Licence application visit on compliance with HTA minimum standards

York Bioanalytical Solutions Ltd.

HTA licensing number 12658

To be 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**

8 September 2016 and 30 September 2016

Background

A site visit of York Bioanalytical Solutions Ltd ('the establishment') was carried out as part of the licence application assessment. The establishment consists of a hub site in York, and a satellite site in Sandwich. The hub and satellite sites were visited on separate days.

This report summarises the visits and provides advice to the establishment to support post-licensing compliance.

Hub site: 8 September 2016

The first site visit was carried out at the hub site at York Bioanalytical Solutions Ltd in York. At the time of the site visit, the establishment made the HTA aware that they had been storing tissue from the living for the purposes of research. Tissue was donated, stored and used both prior to, and following, the HT Act coming into force. The establishment's procedure is to keep tissue up to a maximum of two years before disposing of it. They became aware of the need for a licence when enquiring about importing deceased liver tissue from an external supplier, which prompted them to apply for an HTA licence.

A visual inspection of the establishment was undertaken and included areas where human tissue had been, and is currently being, stored for the purpose of research under the HT Act. All the tissue that is currently being stored is from the living and includes cerebrospinal fluid, faeces, and urine. The establishment previously stored blood for up to 10 days before rendering it acellular. Tissue is stored in -80 or -20 degree freezers. Each sample is anonymised and given a unique identification number. Researchers do not have access to donor information and consent forms are kept in a locked secure room with access by limited staff.

There is CCTV monitoring of the building and an electronic key sensor system that only allows access by a limited number of staff into tissue storage areas. All equipment is on a computerised temperature monitoring system and staff are on call in case of an emergency. There is a contingency procedure in place for equipment breakdown.

A traceability audit was conducted on four urine samples, from the freezers to the computer records, and a reverse traceability audit was conducted on two faecal samples and two cerebrospinal fluid samples, from the computer records to the freezers. Sample locations and unique ID numbers were compared with computer records. Relevant consent forms were also checked. There were no discrepancies.

There was a round-table discussion with the proposed Designated Individual (DI), Corporate Licence Holder contact (CLHc), Persons Designated (PD), and staff who will be involved in licensable activities. The discussion included consent; premises; facilities and equipment; governance and quality management systems and traceability systems.

Satellite site: 30 September 2016

The second site visit was carried out at the satellite site in Sandwich. The satellite site has been storing tissue for use in research since 2011. At the time of the visit, the establishment was storing one human blood sample, obtained from a living donor. A visual inspection of the establishment included the fridge where the blood sample is currently being stored. The human blood is stored in the same fridge as animal tissue, but it is on a separate shelf and the sample is clearly labelled.

The refrigerator is connected to the same alarm and call out system as the hub site. Access to the facility is through locked doors and electronic pass readers. There is CCTV and security personnel on the premises.

A traceability audit was conducted on the blood sample, from the computer records to the location of the sample. No discrepancies were found.

There was a discussion with the proposed DI and PD. The discussion included premises, facilities and equipment, governance and quality management systems and traceability systems. Staff at the satellite site do not seek consent.

Advice

No.	Standard	Advice
1.	GQ1	When removing cells from samples, to make them acellular, the effectiveness is dependent on the protocol used. The proposed DI is advised that sufficient validation data (either in-house or published research) should be identified if techniques are to be relied on to render samples acellular.

2.	GQ2	The proposed DI has put together an audit schedule for licensable activities. Audit processes can benefit from being undertaken by a person who is not normally involved in the activity at the establishment: a ‘fresh eyes’ view. Internal auditors should not be involved in auditing their own work. Some establishments may be able to make use of existing in-house expertise or services.
3.	PFE3	The establishment is advised to label the outside of the fridge at the satellite site to make staff aware that human tissue is being stored there. This may help to reduce the risk of sample mix-ups and ensure staff are aware of the need to manage these samples in line with the regulatory requirements.

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.