Site visit inspection report on compliance with HTA minimum standards

Hammersmith Hospital

HTA licensing number 12275

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**

24-27 November 2014, 4 and 10 December 2014

Summary of inspection findings

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

Although the HTA found that Hammersmith Hospital (the establishment) had met the majority of the HTA standards, one major shortfall was found with regard to the Consent (C) standards. This was in relation to the inappropriate recording of consent. Four minor shortfalls were found with regards to the Governance and Quality Systems (GQS) standards. These were in relation to the absence of standard operating procedures, the carrying out of audits, the reporting of adverse events and the lack of risk assessments. Advice has been given relating to the C, GQS, Premises, Facilities and Equipment (PFE) and Disposal (D) standards.

The HTA's regulatory requirements

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

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. 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 licences 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

This report refers to the activities carried out by the Hammersmith Hospital (the establishment). The establishment's licensing arrangements cover the Hammersmith Hospital Campus (which also incorporates Queen Charlotte's and Chelsea Hospital) – the hub site – and four satellite sites: Charing Cross Hospital; Imperial College London South Kensington Campus; St Mary's Hospital; and, St Mark's Hospital at Northwick Park. Each site has a nominated Person Designate (PD).

The establishment is licensed by the HTA under the Human Tissue Act 2004 for the storage of relevant material for use for scheduled purposes. The scheduled purposes applicable to this licence are: research in connection with disorders, or the functioning, of the human body ('research'); and, quality assurance. The predominant scheduled purpose is research. This was the first site visit inspection of the establishment since it was issued an HTA licence in July 2008. It was a routine site visit inspection and was to assess whether the establishment is continuing to meet the HTA's standards.

The establishment is part of Imperial College Academic Health Science Centre (AHSC), which is one of six AHSCs in England. The AHSCs are NHS and university partnerships and Imperial College AHSC is a partnership between Imperial College London (the College) and Imperial College Healthcare NHS Trust (the Trust). As such, the licence spans sites within both College and Trust.

<u>Governance</u>

The licence covers nine tissue banks which have NHS Research Ethics Committee (REC) approval to collect, store, issue and use human tissue (and associated clinicopathological and demographic data) for research. Each of these registered Research Tissue Banks (RTBs) work directly under the establishment's HTA licence. The largest of these is Imperial College Healthcare Tissue Bank.

Imperial College Healthcare Tissue Bank (ICHTB). ICHTB sits within College premises or premises rented by the College from the Trust and ICHTB staff are either College or Trust employees. Formal ownership of the tissue bank lies jointly with the Trust and the College.

ICHTB contains approximately 195,000 samples from both living and (occasionally) deceased donors. The main storage facility is at the Charing Cross Hospital satellite site. This was inspected on the second day of the inspection. Tissue and fluid specimens collected and stored at other sites within the establishment, under the governance of the ICHTB, are registered as 'sub-collections'. ICHTB contains specimens from adults and children, foetal specimens, brains and hearts. Stored samples include normal and diseased tissue and body fluids. Tissue samples include formalin-fixed, paraffin wax-embedded (FFPE) material (both blocks and slides), optimal cutting temperature (OCT) compound mounted samples for frozen sections, tissue slices, isolated cellular preparations (e.g. peripheral blood mononuclear cells) and fresh frozen tissue. Body fluids include plasma, urine, saliva, sputum, whole blood and cerebrospinal fluid. ICHTB is managed on a day-to-day basis by a team of core staff, including a Tissue Bank Manager.

The ICHTB Tissue Management Committee (TMC) governs the tissue bank. The TMC reviews all applications, reviews results from pilot and interim studies, and reviews extensions to studies. It also reviews all requests for material and data. Membership of the TMC includes the DI and all PDs, the Tissue Bank Manager, senior clinicians, scientists, a lay representative, a representative from the College Research Ethics Committee and a representative from the Joint Research Compliance Office (JRCO). The TMC reports to both Trust and College Senior Executives.

For sub-collections, each has a nominated Principal Investigator (PI) who assumes local responsibility for the sample collection and storage, and who registers their samples with ICHTB. Sub-collections have their own documentation and are subject to their own procedures, whilst being under the overall governance of ICHTB. Each sub-collection holder is responsible for local storage arrangements and documentation. There are approximately 200 sub-collections within ICHTB; some of these were inspected as part of the current site visit inspection.

Stored tissue and fluids with project-specific REC approval and samples stored as part of clinical trials under United Kingdom Ethics Committee Authority (UKECA) approval are also registered with ICHTB. Although exempt from the HTA's licensing requirements while the project or trial lasts, material stored after completion of the project or trial fall under the HTA licence. There are approximately 300 such registered projects and trials. These were not inspected.

Other RTBs. There are eight other REC-approved RTBs within the establishment which come under the HTA licence. These currently each have separate (and similar) governance arrangements to the ICHTB but, in due course, it is planned that each will come under ICHTB governance when REC approval has expired after the five-year renewal period. Five of these RTBs were inspected as part of the site visit inspection (*see Table 1*). There are collectively approximately 40,000 samples under these RTBs,

The total material under the licence at the establishment is therefore approximately 235,000 samples.

Tissue sources: Consent, procurement and receipt

Tissue specimens procured at the establishment include: samples from surgical operations which are surplus to diagnostic requirements; extra samples of biopsy or fluids taken for research at the same time as similar samples are taken for diagnosis; body fluid specimens taken from healthy volunteers (collected by registered phlebotomists or clinicians); and, material obtained from diagnostic pathology archives.

Consent for the use of such samples in research is sought by College or Trust staff, who have received Good Clinical Practice (GCP) training or local consent training. The HTA has given advice to the DI in relation to strengthening the records of staff consent training (*see Advice item 3, below*). The establishment uses ICHTB-, RTB- or project-specific REC-approved consent forms and participant information sheets.

Human tissue can be received into the establishment and stored under the HTA licence. This material may be provided from a variety of sources, including commercial suppliers, NHS Trusts, universities and other RTBs. Suppliers of material to the establishment are approved by the ICHTB TMC (*see Advice item 9*).

Sample storage

During the inspection, the team visually inspected 18 different tissue collections (both RTBs and sub-collections). These are summarised in Table 1. All storage areas were generally of a good standard. Where general improvements or improvements for specific collections could be made, these are given in the Advice section, below.

Table 1: Tissue collections inspected.

Site	**Collection**				
Hammersmith Hospital Campus	Gynaecological Surgical RTB	Airwave Health Monitoring RTB	Milk Bank Collection	Women's Health Research Centre Collections (including Recurrent Miscarriage Collection, RMC)	Respiratory Medicine Collection
Charing Cross Hospital	ICHTB	Chariot Ageing Collection	St Mark's Colorectal Tissue Collection	Breast Cancer Collection	Computation Systems Medicine (CSM) Department Knife Study Collection
Imperial College London South Kensington Campus	CSM Collections (including Metabolome Collection)	Blast Injuries Collection	Biomechanical Engineering Collection		
St Mary's Hospital	Hepatology and Gastroenterology RTB	Communicable Disease RTB	RMC	Immunology Collection	
St Mark's Hospital at Northwick	Airwave Health Monitoring RTB				

Park	

Sample transport and distribution

The establishment distributes tissue samples to other research groups within other organisations and transports specimens between hub and satellite sites.

Electronic management of human tissue use within the establishment

The On-Line database (OLD) maintains records of all sub-collections housed under the HTA licence, and other collections of human tissue that are currently held under project-specific REC approval. The majority of the recently established sub-collections that collect material prospectively enter sample details directly into OLD, whereas some of the large legacy collections that have been brought into ICHTB maintain separate databases to record accrual and use of samples. OLD also records information on the surgical tissue bank, which comprises material left over from surgical operations carried out within the Trust. Access to OLD is password protected, and users can be assigned permissions to view, enter and modify data. The OLD database is accessible from all sites and to sub-collection PIs and staff with appropriate log in credentials. All users of the database are required to register to use the database with the Tissue Bank manager who assigns the relevant permissions. Researchers from outside Imperial can also be provided with log in facilities to view and search the surgical database only following approval by the Tissue Bank Manager.

The inspection process

The timetable for the site visit inspection was developed after consideration of the establishment's licence application, compliance update information and after discussions with the DI. The site visit inspection included a visual inspection of the storage areas and storage facilities summarised in Table 1. A documentation review and a number of horizontal and vertical audits were carried out. Details of the audits are provided below.

Meetings were also held with staff working under the licence. They were: the DI (Professor of Molecular Pathology); the (Corporate) LH Contact (CLHC; JRCO Research Governance Manager); the Tissue Bank Manager; the PDs for the hub and each of the four satellite sites; a Scientific Quality Assurance Consultant; six PIs; the Senior Database Developer; two Research Nurses; and, a Tissue Bank Technician. An audit of traceability records and consent forms was conducted at each of the licensed sites. Details of these audits are provided below.

Audits

Hammersmith Hospital Campus. For the Gynaecological Surgery RTB at the Hammersmith Hospital site, two samples of frozen tissue were selected at random. The freezer storage locations were compared to both electronic databases. These samples were traced to consent forms. No anomalies were identified in this audit.

For the Airwave Health Monitoring RTB at the Hammersmith Hospital, four samples were selected at random. The liquid nitrogen tank locations were compared to the electronic and paper records. No anomalies were identified in this audit.

Charing Cross Hospital. For the ICHTB at Charing Cross Hospital, eight samples of frozen tissue were selected at random, including one sample transferred from the hub site and one sample previously held under a UKECA approved clinical trial. The freezer storage locations were compared with the sub-collection electronic database or, where applicable, the paper-based records. One sample was not recorded in the paper-based traceability record. Three samples of surplus surgical tissue and one clinical trial sample were traced through to consent forms. Consent forms were present for these samples; however, examples of inconsistent completion of date fields were identified on two of these consent forms (*see Advice item 3*).

The audit of the CSM Collection at Charing Cross Hospital traced two frozen samples from storage location to the two electronic databases and consent forms. There were no anomalies in the storage locations recorded for these samples. Although copies of consent forms were available for both samples, one had been amended without appropriate recording of the reason, date and person responsible for the amendment (*see Inspection findings against standard C1, below*). It cannot therefore be assured that valid consent is in place for the use of this sample in research.

The audit of the Chariot Ageing Collection at Charing Cross Hospital traced three frozen samples from storage locations to the electronic database and consent forms. There were no anomalies identified in this audit.

Imperial College London South Kensington Campus. For the CSM collection on this site, three samples were selected at random and traced from the freezer locations to the electronic and paper records. No anomalies were identified in this audit.

St Mary's Hospital. For the Hepatology and Gastroenterology RTB, three participants were selected at random from -80°C storage. These samples were traced from storage to the electronic database and consent forms. No anomalies were identified in storage locations or consent forms.

Two samples in the RCM Collection were traced from the freezer location to the paper and electronic records. There were no anomalies.

St Mark's Hospital at Northwick Park. Samples from two participants in the Airwave Health Monitoring RTB were traced from the paper and electronic records to the freezer location. There were no anomalies and the consent forms were present.

Inspection findings

The HTA found the DI and the (Corporate) LH (CLH) 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.	The inspection team's audit of consent forms revealed one example of a consent record that had been amended without appropriate recording of the reason, date and person who made the amendment. Investigation by the establishment revealed that the box on the consent form pertaining to use of samples in research had not been completed on the original consent form. Documented evidence of consent for use of this sample for research cannot therefore be assured. *Following the inspection, the establishment conducted an investigation of this incident and disposed of the sample in question.*	**Major**

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	Although there are standard operating procedures (SOPs) covering licensable activities for some collections, this was not the case for all collections. For instance, SOPs covering some licensable activities were not available for the Chariot Ageing Collection (Charing Cross Hospital), the CSM Collections (Charing Cross Hospital and South Kensington Campus) and the Airwave Health Monitoring RTB (St Mark's Hospital at Northwick Park). The following activities expected to be covered in appropriate SOPs were missing for these collections: • Disposal • Receipt • Transport • Cleaning and decontamination • Managing abnormal changes in storage temperatures *See Advice item 4*.	**Minor**

GQ2 There is a documented system of quality management and audit.	The establishment has developed an audit schedule and a standard audit procedure. However, audits have not been undertaken of all the collections of relevant material stored under the authority of this licence. Where audits have been undertaken, these have not always been on a regular basis and reporting of audits has not been formalised. *See Advice item 6*.	**Minor**
GQ7 There are systems to ensure that all adverse events are investigated promptly.	There is no formal centralised system for capturing adverse events relating to licensable activities and human tissue. *See Advice item 10*.	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	There are risk assessments relating to Control of Substances Hazardous to Health (COSHH) in relation to laboratory procedures. There are no risk assessments for licensable activities. *See Advice item 11.*	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	The establishment has agreements with organisations supplying relevant material. The DI is advised to ensure that these agreements are up-to-date and are signed by both parties. This is particularly important to ensure that the establishment has assurance that consent for the use of the samples it receives for use in research is obtained in accordance with the regulatory requirements.
2.	C1	The DI is advised to consider implementing centralised records of consent forms. Although consent forms for some collections are currently held in patient medical notes, keeping copies of consent forms may facilitate audits of consent forms.
3.	C3	Staff seeking consent have received local consent training or GCP training. The DI is advised to consider keeping a centralised log of staff who have received consent training. This will help to ensure that all staff seeking consent have received appropriate training and that this training is up-to-date. The audit trail of one of the collections revealed inconsistent completion of consent forms. The DI is advised to ensure that correct completion of these forms is highlighted during the training programme.
4.	GQ1	There is inconsistency in the current format of SOPs covering some of

		the collections (*see Inspection findings against standard GQ1, above*). The DI is advised to consider the inclusion of the following features, to create a more robust system and to ensure that the most up-to-date documents are being used: • document control information, such as a revision history and version number • 'effective from' date • review date (at least every three years) • pagination • author and reviewer names. The establishment may wish to consider reviewing the current SOPs to ensure that they contain document control information and sufficient details of procedures.
5.	GQ1	The DI may wish to consider setting up meetings with other DIs working both within and outside the organisation, to share information and experience with them and their PDs. This may help facilitate learning and understanding of staff at the establishment as well as being a forum for the discussion of good practices.
6.	Principally GQ2 but also relevant to standard GQ4	The DI is advised to ensure that all sub-collection groups undertake audits in line with the establishment's audit schedule. This could be carried out by different members of staff within each RTB and sub-collection. It could include regular process audits to ensure that SOPs accurately reflect current practices, vertical human specimen traceability audits, from records of receipt to storage, use, distribution or disposal, and horizontal audits. The DI may also wish to consider implementing a regular audit against HTA standards. An audit should also be included of a set of slides at Charing Cross Hospital in the ICHTB for which current traceability records require strengthening. The results of all audit findings, and actions taken, should be formally recorded and reported to the TMC to ensure continuing improvement of processes and practices.
7.	GQ3	The DI should ensure that all staff undertaking licensed activities receive ongoing professional development and training appropriate to their role. This may include training in the HT Act 2004 and the HTA's Codes of Practice on Consent, Research and Disposal. The DI may wish to consider including the Medical Research Council (MRC) 'Research and Human Tissue Legislation e-learning Module', part of the MRC Data and Tissues Toolkit (both of which were developed with input from the HTA), as part of the staff training programme: http://www.rsclearn.mrc.ac.uk/.
8.	GQ4	Although the establishment has a policy for the amendment of paper records, some examples of inconsistent amendment of records were identified in the inspection team's audit. The establishment should ensure that all staff are aware of the procedure for amending written

		records. Appropriate amendment of records will help to ensure that a full audit trail is maintained.
9.	GQ5	Other licensed establishments have set up a register of 'approved suppliers'. Each potential supplier is sent a 'due diligence form', asking for details of governance structure, ethical approval, ethical warranties, informed consent forms, consent warranties and regulatory compliance (where appropriate). A Material Transfer Agreement (MTA) is then drawn up with each organisation using these criteria as the supplier's responsibilities. Similar MTAs with receiving organisations are also used. The DI is advised to consider adopting such a method.
10.	GQ7	The DI is advised to keep a central log of all adverse events relating to human specimens. These could include: • specimen loss • missing or incorrect documentation • security breach • abnormalities in storage temperature readings • specimen transport between sites under this licence or to other licensed establishments • inappropriate disposal The results of all actions taken (root cause analysis and corrective and preventative actions) should be formally recorded and reviewed by the TMC. The DI should ensure that all staff are aware of the incidents which need to be reported to the TMC. The establishment may wish to introduce a standard form for incident reporting or use the facility available on their electronic database system.
11.	GQ8	Although not exhaustive, the DI should consider the broad risks to relevant material, such as: Risk assessments should be created for the following: • specimen loss • missing or incorrect documentation • security breach • abnormalities in storage temperature readings • specimen transport between sites under this licence or to other licensed establishments • inappropriate disposal These risks should be evaluated for each of the sub-collections. Risk assessments should be reviewed regularly and also after changes to key procedures. The DI is advised to ensure that staff have access to such risk assessments and that familiarity with them is incorporated into the staff training programme.

12.	PFE3	The DI is advised to consider extending the temperature monitoring alarm and callout system to all facilities storing human tissue under the authority of this licence. This system is not currently used in the Immunology Collection at St Mary's Hospital and the Airwave Health Monitoring RTB at St Mark's Hospital at Northwick Park. The DI is also advised to carry out regular testing of the tissue storage alarm system to ensure that the callout procedure is functioning correctly. The DI is advised to initiate a program by which, at suitable timeframes, the temperature plots from the monitoring system are reviewed. This may help to identify a potential failure of the system before it occurs.
13.	PFE3	The DI may wish to consider extending the temperature mapping of freezers, currently used for some of the freezers, to all freezers and refrigerators containing human tissue.
14.	PFE3	In addition to human tissue samples, the establishment also stores some animal tissues in separate freezer compartments. The DI is advised to ensure that all refrigerators, freezers and cryovessels which contain human tissue are appropriately labelled to indicate this, so that staff are aware of the necessity to maintain the quality, safety and security of such material and prevent mix-ups.
15.	PFE5	Some, but not all, freezers are decontaminated and cleaned appropriately. The DI is advised to extend the decontamination and cleaning programme to all refrigerators, freezers and cryovessels containing human tissue and to ensure that records of this are kept up to date.

Concluding comments

This report outlines the first HTA site visit inspection of this establishment's HTA licence. There were a number of areas of good practice observed during the inspection. The TMC has oversight of the large numbers of samples held under the authority of this HTA licence. Although the HTA has offered advice to further improve the overall management of the licence, the tissue bank management team have worked hard to develop the management of samples held under this licence.

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 the Consent, Governance and Quality Systems, Premises, Facilities and Equipment, and Disposal standards.

The HTA requires that the Designated Individual 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: 12 January 2015

Report returned from DI: 29 January 2015

Final report issued: 13 February 2015

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: 8 October 2015

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below.

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.