Site visit inspection report on compliance with HTA minimum standards

South Devon Healthcare NHS Trust, Torquay

HTA licensing number 11088

Licensed for the

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

25 March 2014

Summary of inspection findings

South Devon Healthcare NHS Trust, Torquay (the establishment) was selected to receive a themed inspection. The themes selected for 2013/14 include quality management, contingency planning and risk management.

The establishment was found to have met all HTA standards relating to each theme.

In addition, the HTA reviewed the establishment's response to previous inspection findings including matters offered as advice and guidance. As the result of the Designated Individual's proactive approach to the inspection process the scope of inspection extended beyond the planned themes and included review of compliance with HTA standards applicable to training and to equipment calibration and maintenance. The establishment was found to have met these HTA Standards.

The HTA previously found the Designated Individual and the Corporate Licence Holder Contact to be suitable in accordance with the requirements of the legislation. Both the Designated Individual and the Corporate Licence Holder were actively involved throughout this inspection with the result that their continued suitability was verified.

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

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, 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.

However, a themed inspection may be carried out on establishments which have been found previously to represent a lower risk. Themes target Standards which the HTA has identified as common shortfalls across the human application sector in 2011. The themes selected for 2012/13 are outlined in the table below.

Themes	**HTA Standards**
Quality management	
Standard operating procedures for licensed activity	GQ1(b)
Document control system	GQ1(d)
Quality Management System – continuous and systematic improvement	GQ2(a)-(c)
Internal audit system for licensable activities	
Contingency Planning	
Plan to ensure records of traceability are maintained for 10 or 30 years as required.	GQ4(m)
Risk Management	
Procedures for the identification, reporting, investigation and recording of adverse events and reactions	GQ7
Risk assessments	GQ8
Traceability	GQ6

In addition to the Standards listed above, the HTA will follow-up on any other issues that have arisen since the establishment's last inspection.

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.

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Bone				**E**			
Tendon				**E**			

Background to the establishment and description of inspection activities undertaken

The establishment is licensed for the storage of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Regulations). Frozen femoral heads, bone struts, bone graft material, in a variety of forms, and tendons, are purchased from another HTA licensed establishment for use in orthopaedic surgery. The frozen femoral heads are securely stored in a freezer located close to the orthopaedic theatres A and B. The bone struts, bone graft material and tendons are stored at room temperature in the theatre implant storage room close to orthopaedic theatres A and B.

The establishment has been licensed by the Human Tissue Authority since 2008 and this routine, themed, inspection was the fourth site visit. The timetable for the site visit was developed following consideration of previous inspection reports and pre-inspection discussion with the Designated Individual (DI). The timetable addressed the HTA standards identified under the components of the themed inspection and comprised a visual inspection of the premises, review of the establishment's documentation and discussion with members of staff conducting licensable activities. The scope of inspection was extended to include review of documentation relating to the calibration and preventative maintenance programme for the freezer that had been purchased just prior to the last HTA inspection.

The inspection included a traceability audit which comprised review of eight examples of tissue product that had been purchased by the establishment. Three examples were in storage awaiting use. The remaining five examples had been used in a variety of orthopaedic surgical procedures. The documentation detailing storage and, where applicable, use of tissue was reviewed for accuracy and detail of stored tissue and the tracking of tissue from original receipt through storage and use. The audit trail was complete and accurate. No anomalies or discrepancies were identified.

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
1.	GQ2 (b)	The DI is advised to extend the existing programme of audits to include audit of the training files of members of staff involved in licensable activities. The scope of this audit should include verification that appropriate members of staff have undergone the induction training covering HTA licensable activities and have verified that they have read, understood and will adhere to relevant procedures.
2.	GQ3 (e)	As part of the review of records it was noted that not all members of staff who may be involved in licensable activities had filed evidence of training within their individual training file. The DI is advised to remind staff of the importance of filing evidence of training so that individual training files accurately reflect the current level of training.
3.	GQ4 (a) & GQ4 (c)	The DI is advised to remind members of staff of the correct method to make alterations to data entered into the tissue register. During the traceability audit it was noted that an entry had been over labelled as a method of amendment. Changes should be made in such a way that the original entry is not masked or obscured.
4.	GQ4 (b)	The DI is advised to include a column to capture the initials of the person responsible for daily cleaning within the template for capturing conduct of routine tasks linked to licensable activities.
5.	GQ4 (e) & GQ4 (g)	The DI is advised to password protect the spread sheet that is used to track and trace tissue use and collate batch specific details of tissue products. Restricting access to the spread sheet, which is held on the theatres computer drive, will safeguard against uncontrolled changes or updates.

Concluding comments

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

The DI has been in post from the start of licensing by the HTA and demonstrates a good working knowledge and understanding of HTA requirements. The DI is Theatre Operations Manager and, as such, has a key role in relation to quality management and regulatory compliance and is the principal point of contact for activities licensed by the HTA. The Corporate Licence Holder Contact (CLHC) is Divisional Manager with a key role in the oversight of activities across the establishment’s suite of operating theatres. There is a close

working relationship between all those involved in licensable activities.

There are a number of good systems in place. These include but are not limited to:

- Member of staff assigned to data input, collation and management to ensure and assure complete and accurate record keeping;
- collaboration with another HTA licensed establishment to conduct external audit against HTA standards;
- well-considered patient information literature;
- use of an electric spur connection for the femoral head freezer to minimise the risk of loss of supply through inadvertent disconnection;
- sound system of governance meetings with a clear route of communication of any matters of significance to the Medical Director.

The HTA has given advice to the Designated Individual where the HTA identified opportunities for improvement to existing systems and procedures.

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

Report sent to DI for factual accuracy: **2 June 2014**
Report returned from DI: **3 June 2014**
Final report issued: **3 June 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) Standard not applicable.
b) Standard not applicable.
c) Standard not applicable.
d) Standard not applicable.
e) Standard not applicable.
C2 Information about the consent process is provided and in a variety of formats.
a) Standard not applicable.
b) Standard not applicable.
c) Standard not applicable.
d) Standard not applicable.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.
a) Standard not applicable.
b) Standard not applicable.

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) Standard not applicable.
f) Standard not applicable.
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) Standard not applicable.
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) Standard not applicable.
n) Standard not applicable.
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) Standard not applicable.
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) Standard not applicable.
k) Standard not applicable.
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) Standard not applicable.
b) Standard not applicable.
c) Standard not applicable.
d) Standard not applicable.
e) Standard not applicable.
f) Standard not applicable.
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) Standard not applicable.
f) Standard not applicable.
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) Standard not applicable.

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) Standard not applicable.
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) Standard not applicable.
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) Standard not applicable.
b) Standard not applicable.
c) Standard not applicable.
d) Standard not applicable.
e) Standard not applicable.
f) Standard not applicable.
g) Standard not applicable.
h) Standard not applicable.
i) Standard not applicable.
j) Standard not applicable.
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) Standard not applicable.
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.

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 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 failure to carry out satisfactory procedures for the release of tissues and cells 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 by adversely affecting the quality and safety of the tissues and cells.

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.