Site visit inspection report on compliance with HTA minimum standards

Chapel Allerton Hospital

HTA licensing number 22505

Licensed for the

- **procurement, processing, testing, storage, distribution and import/export 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**

24 – 27 June 2014

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.

Chapel Allerton Hospital (the establishment) was found to have met all HTA standards.

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

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, 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.

'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**		**E**		
Cord blood	**E**		**E**		**E**		
Ovarian tissue				**E**			
Bone				**E**			
Chondrocytes	**E**						
Cornea				**E**			
Amniotic membrane				**E**			

Heart valves				**E**			
Liver vessels				**E**	**E**		

Background to the establishment and description of inspection activities undertaken

Chapel Allerton Hospital (hub) is one of four hospital sites within the Leeds Teaching Hospitals NHS Trust where licensable activity takes place. The Leeds General Infirmary, Seacroft Hospital and St James's University Hospital are all satellite sites to the hub premises which are also covered by the licence. The Leeds Teaching Hospitals NHS Trust is the Corporate Licence Holder of the licence.

At St James's University Hospital, storage of amniotic membrane and corneal tissue is undertaken. Although the corneal tissue is cellular, it is typically ordered for delivery just before being required in surgery and therefore storage is for less than 48 hours and is not subject to the storage licence requirements. The department, however, applies the same standards in traceability and governance that it applies to other tissue being stored under the authority of the HTA licence. Amniotic membrane tissue is purchased from another licensed establishment and is stored at the establishment until end use in ophthalmic surgery. The supply of tissue from the other licensed establishment is covered by a service level agreement (SLA) which defines each licensed establishment's responsibilities. The ophthalmic surgery department additionally stores and uses acellular material in ophthalmic surgery; however, as this material is acellular, the storage of this material is not required to be undertaken under the establishment's licence. The department, however, as with corneal tissue, treats the acellular material in the same way as cellular tissue with regards to overall governance and traceability systems.

Adult vessels relating to liver transplantation activity are also stored at St James's University Hospital. The vessels are received by the establishment with donor livers being supplied for implantation during transplant surgery. The vessels may or may not be used in the transplantation surgery, depending on the donor organ and the recipient. Any vessels not used in the surgery are stored by the establishment should they be needed in further transplant-related procedures. Vessels that have been opened in the surgical sterile field are marked as only to be used in the same patient for which they were first opened. If vessels were not opened in the sterile field they will still be stored at the establishment and may be used in any subsequent liver transplant surgery on other organ recipients. Vessels may be transferred to other transplant centres in emergencies. The establishment has end user forms in place, which inform the recipient centre of their responsibility 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. The vessels are mainly used in liver transplantation however, on occasion and in emergency circumstances, they have been used in renal transplant surgery. This additional use is acceptable under the establishment's licence as all procedures for recording traceability and other licensable activities are performed in the same way.

Additionally at St James's University Hospital, adult bone marrow is procured for autologous and allogeneic (related sibling donor) use. Adult peripheral blood stem cells (PBSCs) are also procured; however, this is done under an SLA with another licensed establishment and does not fall under the authority of the establishment's licence. Bone marrow is processed under the authority of an SLA with another licensed establishment, which may process and store cells until returning them to the establishment upon request for end use. Mandatory testing of donors is undertaken by the establishment, with the testing being carried out at Leeds General Infirmary and at St James's depending on the location of the laboratory. Additional

mandatory testing is also undertaken by the processing and storage establishment on blood samples collected at the time of the procurement.

Chapel Allerton Hospital is licensed for the procurement, testing, storage and distribution of human tissues and cells. In effect, however, only storage and occasionally procurement take place at this site. Bone and occasionally other tissues, such as tendons, are purchased from another licensed establishment and are stored under the establishment's licence until allogeneic end use, during orthopaedic surgery.

In addition, chondrocytes have previously been procured under the licence at Chapel Allerton Hospital. These were sent to another licensed establishment for processing under the authority of a service level agreement (SLA). Cultured cells that have been processed at the other licensed establishment are returned to Chapel Allerton Hospital for autologous end use. The establishment is currently reviewing the SLA between themselves and the cell processing service provider and is not currently undertaking chondrocyte procurement; however, as the activity remains on the licence, relevant documents and patient notes were reviewed during the inspection.

At Seacroft Hospital, ovarian tissue which may in 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. It is possible that in the future, the establishment will distribute stored ovarian tissue for autologous end use and advice has been offered in relation to developing suitable end user agreements below. Seacroft Hospital is also licensed by the Human Fertilisation and Embryology Authority and operates a fertility service. Discussions were held with the establishment about the suitability of the laboratory facility for undertaking processing of ovarian tissue in the future and again, advice has been offered in relation to this below.

At the Leeds General Infirmary, vessels are also stored for use in paediatric liver transplants. Again, vessels are received by the establishment with donor livers and may be used in transplantation surgery. Again, vessels not used in the transplant surgery are stored by the establishment for use in other transplant related surgery either for the same recipient or, as with the adult vessels, if not opened to the sterile field during the initial transplant surgery, other surgery with other organ recipients.

Paediatric bone marrow is also procured at Leeds General Infirmary for autologous and allogeneic use. PBSCs may also be procured, however, this is undertaken by another licensed establishment under an SLA and is therefore not taking place under the establishment's licence. Bone marrow that has been procured is distributed by the establishment to another licensed establishment under the authority of an SLA where it is processed and stored until being requested back by the establishment for end use. Mandatory testing of donors is undertaken by the establishment, with the testing being carried out at Leeds General Infirmary and at St James's depending on the location of the laboratory. Additional mandatory testing is also undertaken by the processing and storage establishment on blood samples collected at the time of the procurement.

The Leeds General Infirmary site also has procedures in place for the procurement of umbilical cord blood for both autologous and allogeneic use. No cord blood has been procured by the establishment since before the previous HTA inspection in 2012; however, the establishment maintains procedures and systems to collect cord blood if required. Although no cord blood procurement activity has taken place, the premises where procurement would take place and the documented procedures relating to the activity were reviewed as part of the inspection. Detailed procedures relating to the collection of cord blood have been created and procurement would be undertaken by qualified personnel who have been appropriately trained in the procurement procedure. Equipment used to collect cord

blood is provided by another licensed establishment which would also undertake processing and storage of the cells under the authority of an appropriate SLA.

Although the establishment has not procured any cord blood, establishment staff have been involved in the seeking of consent for cord blood collection with the eventual procurement taking place at other centres. Currently only two staff are involved in the seeking of consent for cord blood procurement and have been suitably trained. Consent seeking procedures were reviewed as part of the inspection with records of consent being reviewed in three sets of clinical notes.

Storage of heart valves for use in cardiac surgery also takes place at the Leeds General Infirmary site. Heart valves are purchased from another licensed establishment and are stored by the establishment until allogeneic end use. Provision of the tissue is again covered by an SLA.

The establishment has been licensed by the Human Tissue Authority since 2008 and this routine inspection was the fourth site visit. The timetable for the site visit was developed in consideration of the establishment's recently submitted 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, review of the establishment's documentation and interviews with relevant staff were undertaken. Since the establishment's donor testing laboratories were visited during the previous inspection, they were not inspected on this occasion.

The establishment has a wide variety of licensable activities taking place under its licence and, to assist the DI in maintaining oversight of all the various activities, the establishment's HTA Manager has a key role in the establishment's governance systems. There is a network of Persons Designated (PDs) with each area of activity having two PDs identified. The DI and HTA Manager have regular governance meetings with PDs, where licensable activities, general governance issues, audit, risk assessment and HTA-related matters are discussed. 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 him ensuring that appropriate practices are being undertaken by appropriately qualified staff in appropriate premises.

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

Traceability audits were undertaken in each area of activity across the establishment's licences. These audits included a review of records held in tissue register books, which are maintained for bone and other orthopaedic tissue, corneas and amniotic membranes, heart valves and vessels used for both adult and paediatric recipients. In these areas of activity, tissue details were also reviewed in selected sets of patient's clinical notes. Following advice given to the establishment at the previous HTA inspection, clinical notes reviewed in these audits contained a Tissue Tracking Form which recorded the traceability details of tissue used for a particular patient with the exception of the paediatric vessel related clinical notes. Although traceability of tissue is maintained via the tissue register, Tissue Tracking Forms were not found in some clinical notes which is not in accordance with the establishment's traceability/tissue usage standard operating procedure (SOP). This issue had been identified through the establishment's internal audit systems and further advice has been given below relating to both Tissue Tracking Form usage and follow up of audit findings.

Traceability audits were also performed in notes relating to adult bone marrow procurement and end use. Again, following advice given at the last HTA inspection in 2012, the establishment has revised its filing procedures in relation to this activity. The relevant PD has developed a 'Day 0' form to track some traceability information in addition to requesting donor test results and processing quality reports from the licensed establishment involved in the

processing of cells under the SLA. This additional information helps to record and document details of unique cell identifiers in the patient's clinical notes. Traceability records are also maintained by the other licensed establishment processing the cells under the SLA; however, it is considered good practice to also maintain these records of traceability in the patient's clinical notes. A review of traceability records in paediatric bone marrow procurement and end use was not undertaken due to time constraints, however the establishment shares good practice between the adult and paediatric service and records traceability in the same way. In addition, as with the adult service, traceability records are also maintained by the other licensed establishment processing the cells under the SLA.

In summary, traceability of tissue and cells from donor to recipient was demonstrated in all of the cases that were reviewed.

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

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
Adult and paediatric vessel storage		
1.	PFE3(b) PFE3(c)	The DI is advised to develop a procedure by which both the adult and paediatric vessel storage fridge alarms are tested to ensure that they trigger and sound as expected. This manual challenge to the alarm systems should be repeated at a suitable time interval to assure the DI that they are functioning as expected.
2.	GQ6(b)	During the traceability audits undertaken on paediatric clinical notes, there were no examples of Tissue Tracking Forms being filed in the recipient's notes. The establishment's SOPs state that Tissue Tracking Forms containing details of vessels used should be filed in the recipient's clinical notes. Although traceability was still demonstrated using the Vessel Register, the establishment has not complied with its own SOP. The failure to file Tissue Tracking Forms in recipient's clinical notes had been identified during an internal audit which had recently been performed and had demonstrated only a 30% compliance with the SOP. The DI is advised to develop a system to ensure that Tissue Tracking Forms are filed in all sets of recipient's clinical notes in accordance with the SOP. In doing this, the DI may wish to consider mirroring the system used in the adult service where a document checklist is used to help ensure that all relevant documentation has been completed and filed correctly.
Adult and paediatric bone marrow procurement		
3.	PFE3(a)	During the inspection a review of the area where consumables used in the procurement of adult bone marrow are stored was undertaken. The particular collection kits used have an indicated storage temperature range of $0^{o}C$ – $25^{o}C$; however, upon enquiring with the establishment, the side room where the kits are being stored is not temperature controlled or monitored and may, at times be above $25^{o}C$. During the inspection the establishment staff identified another potential side room off the ward which is temperature controlled as part of the building's environmental management system. The DI is advised to relocate the kits used for the procurement of bone marrow to the newly identified store room to ensure that they are stored at the correct temperature. Although during a similar review of the storage areas where paediatric kits are stored it was thought by the establishment that the store room being used is temperature controlled, the DI is advised to ensure that this is the case. Should the room being used not be temperature controlled then again, the kits should be relocated to a more suitable storage area.
4.	GQ4(j)	Following a review of the bone marrow collection record sheets which are sent along with the cells to another licensed establishment for processing, it was noted that the collection records include details of all consumables coming into contact with the procured cells. It was thought by the establishment during the inspection that a copy of these records are not maintained at the establishment. The DI is advised that records of all materials and consumables coming into contact with the procured cells should be maintained by the establishment for a period of 10 years as required by the Directions. These records are a

		requirement under the Directions; however, as these details are being held at the other licensed establishment processing the cells, meaning that consumables and materials are traceable, this has been given as advice.
5.	C2(a)	A review of a patient information leaflet given to potential donors highlighted that syphilis was not listed as one of the donor serological tests performed prior to donation. The DI is advised to amend this information document so that all mandatory serological tests are listed helping to ensure that the donors are informed about all tests which will be performed.
Orthopaedic tissue storage and chondrocyte procurement		
6.	GQ8(a)	Orthopaedic tissue storage: The establishment's orthopaedic tissue freezer recently failed following a power surge to the theatres, which resulted in loss of stored tissue. A new freezer has been ordered and the establishment are awaiting delivery. At the same time, the establishment is in the process of sourcing a new freezer alarm system and considering the purchase of a contingency storage freezer. The DI is advised to risk assess the need for a contingency freezer and to consider if this would help to mitigate the risk of loosing tissue in the event of a main storage freezer failure.
7.	PFE3(a) PFE3(b) PFE3(c)	Orthopaedic tissue storage: Once the new storage freezer and alarm system are operational, the DI is advised to develop a procedure by which the freezer alarm system is tested to ensure that it triggers and alerts staff as expected. This manual challenge to the alarm system should be repeated at suitable time intervals to assure the DI that it is functioning as expected.
8.	GQ2(b)	Orthopaedic tissue storage: On undertaking a review of the establishment's internal audit of orthopaedic usage, it was noted the establishment audited for the presence of tissue tracking and other relevant traceability documentation rather than a cross check of the actual identifiers. Additionally, where more than one piece of tissue has been used in a particular recipient, not all pieces of tissue are reviewed during these audits. The DI is advised to amend how the tissue audits are undertaken so that tissue identifiers are cross referenced between the tissue tracking form, operation note where tissue stickers are placed into the recipient's clinical notes and the establishment's tissue register. This vertical audit process should be carried out reviewing details of every piece of tissue used in a particular recipient. These vertical audits will not only check for the presence of traceability records but also for completeness and accuracy of completion of records for each piece of tissue used in a recipient.
9.	GQ8(a)	Chondrocyte procurement: On reviewing chondrocyte procurement records, it was noted that three procurements had taken place on the same day. The establishment has mitigated the risk of mix up and loss of traceability of procured tissue between donors and packaging boxes by only starting the next case once packing of the previous case's tissue has been completed. This process, however, has not been documented as a formal risk assessment. The DI is advised to document the consideration that has been given to undertaking multiple procurements on the same day so that these risk assessments can be reviewed to ensure that they continue to mitigate the risk of loss of traceability should any procedures change.

Ovarian tissue storage		
10.	GQ4(k) GQ7(g) GQ7(h)	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) being in force. No tissue has been procured since the introduction of the Regulations. At the time of the inspection the establishment has received two requests for the return of tissue for end use in the original donor. The DI is advised to develop a suitable end user agreement prior to any distribution of ovarian tissue. This agreement should ensure that the end user is aware of their responsibilities to both store traceability data relating to the tissue for 30 years and to report any serious adverse events or reactions to the establishment that relate to the tissue as required by the Regulations. In addition, the end user agreement should make it clear that this tissue has been co-stored with tissue from other 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 end user clinicians can then perform a risk assessment relating to any potential transfer of infectious disease between the stored tissues and therefore potentially, the recipient. In addition the end user clinician will also be able to advise the recipient of the potential risks so that they may make a fully informed decision.
11.	N/A	The establishment enquired about adding processing to the licence and possibly starting new procurements, processing and storage of ovarian tissue in their laboratory. Oral advice was given to the establishment relating to air quality standards, Process Preparation Documents and other facility and governance standards that may be affected by this new activity. The DI is advised to contact the HTA for further advice should he think that such activity may possibly commence in the future.
Adult and paediatric cardiac tissue storage.		
12.	GQ7(d)	The DI is advised to review the storage freezer failure and homograft storage SOPs. The DI is advised to consider whether is it appropriate to include in the SOPs that prior to disposing of tissue, the consultant surgical staff should be consulted in case there was a potential clinical need for the tissue that the storage staff were not aware of. This way, the surgical staff would be able to make a risk benefit analysis regarding the use of such tissue if it were absolutely necessary that it be used and in the recipients best clinical interest before tissue was disposed of. This will help to mitigate the risk of tissue being disposed of without the knowledge of the treating clinician who may be aware of a potential recipient for the tissue that is not known to the staff responsible for storage of the grafts. The SOPs state that in the event of a freezer failure where the temperature exceeds its set point for more than 30 minutes or stored grafts are past their assigned expiry date, then the grafts should be immediately disposed of. The treating clinician may, following an appropriate risk benefit analysis, choose to use tissue over its expiry period or that has been stored outside the normal storage temperatures for a short period of time based upon clinical need and the best interests of the recipient. Although use of tissue outside of the routine parameters would still constitute a reportable SAE to the HTA, it is recognised that on occasion, such use may occur for clinically based reasons based on the needs of the recipient and the scarcity of the tissue. The advice given was that the SOPs be amended to state that prior to disposing of tissue, the consultant

		surgical staff should be consulted in case there was a potential clinical need for the tissue that the storage staff were not aware of. This way, the surgical staff would be able to make a risk benefit analysis regarding the use of such tissue if it were absolutely necessary that it be used and in the recipients best clinical interest before tissue was disposed of.
13.	GQ1(q)	The DI is advised to review the establishment's agreements with other licensed establishments which supply tissue in order to ensure that they are in date and appropriately signed. During the inspection, an example of an agreement which was out of date was found. Additionally, another agreement was found which had not been signed by the supplying organisation but had been signed on behalf of Chapel Allerton Hospital.
14.	GQ1(b)	The establishment's homograft consent SOP states that consent should be sought for the use of homograft tissue and that this should be recorded on a dedicated consent record sheet. The SOP also states that homograft tissue should not be released from storage unless there is an appropriately completed consent record sheet in the recipient's clinical notes. During an internal audit undertaken at the establishment, however, it was found that compliance with the use of the separate consent record sheet was variable. The establishment stated that the treating clinician always seeks the recipient's consent for the possible use of homograft tissue during the pre-surgical consultations and that this is recorded on a Trust general consent to treatment and examination form as part of the consent for the overall procedure. The DI is advised to review the tissue recipient consent process covering the use of homograft tissue and if necessary develop and implement a system to ensure that the separate consent form covering the use of homograft tissue is completed as required by the establishment's SOP. Alternatively, if consent for the use of tissue is sought during pre-surgical discussions with the treating clinician then the DI may wish to amend the establishment's SOP to reflect the more usual consenting procedure undertaken by the clinician. This may then make the requirement to separately record consent for use of homograft tissue unnecessary.
15.	PFE5(c)	The establishment's freezer monitoring SOP states that daily temperature checks will be performed on the establishment's two tissue storage freezers. During the inspection, however, it was found that it was more typical that recorded temperature checks are performed only during normal working days (Monday to Friday but not at weekends or during holiday periods). During the inspection, the establishment indicated that they planned to move to daily monitoring, the Operating Department Practitioner to record the temperatures over weekends and holiday periods. The DI is advised to ensure that appropriate monitoring of the freezers takes place in accordance with the establishment's SOP.
16.	PFE3(b) PFE3(c)	The establishment uses two freezers for the storage of homograft tissue, one located in a side room just behind the paediatric intensive care unit's nurse station and one in a side room in the establishment's theatre complex. As the paediatric intensive care unit's nurse station is continuously manned, the alarm of the freezer (located just behind the station) will always be heard by a member of staff, who can follow instructions on how to respond to a freezer alarm. The freezer located in theatres, however, although audible to theatre staff, may not be responded to by a member of staff familiar with storage of homograft tissue. The DI is advised to assess the risk of a failure to respond appropriately to the theatre freezer alarm. Upon completion of the risk assessment the DI is advised develop corrective and

		preventative actions to address and mitigate any risks that may have been identified regarding an alarm that may not be responded to or responded to appropriately.
Ophthalmic tissue storage		
17.	GQ6(b)	During the traceability audit undertaken on tissue recipient's clinical notes, examples were found of tissue tracking forms in which not all fields had been completed. None of the incomplete fields affected tissue traceability. The DI is advised to include record completeness reviews in the next cycle of internal audits to assure himself that all necessary entries are being made into the appropriate records.
18.	PFE3(a)	During the inspection, it was found that the freezer used to store the amniotic membrane for use in ophthalmic surgery routinely runs at around -37°C. The membranes that are supplied from another licensed establishment indicate that the expiry date issued with the tissue is dependent upon it being stored at or below -40°C. The establishment has asked the supplier about this and had received oral confirmation that the establishment's storage temperature is adequate and that the expiry date issued with the tissue remained valid. The DI is advised to obtain documented assurance from the tissue supplier that the establishment's storage freezer meets the requirements of the supplying tissue establishment in order for the issued expiry dates to remain appropriate. This will augment the establishment's governance systems and allow it to demonstrate appropriate storage of this tissue.
General		
19.	GQ2(b)	Since the last HTA inspection, the establishment has undertaken a particularly detailed independent audit of all licensable activities, including a review of compliance against the HTA standards. In addition, since the last inspection the internal audit processes have become more defined, with clearer objectives and methods of recording the audits that have been undertaken. During the inspection, there were instances where the findings on inspection had also been identified during the establishment's internal audits; however, it was not always clear what corrective and preventative actions arose out of the internal audit. From speaking with staff at the establishment, it was learnt that the more detailed internal audits are relatively new and work is just starting on formalising the recording of corrective and preventative actions, and the recording of progress in implementing them. The DI is advised to increase focus on the internal audits that are taking place within the establishment and work towards formalising the systems used to record any corrective and preventative actions and the progress in implementing them that may have arisen as a result of the audits.
20.	N/A	The DI oversees a large amount of licensable activities, spread over four licensed sites within the Trust. There is a network of PDs, with each area of activity having two nominated PDs. The DI and the establishment's HTA Manager have regular governance meetings with PDs where licensable activities, general governance issues, audit, risk assessment and HTA related matters are discussed. The 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 him ensuring that appropriate practices are being undertaken by appropriately qualified staff in appropriate premises. All of the work required by the establishment's PDs in engaging with the DI and

		HTA manager, in addition to their work in ensuring that the activity continues to meet the legislative requirements, does require each PD to be allowed some protected time. The DI and senior management have recognised this and have written to managers within the establishment explaining the importance of PDs being allocated some protected time in order to carry out their duties under the licence. The DI is advised to continue with his efforts in ensuring that all PDs have sufficient protected time to carry out their roles in helping him ensure that appropriate activities are taking place under the licence in compliance with the legislative requirements.

Concluding comments

Areas of good practice were observed during the inspection.

The establishment demonstrates a willingness to comply with the legislation and this was evident by the way in which advice offered during the previous inspection has been acted upon. For example, regular governance meetings between the DI, HTA manager and the PDs named on the licence are now taking place. SOPs and audit procedures have been standardised across most tissue types. The use of tissue tracking forms is now being used across most tissue types and is helping to maintain traceability.

In addition to the above, the establishment's HTA manager, who is not involved in the day to day licensable activity, has performed a particularly detailed independent audit which involved PDs for all tissue types answering questions regarding all HTA standards and how they comply with them.

The HTA has given advice to the Designated Individual with respect to some of the HTA standards.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 25 July 2014

Report returned from DI: 8 August 2014

Final report issued: 29 August 2014

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.