Site visit inspection report on performance against HTA quality standards
Source Bioscience
HTA licensing number 12344

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**

24 May 2011

Executive Summary

A site visit inspection of Source Bioscience (the establishment) was carried out by the HTA on 24 May 2011.

The establishment was found to have met all HTA standards.

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

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.

All 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 establishment is a commercial company offering contract research and clinical research services to multiple clients. The establishment also provides histopathological diagnostic services to various NHS trusts, however this only includes tissue from the living used for diagnosis and was therefore an area not inspected.

Samples taken for research are consented by research staff at the originating site. The establishment's agreements with customers mandate that all samples are appropriately consented before being sent to the establishment. Upon arrival tissue samples are logged into the establishment's electronic database which also records the results of any analysis undertaken.

This was the first site-visit inspection of the establishment. The timetable for the site visit was developed in consideration of the desk-based assessment of the establishment's licence application and pre-inspection discussions with the DI. During the inspection a visual inspection of the premises, review of documentation and interviews with establishment staff were undertaken.

An audit of tissue blocks sent for analysis as part of different clinical trials was undertaken. Tissue blocks for three participants were audited. The first block represented a case where tissue had been received, analysed and returned to the originating site. In the second case multiple tissue blocks had been sent in from the originating site and in the last case a single block had been received, as per the clinical trial protocol. The audit included locating any tissue blocks and slides still in storage at the establishment and a review of all paper and electronic records pertaining to the sample. All tissue in storage was successfully located and no anomalies were found. In the case of the returned block records were reviewed recording delivery. The audit did however highlight that the number of slides cut from a tissue block was not recorded. Although all trials have specific work orders which specify the number of slides to be cut, if extra slides are cut for any reason there is no record of the extra slide. This has been addressed in the advice section of the report.

A second audit was undertaken in the circulating tumour cell facility. Samples from three study participants were sought in the -80°C storage freezer and their locations cross checked against electronic records. Paper work pertaining to the samples was also reviewed. For two samples there were no anomalies found, however the third sample's location had not yet been recorded in the electronic sample log. Upon finding the anomaly a fourth sample was audited and no anomalies were found. The discrepancy found is addressed in the advice section of the report.

Meeting the HTA's licensing standards

The HTA developed its licensing standards with input from its stakeholders, in order to ensure the safe and ethical use of human tissue. The HTA expects licensed establishments to meet these standards.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a licensing standard is not met, the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor' (see Appendix 3: Classification of the level of shortfall).

Unless otherwise advised, the establishment is required to inform the HTA within 14 days of the receipt of the final report of the corrective and preventative actions that will be taken to ensure that the improvements are addressed. A template for this purpose is provided as a separate Word document.

Please see Appendix 2: Human Application standards, to view all human application standards. Standards which do not apply to this licence are highlighted in Appendix 2.

The establishment was found to have met all HTA standards.

Advice

Below are matters which the HTA advises the DI to consider.

No.	Standard	Advice
1.	GQ1	The DI is advised to circulate the notes taken at the various governance meetings that take place for example, the fortnightly contract review meetings, between the attendees. These will act as a record of the meeting and provide attendees with a vehicle to feed back to other staff who may not attend the meetings.
2.	GQ2	There is a well established system of audit at the establishment. The DI however is advised to include traceability audits into the existing audit schedule. Although sample traceability is audited as part of a process audit, a more focussed traceability audit will provide a further means to identify any gaps in sample traceability records.
3.	GQ6	The DI is advised to record and trace all slides produced as part of the establishments work. Although slides are produced currently in line with the study protocol, extra slides produced for any reason are not recorded. By recording slides in the establishment's sample tracking systems the establishment will improve sample traceability and the tracking of relevant material.
4.	GQ8	The DI is advised to expand the scope of the establishment's risk assessments so that they include the risks to the tissues and cells as opposed to health and safety risks only. The risks to the tissues and cells could include but are not limited to, risks of loss of sample integrity, risks of loss of sample traceability, risks of transfer of tissue to an incorrect address or the risk of the loss of storage eg. Freezer failure.
5.	PFE5	The establishment's freezer monitoring system is calibrated every 6 months however the calibration schedule is not detailed within the calibration Standard Operating Procedure (SOP). The DI is advised to include the frequency of calibration within the establishment's SOP.
6.	D1	The DI is advised to amend the establishment's disposal policy so that it more closely follows the HTA code of practice on Disposal of relevant material. Code of practice on Disposal - http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code5disposal.cfm

Concluding comments

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.

The establishment has well conceived and developed quality systems. These systems facilitate the changing of processes to improve accuracy or reduce risk.

One example of good practice which was noted during the inspection involved the weighing of reagents on a piece of automated equipment. The establishment had identified the potential risk of a false negative result due to reagents not being dispensed automatically by the equipment. In addition to including positive and negative controls with the samples, the establishment weighs reagents before and after a process to ensure that the expected volume of reagents was dispensed. These measurements are documented on the

worksheets allowing a quick review if necessary and providing a means of facilitating any trouble-shooting that may be necessary. Monitoring of critical equipment in this way helps to mitigate the risks around loss of tissue and loss of tissue integrity through equipment not operating as expected.

The establishment also has a well developed system of competency based staff training. Staff are assessed by their managers and competency in a given procedure is signed off. Competency records are held in personal development files which also include CVs and records of any training that has been undertaken. Detail is provided in the training record as to the level of competence a member of staff has achieved, which is recorded as a score of 1-3, and indicates when they are sufficiently competent to train someone else. The level of detail in the training records mark them out as an example of best practice.

Report sent to DI for factual accuracy: 13 June 2011

Report returned from DI: 17 June 2011

Final report issued: 7 July 2011

Appendix 1: HTA inspection process

The Human Tissue Authority regulates the removal, storage, and use of human bodies, body parts, organs and tissue for activities such as research, transplantation, and education and training. The legal requirements for establishments which carry out such activities are set out in the Human Tissue Act 2004 and The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

We license establishments in England, Wales and Northern Ireland that carry out these activities, and inspect them to make sure legal requirements are met.

Inspections

We use the term 'inspection' to describe when we:

- visit an establishment to meet with staff, view premises and facilities, and review policies and procedures (a site-visit inspection); or
- assess written information we have requested from an establishment (a desk-based assessment / inspection).

We carry out inspections to assess if the Designated Individual (DI) is suitable to supervise the activity covered by the licence, as it is their responsibility to ensure that:

- other staff working under the licence are suitable;
- suitable practices are used when carrying out the activity; and
- the conditions of the licence are met.

We also need to be satisfied that the licence applicant or holder, the establishment's premises, and the practices relating to licensed activities, are suitable.

To help us reach our decisions, we have developed standards under four headings: Consent; Governance and Quality; Premises, Facilities and Equipment; and Disposal.

After every site visit inspection, we write a report documenting our findings. Where we find a particular standard is not fully met, we will describe the level of the shortfall as 'Critical', 'Major' or 'Minor'. In most cases, it will be the responsibility of the DI to seek the HTA's agreement on how they will address the identified shortfalls. More information about the classification of shortfalls can be found in Appendix 3.

The majority of our site-visit inspections are announced. If we have concerns about an establishment, we can also undertake an unannounced site visit inspection.

You can find reports for site visit inspections which took place after 1 November 2010 on our website.

Appendix 2: HTA standards

Standards which are not applicable to this establishment have been highlighted.

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 in place 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 3: 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. There are varying levels of 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.

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.

Follow up actions

A template corrective and preventative action plan is available as a separate Word document. 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.