Site visit inspection report on compliance with HTA licensing standards
Inspection date: **22, 23 October 2019**

SCI Leeds

HTA licensing number 11017

Licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

and

Licensed under the Human Tissue Act 2004

Licensable activities carried out by the establishment

'E' = Establishment is licensed to carry out this activity and is currently carrying it out.

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

'TPA' = Third party agreement; the establishment is licensed for this activity but another establishment (not licensed by the HTA) carries out the activity on their behalf.

Licensed activities – Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Hub **SCI Leeds**	E*	E		E	E		
Satellite **St James's University Hospital**	E						

Tissue types authorised for licensed activities – Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Progenitor Cell, Haematopoietic, PBSC; PBSC	Authorised	Authorised		Authorised	Authorised		
Progenitor Cell Haematopoietic, Bone Marrow; Bone Marrow		Authorised		Authorised	Authorised		
Progenitor Cell Haematopoietic, Cord Blood; Cord Blood	Authorised	Authorised		Authorised	Authorised		
Mature cell MNC; PBMC		Authorised					
Mature Cell, MNC; DLI	Authorised	Authorised		Authorised	Authorised		

Licensed activities – Human Tissue Act 2004

Area	Storage of relevant material which has come from a human body for use for a scheduled purpose
Hub **SCI Leeds**	Licensed

Satellite St James's University Hospital	Not licensed

Summary of inspection findings

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

SCI Leeds (the establishment) was found to have met all HTA standards.

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

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 practice:

Number	Standard	Advice
1.	GQ1i	The SCI Processing Record Review form used for audit purposes correctly states that mandatory virology testing on day minus 30 is not applicable for cord blood. The DI is advised to include that DLI (single procurement event) and peripheral blood mononuclear cells (PBMCs) are also not applicable for testing at day minus 30.

2.	PFE2c	The clean room facility has cleaning records which document the cleaning of the floor. The standard operating procedure (SOP) 1311/8 does not state how frequently or when the disposable tacky mat should be changed. The DI is advised to include this information in the SOP to ensure regular maintenance of the clean room.
3.	PFE3c	On review of the temperature monitoring records in the apheresis suite where ACD-A is stored, four incidents were recorded with temperature excursions to 26°C from June to August 2019. The establishment has a SOP stating that temperature excursions are recorded as quality incidents. The DI is advised to review the procedures and forms used to record temperature excursions in the apheresis suite where ACD-A is stored to ensure such events are logged and investigated in line with establishment procedures.

Background

SCI Leeds has been licensed by the HTA since August 2009 under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) and the Human Tissue Act (2004) (HT Act). The establishment carries out procurement, processing, storage and distribution of peripheral stem cells and peripheral blood lymphocytes for donor lymphocyte infusion (DLI) and processing, storage and distribution of bone marrow. Umbilical cord blood is procured under an appropriate third party agreement and is sent to the establishment for processing, storage and distribution. Testing for mandatory donor serology markers and cell sterility is performed by other HTA-licensed NHSBT establishments. The establishment has been authorised to carry out processing of peripheral blood mononuclear cells as a starting material for Advanced Therapy Medicinal Products (ATMP) manufacture, but has not yet undertaken this activity.

This was the sixth site visit inspection of the establishment; the most recent previous inspection took place in October 2017.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection

There are 121 standards in the Human Application sector of which 112 were assessed. Standards GQ1f, GQ1k, GQ1n, GQ5b, GQ5e, GQ7e, GQ7f and PFE1d were not applicable and standard GQ8d was not assessed.

The establishment is not currently storing any relevant material under the HT Act, therefore compliance against these standards was not assessed.

Review of governance documentation

The inspection included a review of documentation relevant to the establishment's licensed activities. This included policies and procedural documents, contracts for servicing of equipment and records of servicing, temperature monitoring for the storage units, agreements with third parties, patient records including records for procurement, processing and test results, meeting minutes, incidents and adverse events, audits, risk assessments and staff training records.

Visual inspection

The inspection included a visual inspection at the satellite site of the apheresis suite and storage areas and at the hub site the cell processing laboratory, the cryostore and storage areas.

Audit of records

The procurement records were audited for the following cells at the satellite site:

- an allogeneic peripheral stem cell donor;
- two autologous peripheral stem cell donors; and
- a DLI donor.

The processing records were audited for the following donors at the hub site:

- four allogeneic unrelated bone marrow donors; and
- two directed cord blood donors.

Records of three peripheral stem cell donors were traced from procurement records to the electronic database. No discrepancies were found.

Meetings with establishment staff

At the satellite site, the inspection included round table discussions with the Consultant Haematologist / Clinical Lead for Apheresis, the Senior Nurse Manager and Lead Nurse for Apheresis, the Therapeutic Apheresis Senior Nurse Manager (Quality Governance), the QA Manager and Regional QA Manager. At the hub site, round table discussions were held with the Head of the SCI laboratory, the Laboratory Manager, the Consultant Haematologist, laboratory staff, the Assistant Director of Quality and Regulatory Compliance, the QA Manager and the Regional QA Manager.

Report sent to DI for factual accuracy: 18 November 2019

Report returned from DI: 2 December 2019

Final report issued: 11 December 2019

Appendix 1: The HTA's regulatory requirements

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

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

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 Human Tissue Act 2004 (HT Act), Human Tissue (Quality and Safety for Human Application) Regulations 2007, 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 HT Act or associated Directions,

   Or

   A number of ‘major’ shortfalls, none of which are 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:

   - A notice of proposal being issued to revoke the licence
   - 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.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - 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 Practice, 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 the final inspection report. Establishments 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 routine site-visit inspection.

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