Site visit inspection report on compliance with HTA minimum standards

Salford Royal NHS Foundation Trust

HTA licensing number 12291

Licensed under the Human Tissue Act 2004 for the

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

17 November 2015

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.

Salford Royal NHS Foundation Trust (the establishment) was found to have met all applicable HTA standards. The HTA has given advice to the Designated Individual on traceability, risk assessments, temperature monitoring and disposal records.

Particular examples of strengths and good practices 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 licenses against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

The Salford Royal NHS Foundation Trust ("the establishment") is licensed by the HTA under the Human Tissue Act 2004 (HT Act) for the storage of relevant material which has come from a human body for use for a scheduled purpose.

The establishment has been licensed by the HTA since November 2007 and was first inspected by the HTA on 6 and 7 March 2008. This report describes the second, routine, site visit inspection of the establishment. The timetable for the inspection was developed in consideration of previous inspection findings, compliance update information and discussions with the Designated Individual (DI). The site visit inspection included a visual inspection of the areas where relevant material is stored under the HTA licence, audits of sample traceability, a review of documentation and meetings with establishment staff.

Consent is sought by staff at the establishment as well as by external members of staff for donations of blood, saliva, gut tissue and brain. A collection of peripheral blood lymphocytes is also stored in liquid nitrogen at the establishment, but donor recruitment is currently closed. Staff use consent forms and participant information sheets specific to each project, which have been approved by an appropriate ethics committee. Blood samples are collected by trained phlebotomists or clinically qualified staff. All samples are de-identified before use and only a limited number of staff have access to participant identifying information. In all cases,

including where samples are imported, the establishment seeks assurances that consent is in place for the removal, storage and use of samples obtained from third party organisations in accordance with the regulatory requirements (including in the country of origin, where samples are imported).

The establishment stores relevant material for use in research, including that within the scope of the HT Act. There are currently ten collections of human samples stored at the establishment under the authority of the HTA licence. These collections include the Manchester Brain Bank, Salford Respiratory Biobank, the Vascular Diseases Biorepository and collections stored by individual research groups.

Samples are kept fixed or as wax blocks and slides at room temperature, frozen or in liquid nitrogen storage. The establishment also stores relevant material for use in projects with approval from recognised research ethics committees (RECs), which is therefore exempt from the licensing requirements of the HT Act. The establishment is in the process of finalising governance arrangements to ensure that when REC approval expires, or samples are stored outside the terms of the approval but within the scope of the consent given, relevant material is stored under the HTA licence (see advice item 1).

Material is occasionally distributed to or issued from the establishment under material transfer agreements (MTAs) with the forwarding or receiving establishments.

Each research group uses electronic records to provide traceability of samples. Some groups maintain additional paper records of sample traceability. Samples are assigned a unique identification number by individual researchers, and these numbers are used to track sample receipt, storage, release for use in research and disposal. Information about each collection is held in a HTA compliance file, maintained by the Person Designated (PD) responsible for that collection.

Samples are stored in dedicated storage facilities in secure locations. Samples are mostly stored in locked freezers, located in rooms with controlled access. All areas where relevant material is stored under the HTA licence were accessed during the inspection.

Freezer temperatures and liquid nitrogen levels are continuously monitored and there are alarms with robust call-out notification procedures in the event of a deviation from the set acceptable ranges for all freezers. The HTA has given advice to the DI on the storage arrangements for the liquid nitrogen dewar, as it is not fitted with an automated temperature alarm (see advice item 6). Maintenance of freezers and temperature monitoring probes is carried out by an external supplier, and the establishment has contingency arrangements for storage in the event of a freezer breakdown.

An audit of traceability records and consent forms was conducted for a number of samples stored under the HTA licence in the liquid nitrogen tank, -75 ^{o}C freezers and room temperature storage for all the collections stored under the licence. Audits were carried out from samples in storage to records and vice versa. No anomalies were found.

An audit of legibility and completeness of consent forms was also carried out as part of the traceability audit for all collections. No anomalies were found.

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.	GQ1	A number of projects have received approval from recognised Research Ethics Committees (RECs) and will be held outside the governance of the licence. The DI is advised to finalise the draft governance arrangements for material held under such projects when REC approval is due to expire, produce final versions of relevant documentation and ensure that any arrangements are communicated to and implemented by all relevant staff.
2.	GQ6	The DI is advised to ensure that labels currently in use in the liquid nitrogen tank are replaced, as information on the current labels is fading with time and may pose a traceability risk if the tank is actively used in the future.
3.	GQ8	Although thorough systems are already in place to mitigate risks for all practices and processes at the establishment, some risk assessments currently in use lack detail describing these systems. The DI is advised to review the current risk assessments and ensure that they accurately reflect current practices.
4.	GQ8	The Manchester Brain Bank stores several hundred brains and is continuing to receive donated brains on an ongoing basis. The DI is advised to risk assess the expansion of the Manchester Brain Bank, which is close to reaching its storage capacity, and keep the arrangements under regular review as the collection expands.
5.	PFE3	The DI is advised to update the log sheets used to record the freezer temperatures at the Manchester Brain Bank to include the accepted temperature range. A tick could then be made on the chart to verify that the freezer temperature is within the expected limits, although it would be preferable to include the actual temperature for trend monitoring.
6.	PFE5	The DI is advised to update the liquid nitrogen filling log currently in place for the peripheral blood lymphocyte collection to record the date and person carrying out the refill and consider the addition of a probe alarm to ensure that the liquid nitrogen level is sufficient at all times.
7.	D2	The Standard Operating Procedure (SOP) for disposal states that the date and method of disposal should be recorded. However when a collection of existing holdings was disposed of in the past, the date of disposal was not recorded. The DI is advised to ensure that all relevant documentation is updated to ensure that current practice reflects the relevant SOP.

Concluding comments

This report outlines the second HTA site visit inspection of Salford Royal NHS Foundation Trust. There were a number of areas of good practice observed during the inspection. Training material for members of staff seeking consent is detailed and provides good information about informed consent requirements. The premises and storage facilities are well-maintained and there are comprehensive temperature monitoring and alarm call-out procedures for the majority of storage units at the establishment. The DI is well supported in his role by the PDs and together they have good oversight of licensed activities. Quality management at the establishment is robust and regular audits are carried out, with findings being addressed in a consistent and timely manner.

The HTA has given advice to the DI with respect to traceability, risk assessments temperature monitoring and disposal records.

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

Report sent to DI for factual accuracy: 27 November 2015

Report returned from DI: 2 December 2015

Final report issued: 7 December 2015

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.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• Consent forms comply with the HTA's Code of Practice • Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose • If the establishment obtains consent, a process is in place for acquiring consent in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Where applicable, there are agreements with third parties to ensure that consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Consent procedures have been ethically approved
C2 Information about the consent process is provided and in a variety of formats
• Standard operating procedures (SOPs) detail the procedure for providing information on consent • Agreements with third parties contain appropriate information • Independent interpreters are available when appropriate • Information is available in suitable formats, appropriate to the situation • Consent procedures have been ethically approved
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• Standard operating procedures (SOPs) detail the consent process • Evidence of suitable training of staff involved in seeking consent • Records demonstrate up-to-date staff training • Competency is assessed and maintained

Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process
• Policies and procedures are in place, covering all activities related to the storage of relevant material for research in connection with disorders, or the functioning, of the human body • Appropriate risk management systems are in place • Regular governance meetings are held; for example, health and safety and risk management

committees, agendas and minutes

- Complaints system

GQ2 There is a documented system of quality management and audit

- A document control system, covering all documented policies and standard operating procedures (SOPs).
- Schedule of audits
- Change control mechanisms for the implementation of new operational procedures

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Qualifications of staff and training are recorded, records showing attendance at training
- Orientation and induction programmes
- Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training
- Training and reference manuals
- Staff appraisal / review records and personal development plans are in place

GQ4 There is a systematic and planned approach to the management of records

- Documented procedures for the creation, amendment, retention and destruction of records
- Regular audit of record content to check for completeness, legibility and accuracy
- Back-up / recovery facility in the event of loss of records
- Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)

GQ5 There are documented procedures for distribution of body parts, tissues or cells

- A process is in place to review the release of relevant material to other organisations
- An agreement is in place between the establishment and the organisation to whom relevant material is supplied regarding the tracking and use of material and eventual disposal or return

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- There is an identification system which assigns a unique code to each donation and to each of the products associated with it
- An audit trail is maintained, which includes details of when and where the relevant material was acquired, the consent obtained, the uses to which the material was put, when the material was transferred and to whom

GQ7 There are systems to ensure that all adverse events are investigated promptly
• Corrective and preventive actions are taken where necessary and improvements in practice are made • System to receive and distribute national and local information (e.g. HTA communications)
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately
• Documented risk assessments for all practices and processes • Risk assessments are reviewed when appropriate • Staff can access risk assessments and are made aware of local hazards at training

Premises, facilities and equipment standards
PFE1 The premises are fit for purpose
• A risk assessment has been carried out of the premises to ensure that they are appropriate for the purpose • Policies in place to review and maintain the safety of staff, authorised visitors and students • The premises have sufficient space for procedures to be carried out safely and efficiently • Policies are in place to ensure that the premises are secure and confidentiality is maintained
PFE 2 Environmental controls are in place to avoid potential contamination
• Documented cleaning and decontamination procedures • Staff are provided with appropriate protective equipment and facilities that minimise risks from contamination • Appropriate health and safety controls are in place
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.
• Relevant material, consumables and records are stored in suitable secure environments and precautions are taken to minimise risk of damage, theft or contamination • Contingency plans are in place in case of failure in storage area • Critical storage conditions are monitored and recorded • System to deal with emergencies on 24 hour basis • Records indicating where the material is stored in the premises

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- Documented policies and procedures for the appropriate transport of relevant material, including a risk assessment of transportation
- A system is in place to ensure that traceability of relevant material is maintained during transport
- Records of transportation and delivery
- Records are kept of any agreements with recipients of relevant material
- Records are kept of any agreements with courier or transport companies

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Records of calibration, validation and maintenance, including any agreements with maintenance companies
- Users have access to instructions for equipment and receive training in use and maintenance where appropriate
- Staff aware of how to report an equipment problem
- Contingency plan for equipment failure

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- Documented disposal policy
- Policy is made available to the public
- Compliance with health and safety recommendations

D2 The reason for disposal and the methods used are carefully documented

- Standard operating procedures (SOPs) for tracking the disposal of relevant material detail the method and reason for disposal
- Where applicable, disposal arrangements reflect specified wishes

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
   - has the potential to become a critical shortfall unless addressed

   or

   A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

   In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

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