Site visit inspection report on compliance with HTA minimum standards

Chapel Allerton Hospital

HTA licensing number 22505

Licensed for the

- **Procurement, testing, storage and distribution of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007; and**

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

21 – 24 June 2016

Summary of inspection findings

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

Although the HTA found that Chapel Allerton (the establishment) had met the majority of the HTA standards, a minor shortfall was found. The shortfall relates to governance and quality systems, specifically regarding the retesting of a donor blood sample for the mandatory serological markers when vessels for transplantation are being stored for more than 48 hours and used in a recipient other than the primary organ recipient.

Particular examples of 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, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual 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.

Licensable activities carried out by the establishment

'E' = Establishment is licensed to carry out this activity.

'E*' = Establishment is licensed to carry out this activity but is not currently carrying it out.

'TPA' = Third party agreement; the establishment is licensed for this activity but another establishment (unlicensed) carries out the activity on their behalf.

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Bone marrow	**E**		**E**				
Cord blood	**E***						
Ovarian tissue				**E**			
Bone + orthopaedic tissues				**E**			
Chondrocytes	**E***						
Cornea				**E**			

Amniotic membrane				**E**			
Heart valves				**E**			
Vessels for transplant				**E**	**E**		
Blood for ATMP production	**E***		**E***				

Background to the establishment and description of inspection activities undertaken

Chapel Allerton Hospital (the hub site) is one of four hospital sites within the Leeds Teaching Hospitals NHS Trust where licensable activity takes place. There are three further hospital sites within the same Trust which are satellite sites to the hub and are licensed by the HTA under the same licence as the hub premises. These satellite sites are the Leeds General Infirmary, Seacroft Hospital and St James's University Hospital. The Leeds Teaching Hospitals NHS Trust is the Corporate Licence Holder of the licence with a named contact having been identified.

The establishment has been licensed by the HTA since 2008 and this routine inspection was the fifth site visit. The timetable for the four-day site visit was developed in consideration of the establishment's annual activity report, previous inspection reports and pre-inspection discussions with the DI and the establishment's HTA Manager. During the inspection, a visual inspection of the premises where licensable activity takes place, review of the establishment's documentation and discussions with relevant staff that have been identified as Persons Designated (PD) under the licence were undertaken. Discussions with the PDs working under the licence took part in a group discussion 'round table format' rather than formal one-to-one interviews. This approach allowed the inspection team to be guided through documentation and patient clinical notes while simultaneously discussing the licensable activity. Formal one-to-one interviews were held however with the DI, the HTA Manager and the Corporate Licence Holder Contact.

The establishment continues to undertake a wide variety of licensable activity under its licence and to assist the DI in maintaining oversight of all these various activities, the establishment continues to maintain a full time HTA Manager role. The HTA Manager has a key role in overseeing the establishment's governance systems. There is a network of PDs across the licence with the establishment aiming to identify two PDs for each area of activity. There have been a number of staffing changes since the last inspection which have resulted in some areas of activity having staff that are new to the role of PD under the licence and other areas only having one PD in place.

The DI and HTA Manager have attempted to hold regular governance meetings with PDs, where licensable activities, general governance issues, audit, risk assessment and HTA-related matters are discussed. However, the ability of PDs to leave their area of responsibility to attend these meetings has been limited due to time constraints which has made holding these meetings more challenging. In order to facilitate regular governance meetings, the DI and HTA Manager have been trialling 'virtual meetings' where PDs email summaries of activity and any questions regarding licensable activity to the HTA Manager. These submissions are then discussed at a face-to-face meeting of the DI and HTA Manager with responses being sent out to the PDs following the meeting.

The establishment's HTA Manager and network of PDs assist the DI in maintaining oversight and control of the licensable activities taking place under the licence, which is essential in the

DI ensuring that appropriate practices are being undertaken by appropriately qualified staff in appropriate premises. Advice has been given to the DI below (see advice item 19) regarding continuing to ensure that there are sufficient PDs and that they have sufficient time to perform their function under the licence. Having sufficient trained PDs and sufficient time for newly identified and existing PDs to learn and carry out their role under the licence is important as this is a key system which the DI uses to maintain appropriate oversight of the licensable activity over a large range of activities and locations.

During the inspection the establishment confirmed that no tissue is being stored for use for a scheduled purpose under the Human Tissue Act 2004 under the Human Application licence 22505.

The Leeds General Infirmary (LGI) site is where vessels for use in paediatric organ transplantation are stored. Arterial and venous vessels are received at the same time as livers for transplantation and which have been retrieved from the same donor as the organ. The vessels may or may not be used during the organ implantation. If only partially used, or if the vessels are opened onto the surgical sterile field, then any remaining vessels will be stored at the establishment for use only in the same recipient. If, however, the vessels were not needed during a particular transplant procedure, they may be stored at the establishment for use in other organ recipients. Stored vessels may be transferred to St James's University Hospital (SGUH) for use in adult transplants or upon request, to other transplant centres outside of the Trust. When sending vessels from LGI, the establishment sends accompanying documentation which acts as ad-hoc end user agreements which infer a responsibility on to the receiving centre to report any serious adverse events or reactions to the establishment and to store traceability data relating to the vessels and their use for 30 years.

Vessels are stored in fridges located within the establishment's theatres. The operating temperature is reviewed and recorded during working weekdays and the freezer is also equipped with a chart wheel temperature recorder which continuously records the temperatures. Additionally, the fridge is alarmed to a dial-out system which contacts staff in a team room which is used 24 hours a day, seven days a week meaning that an alarm call would be responded to. The establishment may, in exceptional circumstances, use these vessels for renal transplant procedures if needed in emergency cases however the majority of vessels are used during liver transplantation. Serological testing of cadaveric liver donors is carried out under the licensing framework of The Quality and Safety of Organs Intended for Transplantation Regulations 2012 and test results are uploaded to NHSBT's Electronic Offering System (EOS) so that they can be reviewed by the implanting establishment.

Vessels may be stored at the establishment for up to 14 days from receipt and as stated in the framework document under the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (Statutory Instrument (SI) 2012 No. 1501), should those tissues be stored for more than 48 hours for use in a patient other than the primary recipient, they must be stored under a storage licence issued under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Regulations). If vessels are being stored under the Regulations, a serology test in accordance with the requirements of the Regulations for the mandatory serological markers should be performed. Testing of a donor blood sample that met these requirements was not taking place at the establishment.

A review of umbilical cord blood procurement at the establishment took place during the inspection and a discussion held with the establishment's PD for cord blood procurement. No cord blood procurement has taken place at the establishment since the last inspection. From discussions with the relevant PD, should any procurement of cord blood be required at the establishment then this activity would be undertaken by a separate organisation which is licensed by the HTA under a different licence number. The establishment maintains a PD

covering this activity although it is not taking place under its licence. The HTA has given advice to the DI regarding maintaining PDs in areas where no activity is taking place or will take place (see advice item 22). The DI has also been given advice to remind establishment staff that procurement is not taking place under the establishment's licence and is currently only being undertaken by the separate organisation (see advice item 5).

At the LGI site the establishment has recently added a new tissue type to its licence. As part of a multicenter clinical trial, participants who have undergone a particular type of myocardial infarction event will undergo stem cell mobilisation followed by the procurement of a whole blood sample. This sample is a starting material for an advance therapy medicinal product (ATMP) and is distributed to another trial site for processing into an ATMP. The distribution of the blood sample is not taking place under the establishment's licence and is the responsibility of the other trial site. Once processed into an ATMP, which will occur under the authority of a Medicines and Healthcare products Regulatory Agency (MHRA) licence, the ATMP will be returned for autologous administration into the trial participant. Donor consent and serological testing for mandatory serological markers is undertaken by the establishment.

Storage of heart valves and pulmonary patches for use in cardiac surgery also takes place at the LGI site. Tissues are purchased by the establishment from another HTA licensed organisation which is covered by a service level agreement between the two organisations. The tissues are stored in a freezer located on the paediatric intensive care unit (ICU). The freezer is subject to daily temperature monitoring by establishment staff and has an alarm that sounds locally should the temperature deviate from the expected range. Although the alarm does not dial out to on call staff in the event of a temperature deviation, its location behind the paediatric ICU nursing station which is staffed 24 hours a day, seven days a week means that any alarms are responded to by these staff. Instructions for staff to follow in the event of an alarm are attached to the front of the freezer. The establishment also has a back-up freezer in the theatre complex. This freezer provides an emergency storage in the event of the main freezer failing. The back-up freezer is monitored and alarmed in the same way as the main freezer. Near its location there is a trauma theatre with 24 hours, seven days a week staff who would be alerted to a freezer failure. Since the last inspection the PD for the cardiac tissue undertook a test to confirm that back-up freezer's alarm would be heard and responded to by other theatre staff. While no tissue was being stored, the freezer was turned off and allowed to alarm. The PD confirmed during the inspection that once the alarm sounded, theatre staff responded appropriately and contacted the PD to alert her of the failure. This exercise helped the establishment asses the risk of a freezer alarm not being responded to appropriately, however it was not documented as part of the appropriate risk assessment (see advice item 8).

The establishment's testing laboratory is also located within the LGI site and was visited as part of the inspection. Appropriately labelled donor blood samples for testing arrive at the laboratory and are entered onto the laboratory's electronic information management system. Following processing, the samples are analysed on automated equipment using CE-marked testing kits and the results are returned to the clinician via the Trust's electronic reporting system.

At the SJUH site, arterial and venous vessels can be stored for use in adult transplants in the same way as vessels for paediatric surgery are stored as detailed above. Systems to record use, transfer of vessels and to monitor the fridge are the same as at the LGI site. Again, as with the paediatric vessel storage, vessels not used in the transplant procedure may be stored for use in the same or other organ recipient's transplant procedures. The fridge is connected to a system that continuously monitors the fridge temperature and also has the capability of a call-out system to alert staff of any deviations from the required temperature.

Tissue for use in ophthalmic surgery is stored at the SJUH site. The establishment maintains a store of amniotic membrane for use in surgery in addition to corneal graft tissue. Corneal tissue is not stored for longer than 48 hours at the establishment and therefore there is no requirement to store this tissue under the authority of an HTA human application licence. However, the establishment applies the same procedures for maintaining traceability, recording its use and general tissue governance as other ophthalmic tissue falling under the licence. Tissue for use in ophthalmic surgery is purchased from another HTA-licensed tissue supplier. The supply of tissue from the other licensed establishment is covered by a service level agreement which defines each establishment's responsibilities.

Corneal tissue is purchased and delivered to the establishment the day prior to the planned procedure. Tissue is stored overnight in the transport box located in a locked room. Amniotic membrane is stored in the establishment's dedicated freezer upon arrival following a series of checks on the packaging identification and integrity. The temperature of the freezer is monitored daily Monday to Friday with a retrospective verification on Monday to investigate if the temperature has gone out of range over the weekend. Additionally, whenever tissue is removed from the freezer a retrospective verification that the temperature has not gone out of range is undertaken. The freezer has a local alarm that sounds in the event of a deviation away from the desired temperature range. These alarms would be responded to by theatre staff who would then contact the on-call PDs whose numbers are listed in the tissue storage room. Additionally, the establishment has secured funding and is in the process of fitting a remote temperature monitor which will record the freezer's temperature and also dial out to an on-call phone in the event of a freezer failure.

The establishment does not return tissue to frozen storage once it has been removed from the freezer even if it is no longer required for the surgical procedure. This helps to ensure that any tissue which has started to defrost is not inadvertently returned to storage.

Adult bone marrow is also procured at the SJUH site for autologous and allogeneic use. Procured cells are transferred to another HTA-licensed organisation for any processing and quality checks. Cells are returned to the establishment for end use upon request. Donor serological tests are undertaken by the establishment's testing laboratory up to 30 days prior to procurement of cells. A second blood sample for mandatory serological markers is also taken at procurement and is sent to the licensed organisation undertaking the processing of the cells. Donor testing and procurement takes place under the establishment's licence with all other activities, including transporting the collected cells for processing and returning them for end use, taking place under the authority of the processing organisation's licence.

Bone marrow collection kits are stored in the establishment's temperature-regulated theatres or on a ward within a temperature-controlled room. Preservative-free heparin and other reagents are prescribed on the day of the procedure and are delivered by pharmacy. Labels for the bags of collected cells are provided by the other licensed organisation undertaking the processing and quality checks on the cells.

The establishment has a bone and orthopaedic tissue storage facility at Chapel Allerton Hospital. Tissue used in orthopaedic surgery is purchased from other HTA-licensed organisations and stored by the establishment for use in orthopaedic surgery. The supply of tissue from the other licensed establishments is covered by a service level agreement which defines each licensed establishment's responsibilities. Tissues that require frozen storage are stored in a dedicated secure freezer located within theatres. The freezer is monitored remotely with temperature data being archived for 30 years. In the event of the freezer temperature deviating from the required range, the remote monitoring software contacts the

PD and in the event of this call not being answered a second call is made to the theatre reception so that staff are made aware of the temperature deviation.

The establishment maintains a PD covering the procurement of chondrocytes however no such activity has taken place since the last inspection. Chondrocytes have previously been procured under the licence at Chapel Allerton Hospital. The establishment does not have an active program of chondrocyte work and prior to commencing any new procedures, new procedures and agreements with a chondrocyte processing company would need to be put in place. The HTA has given advice to the DI regarding maintaining PDs in areas where no activity is taking place or will take place (see advice item 22).

Paediatric bone marrow procurement takes place at the LGI site. The stem cell programme is a single programme with procurement of adult bone marrow being carried out at SJUH and paediatric bone marrow being procured at the LGI site. As a single programme, many of the governance documents cover the activities at both of these sites. Paediatric bone marrow collection kits are stored in a secure drug room on one of the paediatric wards. The room is temperature monitored. However, at the time of the inspection this room was at the upper temperature limit as defined by the collection kit's manufacturer. Advice has been given to the DI regarding the ongoing monitoring of this room to assess its suitability (see advice item 14).

At Seacroft Hospital ovarian tissue, which may in the future be implanted back into the donor, is being stored under the establishment's HTA Human Application licence. The storage of ovarian tissue is the only licensable activity taking place at Seacroft Hospital. The ovarian tissue is stored in the liquid phase of a liquid nitrogen storage vessel which is appropriately monitored. A remote alarm system contacts staff in the event of an issue with the storage temperature. Staff would attend the store and move the stored ovarian tissue to one of the contingency storage tanks if necessary. Since the last inspection one donor's tissue has been released for end use at another establishment. Additionally, the establishment has been contacting the donors to enquire if they still wished the tissue to be stored. Some donors opted for no further storage and consented this tissue to be used in research. This tissue has been transferred to other licensed premises for storage for the use in the scheduled purpose of research.

Traceability audits were undertaken in the above areas where licensable activity is taking place. A summary of these audits is given below.

Paediatric vessels for transplant

One set of recipient's clinical notes were reviewed. Vessel donor number and recipient details were cross-checked between the vessel usage form in the clinical notes and the vessel register. All details correlated and no anomalies were identified.

Cardiac tissue
Four sets of patient clinical notes were reviewed from patients who had received tissue. Tissue identifiers and date of surgery were cross-checked between the records in the notes and the tissue register. In two cases all identifiers and dates matched however in the remaining two, the date of use had been incorrectly entered into the tissue register. These were transcription errors where in one case the day had been entered incorrectly and in the other case, the incorrect month had been entered. Although transcription errors were found, traceability was still maintained in the patient's clinical notes and the inspectors were satisfied that the establishment's audit systems were sufficient to detect if errors became more frequent.

Adult vessels for transplant
A check of the physical vessels that were in storage was undertaken where the details of two sets of vessels in storage were cross-checked against the tissue register. In addition, the total number of sets of vessels was also checked against the expected number recorded in the register. No anomalies were identified as part of the audit of vessels currently in storage.

Additionally, a review of three sets of patient clinical notes was undertaken. Vessel details were cross-checked against the records in the patient's clinical notes and the tissue register. Again, no anomalies were found.

Ophthalmic tissue
Three sets of patient clinical notes were reviewed which, across the three sets of notes, included the use of two amniotic membrane patches and 3 corneas. Details of the tissue were cross-checked between the records in the patient's clinical notes, the supplying organisation's tracking paperwork (where applicable) and the establishment's tissue register. One discrepancy was identified where the tissue identifier for one cornea had been incorrectly entered into the tissue register. The discrepancy was due to one of the identifier's digits being duplicated when it was being entered into the register. The tissue identifier had been correctly entered into the patient's clinical notes and on the supplying organisation's use tracking form. Although transcription errors were found, traceability was still maintained in the patient's clinical notes and the inspectors were satisfied that the establishment's audit systems were sufficient to detect if errors became more frequent. During the audit, a record was also seen where amniotic tissue had been removed from storage but not used in surgery. In this case the tissue register included appropriate details of tissue disposal.

Adult and paediatric stem cells
Firstly, procurement records from an adult donating cells to a paediatric recipient were reviewed. In-house testing results and testing results from the organisation carrying out any processing were reviewed in addition to the Trust's and processing organisation's consent forms, records of consumables used during procurement and the records of transportation. During the visit to the paediatric stem cell unit, the clinical notes of the recipient were reviewed and the cell identifier issued by the processing organisation to the adult cells was verified in the recipient's clinical notes demonstrating traceability from donor to recipient.
Additionally, while at the paediatric unit a second set of donor and recipient notes from an allogeneic sibling transplant were reviewed. Again, records of consent and cell traceability using the tissue identifier issued by the processing organisation were reviewed. No anomalies were identified during the audit.

Orthopaedic tissue

Six sets of patient clinical notes were reviewed where tissue identifiers and expiry dates were cross-checked between the details in the clinical notes and the tissue register. Details in the clinical notes that were checked included the tissue tracking form and operation notes. Additionally, in one of these cases, tissue identifiers were also checked in the theatre's implant log. One minor discrepancy was found in the theatre implant log where the tissue identifier had the last digit entered as a number '4' instead of the letter 'L' in the implant log. The correct identifier was present however in the patient's clinical notes and tissue register meaning traceability from donor to recipient has not been compromised.

Ovarian tissue

No tissue has been used at the establishment and therefore a review of clinical notes was not undertaken. A desk-based review of the tissue storage records was undertaken including details of where tissue had been disposed of or transferred to another centre for use in research following instructions received from the donor.

As no activity has taken place since the last inspection, no audits were undertaken of chondrocyte tissue, cord blood or the new tissue type being procured for processing into an ATMP.

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

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.		
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 003/2010.	Serology testing of cadaveric liver donors is carried out under the licensing framework of The Quality and Safety of Organs Intended for Transplantation Regulations 2012, and test results are uploaded to NHSBT's Electronic Offering System (EOS). Vessels that are procured with the liver may be used in the patient who received that liver or could, potentially, be used instead in another recipient. Where vessels are being stored for more than 48 hours for use in a patient other than the recipient of the associated liver, donor serology testing of the donor's blood sample must be performed in accordance with the requirements of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Regulations). Testing of a donor blood sample that met the requirements of the Regulations was not taking place at the establishment.	**Minor**

Advice

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

No.	Standard	Advice
Adult and paediatric vessels for transplant		
1.	GQ1(d)	Not all of the standard operating procedures (SOPs) that were reviewed had been signed by a person to authorise them. The DI is advised to ensure that all SOPs are authorised by an appropriate member of staff so that it is clear to staff following the SOP that it is current and has been authorised for use.
2.	GQ1(d)	Some of the SOPs had been reviewed at six monthly intervals. The establishment has an overarching document control SOP which requires a regular review of SOPs every two years. The DI is advised to request that PDs review SOPs on a cycle that is in accordance with the document control SOP.
3.	GQ2(b)	Audits are undertaken of vessel use against the tissue register and recipient's clinical notes. These are undertaken according to an audit schedule and is a retrospective review. The DI is advised to also undertake periodic audits while vessels are being stored in the establishment's fridges so that a 'real time' review of the details on the vessels against the details recorded in the tissue register can be undertaken. It was noted that by the end of the inspection the establishment's PDs had already undertaken such an audit for stored vessels for adult use.
4.	GQ1(b) GQ7(d) D1(b)	A review of the establishment's disposal procedure for vessels found a statement relating to vessels which states that "in exceptional circumstances vessels can be kept past their expiry date as agreed by the HTA inspectors". The HTA did not authorise this additional storage. The DI is advised that in exceptional circumstances and where there is an urgent clinical need and no other vessels other than ones at the end of their use period are available, that a clinical risk assessment should be undertaken by the implanting surgeon regarding the risks verses the benefits of their use. This risk assessment should be documented by the implanting surgeon. Any use of tissue outside of its validated period of storage should also be reported as an incident to the DI. The DI is also advised to amend the SOP removing the statement authorising the storage of vessels past their expiry date in light of the advice given regarding using vessels that are out-of-date.
Umbilical cord blood		
5.	General	The DI is advised to remind all staff within the maternity department of the LGI site that umbilical cord blood (UCB) is currently only being procured by another organisation and not by staff from the establishment. This had been suggested by the PD for UCB as it was felt that this would help minimise the risk of any confusion for staff regarding this activity.
Blood for ATMP production		
6.	C1(a) C2(a)	The establishment has been given an example consent form from another organisation taking part in the same clinical trial. This form will be used to record participant consent for donor testing, procurement and storage. Although the form includes most mandatory serological markers it does not reference HTLV which will be tested for in all donors. The DI is advised to amend this form so

		that details of all serological tests that are being undertaken are included.
7.	GQ4(j)	Although kits used for procurement will be tracked by the trial sponsor, the DI is advised to keep a local record of all materials coming into contact with the procured tissue.
8.	GQ8(a)	The risk assessments associated with the new tissue type relate mainly to health and safety risks and not the risks associated with the procurement of the tissue, for example, procurement without consent or without appropriate donor testing. The DI is advised to review the risk assessments and ensure that all risks relating to the procured tissues are identified and documented so that measures to mitigate against these risks can be put in place prior to any procurement taking place.
Cardiac tissue		
9.	GQ4(a) GQ4(c)	During the inspection, examples where records had been amended and the original record had been overwritten or obscured were found. The DI is advised to remind staff that when correcting records the original entry should be struck through with a single line so that it remains readable and available for audit and future review purposes. The DI may also wish to consider requiring that all staff working under the licence sign and date any corrections.
10.	GQ8(b)	The PD for the cardiac tissue undertook a test to confirm that the back-up freezer's alarm would be heard and responded to by other theatre staff. While no tissue was being stored, the freezer was turned off and allowed to alarm. The PD confirmed during the inspection that once the alarm sounded, theatre staff responded appropriately and contacted the PD to alert them of the failure. This exercise helped the establishment asses the risk of a freezer alarm not being responded to appropriately. However, it was not documented as part of the appropriate risk assessment. The DI is advised to document this exercise as part of the establishment's risk assessments as it helps to support the decision that the mitigating process that has been identified against an alarm not being responded to appropriately does work.
Ophthalmic tissue		
11.	GQ8(a)	There are a range of risk assessments and measures identified to mitigate the risks relating to the use of ophthalmic tissue. However, the establishment has implemented further systems and processes to mitigate the risks related to the use of the tissue which were not documented. For example, a new alarm system providing a dial-out service to an on-call member of staff in the event of a freezer failure has been purchased to help mitigate the risk of loss of tissue from freezer failure. Also, only trained staff can access the tissue storage freezer which helps to mitigate against the risk of untrained staff not recording use appropriately. The DI is advised to include all mitigating practices in the establishment's risk assessments so that they can be reviewed and their continued suitability be assessed.
12.	GQ8(a) PFE5(f)	The establishment currently defrosts the tissue storage freezer for cleaning more than once per year. The inspection team understood that this defrosting was only to clean the freezer and was not to clear any ice build-up. The DI is advised to review and risk assess the frequency at which the freezer should be defrosted for cleaning/maintenance to assure himself that the time between cleaning events is appropriate.
13.	PFE5(c)	The storage freezer has a sign indicating to staff that the temperature of the

		freezer should be "below -35^{o}C and above -45^{o}C. The inspection team felt that this could lead to confusion and staff misinterpreting the correct temperature range. The DI is advised to review this notice to consider whether it is more appropriate to indicate an acceptable temperature range, for example "temperature should be between -35^{o}C and -45^{o}C".
Adult and paediatric stem cells		
14.	PFE3(a)	Paediatric bone marrow collection kits are stored in a secure drug room on one of the paediatric wards and the room is temperature monitored. However, at the time of the inspection this room was at the upper temperature limit as defined by the collection kit's manufacturer. The DI is advised to risk assess the use of this room for the storage of collection kits and undertake further monitoring to assure himself that it remains an appropriate place to store the kits as defined by the manufacturer.
Orthopaedic tissue		
15.		The establishment's storage freezer operates at between -40^{o}C and -45^{o}C. The establishment staff have, however, decided that in order to minimise the risk of any deterioration of stored tissue through exposure to higher temperatures during periods when the freezer door is opened during the selection of stored tissue, that when ordering fresh frozen femoral heads that they request an expiry date in line with storage at below -20^{o}C. The establishment's SOP regarding the receipt of tissue states that if a fresh frozen femoral head is received and marked for storage at below -40^{o}C that it will be disposed of. However, it was learned during the inspection that in the event of a fresh frozen femoral head being received which is marked for storage at below -40^{o}C the tissue is not disposed of and is stored however it is used first so that it is not stored for more than six months, which is the suitable storage period for tissue marked for storage at -20^{o}C. The DI is advised to amend the receipt of tissue SOP to reflect this practice of continuing to store tissue marked for storage at below -40^{o}C to minimise the risk of staff disposing of tissue unnecessarily. The storage of the tissue is permissible as the establishment's freezer does operate at below -40^{o}C and any warming as a result of opening the door is only transient.
Chondrocyte		
16.	General	The DI is advised to write to the PD currently associated with the procurement of chondrocytes in order to document a recognition that this activity is not taking place. In addition, the PD should be reminded that procurement activity cannot recommence without the approval of the DI and a suitable governance system being put in place to cover the activity.
Ovarian tissue		
17.	GQ2(b)	The establishment currently undertakes an annual audit of ovarian tissue that is stored in the liquid nitrogen tank. The DI is advised to review the frequency of audits undertaken of these tissues taking into account the risk of removing tissue from storage versus the benefit of auditing a mainly static collection of tissue. The DI may consider it to be appropriate to extend the period in-between audits provided that he has the assurance that no samples have been added or removed.
18.	GQ8(a)	The establishment is storing ovarian tissue for autologous use which was procured prior to the Human Tissue (Quality and Safety for Human Application)

		Regulations 2007 (the Regulations) coming into force. This tissue has been co-stored with tissue from multiple donors, in the liquid phase of a liquid nitrogen storage vessel, some of whom may not have been tested for all of the serological markers required by the Regulations. The establishment had a good range of risk assessments relating to the stored ovarian tissue however the potential risks posed by storing tissue which has come from donors with different serological screening data in the same tank has not been risk assessed. The DI is advised to risk assess the storage of these tissues with regards to any potential risks posed by storing tissue which has come from donors with different serological screening data in the same tank.
Licence-wide advice and guidance applying to all activities		
19.	GQ3(k)	There have been a number of staffing changes since the last inspection which have resulted in some areas of activity having staff that are new to the role of PD under the licence and other areas only having one PD identified and in place. The DI and HTA Manager have been trying to hold regular governance meetings with PDs, where licensable activities, general governance issues, audit, risk assessment and HTA-related matters are discussed. However, the ability of PDs to leave their area of responsibility to attend these meetings has been limited due to time constraints which has made holding these meetings more challenging. Having sufficient trained PDs and sufficient time for newly identified and existing PDs to learn and carry out their role under the licence is important as this is a key system which the DI uses to maintain appropriate oversight of the licensable activity over a large range of activities and locations. The DI is advised to continue to work with the various area managers to ensure that sufficient PDs can be identified and that they have adequate time to carry out their roles in overseeing licensable activity and undertaking audits to assure the DI that it is taking place as expected.
20.	GQ2(b)	During the inspection and across several of the areas of licensable activity evidence that audits were taking place was seen. Although the fact that audits were taking place was routinely documented, there were examples where the findings of, and actions arising from, audits were less well documented. For example, where a PD had spoken with staff at the establishment to remind them of the correct procedure this may not have been documented as an action arising from the audit findings. The DI is advised to put in place systems by which audits, their findings and the action taken as a result of these findings is more clearly documented. The DI may wish to consider the use of standardised audit forms which were used in some of the areas under the licence. By having a standard form that can be completed by staff undertaking the audits, provided there are entry fields to capture findings and actions taken, this may help give the DI a more consistent approach to the capturing of audit findings and actions taken.
21.	PFE3(b) PFE3(c)	Temperature-sensitive tissue is stored at various temperature ranges across different areas of the licence. The temperature of the storage is monitored in a variety of ways from local alarms to full time monitoring with automated dial-outs to on-call staff. The DI is advised to, in a way as to not risk the appropriate storage conditions of the tissues, challenge the various alarm systems to assure himself that alarm conditions are responded to appropriately and as expected. An example of this

		was seen during the inspection in the cardiac tissue storage area. In this example, while no tissue was being stored in the contingency freezer the freezer was allowed to rise in temperature until the alarm sounded. The PD did not forewarn theatre staff of this test and waited to see if other staff in the theatre area would contact her to alert her to the alarm condition, which they did. This type of exercise helps to assure the DI that systems to deal with temperature deviations are operating as expected.
22.	GQ7(a)	The establishment has an overarching serious adverse events and adverse reactions (SAEARs) SOP for staff working under the licence to follow which stipulates that all SAEARs must be reported to the DI and on to the HTA within 24 hours. Some teams using tissue under the licence also have local SAEARs SOPs as they have a requirement under their SLA with the tissue supplier to also report adverse reactions to them. The DI is advised to continue with his plans to review these local SOPs to ensure their suitability and that it remains clear that all SAEARs are reported to the DI, HTA Manager and on to the HTA within 24 hours. Additionally, the DI is advised to continue with his reminder to PDs that they must have access to the HTA SAEARs reporting portal so that in his absence or the absence of any other staff delegated to report SAEARs that the PDs can report SAEARs directly.
23.	General	In some areas under the licence the DI has a PD identified to cover an activity that is not currently taking place nor planned. These areas are UCB procurement and chondrocyte procurement. The DI is advised to consider whether these activities can be suspended under the licence to reduce the oversight required by the establishment's governance systems. If suspended the DI should notify the HTA that these activities are no longer taking place under the licence and should they recommence, he would need to inform the HTA that activity with those tissue types is planned to restart.

Concluding comments

Areas of good practice were observed during the inspection;some examples have been recorded below.

Blood for ATMP
The establishment has developed a proforma for staff at the Trust to alert the DI of potential new activity under the licence. The proforma included details of the proposed work in addition to a self-assessment by the group wishing to start the work of their compliance with the HTA standards. This proforma had been used by the group wishing to start procuring samples for manufacture into an ATMP. The form both helped the DI in gaining an understanding of the proposed work and the group involved in the requirements of the HTA.

Vessels for transplant
Audits had revealed minor errors being made by staff with regards to record keeping relating to the use of vessels. As training in the correct way in which use should be recorded had been given to staff a number of times, the PDs re-formatted the training given to staff making it more interactive and including competency based questions linked to possible scenarios. By amending the type of training given, the hope was that staff would be more engaged and take back the messages from the training to their work. This was a good example of PDs reacting to audit findings and then using novel ways to re-inform staff of the correct procedures.

Ophthalmic tissue
On occasions, there are times when a cornea may be requested for surgery but the surgery is cancelled for an unforeseen reason, such as the patient being ill. So that the graft is not wasted the establishment has a process through which they seek other potential recipients on the waiting list for whom the graft may be used or it offers the graft back to the supplying organisation who may be able to find another centre that could use it. This good practice helps to maximise the benefit of these donated grafts on the rare occasions that planned surgery does not go ahead.

Orthopaedic tissue
The PD has created a pictorial guide for staff to follow in theatre regarding the systems around use of the tissue. This pictorial training serves as a helpful aide memoire on how to receipt tissue and use tissue, and reminds staff about ensuring that women of child bearing age receive rhesus negative tissue.

General
All new PDs undergo a thorough training session provided by the HTA manager to inform them about the regulatory environment and the HTA’s requirements.

General
The Trust has developed a system to monitor all staff’s mandatory training and appraisal statuses. This system alerts staff to when their training and/or appraisals are due meaning that there is a decreased risk that staff will not undertake the appropriate training within the required timeframe.

There are a number of areas of practice that require improvement, including one minor shortfall. The HTA has given advice to the Designated Individual with respect to various other standards relating to consent, governance and quality systems, premises facilities and equipment and disposal.

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 shortfall identified during the inspection.

Report sent to DI for factual accuracy: 22 July 2016

Report returned from DI: 29 July 2016

Final report issued: 25 August 2016

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.

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the HTA's Codes of Practice
b) If there is a third party procuring tissues and / or cells on behalf of the establishment the third party agreement ensures that consent is obtained in accordance with the requirements of the HT Act 2004, the Q&S Regulations and the HTA's Codes of Practice.
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
d) Consent forms comply with the HTA Codes of Practice.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.
C2 Information about the consent process is provided and in a variety of formats.
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 003/2010 is included.
b) If third parties act as procurers of tissues and / or cells, the third party agreement details what information will be provided to donors. As a minimum, the information specified by Directions 003/2010 is included.
c) Information is available in suitable formats and there is access to independent interpreters when required.
d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.
a) Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent.
b) Training records are kept demonstrating attendance at training on consent.

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.
f) There are procedures for tissue and / or cell procurement, which ensure the dignity of deceased donors.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the European directives on medical devices and in vitro diagnostic medical devices.
k) There is a procedure for handling returned products.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 003/2010.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 003/2010.

s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.

e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
f) There are procedures to ensure that donor documentation, as specified by Directions 003/2010, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 003/2010.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 003/2010 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 003/2010.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 003/2010.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 003/2010.
c) In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
e) Testing of donor samples is carried out using CE marked diagnostic tests.
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured,

processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.
f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.
h) Establishments distributing tissues and / or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.

d) Where appropriate, there are procedures to ensure that the premises are of a standard that ensures the dignity of deceased persons.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 003/2010.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 003/2010.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.

i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal

Standard
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
b) The disposal procedure complies with Health and Safety recommendations.
c) There is a documented procedure on disposal which ensures that there is no cross contamination.
D2 The reasons for disposal and the methods used are carefully documented.
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.
b) Disposal arrangements reflect (where applicable) the consent given for disposal.

Human Tissue Act 2004 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 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 (HA)

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 direct risk of causing harm to a recipient patient or to a living donor,

Or

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 number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

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.

A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

or

A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

or

A shortfall which indicates a major deviation from the **Human Tissue (Quality and Safety for Human Application) Regulations 2007** or the **HTA Directions**;

or

A shortfall which indicates a breach in the relevant Codes of Practices, the HT Act and other relevant professional and statutory guidelines;

or

A shortfall which indicates a failure to carry out satisfactory procedures or a failure on the part of the designated individual to fulfil his or her legal duties;

or

A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall.

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 and, which can be addressed by further development by the establishment.

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 review or at the time of the next inspection.

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.