staff are provided with appropriate protective equipment and facilities that minimise risks from contamination • Appropriate health and safety controls are in place
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.
• Relevant material, consumables and records are stored in suitable secure environments and precautions are taken to minimise risk of damage, theft or contamination • Contingency plans are in place in case of failure in storage area • Critical storage conditions are monitored and recorded • System to deal with emergencies on 24 hour basis • Records indicating where the material is stored in the premises

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination
• Documented policies and procedures for the appropriate transport of relevant material, including a risk assessment of transportation • A system is in place to ensure that traceability of relevant material is maintained during transport • Records of transportation and delivery • Records are kept of any agreements with recipients of relevant material • Records are kept of any agreements with courier or transport companies
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored
• Records of calibration, validation and maintenance, including any agreements with maintenance companies • Users have access to instructions for equipment and receive training in use and maintenance where appropriate • Staff aware of how to report an equipment problem • Contingency plan for equipment failure

Disposal Standards
D1 There is a clear and sensitive policy for disposing of human organs and tissue
• Documented disposal policy • Policy is made available to the public • Compliance with health and safety recommendations
D2 The reason for disposal and the methods used are carefully documented
• Standard operating procedures (SOPs) for tracking the disposal of relevant material detail the method and reason for disposal • Where applicable, disposal arrangements reflect specified wishes

Appendix 2: 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.

1. Critical shortfall:

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:

(1) A notice of proposal being issued to revoke the licence

(2) 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.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall that:

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

or

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.

3. **Minor shortfall:**

   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.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.