Site visit inspection report on compliance with HTA minimum standards

UK Biostores & Services Ltd

HTA licensing number 12623

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**

14 July 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.

UK Biostores & Services Ltd (the establishment) was found to have met all of the applicable HTA standards. The HTA has given advice to the establishment with respect to the consent, governance and quality systems and disposal standards.

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 (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 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

UK Biostores & Services Ltd (the establishment) stores and processes biological samples on behalf of third party organisations, including other HTA-licensed establishments.

The establishment has been licensed by the HTA since August 2014 under the Human Tissue Act 2004 (HT Act) for the storage of relevant material for use for scheduled purposes. The HTA visited the establishment in July 2014 as part of the licence application process.

This report describes the first, full routine site visit inspection of the establishment. The inspection timetable was developed in consideration of the activities undertaken under the HTA licence, discussions with the DI and the findings of the licence application site visit. The inspection comprised a review of the processes for conducting activities under the licence, an audit of biological samples stored at the establishment and a review of documentation.

The establishment receives biological samples, including urine and saliva, from third party organisations. As part of agreeing a contract with a third party organisation for processing and/or storing samples, the establishment seeks assurance that consent for storage and use of the samples has been sought in accordance with the legislative requirements. The establishment requests to review template consent forms and participant information documentation used by the third party organisation. Records of these checks of consent are maintained and audited as part of the establishment's periodic audit of projects.

Sample transport may be arranged by the third party organisation or the establishment. The establishment provides a specialist sample transport service, including use of temperature-controlled conditions to protect sample integrity. Sample transport and receipt at the establishment are recorded on paper forms, which are also stored electronically, and on the establishment's sample management database.

The establishment may process samples to aliquots and for storage in specialised cryovials, as requested by the third party organisation. All samples are assigned a unique identification code which is used to provide sample traceability. An automated reader is used to scan identification codes to facilitate sample traceability by preventing transcription errors. An electronic sample management system is used to maintain a database which maintains details of sample transport, receipt, processing, storage and use or disposal.

The establishment has facilities to store samples at room temperature or frozen in -20°C or -80°C mechanical freezers. Freezer storage temperatures are continually monitored and there is an automated alarm with a robust call-out notification procedure in the event of a deviation from the set acceptable temperature ranges. The establishment's freezers and temperature alarm system are regularly maintained and the establishment has contingency arrangements in the event of power failure or freezer breakdown. The establishment conducts periodic tests of the temperature alarm call-out system.

The establishment's disposal policy was reviewed by the HTA during the inspection. At the time of the inspection, the establishment had not disposed of any biological samples.

At the time of the inspection, the establishment had not stored any samples under the HTA licence. All samples stored by the establishment are exempt from the licensing requirements of the HT Act because they are either: acellular and so not considered to be relevant material under the HT Act; or stored for research projects which have received approval from recognised research ethics committees. The establishment handles all biological samples using the same procedures.

An audit of storage locations and traceability records, including transport and processing records, was conducted for five samples. Although these samples are exempt from the licensing requirements of the HT Act, this audit allowed the establishment to demonstrate

their systems for sample traceability. No discrepancies were identified by this audit and the establishment was able to demonstrate full traceability of these samples with ease.

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.	C1	The establishment obtains formal assurances from third party organisations that consent for the storage and use of samples has been obtained in accordance with the requirements of the HT Act. The establishment is advised to further strengthen its documentation of the assurance provided by third party organisations, for example, by including this in the storage contract terms of agreement.
2.	GQ1	The DI is advised to ensure that the temperature alarming arrangements are documented, including the temperature trigger points for the alarm and the procedure for undertaking periodic testing of the alarm.
3.	GQ3	The establishment's induction programme for new staff includes training in the requirements of the HT Act and the establishment's local procedures for working under the HTA licence. The establishment plans to also require staff to undertake periodic refresher training in the requirements of the HT Act. The DI may wish to consider utilising the e-learning package developed by the Medical Research Council in conjunction with the HTA which covers the requirements of the HT Act for the research sector: www.rsclearn.mrc.ac.uk/.
4.	GQ8	The establishment has a risk register which documents the risks of activities undertaken by the establishment, including risks of sample transport, storage of samples without appropriate consent, loss of sample traceability and failure of storage facilities. The DI is advised to extend this risk register to provide additional details of the mitigating steps in place for the risks associated with undertaking licensable activities.
5.	D1	The DI is advised to review the standard operating procedure (SOP) for sample disposal to include additional details of the process for disposal. This SOP should document the procedures implemented to ensure that samples are disposed of in accordance with the HTA's code of practice on disposal. Further advice on the disposal of relevant material can be found in the HTA's code of practice on disposal: www.hta.gov.uk/code-practice-5-disposal.

Concluding comments

This report outlines the first, routine HTA site visit inspection of UK Biostores & Services Ltd. There were a number of areas of good practice observed during the inspection. The establishment demonstrated a commitment to continual improvement of practices. They have worked to ensure on-going compliance with the HTA standards and have implemented advice provided by the HTA during the licence application site visit.

Staff at the establishment have a good knowledge of the requirements of the HT Act and the HTA's codes of practice. The DI has developed a briefing note for all staff working under the HTA licence to ensure that they are familiar with the legislative requirements and practical arrangements at the establishment for working under the licence.

The establishment's storage facilities are well-maintained and secured. There are robust arrangements for temperature-controlled storage of samples, including temperature monitoring and alarming procedures, and extensive arrangements for contingency storage.

The establishment has developed robust procedures for sample management, including use of an automated identification code reader and electronic sample management software. The establishment were able to demonstrate full traceability of samples during the HTA's audit with ease, including records of sample transport, receipt, processing and storage.

The establishment has a well-developed quality management system and is certified to ISO9001:2008 Quality management systems standards. All policies and procedures relating to the HTA licence are managed using electronic quality management software. The DI is experienced in auditing and has implemented well-defined audit processes and documentation, including for tracking the implementation of any actions required. The establishment undertakes a comprehensive range of audits, including of processes, sample management and compliance with the HTA standards.

The HTA has given advice to the DI with respect to its documentation of the assurance of consent, staff training, risk assessments and disposal.

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

Report sent to DI for factual accuracy: 5 August 2015

Report returned from DI: 11 August 2015

Final report issued: 12 August 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.